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Swansea University
Prifysgol Abertawe

Research Integrity

Policy Framework

Swansea University
Prifysgol Abertawe

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FOREWORD

At Swansea University, we are very proud of our reputation for excellent research, and for the calibre, dedication, and professionalism of our research community. We understand that integrity must be an essential characteristic of all aspects of our research, and that as a University entrusted with undertaking research, we must clearly and consistently demonstrate that the confidence placed in our research community is rightly deserved.
The University therefore expects everyone engaged in research, to adhere to the very highest standards of research integrity and to conduct themselves and their research activities accordingly. This Framework clearly lays out those expectations, and systematically sets out how the University will seek to ensure that they are met in all of our research activity.
The Framework is fully aligned with the Universities UK's ***Concordat to Support Research Integrity***, whose five key commitments we share and wholly endorse:

- We are committed to maintaining the highest standards of rigour and integrity in all aspects of research;

- We are committed to ensuring that research is conducted according to appropriate ethical, legal, and professional frameworks, obligations, and standards;

- We are committed to supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice, and support for the development of researchers;

- We are committed to using transparent, robust, and fair processes to deal with allegations of research misconduct should they arise; and

- We are committed to working together to strengthen the integrity of research and to reviewing progress regularly and openly.

We all share the responsibility for understanding, upholding, and promoting research integrity and research excellence, and for ensuring that we continue to merit being entrusted with so many vitally important research projects across the full spectrum of our research portfolio, subject areas, and research community. This Framework demonstrates our determination to embed research integrity at the heart of all that we do.

Professor Helen Griffiths
Pro Vice Chancellor (Research & Innovation)

SCOPE

The document provides a framework for research ethics and governance at the University and applies to all academic disciplines. It is the central reference point for matters relating to research governance and should be used and referred to accordingly by research staff and students.

The framework is a 'live document' and is reviewed regularly by the University Research Ethics and Governance Committee to reflect 'best practice,' and legislation, where applicable, within research.

The aim of the framework is to set standards and expectations that enhance research quality, integrity and compliance and safeguard both the public and researchers. Research principles and standards set out in the framework apply to all stages of a research project and provide information on what research requires ethical approval.

Research involves information gathering, and research ethics concerns the means (methods) used to gather and analyse that information as well as its presentation and publication. When the information to be gathered is:

- not in the public domain; and/or
- Involves using other human participants (e.g., in questionnaires or interview), human tissue, or animals, then some form of ethical review of that research is normally required. Research pursued by undergraduate and postgraduate students and staff that satisfies the above criteria will need some form of ethical review.

As per the Frascati manual, **research** is also defined as creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of humanity, culture and society, and the use of this stock of knowledge to devise new applications.

Researchers are defined as members of the University, including staff and postgraduate research students, and other students insofar as they are engaged in research, and those individuals who are not members of the University but who are conducting research on University premises or using University facilities.

The University requires all employees, students, independent contractors, and consultants, visiting or emeritus staff, staff on joint clinical or honorary contracts, and anyone conducting research using institutional facilities or on institutional premises or under the auspices of the University to abide by and promote the principles highlighted in this Framework, irrespective of their source of funding and area of research.

EXECUTIVE SUMMARY

The ***Research Integrity Policy Framework*** is an overarching document specifying standards, policies, and procedures for implementing and ensuring 'good research governance' practices in all subject areas. It outlines the University's approach to research integrity in relation to ethical approval, research misconduct, research funding, peer review, registration of research projects, and research data management.

The Framework has been developed in accordance with the guidelines of the ***Concordat to Support Research Integrity***, ***UK Research & Integrity Office Code of Practice*** and ***UK Policy Framework for Health & Social Care Research***

Based on guidelines provided in this Framework, subject specific research ethics and governance policies and procedures are developed.

The Framework is owned, implemented, monitored, and reviewed by the University Research Integrity: Ethics and Governance Committee, with regular reporting to Senate.

INTRODUCTION

As an organisation conducting research, employing researchers, and as a signatory to the ***Concordat to Support Research Integrity***, the University has a responsibility to demonstrate that appropriate mechanisms of 'Research Integrity: Ethics and Governance' are embedded in its practices.

The University seeks to conform to all applicable external research governance guidelines and codes of practice including those developed or adopted by major funding bodies.

RESPONSIBILITY AND ACCOUNTABILITY

Demonstrating evidence of good 'research governance' is a responsibility of all. Researchers should comply with all applicable laws and statutes relevant to the conduct of research, including the Data Protection Act 1998, the Human Tissue Act 2004, the Mental Capacity Act 2005, the Safeguarding Vulnerable Groups Act 2006, the Medicines for Human Use (Clinical Trials) Regulations 2004, the Animals (Scientific Procedures) Act 1986 and the International Committee on the Harmonisation of Good Clinical Practice (ICH GCP).

A commitment to research integrity should be reinforced through the research environment, research culture, research practices and the training of researchers. The University is responsible for:

- Maintaining the highest standards of rigour and integrity in all aspects of research;
- Compliance with all current health and safety legislation;
- Demonstrating clear codes of practice and a research governance framework;
- Ensuring that principal investigators, research staff and students, and anyone else conducting research using institutional facilities and on institutional premises, are aware of the research governance framework and comply with it;
- Ensuring that appropriate indemnity/insurance arrangements are in place for any authorised research activity;
- Discharging the role of a 'sponsor' in the management and monitoring of any research-related work;
- Demonstrating systems for continuous professional development of staff at all levels;
- Having agreements and systems to identify, protect, and exploit intellectual property;
- Ensuring that processes are in place to enable individuals to seek redress if harmed as a result of whistleblowing on the part of the University's research staff to research students, and others for whom the University is responsible;
- Ensuring that systems are in place to detect fraud and other forms of research misconduct;
- Ensuring that systems are in place to process, address and learn lessons from any errors or complaints brought against any University staff or students; and

- Ensuring that systems are in place for permitting and assisting with any statutory inspections, audits or investigations arising from errors or complaints associated with the research undertaken by University staff or students.

RESEARCH GOVERNANCE

Research Governance requires well defined quality and risk-management policies and procedures that:

- Define clear standards;
- Ensure that standards are met; and
- Ensure that arrangements are in place to assess, monitor, manage and report adherence to the standards.

Research Governance aims continuously to improve standards by setting out principles, requirements, and mechanisms. It describes assessments and monitoring practices to ensure that:

- Rigour and integrity are maintained in all aspects of research;
- Research is conducted in accordance with appropriate ethical, legal and professional frameworks, obligations and standards;
- A culture of integrity and support is available to researchers;
- Decision-making processes are transparent, with clear allocation of responsibilities and effective monitoring arrangements;
- Robust and fair processes are in place to deal with allegations of research misconduct; and
- Regular auditing and reviewing of research practices are conducted.

Research Governance is applicable to all those who:

- Design research studies;
- Undertake research;
- Host research in their organisation;
- Fund research proposals or research infrastructure; and
- Undertake and manage research in all professional groups.

Staff and students undertaking research are expected to familiarise themselves with all relevant guidelines, be accountable for their actions and conduct, and observe the highest standards of integrity, honesty, professionalism, transparency, and rigour in every aspect of their research work.

RESEARCH ETHICS

Research involves information gathering and research ethics concerns the means (i.e., methods) used to gather and analyse that information in addition to its presentation and publication. When the information to be gathered is not in the public domain, or where its

collection involves using other human participants (e.g., in questionnaires or interviews or interventions), human tissue, or animals, then it is highly likely that some form of ethical review and approval of that research is required. The dignity, rights, safety, and well-being of participants should be the primary consideration of any research study. Informed consent should be at the heart of any ethical research involving human participants. Maintaining good ethical conduct lies, in the first instance, with researchers themselves. Ethical research is therefore a matter of being risk aware, and not necessarily of being risk averse.

RESEARCH PRINCIPLES

A glossary of important ethical terms and ideas is provided in *Appendix 4* of this Framework.

Section 1

SWANSEA UNIVERSITY'S RESEARCH GOVERNANCE STRUCTURE

1.1. Institutional responsibility & arrangements for Research Ethics and Governance

The University has the organisational structure to ensure that research conducted meets the highest levels of integrity, including sponsorships, appropriate frameworks, research design, and that research findings are robust and defensible.

At the Institutional, level the **University Research Integrity: Ethics and Governance Committee** has the overarching responsibility for managing the University's research ethics and governance arrangements. This Committee is not responsible for conducting ethical reviews *per se* but for ensuring that the appropriate committees, groups, structures, and processes are in place at Faculty level in order for ethical reviews to be conducted to whatever point necessary on all relevant research.

The University Research Integrity: Ethics and Governance Committee provides policy direction and ethical oversight to Faculty's in relation to arrangements for ethical reviews and quality assurance. Any exceptional cases/issues that cannot be dealt with by Faculty level Research Ethics & Governance sub-committees are dealt with by the University Research Integrity: Ethics and Governance Committee.

The Committee provides an annual progress report to the Senate and the Higher Education Funding Council of Wales (HEFCW)

1.2 University Research Integrity: Ethics and Governance Committee

Terms of Reference

- To monitor the University's compliance with the commitments of the '*Concordat to Support Research Integrity'.*
- To own and Implement the Policy Framework on 'Research Integrity: Ethics & Governance'.
- To work with University committees with particular responsibility of research ethics and governance matters, including Faculty Research Ethics & Governance Committees, Animal Welfare and Ethical Review process group, Sponsorship Oversight sub-committee, Human Tissue sub-committee and any other subject or area specific oversight groups or sub-committees.
- To monitoring compliance with internal ethical policies/procedures and external regulations/legislation relating to research ethics and governance;
- To monitor, review and where necessary update policies and procedures relating to research Integrity: Ethics & Governance;
- To provide assistance and guidance to Faculties &, Schools ensure that appropriate mechanisms and structures are developed at Faculty and School level for the management of research ethics and governance.

- To ensure that research ethics and governance is a standing agenda item for the Faculty Research Committees
- To ensure that research risks are managed appropriately and that risks are mitigated for business continuity and emergency planning.
- To promote best practice and encourage consistency in matters of research Integrity: Ethics and Governance across the University through training and raising awareness;
- To ensure oversight and compliance of sponsorship requirements, audits, and inspections by external bodies (e.g., MHRA, HTA, UKRI, Internal Audit Services)
- To update and disseminate all institutional research integrity related documentation with a view to raising stakeholder awareness of the processes relating to research governance and ethical approval; and
- To approve and review periodically, subject-specific research ethics and governance frameworks produced by the Faculty Research Ethics & Governance Committees

Sub Committees/ Groups and their remit

- Sponsorship and Oversight sub-committee
- AWERB

Other:

To consider any other matters referred to the Committee by the

- Research Impact & Innovation Committee.
- Sponsorship and oversight sub-committee
- Human Tissue Board.

Membership

- Pro Vice Chancellor Research & Innovation (Chair)
- Deputy Pro Vice Chancellor (Research Culture) (Deputy Chair)
- Deputy Pro Vice Chancellor (Postgraduate Research)
- Faculty Research Ethics Leads.
- Chairs of School Ethics Committees.
- Chair of Sponsorship Oversight sub-committee.

In Attendance:

- Professional Staff representatives from Research, Engagement & Innovation Services (REIS)
- Representative from Library & Academic Services and Health & Safety (as required)
- Representative of AWERB
- Named Animal Care Welfare Officer (NACWO) (Science)
- Human Tissue Officer
- Swansea Trials Unit Manager
- Research Governance Manager
- Research Integrity Manager (Secretary to the Committee)

Frequency of meetings

Normally once per term with the option of special meetings being held as and when required.

1.3. Faculty Research Ethics & Governance Sub-Committees

Each Faculty has a single Faculty Research Ethics & Governance sub-committee that reports to the Faculty Research Impact & Innovation Committee. If a single Research Ethics & Governance sub-committee is insufficient for the needs of the Faculty, then the additional capacity is configured as sub-committees or oversight groups. All Faculty sub committees and oversight groups report to the Faculty Research Ethics & Governance sub-committee.

Chairs of Faculty Research Ethics & Governance sub-committees and any sub-committees/oversight groups must have competence in the ethical review of research. It is recommended practice that Faculty committees involve a lay member to ensure some independence of judgement and to help avoid conflicts of interest. Faculty Research Ethics & Governance sub-committees and any sub-committees/oversight group should foster a culture in which research integrity is recognised as integral to research excellence. Faculty Research Ethics & Governance sub-committees and any sub-committees should also be aware of when it needs to refer out to external ethics committees such as the NHS ethics review or AWERB (Animal Research Review Board).

To ensure that all research undertaken by staff and students at Swansea University embodies high standards of research ethics and governance, each Faculty is expected to produce a research ethics and governance framework for its subject area(s) and community of researchers. These frameworks should accord with appropriate disciplinary, professional, regulatory, and legislative requirements, and be aligned with the University Framework. Each of the Faculty frameworks should be approved and reviewed by the University Research Integrity Ethics and Governance Committee on a regular basis

The Faculty frameworks should provide guidance on research integrity to staff and students within the Faculty, including the requirements and procedures for undertaking ethical review and securing ethical approval, which may, where appropriate, be differentiated according to the particular needs of the Faculty (e.g. discipline-specific ethical review procedures; provision for light-touch reviews and expedited reviews as well as full ethical reviews; and approved protocols for commonly occurring research).

It is expected that the Faculty committees will consider matters of '*conflict of interest*' whilst undertaking ethical approval of a research project and the approval must be confirmed as a committee decision.

1.4 REPORTING STRUCTURE

The Faculty Research Ethics & Governance Sub-Committee (and any of its Sub-Committees/oversight groups) should meet regularly to undertake ethical reviews and assess ethical risks of research and should report regularly to the Faculty Research Impact & Innovation Committee, and/or to the Faculty Management Boards as appropriate.

The Faculty Research Ethics & Governance sub-committees should provide a report **once per**

term, to the University Research Integrity: Ethics and Governance Committee with oversight information on ethical reviews, data on high-risk research and it's monitoring, and identifying any difficulties encountered in the process of ethical reviews. An annual audit of each Faculty Research Ethics & Governance sub-committee should be undertaken and reported to the University Research Integrity: Ethics & Governance Committee at the last meeting of each academic year.

It is expected that cases of disagreement of ethical approval by Faculty Research Ethics & Governance sub-committees would be referred to the University Research Integrity: Ethics and Governance Committee. More broadly, the University Research Integrity: Ethics and Governance Committee should seek to resolve any problems that cannot be dealt with at Faculty level and provide advice to the Chairs of Faculty Research Ethics & Governance Committees, where appropriate.

The Faculty website should include links to relevant information on Faculty Research Ethics & Governance sub-committees and/or other sub-committees/oversight groups; their terms of reference, membership, meeting dates etc. along with research guidelines; procedures for obtaining ethical approval; and links to relevant external websites. The Chair of the Faculty Research Ethics & Governance Sub-Committee should be a member of the Faculty Research Impact & Innovation Committee.

Faculty's are expected to bring to the attention of the Pro Vice-Chancellor (Research & Innovation) or the University Research Integrity Manager any cases of alleged research misconduct should they arise by emailing: researchmisconduct@swansea.ac.uk

Faculty and subject-specific ethics information and policies can be accessed through the following links:

- **Faculty of Arts & Humanities**
  Arts and Humanities Research Ethics - Swansea University

  Hilary Rodham Clinton School of Law
  https://www.swansea.ac.uk/law/research/researchethics/
  School of Management
  https://www.swansea.ac.uk/som/research/researchethics/

- **Faculty of Science & Engineering**
  FSE Research Ethics Committee (REC) - Swansea University

- **Faculty of Medicine, Health, and Life Sciences.**
  Research Ethics and Governance - Swansea University

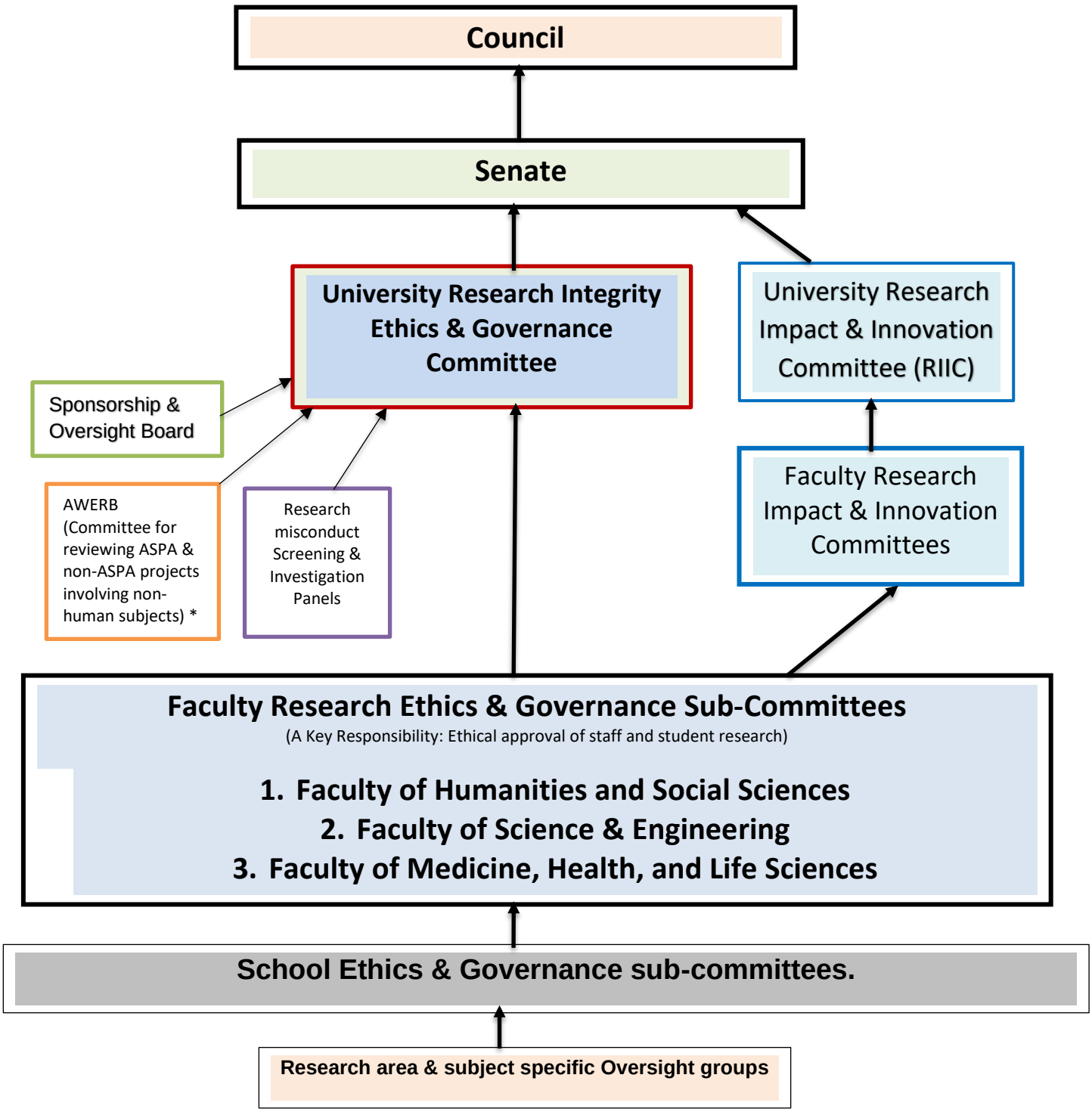
1.5 COMPLIANCE REQUIREMENTS

- **Compliance with NHS ethics policies**: The Framework is designed to complement the National Health Service (NHS) ethics review system.

- **Compliance with research funding body ethics policies**: Research funding bodies may have their own research ethics policies and requirements. In such cases, it is expected that the researcher will observe these policies and requirements, and the conditions of receiving funding will be considered alongside University policies. It is always advisable to observe the University policies and associated procedures as an additional layer of research ethics governance.

- **Compliance with external stakeholder ethics policies**: Professional bodies and learned societies may also have their own ethics policies, guidelines, and requirements. Whilst these should be followed where it is appropriate so to do, researchers must also adhere to the University's Framework.

RESEARCH INTEGRITY: EHICS & GOVERNANCE COMMITTEE REPORTING STRUCTURE



**AWERP: Animal Welfare & Ethical Review Process Group.*

Section 2

POLICY ON INTERNAL ETHICAL APPROVAL

(Excludes NHS REC approval process through IRAS)

2.1 Ethical standards

Upholding highest ethical standards in the conduct of research means accepting and respecting principles of integrity, honesty, and openness. Conducting research with integrity means embracing intellectual honesty and accepting personal responsibility for one's own actions.

Prior to, during, and following the completion of research activities, researchers are expected to consider the ethical implications of their research depending on its nature and context.

Researchers should always consider their research from the perspective(s) of all interested parties.

2.2 Assessing research risks and determining whether ethical approval is required

If research involves data that are not in the public domain, and/or involves using human participants (e.g., in questionnaires, interventions or interviews), human tissue, or animals, then some form of ethical review of the research would normally be required. Where there are no explicit legislative or regulatory requirements for ethical approval, there are a number of questions that should be considered when determining the level of ethical approval required for a research proposal. Such questions should include at least the following:

- Does the research involve vulnerable groups, such as children or people with cognitive impairment?
  (Please consult the University Policy of Working with Children and Vulnerable Adults within this framework document)
- Is there any risk that potential participants might feel pressured into agreeing to take part in the research? This could be the case, for example, where there is an imbalance of power between the researcher and the participants (e.g., doctor and patient, lecturer and student, line manager and employee).
- Will the study discuss sensitive topics (e.g., bereavement, sexuality, or drug use)?
- Could the research compromise the anonymity of the participants (e.g., via use of email or the Internet)?
- Could the study cause embarrassment, anxiety, or distress to participants?
- Would the research involve animals, organisms, human tissue, personal data or cause any harm to the environment?

(The above examples comprise the kinds of considerations that should be thought through, but by no means constitutes an exhaustive list).

It will be the responsibility of the Faculty Research Ethics and Governance Sub-Committees to determine the requirements for ethical approval and determine the level of ethical risk

associated with the research project. Any lead researcher or Principal Investigator (or the supervisor of student research) preparing an application should review the checklist and exercise appropriate professional judgement by way of good practice.

2.3 Procedures on quality checks and assurance

The University will give guidance to researchers and will work to create and maintain a culture of research integrity that encourages and supports researchers by providing training to enable them to understand and meet their obligations.

The University will provide the following tools and training to enable compliance with this Policy Framework:

- The risk assessment processes are separate from ethics approval. All ethics approval are given on the basis of risk assessment being completed.
- Training and education in the regulations governing these areas of research through staff development, e-learning, and external training providers;
- Monitoring of research projects in accordance with University monitoring/audit procedures;
- Support of and engagement with internal and external audits and inspections of projects in the area of research; and
- An annual report to the Senate and the Higher Education Funding Council of Wales (HEFCW).

2.4 Ethical approval of External Collaborative Projects

In collaborative projects where the Principal Investigator is not an employee of the University, or where Swansea University is not the lead, the ethical approval granted by another institution will be accepted provided that the Faculty Research Ethics & Governance sub-committee approve elements of the research conducted at the University or by an employee of the University. In such cases the Faculty Research Ethics and Governance sub-committee must keep a record of the project by uploading relevant documentation in the online system (e.g., a copy of the external ethics application form and any other documentation confirming ethical approval) and include these projects in their quarterly report to the University Research Integrity: Ethics & Governance committee.
Where Swansea University is the lead institution partnering with another University or an Institution, a copy of the ethical approval provided by the partner University or Institution must be requested for our records and uploaded into the online system. In such cases the ethical approval granted by an ethics committee at Swansea University with be accepted as the primarily approval. The partner institution will be sent a copy of Swansea University ethics approval.

2.5 Research Ethics review appeals:

An appeal can be made in instances of procedural irregularities in the review process, or if bias or prejudice has influenced the decision of the committee. Any material relating to the

case that was not brought to the attention of the Faculty Research Ethics & Governance sub-committee when the initial review decision was taken should be re-submitted for approval to relevant body with the updated information rather than as an appeal against the original decision.

- Researchers are encouraged to refer any 'appeals' on ethics approval to the Chair or Deputy Chair of the Faculty Research Ethics & Governance Sub-Committees in the first instance.
- Issues that cannot be resolved by the Faculty Committees due to the above body/persons being conflicted should be referred to the Chair of the University Research Integrity: Ethics and Governance Committee.
- In the event that all of the above bodies/persons are conflicted, the matter must be referred either to the Registrar through the University Secretary.
- Persons making appeals will be protected by the University policies on Whistleblowing, Victimisation and Harassment.

Procedure for making appeals:

- Researcher to notify the Administrator of the Faculty Research Ethics & Governance sub-committee, in writing, within 10 working days of having received the original committee decision.
- The appeals documentation should include the following details: Title of the research project, name of lead researcher or supervisor, date of the committee decision against which the appeal was being made, and grounds for appeal with any further supporting documentation.
- The Chair of the Faculty Committee should screen the application and confirm in writing if he/she is the most appropriate person to Chair the appeal committee.
- If the Chair is conflicted, then the appeal should be referred to either the Deputy Chair of the Faculty Research Ethics & Governance Sub-Committee, or Chair of the University Research Integrity: Ethics & Governance committee, as appropriate through the relevant committee secretary (Faculty or the University).
- Where the appeal is based on valid grounds, a suitable panel will be convened comprising researchers with expertise in the area and an academic member of staff from a different area and if appropriate, an external lay member.
- The panel may meet virtually, or face to face, at the discretion of the Chair of the appeals panel.
- The panel will process the appeal as soon as possible and preferably within four working weeks from the receipt of the original appeal.
- The applicant will be informed in writing of the date of the meeting and the decision of the panel.
- The decision of the appeal panel will be final.

Records of appeals at Faculty Research Ethics & Governance sub-committees will be kept and included in the annual summary report to the University Research Integrity Ethics & Governance committee.

The Administrators to the Faculty and University Research Integrity Ethics & Governance committees will ensure that institutional or contractual obligations in case of funded projects are identified with relevant staff in Research Engagement & Innovation Services (REIS).

Section 3

POLICY ON HEALTHCARE RESEARCH

It is a requirement for some research to have a formal sponsor. The sponsorship responsibilities for health and social care research are documented within the UK Policy Framework for Health & Social Care Research (2017) ***Clinical Trials of Investigational Medicinal Products*** (CTIMP's) are governed by the ***EU Clinical Trials Directive***, and further clarified by the ***Good Clinical Practice (GCP) Directive 2005/28/EC***. Other types of research may require a formal sponsor, with its own particular set of responsibilities.

NHS Research Ethics Committees (RECs) require evidence that a sponsor has accepted the role on submission of an application. The Medicines and Healthcare Products Regulatory Agency (MHRA) requires evidence that a sponsor has accepted the role before any Clinical or Device Trials are authorised.

The sponsor is the individual, organisation or partnership that takes on overall responsibility for appropriate arrangements being in place to set up, run and report a research project. All health and social care research must have a sponsor. The sponsor is normally expected to be the employer of the chief investigator/principal investigator in the case of non-commercial research, or the funder in the case of commercial research. The sponsor has overall responsibility for the design and management of the research, including:

a. verifying that everything is ready for the research to begin in a safe and timely manner;

b. putting and keeping in place arrangements to finance and manage the research project, including its competent risk management;

c. identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications;

d. ensuring that the research proposal or protocol is scientifically sound (e.g. through independent expert review, if appropriate) and that the investigators, research team and research sites are suitable;

e. satisfying itself that, where expected or required, the research has a favourable research ethics committee opinion and all relevant approvals before it begins;

f. satisfying itself that the chief investigator/principal investigator has made appropriate arrangements for making information about the research publicly available, normally before it starts, and for retaining and making accurate findings, data and tissue accessible, as appropriate, after it has finished;

g. ensuring that roles and responsibilities of the parties involved in the research are agreed and appropriately documented;

h. ensuring appropriate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project and any commercialisation of the findings; and

i. ensuring that appropriate, effective procedures and arrangements are kept in place and adhered to for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

The University will act as a 'Sponsor' only if it is satisfied that:

- the Project respects the dignity, rights, safety, and well-being of participants and the relationship with care professionals;
- an appropriate process of independent expert review demonstrates that the Project proposal is worthwhile, of high scientific quality, and represents good value for money;
- an appropriate Research Ethics Committee & Sponsorship Review and Approval Committee has reviewed the Project and has given a favourable opinion in writing;
- appropriate arrangements are in place for the registration of the trial or where appropriate other health-related research;
- the Principal Investigator/Chief investigator and other key researchers, including those at collaborating sites, have the necessary expertise and experience, and have access to the resources and support, needed to conduct the proposed Project successfully;
- the proposed arrangements and resources allow the collection and proper retention of high-quality data, and the proposed systems and resources are those required to allow appropriate data analysis and data protection;
- arrangements proposed for the Project are consistent with all applicable Regulations, statutes, and guidelines;
- organisations and individuals involved in the Project agree the division of responsibilities between them to ensure that:

    - satisfactory arrangements are in place for the management and monitoring of the Project, and that these are documented;
    - satisfactory arrangements are in place for the conclusion of the Project including appropriate plans for reporting the Project, disseminating the findings, archiving, data retention and destruction; and
    - the Trial Master File or study documentation includes copies of the following: the informed consent form; the Principal Investigator's CV; the application to the relevant NHS REC, MHRA and the approval letters when received; the Protocol, and any approved amendments thereto; and

- there is agreement in writing on appropriate arrangements for:
    - recording, reporting and reviewing adverse events and any significant developments as the Project proceeds, particularly those that put the safety of individuals or the reputation of the University at risk;
    - approval of any modifications to the Project design;
    - a robust system to alert the University and other stakeholder organisations, including

the NHS REC and MHRA, if significant developments occur as the Project progresses, whether in relation to the safety of individuals or the scientific direction;

- ensuring that all members of the research team have appropriate contracts in place to fulfil their obligations in the Project and enable the Principal Investigator and the University as Sponsor to fulfil their obligations; and
- the University has put in place a service level agreement (SLA) to enable a delegated individual to undertake certain Sponsor responsibilities on its behalf for all University sponsored studies, regardless of where they are hosted.

Where projects are co-sponsored, formal arrangements should be put in place:

a) Between the Co-sponsors – so it is clear where all liabilities of fulfilling requirements lie. This should ideally be documented using a contract or a Memorandum of Understanding, either issued on a trial–by-trial basis or as an overarching master agreement for all clinical trials where two or more organisations are closely connected and often collaborate (e.g. NHS Trust and the University); and

b) Between sponsors and those delegated sponsor functions – to ensure all parties are aware of their delegated functions.

OBLIGATIONS OF THE PRINCIPAL/CHIEF INVESTIGATOR

As a University employee or for a University sponsored CTIMP or Devices trial, the Principal Investigator of the project must ensure that they adhere to the following:

- the dignity, rights, safety, and well-being of research participants will be given priority at all times;
- the Protocol shall be strictly adhered to. However, adhering to the Protocol shall not override the Principal Investigator's clinical judgement to use alternative measures if they believe these are needed to protect research participants for whom they are clinically responsible;
- the Principal Investigator has the necessary experience, suitable qualifications, training, and expertise to undertake the tasks associated with the Project;
- the Principal Investigator is responsible for ensuring that any research staff undertaking the project have suitable qualifications, necessary experience, training, and expertise to undertake tasks associated with the Project. For Clinical Trials Projects, the training should include Good Clinical Practice (GCP) and copies of the training should be included in the Trial Master File; and
- the Principal Investigator should ensure that students and research staff have adequate supervision, support, and training to undertake their roles in the project.

The University reserves the right to withdraw sponsorship and take whatever action necessary to ensure the safety of research participants and its ability to act as sponsor if it believes the Principal Investigator is not fulfilling their obligations. In addition, non-compliance with the obligations by the Principal Investigator may lead to action under the

University's Staff Disciplinary Procedures and may invalidate the terms of any University Insurance for the trial.

Please contact Research Governance Manager (researchgovernance@swansea.ac.uk) for further information.

Section 4

POLICY ON HEALTH & SOCIAL CARE RESEARCH

The UK policy framework for health and social care research sets out principles of good practice in the management and conduct of health and social care research that take appropriate account of legal requirements and other standards. These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

All forms of research involving human participants (including their tissue, organs, or data) will follow the highest standards of research ethics, governance, and relevant legislation, and will be conducted with the utmost care and respect for human welfare and rights.

Human participants in research must take part voluntarily and free of any coercion. Research involving humans will usually occur under informed consent. All research staff and participants would normally be fully informed of the purpose and methodologies of the research, the associated risks of participation and the proposed uses of the research data. Consent must be sought for any biological samples that might be used for future research.

Ethical consideration will be given to all research involving human participants or biological samples. Review by a relevant ethics committee (both internal and external to the University) will be undertaken as appropriate. Approval from other regulatory bodies, such as the Medicines and Healthcare products Regulatory Agency (MHRA), Human Fertilisation and Embryology Authority (HFEA), the Gene Therapy Advisory Committee (GTAC), or Health and Social Care Information Centre (HSCIC), Human Tissue Authority (HTA) will also be sought where necessary. Researchers should ensure the confidentiality of personal information relating to the participants in research and fulfil any legal requirements such as those of the Data Protection Act 1998 and GDPR for such research.

4.1 Health and Social Care Research.

The Welsh Government's Health & Care Research Wales (HCRW) sets out a clear framework for research governance and ethics for health and social care research in Wales. HCRW is responsible for developing research ethics policy in Wales.

NHS Research Ethics Committees act as part of an efficient, accountable, and independent Research Ethics Service to protect the dignity, rights, safety, and well-being of the people who take part in research.

4.2 NHS Research Ethics Committees

For Health and Social Care research, researchers must satisfy an NHS Research Ethics Committee, that the research they propose will be ethical and worthwhile. The NHS Research Ethics committee has to be assured that any anticipated risks, burdens, or intrusions will be

minimised for the people taking part in the research, and any risks are justified by the expected benefits for the participants or for science and society.

An NHS Research Ethics Committee is a group of people appointed to review research proposals to assess formally if the research is ethical. In Wales, there are 8 NHS Research Ethics Committees set up to provide ethical approval to research being conducted in the NHS. Four of these have been recognised by the United Kingdom Ethics Committee Authority to be able to review Clinical Trials of an Investigational Medicinal Products as required by The Medicines for Human Use (Clinical Trials) Regulations 2004. The other four Research Ethics Committees are authorised to review all other research applications except those relating to Clinical Trials of an Investigational Medicinal Product.

4.3 The Human Tissue Authority

The Human Tissue Authority (HTA) licenses organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. In the School of Medicine there are designated individuals responsible for ensuring compliance with the relevant Human Tissue legislation for both research and teaching. For further information on HTA contacts in the University, visit: https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/

4.4 School of Medicine - The Secure Anonymised Information Linkage Databank

The Secure Anonymised Information Linkage **(SAIL)** Databank is an excellent, anonymous data linkage system that securely brings together the widest possible array of routinely collected data for research, development, and evaluation. Robust Governance arrangements underpin all areas of the work so that SAIL represents a valuable data resource, whilst complying with data protection legislation and confidentiality guidelines.

SAIL is committed to:

- robust Governance arrangements and Public Engagement to ensure that our work complies with the relevant legislative and regulatory frameworks and is in the public interest.
- has an Advisory Board to provide strategic input from members of the public and leaders in the field of health information and research in Wales.
- benefits from an active Consumer Panel to provide a public perspective on data linkage research.
- has a Management Board that comprises of the SAIL Directors and Management Team, to oversee and direct operational arrangements.
- has an Information Governance review Panel (IGRP) that provides independent advice on Information Governance and reviews all proposals to use SAIL data to ensure that they are appropriate and in the public interest.

The membership of the IGRP is comprised of representatives from: British Medical Association

(BMA), National Research Ethics Service (NRES), Public Health Wales, NHS Wales Informatics Service (NWIS) and Consumer Panel.

POLICY ON RISK ASSESSMENT OF RESEARCH PROJECTS

Policy No. **P1617-1012 (Version 3)**
Effective Date: 2020.
Last Revised: December 2022.
Next review Date: October 2027.
Policy Owner: Research Engagement & Innovation Services.
Policy Author: Various.
Approval Body: University Research Integrity: Ethics & Governance Committee.

Summary:

Swansea University is committed to maintaining the highest standards of rigour and integrity in all aspects of research. The University has developed a **Research Integrity Policy Framework** of ethical policies, processes, and guidelines, which all research active staff and students must follow prior to embarking on a research project and during the lifespan of a project. On behalf of the University, Faculties, Schools, and Departments are responsible for ensuring that all staff and students conducting research are aware of the requirements of conducting research according to the University's ethical standards.

This policy focuses on providing guidance to assess ethical risks of research projects. Comprehensive policies and guidance on University's Health and Safety assessments for Research is available on: Policies and procedures - Swansea University. Faculty & School Research Ethics and Governance Sub-Committees must comply with this policy whilst conducting an ethical review to determine the risk level of a research project.

Purpose:

All research projects should be reviewed to categorize the risks of research so that proportionate levels of monitoring can be undertaken.

The **UKRI Framework for Research Ethics** advises researchers to follow six key principles whilst planning a research project and conducting research:

- research should aim to maximise benefit for individuals and society and minimise risk and harm
- the rights and dignity of individuals and groups should be respected
- wherever possible, participation should be voluntary and appropriately informed
- research should be conducted with integrity and transparency
- lines of responsibility and accountability should be clearly defined
- independence of research should be maintained and where conflicts of interest cannot be avoided, they should be made explicit.

Ethical approval process is part of good research practice and should be integrated into the planning and management of a research project. Researchers, Research organisations and Research Ethics Committees should consider ethics issues throughout the lifecycle of a research project and promote a culture of ethical reflection, debate, and mutual learning.

Assessing risks is not simply a procedural requirement, rather, committees and researchers need to reflect on three key questions in relation to project plan:

- What is 'harm'?
- What is 'risk'?
- What are the potential benefits?

The aims of the ethical approval process are:

- To seek to protect participants, subjects, and objects of research from psychological, physical, and social harm. These may include humans, animals, the natural and built environment and cultural objects.
- To seek to protect the researcher (from complaint or harm)
- To seek to protect the Institutional reputation (from complaint, negative publicity, public and academic mistrust)

Ethical Risk assessment of a research project:

1. **Identifying ethical risks of research (Research design)**

(For further guidance: Please refer to Appendix: UKRIO Checklist for Researchers)
Research risks may vary according to a discipline or subject area. Prior to commencing a research project, an initial risk assessment of the project must be undertaken by the researcher in consultation with the Principal Investigator (PI) of the project for staff research, and the Supervisor for student research. This initial risk assessment should be conducted in accordance with discipline specific or funder guidelines and policies. The researcher should prepare the research proposal, identifying the ethical issues in relation to the research method, and propose methods for mitigating any risks. The ethics application or research proposal should be submitted thereafter for an ethical approval using the University online system for review by designated assessor(s) of the Faculty Research Ethics & Governance sub-committee. Supporting documentation, including data management strategy, statutory checks such as DBS certificates, documents to support compliance (e.g., GDPR, Prevent Security checks etc.), template of a participant information sheet, template of consent forms, participant support strategies, debriefing information, other statutory or regulatory permissions and approvals, evidence of completion of the research integrity training, or any other relevant ethics training should be submitted along with the application form. Researchers preparing a proposal for NHS and requiring University sponsorship should contact researchgovernance@swansea.ac.uk for further assistance and guidance or visit the University Research Governance webpages for information.
Researchers should declare any potential or actual conflict of interest in research: This refers to instances where financial situations or personal relationships may compromise, or have the appearance of compromising, a researcher's professional judgment in conducting or reporting research. When addressing a conflict of interest, it must be decided whether it is of a type and/or severity that poses a risk of fatally compromising the validity or integrity of the research. If such is the case, then the researcher(s) and organization(s) should not proceed

with the research. If, however, the risks can be adequately addressed through declarations and/or special safeguards relating to the conduct and reporting of the research, then the research can proceed (UKRI).
Conflicts of interest must be disclosed as soon as Researchers become aware of them. The University requires researchers to follow UKRI guidelines to identify, disclose, and address actual or potential conflicts of interest relating to their research and bring them to the attention of the University by emailing innovations@swansea.ac.uk or the Research team leaders or Faculty Research Ethics Leads and report their findings at meetings or in publications. Researchers must agree to abide by the University Conflict of interest policy and follow the direction provided by the relevant Faculty Research Ethics & Governance Sub-Committees.

2. Assessing ethical risk levels

Researchers should have respect for all participants, and subjects of research including humans, animals, the environment, and cultural objects. The University expects all researchers to consider the ethical implications of their research and to be aware of their responsibilities to society, the environment, their profession, the University, research participants and the organisation(s) funding the research.
Ethical scrutiny of the risks of a research project determines the category of risk of the research being conducted and this in turn determines the level of approval and monitoring that the project would require. For a research student project, the initial ethical risk assessment should be carried out with support from the Supervisor, at the point of Confirmation of Candidature (3 months since enrolment).
The following guidance will assist researchers and supervisors self-assess and categorise the research proposals into one of the three categories at the initial review stage so that appropriate supporting documentation can be submitted with the research proposal. The assessor of the research application would thereafter confirm the final risk level with assistance from the guidance below.

Guidance for Assessing Risk of Research Projects

According to the UKRIO (2020) guidelines for any academic research, risk is best assessed by practitioners in the department who are familiar with their discipline.
Risks can be evaluated using four criteria (adapted from Raan 2009, and UKRIO 2020):

1. How **routine** is the research being proposed? Is it routine? or infrequent?
2. What **permits** and training are required? Can anybody do this work? or are there any special permits, licences, or restrictions in place? Is a specialist training required?
3. If things went wrong what would be the potential **impact** to participants, researchers, University, general Environment, or society? Would this be moderate, significant, or serious?
4. What is the **likelihood** that an impact will occur? Is it negligible, possible, or probable?

According to these criteria each research project can be classified into **three risk categories** using the Risk Matrix given below (Table 1)

Table 1. Impact vs Likelihood Risk classification matrix (adapted from Raan 2009)

Potential impact	Likelihood that an impact will occur		
	Negligible	Possible	Probable
Serious	Low	Moderate	High
Significant	Low	Moderate	Moderate
Moderate	Low	Low	Low

Low Risk: Routine research work that does not require any additional permits or dispensations, specialist training or courses and whose potential reputational impact is moderate or if potentially significant, its likelihood is deemed negligible. No further monitoring is necessary.

Examples: *(Further examples included in Appendix 1)*

Animals

– Non interventional observation of wild animals in their natural habitat with minimal disturbance

– Non interventional (does not involve capture, handling, and/or confinement) observation of behaviour of captive animals in their holding areas

– Interventional studies which may only cause sub-threshold, temporary discomfort, but never pain, suffering, prolonged distress, or lasting harm

Human participants

– Questionnaire surveys with consenting non-vulnerable adult human participants that do not collect personal or sensitive data or involve a sensitive topic.

Environmental

– Work with invasive species/GMOs within closed systems where biocontainment procedures are in place and there no possibility of accidental release into the environment

Moderate Risk: Non-routine research work that may require a special permit, licence or dispensation, specialised training or courses and whose potential reputational impact is not moderate and the likelihood not negligible. Further monitoring might be necessary.

Examples: *(Further examples included in Appendix 1)*

Animals

–The direct intervention of wild or captive animals which may cause mild to moderate pain, suffering, distress, or lasting harm (as defined by ASPA) and may require appropriate training and licences.

Human participants

– Research with human participants that requires them to provide personal and/or sensitive information, but which is unlikely to lead to significant levels of distress

– Research on topics which are neither contentious nor sensitive, and which only result in temporary distress only in rare instances

– Reviews or evaluations of topics that may be of a sensitive nature, but that are not personal to the participants

Environmental

– Work with non-native species or genetically modified organisms in an open system under controlled conditions with biocontainment procedures in place

High Risk: Infrequent research work that due its nature always requires a special permit, licence, dispensation, specialist training or courses and whose potential reputational impact would probably be serious. Regular and closer monitoring would be required.
Examples: *(Further examples included in Appendix 1)*

Animals

– The direct intervention on wild or captive animals which may cause moderate to severe pain, suffering, distress, or lasting harm (as defined by ASPA) and would always require appropriate training and licences.

Human participants

– Research with vulnerable human participants who are unable to give informed consent should be considered by the NHS Ethics. Research with vulnerable human participants who may need additional support and assistance to enable them to participate.

– Research that addresses themes or issues in respect to participant's personal *experience* which may be of a sensitive nature and involves a risk of psychological damage or distress to the subject, or to the subject's family

– Research which directly involves human subjects in sensitive topics such as terrorism, abuse, sexual experience.

Environmental

– Work with highly invasive species in open natural systems which involves the deliberate introduction outside their natural range or when there is a high probability that may happen accidentally due to the nature of the work.

Guidance on the Risk Assessment of Collaborative Research not led by the University:

All research led by a third party needs to go through a committee and is subject to review and an approval by a Chair. The reviewer should have the approval letter from the lead organisation, the application, and the supporting documents.

The review is slightly different in that it is addresses the following 2 questions:

1. **Is the review process as rigorous /equivalent as that of Swansea University?**
   No – go to 2
   Yes – recommend application approval
2. **Is there a significant risk of non-trivial harm or moderate or high reputational risk to Swansea?**
   No - recommend application approval
   Yes - recommend reject the application.

Once the review is complete and the reviewer is satisfied with the ethical review undertaken by the lead organisation, the reviewer will allocate a risk level. The online application will then be sent to the Chair/delegate Chair to finalise the risk level and generate the approval /rejection letter. The same approval/rejection letter would be provided to the applicant for all applications.

If further information is required, the online application would be sent back to the applicant to supply clarification of minor points by using the general comments box. If the application

is deemed to be unacceptable the risk will be accessed by the reviewer and a timeline note added to reject the application. The Ethics Chair will comment on the application in general comments, finalise the risk, and reject the application.

3. Monitoring a research project

Once a research projects ethical risks have been assessed and the risk levels categorised as low, moderate, or high, and then confirmed and approved by the relevant Research Ethics committee, then the research can commence. Monitoring of a research project should be undertaken on the basis of the risk classification matrix (Table 1).
Research projects classified as 'high risk' will require closer and regular monitoring by the relevant Faculty Research Ethics & Governance Sub Committees before project completion. Faculties must have a register of all high-risk projects and build in a monitoring cycle for each project. Quarterly reports to the University Research Integrity: Ethics & Governance Committee should enlist the status of all high-risk projects within the Faculty.

4. Referral of a project to higher Committees:

In instances where the reviewers/assessors are unable to agree or arrive at a satisfactory decision regarding the risk categorisation or come to an ethical decision on a research project due to the wider strategic implications that the proposal may have on the University, then the proposal must be referred to the University Research Integrity: Ethics & Governance Committee. Referral of such applications to the University Research Integrity; Ethics & Governance Committee is the responsibility of the Faculty Ethics & Governance sub-committee.

Referrals to the University committee should be accompanied by:

- a written statement of specific issues for advice or guidance,
- the statement should be supported by the papers considered by the Faculty Ethics & Governance Committee.
- A summary of the reasons for doubt or disagreement on each specific issue.

In order to arrive at a resolution, the University Research Integrity: Ethics and Governance Committee (URIEGC) can, if necessary, undertake the following:

- invite for discussion members of the Faculty Research Ethics & Governance sub-committee.
- request attendance of the proposers of the research application and any other member of staff involved in reviewing the application.

The University Research Integrity Ethics & Governance Committee (URIEGC) shall seek advice as appropriate and give guidance based on the information made available to it. The procedures of the URIEGC shall be publicly available in writing. The discussions of the URIEGC shall be strictly confidential, subject to legal data protection requirements. The guidance given shall be recorded in writing and sent to the Faculty Research Ethics & Governance sub-committee.
The University Research Integrity: Ethics & Governance Committee (URIEGC) will give

guidance to the Faculty Research Ethics & Governance sub-committee, but it will remain the responsibility of the Faculty Committee to make the final decision on the research application and to notify the researchers of the progress of the application and the outcome of review.

5. **Appeals**

The University Research Integrity: Ethics & Governance Committee (URIEGC) will consider appeals from Faculty Ethics Committee on the following matters:
(a) Questions that arise out of applications for ethical approval that have a broader strategic implication for the University and therefore require a deeper consideration should be referred to the attention of the University Research Integrity: Ethics and Governance committee.
(b) Appeals against decisions made by the Faculty Research Ethics & Governance sub-committees, but only once the local procedure for resolving difficulties has been exhausted as highlighted in 4 above.

Policy History

Version	Author	Summary of changes	Approved by	Date
1	Anjana Choudhuri, Dr Jeanette Hewitt, Ciaran Whyte, Gail Evans.	First Version	*UREGSC*	May 2017
2	Feedback from University Research Ethics & Governance sub- committee members, Corinna Summerill, Andrew Jones, Dr Lisa Wakeman, Dr Sherrill Snelgrove, Professor Carlos Garcia De-Leaniz, Dr Rebecca Stringwell, Directors of College/School PGR committees.	Second Version	UREGSC	Nov 2019
3	Anjana Choudhuri, Professor Carlos Garcia De-Leaniz,	Third Version	URIEGC	Feb 2023

	Dr Rebecca Stringwell, Faculty Ethics Committee Members.			

Examples of research and their risk classification:

(Please note that this is not an exhaustive list, and it is the responsibility of the assessors to confirm the risks of a research project)

High-risk research involves one or more of the following:

- research undertaken with groups within society in need of special support,
- research that is carried out in an unstable or volatile setting, involve non-standard methodologies or approaches,
- research that presents risks to the personal safety of the researcher or research participants/subjects beyond what is normal in the setting,
- research that has the potential to cause distress as it may be distressing to the researcher or research participant or subject in one or more ways
- The research engages children under the age of 16 years outside of a cultural institution, which has been accredited to work with children and young people, school, youth club, or other accredited organisations.
- Adults or children with learning difficulties unable to self-consent are subject to NHS ethics.
- Children with learning difficulties who are unable or unwilling to consent/assent to the research.
- Adults or children with acute mental illness
- Patients detained under mental health legislation
- Those who could be considered to have a particularly dependent relationship with the researcher and are liable to coercion.
- Prisoners or young offenders will be the subject to NHS ethics
- Any other group who can be regarded as vulnerable or dependent (asylum seekers with a culturally and linguistically diverse background)
- Research that takes place in an international setting that the UK Foreign and Commonwealth Office advises against 'all but essential' travel. Advice for travel for research can be obtained via the Home Office webpages (https://www.gov.uk/foreign-travel-advice) or by consulting the Head of Business Continuity in the University.
- Research that addresses themes or issues in respect to participant's personal *experience* which may be of a sensitive nature and that therefore may involve any risk of psychological damage or distress to the subject (or the subject's family
- Research which directly involves human subjects in sensitive topics such as terrorism, abuse, sexual experience etc. https://www.gov.uk/guidance/official-sensitive-data-and-it
- Research that cannot be completed without data collection or associated activities, which places the researcher and/or participant (or the participant's family) at physical risk or serious inconvenience.
- Research that requires participant informed consent and/or withdrawal procedures, which are not consistent with, accepted practice.
- Research that involves primary data collection on an area of public or social objection (e.g. terrorism, paedophilia)
- Research that involves the necessary deception of research participants.

- Research that makes use of video or other images captured by the researcher, and/or research study participants, where the researcher cannot guarantee controlled access to authorised viewing.
- Research that includes or considers aspects of terrorism and extremism related issues. *(Guidance regarding such research should be sought from the University Prevent co-ordinator or Head of Business Resilience within the Professional services departments).* (https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/security-sensitive-research-material-UK-universities-guidance.aspx
- Research that involves the administration of drugs or use of invasive or semi-invasive procedures.
- Research that involves the collection, storage, or use of tissue from deceased or living subjects and considered 'relevant material' under the Human Tissue Act 2004. This includes material such as bodies, organs, and tissues, consisting largely or entirely of cells, and clearly identifiable. A separate risk assessment will need to be completed in conjunction with the designated individual identified within the Universities license (contact researchgovernance@swansea.ac.uk) in the first instance
- Work with a highly invasive species where there is a direct risk of species relocation or spread due to the nature of the work.
- Work with animals under Home Office approved Project licence with severity classification of moderate to severe and a high reputational risk profile.

While formulating a research proposal, researchers must consider the following:

- Indemnity arrangements,
- health & safety implications,
- Data protection implications,
- Official Secrets Act implications
- Any necessary Health Safety Executive approvals
- Requirement for licences for specific regulatory requirements. [e.g., National Health Service (NHS), Medicines and Healthcare products Regulatory Agency (MHRA), Human Tissue Authority (HTA), Animals (Scientific Procedures) Act 1986, or UK Government]

Research undertaken to create the following or with the following will require stringent regulatory approval from various authorities

- Medicinal products
- Clinical trial
- Pharmacologically active substances
- Animals*, or material derived from live animals
  *(*Animals defined as any living vertebrate other than man and any living cephalopod*).
- Children and vulnerable adults
- NHS staff, patients, premises, or equipment
- Human tissue (e.g., blood or saliva samples, tissue from cadavers)
- Research that causes significant concerns around personal safety or physical discomfort beyond normal experience, for the participants /subjects or researchers.
- Sensitive topics such as trauma, bereavement, drug-use, sexual health.

- Security Sensitive Research Material and Data which comes under the Official Secrets Act

A separate **Fieldwork risk assessment** must be completed, if the research takes place off site even if it does not involve human participants, subjects, or animals. A risk assessment identifies risks associated with activities that the research participants are engaging in, and risks associated with travel to areas inside or outside the UK. It also outlines how the researcher will manage those risks. Please consult the University Policy on Fieldwork (Health & Safety in Research - Swansea University)

Moderate risk research: Moderate risk research can involve any one or more of the following:

- Non-vulnerable adults
- Personal data referring to a living individual
- Secondary data not in the public domain
- Environmental issues (Pollution, recycling methods etc.)
- Commercially sensitive information
- Invasive live animal research

Moderate risk research can be described as research that does not contravene or conflict with *any* of the following:

Research carried out by Swansea University staff or students involving:

- Live animals (as defined by Animal Scientific Procedure Act) (ASPA): which is invasive, and would require a project licence, approved by the Home Office, and would have a severity classification of moderate to severe and a moderate reputational risk profile
- Deliberate release of a non-native species or genetically modified organisms under controlled conditions
- Research involving fire which if not controlled properly to spread and cause harm to the immediate environment
- Research that engages adults and/or children (the latter in an accredited setting such as a cultural institution, school or youth club and accompanied by a carer or professional with a duty of care) who are able to give informed consent in a way that accords with accepted practice.
- Research that does not involve vulnerable or dependent groups.
- Research that does not require research participants to provide personal and sensitive information likely to lead to significant levels of distress (research where the topics are either not contentious or sensitive at all, or where a reasonable person would agree the topic is of legitimate interest and may result in distress in *rare* instances);
- Research that is a review or evaluation, involving topics that may be of a sensitive nature, but that are not personal to the participants.
- Research that makes use of video or other images captured by the researcher, and/or research study participants, where the researcher is able to guarantee controlled access to authorised viewing.

Low risk research: examples of Low-risk research:

- The analysis of secondary data which has been previously published
- Desk or lab-based research which does not involve collecting data from people or animals
- Research carried out by Swansea University staff or students involving live animals (as defined by ASPA) which is invasive and would require a project licence, approved by the Home Office, and would have a severity classification of mild (species/subject dependant).
- Collection of data from observation of live animals with little or no disturbance to habitats
- Collection of tissue from animals with little or no disturbance to the animal
- Collection of personal data from humans who are not vulnerable, protected, or unable to give informed consent.
- Collection of data on human subjects which does not involve sensitive topics or materials
- Sampling of vegetation which does not pose any risk to the environment
- Research that recruits healthy adults and/or children (the latter in an accredited setting such as a cultural institution, school or youth club and accompanied by a carer or professional with a duty of care) who are able to give informed consent in a way that accords with accepted practice.

- Primary research on professional practice with participants in professional roles conducted in their work setting.
- Research that recruits participant groups limited to peers, colleagues, family members and friends and that is not of a contentious or sensitive nature.
- Research that does not involve vulnerable or dependent groups.
- Unobtrusive observation of animal habitats (subject dependant)
- Market research (i.e., the research may involve data collection from the general public approached or observed in public locations for the purposes of market investigation but does not involve the gathering of personal data).
- Primary research using an anonymous questionnaire completed and returned by participants with no direct contact with the researcher, where the topic is not sensitive or personally distressing.
- Research that does not involve the collection of video/photographs of research participants.

Even if a piece of research is classed as low risk, researchers need to be ethically aware and ensure that they have not breached plagiarism, copyright regulations or licenses and have adequately referenced their research material.

Section 6

POLICY ON RESEARCH INVOLVING THE USE OF ANIMALS

ANIMAL RESEARCH AT SWANSEA UNIVERSITY

The University is fully committed to the widespread promotion and implementation of the 3Rs (Reduction, Refinement and Replacement) and is a signatory to the Concordat on Openness on Animal Research.

In order to conduct high quality research, it is sometimes necessary for animals to be involved. Our research involving animals is undertaken with the highest standards of animal care and is only conducted when there are no feasible alternatives.

At Swansea University, some research involving animals is conducted in the fields of animal welfare, behaviour and cognition, ecology and conservation, immunology, and neuroscience.

The work our scientists undertake is governed and regulated by the Animals (Scientific Procedures) Act 1986 (ASPA). ASPA regulates procedures that are carried out on 'protected animals' for scientific purposes that may cause pain, suffering, distress, or lasting harm. 'Protected animals' are defined as all living vertebrates, other than a human, including certain immature forms and any living cephalopod.

The official Swansea University policy on the involvement of animals in research can be found here

GOVERNANCE

Swansea University have an Animal Welfare and Ethical Review Body (AWERB) which oversees any research or teaching which involves interventions with animals within the University facilities or in the field. The AWERB is comprised of individuals from a variety of backgrounds, including vets, animal welfare officers, scientists, and lay people. Its role is to:

- promote the ethical considerations of animal use;
- ensure that the principles embodied in the 3Rs are implemented;
- ensure high standards of animal care and welfare.

Applications to hold project licences (which are ultimately reviewed, authorised, and issued by the Home Office) must first be reviewed and approved by the University's AWERB. The procedure for AWERB review of licence applications is shown here: AWERB review of PPL applications.

In addition, we have an ethical review process for the use of animals in scientific research not regulated under ASPA because the research does not involve regulated procedures (for example, behavioural and observational projects).

As well as reporting to the Establishment Licence holder, the activities of AWERB are also reported to our Research Integrity: Ethics & Governance Committee (URIEG). This Committee sets standards and ensures the University meets its obligations to comply with regulations that govern research. URIEG conducts an annual review of the activities of the AWERB and reports to Senate.

The AWERB may be contacted via erp@swansea.ac.uk

Further information on the University's work with animals can be found at:
Animals in research - Swansea University

Section 7

POLICY ON MANAGING ENVIRONMENTAL RISKS OF RESEARCH

All research and teaching activities undertaken by staff and/or students, at the University or in the field, which involve a potential risk to the environment, such as the escape of invasive species or genetically modified organisms (GMO) or work involving human or animal pathogens, require an ethical approval from the Faculty Research Ethics & governance committee. The application should detail how the risk will be managed and demonstrate Knowledge and compliance with all existing regulations and laws. It is expected that appropriate contained-use facilities will be used, as detailed by the Health and Safety Executive (http://www.hse.gov.uk/biosafety/GMO/index.htm).

For the regulations, involving the use of GMO the competent authority is the Health and Safety Executive (HSE) and the Secretary of State (represented by officials from DEFRA). In particular, the HSE Notification Team and Specialist Inspect Teams should be contacted. Similarly, for research involving blood-borne viruses (BBV), compliance with the law must be demonstrated and appropriate risk assessment and risk reduction procedures must be in place, likely after having sought advice from the Advisory Committee on Dangerous Pathogens (http://www.hse.gov.uk/biosafety/blood-borne-viruses/index.htm).

Researchers and those with responsibility for the University estate should be mindful of the state of buildings and facilities in which work on animals and plants are undertaken and ensure that they are appropriate for the research. In some instances, modification to buildings and facilities may be required, and/or regulations put in place, to avoid shared use and risks of contamination or escape.

High-risk areas should be best placed outside main buildings, with a direct access for the delivery and elimination of the samples.

The Nagoya Protocol

What is the Nagoya Protocol and what is its objective?

The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity* is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

The Nagoya Protocol on ABS was adopted on 29 October 2010 in Nagoya, Japan and entered into force on 12 October 2014, 90 days after the deposit of the fiftieth instrument of ratification. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.

Why is the Nagoya Protocol important?

The Nagoya Protocol will create greater legal certainty and transparency for both providers and users of genetic resources by:

- Establishing more predictable conditions for access to genetic resources.
- Helping to ensure benefit-sharing when genetic resources leave the country providing the genetic resources

By helping to ensure benefit-sharing, the Nagoya Protocol creates incentives to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to development and human well-being.

What does the Nagoya Protocol cover?

The Nagoya Protocol applies to genetic resources that are covered by the CBD, and to the benefits arising from their utilization. The Nagoya Protocol also covers traditional knowledge (TK) associated with genetic resources that are covered by the CBD and the benefits arising from its utilization.

What are the core obligations of the Nagoya Protocol with respect to genetic resources?

The Nagoya Protocol sets out core obligations for its contracting Parties to take measures in relation to access to genetic resources, benefit-sharing and compliance.

Access obligations

Domestic-level access measures are to:

- Create legal certainty, clarity and transparency
- Provide fair and non-arbitrary rules and procedures
- Establish clear rules and procedures for prior informed consent and mutually agreed terms
- Provide for issuance of a permit or equivalent when access is granted
- Create conditions to promote and encourage research contributing to biodiversity conservation and sustainable use
- Pay due regard to cases of present or imminent emergencies that threaten human, animal or plant health
- Consider the importance of genetic resources for food and agriculture for food security

Benefit-sharing obligations

Domestic-level benefit-sharing measures are to provide for the fair and equitable sharing of benefits arising from the utilization of genetic resources with the contracting party providing genetic resources. Utilization includes research and development on the genetic or biochemical composition of genetic resources, as well as subsequent applications and commercialization. Sharing is subject to mutually agreed terms. Benefits may be monetary or non-monetary such as royalties and the sharing of research results.

Compliance obligations

Specific obligations to support compliance with the domestic legislation or regulatory requirements of the contracting party providing genetic resources, and contractual obligations reflected in mutually agreed terms, are a significant innovation of the Nagoya Protocol. Contracting Parties are to:

- Take measures providing that genetic resources utilized within their jurisdiction have been accessed in accordance with prior informed consent, and that mutually agreed terms have been established, as required by another contracting party
- Cooperate in cases of alleged violation of another contracting party's requirements
- Encourage contractual provisions on dispute resolution in mutually agreed terms
- Ensure an opportunity is available to seek recourse under their legal systems when disputes arise from mutually agreed terms
- Take measures regarding access to justice
- Take measures to monitor the utilization of genetic resources after they leave a country including by designating effective checkpoints at any stage of the value-chain: research, development, innovation, pre-commercialization or commercialization.

How does the Nagoya Protocol address traditional knowledge associated with genetic resources and genetic resources held by indigenous and local communities?

The Nagoya Protocol addresses traditional knowledge associated with genetic resources with provisions on access, benefit-sharing, and compliance. It also addresses genetic resources where indigenous and local communities have the established right to grant access to them. Contracting Parties are to take measures to ensure these communities' prior informed consent, and fair and equitable benefit-sharing, keeping in mind community laws and procedures as well as customary use and exchange. More information on the Nagoya Protocol and traditional knowledge can be found on the Traditional Knowledge programme of work webpage.

Tools and mechanisms to assist implementation

The Nagoya Protocol's success will require effective implementation at the domestic level. A range of tools and mechanisms provided by the Nagoya Protocol will assist contracting Parties including:

- Establishing national focal points (NFPs) and competent national authorities (CNAs) to serve as contact points for information, grant access or cooperate on issues of compliance
- An Access and Benefit-sharing Clearing-House to share information, such as domestic regulatory ABS requirements or information on NFPs and CNAs

- Capacity-building to support key aspects of implementation. Based on a country's self-assessment of national needs and priorities, this can include capacity to
    - Develop domestic ABS legislation to implement the Nagoya Protocol
    - Negotiate MAT
    - Develop in-country research capability and institutions
- Awareness-raising
- Technology Transfer
- Targeted financial support for capacity-building and development initiatives through the Nagoya Protocol's financial mechanism, the Global Environment Facility (GEF)

Submitting a Due Diligence Declaration

PART A

Information to be transmitted to the ABS Clearing House in accordance with Access and Benefit Sharing (ABS) legislation[1]

If the information provided is confidential tick the respective box and provide the justification for confidentiality at the end of this form; this material will not be submitted to the ABS Clearing House, but it may be passed on directly to the competent authorities of the provider country.

Please send any questions relating to due diligence declarations, or the completed application form to Defra at abs@defra.gov.uk.

If the utilisation has involved more than one genetic resource or any traditional knowledge associated with genetic resources, please provide relevant information for each genetic resource or any traditional knowledge utilised.

Please tick or complete the appropriate box(es) below.

1. Person or entity responsible for utilisation of the genetic resources and making information available to the checkpoint[2]	
Name	
Address	
Email	
Telephone	
Website (where available)	
Confidential	
2. I am making this declaration for the utilisation of (Please check one or both if appropriate)	
Genetic resources	
Traditional knowledge associated with genetic resources	
Confidential	

1 'ABS legislation' means legislation implementing the requirements of the Nagoya Protocol (on Access and Benefit Sharing (ABS)) in the UK, comprising The Nagoya Protocol (Compliance) (Amendment) Regulations 2015 (1691) and retained EU direct legislation (Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 and Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015), as amended by the Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 (SI 2018/1393) and the Environment and Wildlife (Legislative Function) (EU Exit) Regulations 2019 (SI 2019/473)).

2 This information allows the provider of the genetic resource to check whether the person or entity to whom the Prior Informed Consent (PIC) was granted is the same person or entity providing evidence of PIC and Mutually Agreed Terms (MAT) at the checkpoint. For the purposes of the ABS Clearing House this information can be confidential.

3. Title of Due Diligence Declaration[1]	
4. Source of the genetic resource[2]	
Confidential	
5. Subject matter or genetic resources collected or received[3]	
Confidential	
6. Short description of the information relevant to the utilization of genetic resources, including the type of use[4].	
Confidential	
7. I am making this declaration	
At the stage of research funding: please complete **column A** only	
At the stage of final development of a product: please complete **column B** only	

Column A		**Column B**	
The research grant is funded by the following sources (please check one or both if appropriate).		I have previously submitted a due diligence declaration at the stage of research funding.	
Private		Yes	
Public		No	
Confidential		Not applicable	
		Confidential	
		This Declaration is being made at the following stage	

1 This field serves as the title of the record, therefore it should be distinct and help to easily identify the record in the ABS Clearing House.

2 Select the country/ies which is /are the source of the genetic resource. The country/ies selected will be the ones receiving the Check Point Communique issued from the information registered. If marked as confidential the information will not be made public on the clearing house but the National Focal Point of the provider country will be notified.

3 Please provide details on the subject-matter or genetic resources relevant to the information collected or received by the checkpoint. This could include biota at any taxonomic rank, which may carry a taxonomic name. It may also include a locality of collection of the material. It may also be possible to identify the genetic resource through reference to a voucher specimen or field notes held in an identified archive or collection.

4 This could include information on utilization of genetic resources at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization. The information provided will allow the provider of the genetic resource to check whether the use of the genetic resource is in conformity with PIC and MAT and that benefits are shared in accordance with MAT.

	Market approval or authorisation sought for a product developed as a result of utilisation of a genetic resource.	
	A notification required prior to placing a product, developed as a result of genetic resource utilisation, on the market for the first time.	
	Placing a product, developed as a result of utilisation, on the market for the first time, for which no market approval, authorisation or notification is required.	
	The result of utilisation is sold or transferred in any other way to a natural or legal person within the UK in order for that person to carry out one of the activities referred to above)	
	The utilisation has ended in the UK and its outcome is sold or transferred in any other way to a natural or legal person outside the UK.	
	Confidential	
8. Information on exercise of due diligence		
An internationally recognised certificate of compliance was issued for the genetic resources and / or associated traditional knowledge to which I have been granted access.		
Where this box is ticked, please indicate the unique identifier of the internationally recognised certificate(s) of compliance and proceed to Part B on Confidentiality[1]		
Confidential		
Where there is no internationally recognised certification of compliance, please submit the following information		
Date of access[2]		
Confidential		
Identifier of access permit or its equivalent[3]		
Confidential		
Person or entity **that granted** prior informed		

1 Links to internationally recognized certificate(s) of compliance (IRCC) that relate to this communiqué.

2 Date of access means the point at which users obtain the physical genetic resource from the provider country. This is typically when researchers are in the provider country and sample / collect the material. If a genetic resource is obtained from a third party (e.g. from a collection / biobank or similar), the time of access would still be considered as the point at which the initial material was sampled / collected in the provider country.

3 This field is to provide information on PIC. This includes information on any national reference or identifiers that may aid countries to search and retrieve information related to PIC, or the permit or its equivalent in their national files.

consent[1]	
Confidential	
Person or entity **to whom** the prior informed consent was granted[2]	
Confidential	
Reference or evidence of establishment of mutually agreed terms including benefit sharing:[3]	
Confidential	

PART B

Confidentiality	
If you have declared that some information is confidential please state the reasons for each piece of information for which you have declared that confidentiality applies	
Date	
Signature	

1 Full details of person or entity plus contact telephone number, address, and email.

2 Full details of person or entity plus contact telephone number, address, and email.

3 This field is to provide information on MAT. This includes information on any national reference or identifiers that may aid users to search and retrieve information related to MAT, the permit, or its equivalent in their national files. Please refer to and include attachments if appropriate.

Section 8

POLICY ON HANDLING ALLEGATIONS OF RESEARCH MISCONDUCT

Summary & Purpose:

The ***Concordat to Support Research Integrity*** defines misconduct as behaviours or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld. The University is a signatory to the Concordat, and as an employer of researchers, the University is expected to have clear, well-articulated and confidential mechanisms for reporting allegations of research misconduct alongside having robust, transparent, and fair processes for dealing with such allegations should they arise.

The Policy on Handling Allegations of Research Misconduct was originally drafted and approved by Senate in July 2015. This policy has been revised taking into account further guidance from UKRIO, UKRI, and Russell Group statement of Cooperation with respect to cross-institutional research misconduct allegations and investigations.

Scope and Exemptions

The policy on handling allegations of research misconduct will also be used to investigate and deal with allegations relating to misappropriation or misuse of research funds and equipment.

This Policy can be used in conjunction with the 'University Policy on Whistleblowing', 'Policy of Dignity at Work and Study' and the 'University Code of Practice on Authorship'.

1. Definition of Research Misconduct

The **Research Council UK** *definition of* ***Research misconduct*** is **fabrication, falsification, plagiarism or other serious deviation from commonly accepted practices in research** for proposing, performing, or reviewing research, or in reporting research results.

Fabrication is making up data or results and recording or reporting them.
Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Misrepresentation including

- Misrepresentation of data, for example suppression of relevant findings and/or data, including the researchers own ideas, or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data.
- Undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts for publication.
- Misrepresentation of interests, including failure to declare material interests, either of the

researcher or of the funder's of the research.

- Misrepresentation of qualifications and/or experience, including claiming or implying qualifications or experience which are not held.
- Misrepresentation of involvement, such as inappropriate claims to authorship and/or attribution of work where there has been no significant contribution, or the denial of authorship where an author has made a significant contribution (improper authorship).

Breach of duty of care, whether deliberately, recklessly or by gross negligence:

- Disclosing improperly the identity of individuals or groups involved in research without their consent, or other breach of confidentiality,
- Placing any of those involved in research in danger, whether as subjects, participants, or associated individuals, without their prior consent, and without appropriate safeguards even with consent; this includes reputational danger where that can be anticipated.
- Not taking all reasonable care to ensure that the risks and dangers, the broad objectives and the sponsors of the research are known to participants or their legal representatives, to ensure appropriate informed consent is obtained properly, explicitly, and transparently.
- Not observing legal and reasonable ethical requirements or obligations of care for animal subjects, human organs or tissue used in research, or for the protection of the environment.
- Improper conduct in peer review of research proposals or results (including manuscripts submitted for publication); this includes failure to disclose conflicts of interest; inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for peer review purposes.

Research misconduct does not include honest error or differences of opinion. Unlike poor research practice which needs to be identified and dealt with through training and mentoring, research misconduct needs to be investigated and dealt with appropriately through the disciplinary procedures.

2. Key Principles:

This policy on research misconduct will also be used to investigate and deal with allegations relating to misappropriation or misuse of research funds and equipment.

The University is committed to operating on the following principles while investigating allegations of research misconduct:

- Misconduct in research is a serious matter.
- Investigation of allegations of misconduct in research will be conducted in accordance with the highest standards of integrity, accuracy, and fairness.
- The University wishes to enable all stakeholders (including funders, sponsors, regulators, staff, scientific publishers, students, research participants and patients) to have confidence that high standards of research integrity are upheld by the University at all times, and that allegations of research misconduct are treated seriously and investigated as confidentially as is reasonably practicable.

- The University will ensure that those responsible for carrying out investigations of alleged misconduct in research will act with integrity and sensitivity at all times.
- The University will ensure that investigators of such cases will conform to the statutory obligations of the University and the rights of the employees according to current law along with any rights and obligations bestowed to employees by its ordinances and statutes.
- Anyone accused of misconduct in research is entitled to the presumption of innocence.
- It is acknowledged that allegations may be made for what appears to be malicious reasons.
- Where anyone is formally accused of misconduct in research, that person will be given full details of the allegations in writing and will be given the opportunity to set out his/her case and respond to the allegations against him/her.
- The University is committed to protecting the reputation of those suspected of, or alleged to have engaged in, misconduct, when the allegations or suspicions are not confirmed.
- Staff undertaking research will be able to exercise their right to academic freedom under the University Statutes but must also take responsibility in ensuring that the integrity of research is upheld, and that they are aware of the legal requirements that regulate their work.
- All employees and students and any individuals authorised to work in the University, its facilities or otherwise undertaking research on behalf of the University, are obliged and have a responsibility to report to the University any concerns about potential research misconduct, whether witnessed, or where there is reasonable belief that this is, has, or is likely to occur.
- Employees and students who raise such concerns in line with this policy will not be penalised or suffer detriment by the University for doing so, provided that they do so in confidence and reasonably believe that potential research misconduct is, has or is likely to occur.
- The basis for reaching a conclusion that an individual is responsible for misconduct in research relies on a judgment that there was an intention to commit the misconduct and/or negligence in the conduct of any aspect of research undertaken and that the burden of proof required is that of 'on the balance of probabilities.'
- Where appropriate, issues may be resolved through informal discussions, advice, guidance, or agreed mediation, without the requirement for a formal investigation.
- If the route of investigation is undertaken, then depending upon the outcome of the investigation, other relevant formal procedures may be initiated including for example the University's disciplinary or capability procedures.
- In such cases the information/findings of an investigation may be used in whole or in part, to form the investigation element of such procedures.
- All parties involved are under an obligation to inform the 'Named Person' (Pro Vice Chancellor Research & Innovation) immediately of any conflict of interest.
- In such circumstances, the Pro Vice Chancellor (R&I) should decide if a declared interest warrants exclusion from involvement in the investigation.
- In the case where the Pro Vice Chancellor (declares an interest his/her nominated alternate should decide if he/she should be excluded from involvement.

Practices / Code of Conduct

All allegations of research misconduct will be received and processed in accordance with the 'Procedure of receiving allegations of Research Misconduct'. A copy of this is available as part of the 'University Policy Framework on Research Integrity' and can be accessed through the Research Integrity web pages https://staff.swansea.ac.uk/media/P1415-956-Research-Integrity---Policy-Framework-updated-Jan-2020.pdf)

A copy of the procedure will be provided to the Complainant, Respondent, and the Screening & Investigation Panel members prior to the commencement of any research misconduct procedure.

Compliance

Failure to comply with this policy will be addressed according to the University statutes and ordinances.

Policy History

Revision Date	Author	Description
July 2015	Anjana Choudhuri/ Vice Chancellor's Office	Policy on Handling Allegations of Research Misconduct drafted and approved by University Research Committee, University Research Ethics & Governance sub- committee & Senate.
January 2020	Anjana Choudhuri/ Research Engagement & Innovation Services	1. Inclusion of further guidance from UKRIO, UKRI and Russell Group statement of Cooperation with respect to cross-institutional research misconduct allegations and investigations. 2. Change of 'Named Person' from the Registrar to the Pro Vice Chancellor (Research & Innovation)

PROCEDURE FOR HANDLING ALLEGATIONS OF RESEARCH MISCONDUCT

This procedure will be used with the 'Policy on Handling Allegations of Research Misconduct' to investigate research misconduct cases and/or any allegations of misappropriation or misuse of research funds and equipment.

A. Procedure:

The objective of the procedure outlined below is:

1. to ensure that any allegations of research misconduct brought to the University as the organisation employing the individual against whom allegations are made, or brought to the University in its capacity as the host or sponsor of research, are dealt with agreed standard practices adopted nationally by other Universities and research organisations and
2. to determine the truth of the allegations.

B. Receiving allegations:

Any allegations of 'misconduct in academic research' should ideally be submitted to the Pro Vice Chancellor (Research & Innovation) in writing, with supporting documentary evidence, though postal mail or email (researchmisconduct@swansea.ac.uk)

Any allegations received by the Pro Vice Chancellor (Research & Innovation) will be initially assessed to determine:

1. whether it requires urgent and immediate action to prevent further risk or harm to staff or student participants or other persons or suffering to animals or negative environmental consequences; or
2. whether the complaint relates to the University or should be directed to another organisation, external body, or regulator; or
3. whether the allegation falls within the scope of the research misconduct process or if another internal procedure, for example the disciplinary procedure needs to be used; or
4. whether any immediate action needs to be taken, based on the concerns outlined in the allegation (i.e., to protect participants, or secure funds or evidence)

The Pro Vice Chancellor (Research & Innovation) will also take all reasonable steps to secure the necessary evidence, consider potential risks and take steps to remove or minimise any risk. Risks may relate to the health, safety and security of employees, research participants, or other persons, the welfare of animals or negative environmental consequences. Immediate action must be taken to ensure that any such potential or actual danger, illegal activity or risk is prevented/eliminated. If necessary, the Pro Vice Chancellor (Research & Innovation) may in consultation with the Director of Human Resources take the decision to suspend the Respondent on full pay pending the outcome of the Screening/Formal investigation. In taking such actions it would be made clear to all parties that the actions taken were not to be regarded as disciplinary and do not in themselves indicate that the allegation is considered to be true by the University. The suspension period will be kept to a minimum and will be regularly reviewed, but not normally exceed 10 days.

C. Preliminary Stage:

1. Upon receipt of an allegation of misconduct in research, the Pro Vice Chancellor (Research & Innovation) will formally acknowledge receipt by letter or email (whichever appropriate), advising the complainant of the procedure to be followed. The Pro Vice Chancellor (Research & Innovation) will also inform the Respondent of the substance of the allegation in writing and invite them to respond. The 'Respondent' will be provided a copy of the allegation (to be redacted only if necessary or requested), along with a copy of the University procedure to be followed. The Respondent shall confirm receipt and provide a response in writing **within 5 working days** of receipt or such longer period as may be agreed by the Pro Vice Chancellor (Research & Innovation).
   If the allegations are made against more than one Respondent, the Pro Vice Chancellor (Research & Innovation) will inform all parties separately, without divulging any information on the identity of the other 'Respondents'. If the Pro Vice Chancellor (Research & Innovation) is satisfied with the Respondent's response and/or decides that the allegations are mistaken, frivolous, vexatious and/or malicious, the allegations will then be dismissed. The Pro Vice Chancellor (Research & Innovation) will record their justification for that decision, and inform in writing, the Complainant, Respondent and any other parties who had been informed initially. The Complainant would be given an opportunity to respond if they believe that they have been misunderstood or key evidence overlooked.

   If an allegation falls outside the definitions of 'research misconduct', the Pro Vice Chancellor (Research & Innovation) will communicate to the Complainant in writing:

2. the reason why the allegations cannot be investigated using the University procedure;
3. which process for dealing with complaints might be appropriate for handling the allegations (if any); and
4. to whom the allegations should be reported.
5. If the allegations were found to be frivolous, vexatious and/or malicious, the Pro Vice Chancellor (Research & Innovation) will consider recommending to the Human Resources Department that action be taken under the disciplinary procedures against the Complainant and will take appropriate steps to support the reputation of the Respondent and the research project (s). Those making allegations in good faith will not be penalised, and would be provided with support, including training if they are employees of the University.

The University will aim to complete the Preliminary stage within 10-15 working days from the receipt of the allegations.

D. Screening stage:

1. If the allegations cannot be entirely discounted by the Pro Vice Chancellor (Research & Innovation), then a '**screening panel**' would be set up to determine whether there is prima facie evidence of misconduct in research.
2. The purpose of the screening is to gather evidence and information and determine

whether an allegation or apparent instance of misconduct warrants a formal investigation.

3. The screening panel would consist of at least two individuals who do not have conflicts of interest in the case and have appropriate expertise to evaluate the scientific issues.
4. The Pro Vice Chancellor (Research & Innovation) will notify both the Respondent and the Complainant of the Screening in writing, as soon as reasonably practicable, reminding both the Respondent and the Complainant of their obligation to co-operate in the Screening, and to observe confidentiality.
5. The Respondent would be requested to confirm receipt of the notification in writing.
6. The Pro Vice Chancellor (Research & Innovation) will notify the Respondent of the proposed committee membership in writing as soon as reasonably practicable. The Respondent will be given **5 working days** to submit an objection to the persons appointed to the committee. If the Respondent submits a written objection to any of the persons appointed to the Committee, the Pro Vice Chancellor (Research & Innovation), may decide to replace the person with another qualified substitute. If a decision not to substitute the member is taken, then the reason will be communicated to the Respondent in writing.
7. The Screening panel will specifically limit its scope to that of evaluating the facts only to determine whether there is sufficient evidence of misconduct in research to warrant an investigation.
8. To perform its functions, the Screening Committee should review the submission and supporting evidence provided by the Complainant and review the evidence and supporting documentation provided by the Respondent.
9. The Screening panel would normally aim to complete its work within **30 days** of being convened. If for any reason, the screening panel is unable to complete its work within the specified time period, the Pro Vice Chancellor (Research & Innovation) may take the decision to extend the time limit and inform both the Respondent and Complainant the reasons for the extension.
10. The Screening panel must determine whether the allegations are sufficiently serious and have sufficient substance to justify a formal investigation or whether they may be addressed through education/training or through some other non-disciplinary approach. The conclusions and recommendations should be set out in the written report.
11. A report from the screening panel would be made available to the Respondent and the Complainant for factual accuracy, and only in circumstances, where the report includes errors of fact will the screening panel modify the report.
12. Any comments from the Complainant or Respondent must be submitted to the Screening panel within **10 working days** of receipt of the report. Any comments submitted from either the Respondent or Complainant will be attached as an addendum to the report.
13. Where the allegations are considered mistaken, frivolous, vexatious and/or malicious, they will be dismissed, and appropriate measures taken to protect the reputation of the Respondent and relevant research projects.
14. Measures may include recommending to the appropriate authorities that action would be taken under the University's disciplinary procedures.
15. Where the allegations have some substance, but due to a lack of clear intent to deceive or due to their relatively minor nature, the matter will be addressed through the University's competency, training and education or other non-disciplinary process, rather than through a formal investigation for a University employee.
16. The Pro Vice Chancellor (Research & Innovation) would ensure that a programme of

training or supervision is established in conjunction with the Respondent and his/her line manager.

17. When the screening panel considers that the allegations are sufficiently serious and have sufficient substance to warrant recommending a Formal investigation, the Pro Vice Chancellor (Research & Innovation) would take immediate steps to set up a Formal investigation.
18. The Complainant and Respondent will be informed in writing of the outcome of the Screening process within 5 working days of the Pro Vice Chancellor (Research & Innovation) making their decision.
19. Where appropriate, and for awareness only, the Pro Vice Chancellor (Research & Innovation) would inform the appropriate Senior staff within the University (Vice Chancellor, Registrar, Director of Human Resources) and any other partner organisation with which either the Respondent/and or Complainant has an honorary contract of the decision to progress the matter to a formal investigation.

Once initiated, the procedure will progress to the natural end-point irrespective of:

- whether the Complainant has withdrawn the allegation;
- the Respondent admitting or having admitted the alleged misconduct, in full or in part and/or
- the Respondent or the Complainant resigning, or having already resigned, his/her post.

E. Formal Investigation:

The purpose of the Formal investigation is to examine and evaluate all relevant facts and determine whether misconduct in research has been committed, and if so, the seriousness of the misconduct and the responsible person.

1. The Pro Vice Chancellor (Research & Innovation) would notify the Respondent and the Complainant in writing, the decision to proceed to a formal investigation and the obligation to co-operate in the formal investigation along with maintaining confidentiality.
2. The Respondent must confirm in writing, the receipt of notification.
3. The Pro Vice Chancellor (Research & Innovation) will then convene a formal investigation panel consisting of **at least 3 persons**, who have not previously been involved with appropriate knowledge/experience to evaluate the scientific issues and with knowledge of the investigating procedures. If necessary, a member external to the University, or a member of the University Council would be invited to either Chair the panel or be a member.
4. The Pro Vice Chancellor (Research & Innovation) will notify the Respondent of the proposed investigation panel membership in writing as soon as is reasonably practicable.
5. The Respondent will be given **5 working days** to submit an objection to the persons appointed to the Investigation committee.
6. If the Respondent submits a written objection to any of the persons appointed to the investigation panel, the Pro Vice Chancellor (Research & Innovation) may decide to replace the person with a more qualified substitute. If the decision not to replace the panel member is taken, then the Respondent will be notified in writing with the reason.
7. The date of the investigation panel to be officially appointed will be either

- After the 5 working days if the Respondent has not submitted a written objection or
- The date on which the Pro Vice Chancellor (Research & Innovation) responds to the Respondent's objections.

8. Those on the investigation panel should not have any conflicts of interest with the Respondent or the case in question, and they must have the necessary expertise to examine the evidence, interview the witness and to conduct the investigation.
9. The investigation panel would examine all evidence and documentation collected during the screening panel's investigation (e.g. relevant research data materials, proposals, publications, correspondence, memoranda and notes of telephone calls) following the original allegation and investigate further as required.
10. During the Formal investigation, the investigation panel will interview the Respondent, the Complainant and all other individuals who might have information regarding key aspects of the allegations. The Respondent will be able to name any relevant witnesses.
11. The Respondent will have the right to be accompanied by a work colleague or represented by a recognised trade union representative to the meetings.
12. The investigation panel will review all evidence and documentation to conclude whether the allegations of misconduct in research are **upheld in full, upheld in part or not upheld**.
13. The standard of proof to be used by the Investigation panel will be that of '**on the balance of probabilities'.**
14. The Investigation Panel may conclude that allegations are not upheld for reasons of being mistaken, frivolous, vexatious, or malicious.
15. During the investigation, should new evidence come to light regarding further, distinct instances of misconduct in research by the Respondent, unconnected to the allegations under investigation or of misconduct in research by another person/persons, then the investigation panel would submit the new allegations to the Pro Vice Chancellor (Research & Innovation) to be considered under the initial steps in the procedure.
16. The investigation panel will be appointed within 30 working days of the submission of the screening panel's report for recommending a formal investigation
17. The investigation panel will not work to a deadline or timetable but would aim to achieve completion of the investigation as quickly as possible without compromising the principles of the procedure.
18. If the investigation takes a long time, the Chair of the panel would provide regular monthly updates to the Pro Vice Chancellor (Research & Innovation) who should provide appropriate information on the progress to the interested parties.
19. Written notes will be made of the proceedings; these are not meant to be verbatim but will be an accurate reflection of the points discussed, will form the official record, and will be included as part of the investigation report.
20. On completion of the investigation, a draft report would be provided by the panel to the Pro Vice Chancellor (Research & Innovation) for forwarding to the Respondent and the Complainant for factual accuracy.
21. All parties (Respondent & Complainant) would be given 5 working days to send a response to the report
22. Only when the report contains errors of fact and matters that have a bearing on the facts as indicated by the Respondent and/or the Complainant, and accepted by the Investigation Panel, should the Chair modify the report.
23. If the report is not modified, then comments would be attached as an addendum.

24. The investigation panel should then produce a final report summarising the conduct of the investigation, stating their decision on the allegations of misconduct in research, making recommendations and addressing any procedural matters that have been brought to light during the investigation.
25. The panel recommendations may include further action including retraction/correction of articles/papers and actions to inform or protect participants and patients, and where required reporting to regulators, funders, partner bodies or professional bodies.
26. If all or any part of the allegations are upheld, the Pro Vice Chancellor (Research & Innovation), the Director of Human Resources and another Senior Staff member (Registrar or Head of Faculty) should decide whether the matter should be referred to the University's disciplinary process or for other formal actions.
27. The Pro Vice Chancellor (Research & Innovation) would inform the Respondent and the Complainant (or their representatives) in writing of the conclusion of the formal investigation.
28. The Pro Vice Chancellor (Research & Innovation) would also inform the Vice Chancellor, Registrar and any other relevant personnel within the University along with any partner organisations, funding bodies and or regulatory or professional bodies.
29. Should the allegations proceed to the University's disciplinary procedure, the report of the investigation panel would form the basis of the evidence that the Disciplinary Panel receives. Actions which may be implemented by the Pro Vice Chancellor (Research & Innovation) in Consultation with the Director of Human Resources may comprise one or more of the following:
    - Removal from a particular project
    - Final written warning
    - Special monitoring of future work
    - Requirements to undertake specified training
    - Removal of eligibility for pay progression for one year
    - Withdrawal of funding for programme
    - Down-banding of appointment
    - Recommendation of termination of employment (To be undertaken in accordance with University Ordinances)

F. Appeals:

Where the formal investigation panel finds that the allegations have been substantiated in whole or in part, but the nature of misconduct is such that it should be disposed of informally, for example, through an informal warning, the Respondent may appeal against the decision on one or more of the following grounds:

(a) that the allegation of misconduct was not heard in accordance to the above procedures; and/or

(b) that fresh evidence has become available which was not or could not have been made formally available to the panel before**.**

<u>The intention to appeal against any decision should be made in writing by the Respondent to the Pro Vice Chancellor (Research & Innovation) within 28 days of the date of the notification of the panel's decision**.**</u>

The Respondent's letter should include a written statement stating clearly the basis for

appeal.

Appointment of an appeals panel:

The purpose of the appeals panel is to consider/review the appeal submitted by the Respondent against the decision and/or sanctions resulting from completion of the investigation into an allegation of misconduct in research. **The outcome of the appeal panel is final and the Respondent has no further right of internal appeal against the decision and/or sanctions.**

1. The Pro Vice Chancellor (Research & Innovation) will convene an appeals panel, normally within 15 working days of the receipt of an appeal by the Respondent.
2. The appeal panel will consist of **3 or more** members, none of whom should be a member of the Screening or Investigation panel. The panel may include external members.
3. The Pro Vice Chancellor (Research & Innovation) will notify the Respondent of the proposed appeal panel membership in writing as soon as reasonably practicable.
4. The Respondent will have 5 working days to submit any objection to the panel membership.
5. If the Respondent submits a written objection to any of the appeal panel members, then the Pro Vice Chancellor (Research & Innovation) may decide to replace the person with a qualified substitute.
6. If the Pro Vice Chancellor (Research & Innovation) decides not to replace the panel membership, then the decision with the reasons will be communicated to the Respondent in writing and will be added to the final report as an addendum.
7. The purpose of the appeal panel would be to review the evidence and determine whether the decision and any other sanction (s) applied was fair and reasonable in all the circumstances and to determine whether the procedure was followed correctly.
8. The Respondent will be invited to attend a meeting to give oral evidence. The Respondent may submit any relevant additional supplementary material in support of their appeal.
9. The Respondent will have the right to be accompanied by a work colleague or a trade union member.
10. A report from the appeals panel should be submitted to the Pro Vice Chancellor (Research & Innovation) within **20 working days** of the panel convening.
11. The Appeal panel will also recommend, as appropriate, whether professional bodies or regulators, research funders/sponsors and other interested parties including collaborators should be notified of the outcome of the case. Where a distortion on inaccuracy in the published research record is found, all necessary steps should be taken to notify all relevant parties and to correct the published record.

G. Cross institutional research misconduct investigations

(Adopted from Russell Group Statement of Cooperation)

On receipt of an allegation that crosses institutional boundaries, the University will:

- endeavour to ensure that the allegations are considered fully, proportionately, and fairly.
- Contact the party institutions.
- Contact relevant funders and other third parties who may need to be notified (e.g., regulators, hospital trusts) to inform them of an allegation/investigation.
- Maintain respectful co-operation and communication between all institutions involved.

- Be open and transparent while ensuring that legal obligations and duty of care to staff are maintained.
- Avoid unnecessary duplication
- Be supportive and enable each institution to meet their responsibilities in respect of reviewing misconduct allegations, as well as the responsibilities they bear as an employer to any individual against whom allegations are being considered.
- Ensure that all individuals involved, affected institutions and relevant research funders are kept apprised of progress as required.
- Where a single institutional process is to be followed, agree what involvement the other institutions will have in the process (e.g., providing observers or panel members, approving Terms of Reference of any formal investigation panel, agree a lead institution with clear lines of responsibility for and within each institution including contact points)
- Agree clear lines of communication between institutions during and after the review process both for those involved and those affected (e.g., funders, journals and any third parties)
- Agree timescales regarding the investigation process as well as agreed points of communication as stated above, including informing the relevant institutions and individuals of any need to extend timelines.

Research Misconduct Procedure (UKRIO guidance)
Additional considerations (March 2023)

Recommendation that organisation define research misconduct according to what is prescribed in the Concordat to Support Research Integrity with the exact page and paragraph number:

The Concordat to Support Research Integrity (2019), Commitment 4, pages 12- 13:

Research misconduct 'is characterised as behaviours or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld. It can cause harm to people and the environment, wastes resources, undermines the research record, and damages the credibility of research.

The Concordat recognises that academic freedom is fundamental to the production of excellent research. This means that responsibility for ensuring that no misconduct occurs rests primarily with individual researchers.

Research misconduct can take many forms, including but not limited to:

a. **fabrication:** making up results, other outputs (for example, artefacts) or aspects of research, including documentation and participant consent, and presenting and/or recording them as if they were real.

b. **falsification:** inappropriately manipulating and/or selecting research processes, materials, equipment, data, imagery and/or consents.

c. **plagiarism:** using other people's ideas, intellectual property, or work (written or otherwise) without acknowledgement or permission.

d. **failure to meet**: legal, ethical and professional obligations, for example:

i. not observing legal, ethical, and other requirements for human research participants, animal subjects, or human organs or tissue used in research, or for the protection of the environment.

ii breach of duty of care for humans involved in research whether deliberately, recklessly or by gross negligence, including failure to obtain appropriate informed consent.

iii. misuse of personal data, including inappropriate disclosures of the identity of research participants and other breaches of confidentiality.

iv. improper conduct in peer review of research proposals, results or manuscripts submitted for publication. This includes failure to disclose conflicts of interest; inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for the purposes of peer review.

e. **misrepresentation** of:

i. data, including suppression of relevant results/data or knowingly, recklessly or by gross negligence presenting a flawed interpretation of data.

ii. involvement, including inappropriate claims to authorship or attribution of work and denial of authorship/attribution to persons who have made an appropriate contribution.

iii. interests, including failure to declare competing interests of researchers or funders of a study.

iv. qualifications, experience and/or credentials v. publication history, through undisclosed

duplication of publication, including undisclosed duplicate submission of manuscripts for publication.

f. **improper dealing with allegations of misconduct**: failing to address possible infringements, such as attempts to cover up misconduct and reprisals against whistle-blowers or failing to adhere appropriately to agreed procedures in the investigation of alleged research misconduct accepted as a condition of funding. Improper dealing with allegations of misconduct includes the inappropriate censoring of parties through the use of legal instruments, such as non-disclosure agreements.

Honest errors and differences in, for example, research methodology or interpretations do not constitute research misconduct.'

For the avoidance of doubt, misconduct in research includes acts of omission as well as acts of commission.

In addition, the standards by which allegations of misconduct in research should be judged should be those prevailing in the country in which the research took place and at the date that the behaviour under investigation took place (the requirements on the processing and storage of personal and research data). This is particularly important (and not straightforward) when investigating allegations relating to research that was carried out many years previously.

The basis for reaching a conclusion that an individual is responsible for misconduct in research relies on a judgement that there was an intention to commit the misconduct and/or recklessness in the conduct of any aspect of a research project.

Where allegations concern an intentional and/or reckless departure from accepted procedures in the conduct of research that may not fall directly within the terms detailed above, a judgement should be made as to whether the matter should be investigated using the Procedure.

Principles:

Misconduct in research is a serious matter. The investigation of allegations of misconduct in research must be conducted by the highest standards of integrity, accuracy, and fairness. Those responsible for carrying out investigations of alleged misconduct in research should always act with integrity and sensitivity.

The principles of Data Protection, Fairness, Confidentiality, Integrity, Prevention of Detriment, and Balance must inform the use of the Procedure for the investigation of allegations of misconduct in research.

Nothing in the Procedure prevents anyone from making a disclosure under whistleblowing law (the Public Interest Disclosure Act).

Fairness:

The investigation of any allegations of misconduct in research must be carried out fairly and in accordance with the statutory human rights of all parties involved. Matters should be dealt with promptly - without unreasonable delay of meetings, decisions, or outcomes. Respondents should be dealt with consistently - dealing with similar cases in different ways or by delivering very different outcomes creates a risk of unfair outcomes, claims and reputational damage for the organisation. Those responsible for carrying out the Procedure should do so with knowledge of the statutory obligations of the Organisation and the rights of employees according to current law; any additional rights and obligations particular to the institution and/or its employees and/or its students - for example, those bestowed by

university statutes and ordinances. Those responsible for carrying out this procedure should be mindful of equality, diversity, and inclusion, and also ensure that all related obligations are met. Where the allegations concern any equality, diversity, or inclusion issues, those carrying out the procedure will be appropriately trained or have relevant experience in dealing with equality, diversity, and inclusion matters.

Where anyone is formally accused of misconduct in research, that person must be given full details of the allegations in writing at the appropriate stage.

When someone is investigated for alleged misconduct in research under the procedure, they must be given a reasonable opportunity to set out their case and respond to the allegations against them. They must also be allowed to:

a. ask questions;

b. submit evidence in their defence;

c. suggest witnesses for the Investigator and/or Full Investigation Panel to interview; the Investigator and/or Full Investigation Panel may then choose to invite the suggested witnesses to interview;

d. raise points with the Investigator and/or Full Investigation Panel, as appropriate, about any information given by any witness (regardless of who has called the witness in question).

Confidentiality: The identity of the Complainant or the Respondent should not be made known to any third party unless:

a. it has been deemed necessary (by those conducting the investigation) to carry out the investigation and/or to carry out required/necessary actions or disclosures following the outcome of the investigation.

b. it is necessary as part of the action taken against the Respondent if (at the end of the Procedure and/or any subsequent process, such as a disciplinary process, and after any appeals processes) the allegations have been upheld.

c. it is necessary as part of the action taken against a person who has been found to have made malicious, vexatious or frivolous allegations;

d. it is the stated policy of the employer/ funder/ other national body that the identity of individuals proved through appropriate disciplinary and appeals processes to have committed misconduct in research should be made public.

e. any party to the Procedure is seeking legal advice or other advice from another third party who owes them a duty of confidentiality; f. it is already in the public domain; g. it is required by law or by the Organisation's regulator.

Any disclosure to a third party of the identity of the Complainant or Respondent, or of any other details of the investigation, should be made on a confidential basis. The third-party should understand this, and that they must respect the confidentiality of any information received. The Organisation and/or its staff may have contractual/legal obligations to inform third parties, such as funding bodies or collaborating organisation(s), of allegations of misconduct in research. In such cases, those responsible for carrying this Procedure out should ensure that any such obligations are fulfilled at the appropriate time through the correct mechanisms, always keeping in mind the legal rights of the employees, students and others involved in the allegations. While the allegations are under investigation using the Procedure (and/or the Organisation's disciplinary process), the Complainant, the Respondent, witnesses, or any other persons involved in the Procedure should not make any statements about the allegations to any third parties, unless formally sanctioned by the Organisation or

otherwise required to by law. Breaching confidentiality may lead to disciplinary action unless covered by the Public Interest Disclosure Act and/or the Organisation's grievance or whistleblowing procedures.

In the event of any conflict between the principle of confidentiality and any of the other principles of the procedure, those conducting the procedure should consider the 'principle of balance' and use their judgement to choose the appropriate solution.

Prevention of Detriment

The Organisation must take all reasonable steps to ensure that the Respondent (or any other party) does not suffer because of unconfirmed or unproven allegations.

Involvement of the Respondent in the procedure should not prevent the Respondent from being considered:

a. for promotion.

b. or the completion of probation.

c. or other steps related to their professional development.

The Organisation may choose to suspend the implementation of any promotion, completion of probation or any similar step, for the period that allegations are investigated using the procedure, rather than delay the actual consideration of such matters. If the allegations are upheld at the end of the Procedure, subject to the Organisation's disciplinary process and/or appeals process, the Organisation's normal rules concerning steps related to professional development, such as those detailed above, should apply.

Balance

Those responsible for carrying out the Procedure must be aware that there may be occasions when a balance has to be struck in the application of the principles and/or its standards for example, it may, in certain circumstances prove to be impracticable to undertake a thorough and fair Initial Investigation of the allegations without releasing the Complainant's identity to the Respondent.

The Named Person should be responsible for resolving any such conflicts between the principles, between the Standards, and/or between the Principles and the Standards, keeping in mind at all times that the primary goal of this Procedure is to determine the truth of the allegations via a thorough and fair investigation, conducted in a timely and transparent manner, and with appropriate confidentiality.

Named Person: The Named Person should have a nominated alternate who should carry out the role in their absence or in the case of any potential or actual conflict of interest.

The Named Person and the nominated alternate should not be the Organisation's Principal or equivalent, or Head of Human Resources

Discussion: This provision allows an Organisation to use this procedure to investigate matters of concern that are not formally lodged with it, but which are highlighted via other means.

Research Misconduct Procedure for Allegations involving research students:

1. If the Organisation is a higher education institution this procedure will normally apply to research students, who are registered for an MPhil, a DPhil, or a Professional Doctorate, but not normally to undergraduate, taught postgraduate and other types of students (they will usually be subject to the appropriate academic misconduct regulations)

2. Alleged misconduct in research relating specifically to the assessed element of a research degree, i.e., to a thesis which has been submitted for examination may be investigated under the Organisation's examination regulations, academic misconduct process or equivalent, instead of under this procedure. However, at the discretion of the Organisation, related allegations of misconduct in research may be dealt with under this procedure.
3. Organisations need to be clear on the status of research students and degrees and how they fit into the procedure, including for example students who are also staff members.
4. The decision on which process to use to investigate allegations of misconduct involving students should take account of the nature of the allegation and which process would be most suitable to carry out a full, fair, and transparent investigation of the allegation(s) in question, in a timely manner and with appropriate confidentiality. Organisations should also be mindful of legal and other obligations regarding investigations relating to students, including those set by external bodies (e.g., the Office for Students). For example, an Organisation's examination regulations/academic misconduct process/equivalent may be viewed as a more suitable process to investigate an allegation relating to work submitted as part of the assessment process (including but not limited to a thesis), while the misconduct investigation procedure may be viewed as a more suitable process to investigate allegations relating to the conduct of the research itself.
5. If the student has an employer relationship with the organisation, then they should be dealt with under employee procedures. Advice should be sought from the Research Integrity Manager, Student Services, Human Resources and Legal Services (or equivalents), as necessary, and can also be sought from UKRIO.
6. When allegations of misconduct in research are raised that include/relate to allegations of bullying/harassment, the Organisation will determine whether those allegations are investigated under this procedure and/or another Organisational process, for example, the bullying/ harassment procedure or disciplinary process.
7. Financial fraud or other misuses of research funds or research equipment may be addressed under the Organisation's financial fraud investigation process or equivalent, instead of under this procedure.
8. The Organisation will follow the procedure through to its natural end point as far as possible even in the event that any individual(s) concerned leaves or has left the jurisdiction of the Organisation, either before the operation of the Procedure is concluded or before the allegation(s) of research misconduct was made; or the Complainant(s) withdrawing the allegation at any stage; or the Respondent(s) admitting, or having admitted, the allegation in full or in part; or the Respondent(s) admitting, or having admitted, other forms of misconduct, whether research misconduct or otherwise; and/or the Complainant(s) and/or the Respondent(s) withdrawing from the Procedure.

9.After an investigation into alleged misconduct when a Respondent who is not a current member of staff/student of the Organisation (such as former staff or students, visiting staff,

those on honorary contracts and students from other institutions conducting research on the Organisation's premises), the Named Person will determine the nature of any further action to be taken in relation to the investigation and its outcome.

10. Similarly, after an investigation when a Respondent is deceased, the Named Person will determine the nature of any further action to be taken in relation to the investigation and its outcome.

11. The Organisation will need to ensure that they have arrangements in place for collaboration with other organisations over investigations where appropriate. This could include when an individual has moved during the course of the matter being investigated, where the Respondents are based in more than one institution, or when individuals fall under the auspices of the Organisation and another body (e.g., persons with visiting status who are employed by another.

    Reminder: Matters for investigation can also be across national boundaries.

12. If at any stage of this Procedure, a Respondent or anyone else whether involved in the matter or not, raises a counter-allegation of misconduct in research or an allegation of misconduct in research unrelated to the matter under investigation, these allegations will be addressed under the Procedure as separate matters and will be forwarded to the Named Person for consideration.

13. If at any stage of the Procedure, a Complainant, Respondent, or other person raises a complaint about the use or operation of the procedure or any decision or action proposed or taken under this procedure, or raises any other grievance, then the Named Person will seek the advice of Human Resources, Student Services and other relevant departments, in confidence, to determine an appropriate course of action.

14. Disability adjustments: Where a Complainant, Respondent or other person involved in the investigation has difficulties at any stage of the procedure due to a disability, they should discuss this with the Named Person as soon as possible and reasonable adjustments will be made to ensure they are able to fully participate in the procedure.

15. However well managed, research misconduct matters can be difficult for all parties involved, including the complainant, respondent and those managing and running investigations. The Organisation should consider how best to support all parties in terms of their health and well-being at all stages of the procedure.

16. If required to facilitate a full and fair investigation and/or the operation of any aspect of the Procedure, the Named Person, those persons, and panels conducting and supporting Initial Investigations and Full Investigations shall be free to seek confidential advice from persons with relevant expertise, both within the Organisation and outside it. To address technical aspects raised by a matter, they may also employ relevant expertise and use of tools or computer software for assessing different forms of misconduct such as plagiarism, data manipulation and fabrication.

17. Those seeking advice will, so far as is possible, anonymise the information provided to make no information available which could lead to the identification of the Complainant, Respondent or other individuals involved in the case.

18. Persons consulted will be subject to the same requirements on confidentiality as others involved in the process.

19. Persons who might be consulted include but are not limited to an expert (s) in particular disciplines of research; or experts in particular aspects of the conduct of research, such as members of research ethics committees, statisticians, editors of academic journals or equivalent persons from relevant areas of dissemination in research; and/or experts in addressing misconduct in research and poor practice; or representatives of Organisational departments such as: Legal Services, Human Resources, Student Services, Finance; Governance/Registry, Research Office, Health and Safety Office, Library Services, Information and Technology Services or the equivalents; or the Advisory Service of the UK Research Integrity Office; or Legal advisers.
20. Record retention of procedures: In the absence of Organisational standards, the normal retention period for such records will be 6 years plus current (also known as 6 years +1), defined as 6 years after the last entry in a record, then followed by first review or destruction to be carried out in the additional current (+1) year. After the retention period, organisations must retain anonymised summary information of investigations (i.e., of the sort which is reported in annual statements required by The Concordat to Support Research Integrity). Records must only be retained beyond the normal retention period if their retention can be justified for statutory, regulatory, or legal reasons; and/or the research project to which the records relate is still ongoing; and/or the retention period of the research project to which the records relate is longer.
21. Initial screening by 'Named person': Allegations of research misconduct can be complex, even when they initially present as straightforward situations, and all humans can be subject to biases and gaps in expertise. As this stage of the Procedure puts a large amount of responsibility on the Named Person role, it is advised that the Named Person seeks confidential advice from persons with relevant expertise before making any decisions on the outcome of this stage.
22. Making allegation: When raising concerns, complainants should provide a summary of the allegation along with any other information and enclose any evidence to support their concerns. It is helpful if allegations are made in a single submission on a single occasion, as this facilitates a thorough assessment of the complainant's concerns and reduces procedural challenges that can arise from additional allegations being made during subsequent stages of this procedure. However, the Named Person should recognise that complainants may understandably be unfamiliar with the requirements of this Procedure and/or nervous about raising concerns. The priority should be a thorough and fair assessment of the complainant's concerns and at the discretion of the Named Person the timescale of this stage of the Procedure can be extended if necessary to gather more information from the Complainant. If this takes place, care should be taken to stay within the scope of this stage and not undertake actions which fall within the scope of subsequent stages of this Procedure, such as the Initial Investigation stage. Complainants will normally put their name to any allegations they make. However, it is recognised that complainants can be concerned about revealing their identity. Allegations raised which are anonymous, or matters identified where

there is no specific complainant, will be considered at the discretion of the Named Person, taking account of the seriousness of the concerns raised and the likelihood of confirming the concerns from alternative sources/ evidence. Where appropriate, advice will be sought, and consideration given to whether the respondent will be able to defend themselves.

23. Conflict of interest of the 'Named person': If the Named Person is the Complainant or the Respondent or is personally associated with the work to which the allegation relates or has any other conflict of interest, they will instead refer the allegation to their nominated alternate who will notify the Complainant accordingly. The nominated alternate will then take on the role of the Named Person as regards the conduct of the Procedure and will be responsible for fulfilling the duties allocated to that role by the Procedure.
24. Initial investigation or screening panel stage: The Named Person can decide that an Initial Investigation may instead be conducted by an Initial Investigation Panel consisting of two or three persons, which may include external members or an external Chair.
25. The standard of proof used by the Initial Investigation is that of "on the balance of probabilities". This means that the activity was more likely than not to have occurred.
26. Full investigation stage: The purpose of the Full Investigation is to review all the relevant evidence and conclude whether an allegation of misconduct in research is upheld in full, upheld in part or not upheld; and make recommendations as appropriate, for consideration by the appropriate Organisational authorities, regarding any further action the Full Investigation Panel ("the Panel") deems necessary to address any misconduct it may have found; correct the record of research, and/or address other matters uncovered during its work. The Concordat to Support Research Integrity requires external membership on Full Investigation Panels or their equivalents, as do the terms and conditions of some research funders. At least two members of the Panel shall be academic specialists in the general area within which the misconduct is alleged to have taken place, and where allegations concern highly specialised areas of research the Panel should have at least one member with specialised knowledge of the field. Such specialists can be drawn from within the Organisation, bearing in mind the conflict-of-interest requirements or from the Panel's external member(s).
27. For allegations that involve staff on joint clinical/honorary contracts it may be helpful to include representation from the other employing Organisation(s). In these circumstances, they are not classified as the external member of the panel.

28.Respondents will normally be informed of the name of any Complainant(s) who have made the allegation(s) concerning them at the discretion of the Named Person, in exceptional circumstances the identity of the Complainant(s) may remain confidential. Any such decision should be made after seeking advice from human resources/ student and/or legal services; considering the Organisation's whistleblowing policy or equivalent and the impact on the Respondent(s) ability to respond to the allegation(s) that have been made against them. No decision should be made that compromises the Principles and Standards of this Procedure or

the thorough and fair investigation of the allegation(s) in question. The Complainants will be informed that their identity is being disclosed to the Respondent(s) at this point unless it has been determined that it should remain confidential.

Optional: If it is the norm for their internal procedures, some Organisations may wish to allow the Respondent to call witnesses to be interviewed by the Panel (rather than suggest witnesses which the Panel might interview) and/or to ask questions of the Complainant(s) and witnesses. Any such changes to this Template Procedure should only be made after consultation with Human Resources, legal and other relevant bodies/ groups. This Template Procedure includes separate interviews of the Complainant(s), Respondent(s) and witnesses. If it is the norm for their internal procedures, some Organisations may wish to instead hold a formal hearing which the Complainant(s), Respondent(s) and witnesses all attend. Any such changes to this Template Procedure should only be made after consultation with Human Resources, legal and other relevant bodies/ groups. It should be noted that such hearings can be difficult for participants, which can impact on the effectiveness of the investigation, and also challenging to operate effectively, which lead to challenges on procedural grounds. It also can change the nature of the Template Procedure from an investigation to a quasi-disciplinary hearing or 'courtroom'-style adversarial process. As such, UKRIO advises that Organisations consider all these factors carefully before introducing a formal hearing element into their version of the Template Procedure.

If the Complainant or Respondent does not wish to be interviewed, they should be asked to engage with the process through other means, such as providing written answers to questions posed by the Panel.

29.Report of the Investigation: After the Full Investigation, the Panel will conclude, giving the reasons for its decision and recording any differing views, whether the allegation of misconduct in research is:

a. is upheld in full; or

b. is upheld in part; or

c. has some substance but due to its relatively minor nature or because it relates to poor practice rather than to misconduct, will be addressed through education and training or another non-disciplinary approach, such as mediation, rather than through the next stage of the Procedure or other formal processes; or

d. warrants referral directly to another formal process of the Organisation, including but not limited to examination regulations, academic misconduct process or equivalent; bullying/ harassment procedure or equivalent; financial fraud investigation process or equivalent; disciplinary procedure; or

e. warrants referral directly to an external organisation, including but not limited to the current employer, statutory regulators or professional bodies, the latter being particularly relevant where there are concerns relating to Fitness to Practise; or

f. is unfounded, because it is mistaken or is frivolous or is otherwise without substance and will be dismissed.

g. is unfounded, because it is vexatious and/or malicious, and will be dismissed; or

The Panel may also make recommendations, for consideration by the Named Person and/or appropriate Organisational authorities, regarding any further action(s) which should be taken by the Organisation and/or other bodies to address any misconduct the Full Investigation may have found; correct the record of research, and/or address other matters uncovered.

Such recommendations might include but are not limited to:
a. whether the matter should be referred to the Organisation's relevant disciplinary procedure; and/or
b. whether the matter should be referred to another relevant Organisational process, such as the examination regulations, academic misconduct process or equivalent or the Organisation's financial fraud investigation process; and/or
c. what external organisations should be informed of the findings of the investigation, with appropriate confidentiality, including statutory regulators, relevant funding bodies, partner organisations and professional bodies, the latter being particularly relevant if concerns relate to Fitness to Practise; and/or
d. whether any action will be required to correct the record of research, including informing the publishers and editors of any journals that have published articles concerning research linked to an upheld allegation of misconduct in research or to correct honest errors; and/or
e. whether procedural or organisational matters should be addressed by the Organisation or other relevant bodies through a review of the management of research; and/or
f. informing research participants or patients or their doctors; and/or
g. other matters that should be investigated, including allegations of misconduct in research which are either unrelated to the allegation in question or alleged to have been committed by persons other than the Respondent and/or other forms of alleged misconduct.

The potential outcomes listed above reflect the dual purpose of the Full Investigation stage: the Panel must reach a conclusion on the allegation(s) under investigation and may also choose to make recommendations on further actions which might be necessary for the Named Person and/or the Organisation to take in order to address what the Full Investigation discovers.

Whether the Panel makes such recommendations or not, these issues should be considered by the Named Person working with the Research Integrity Manager, and with others as necessary, during the Outcomes and reporting stage.

30.Outcome & Reporting stage: The Outcomes and Reporting stage encompasses many potential situations, and its operation can involve considerable decision-making by the Named Person, Research Integrity Manager, and others. While some steps are required in any use of this Procedure, others apply only during certain outcomes of an investigation. Given the sheer breadth of scenarios which this stage can address, the guidance is general in nature and those operating this Procedure will need to determine how best to apply it during specific investigations. Decisions made during the operation of this stage, and the reasoning behind them, should be recorded in a brief format, in case they need to be referred to subsequently. The Named Person is responsible for ensuring that the actions described under this stage are carried out. Some actions may require the involvement of other departments within the Organisation and/or external organisations.
POSSIBLE OUTCOMES: the Named Person is responsible for ensuring that any necessary actions are carried out after the investigation is completed. In general terms, these actions may include:
a. Actions relating to the operation and conclusion (subject to any subsequent appeal) of this

Procedure, including appropriate transfers of information to any subsequent Organisational processes or informal measures, and/or to any relevant processes of external organisations.
b. Reporting the outcomes to relevant colleagues/bodies within the Organisation, for example, line managers, Human Resources and/or Student Services, Academic Board or equivalent.
c. Making necessary disclosures on the outcomes of uses of the Procedure to external organisations and other interested parties.
d. Duty of care to Complainants, Respondents, and other involved parties, including but not limited to research participants.
e. Ensuring that appropriate efforts are made to correct the research record.
f. Addressing procedural or organisational matters uncovered during the investigation.
TIMESCALE: This will vary depending on the scale of action needed, but the Named Person should aim to ensure they are completed within three months of completion of the investigation. However, some actions may require longer to complete. Any delays to this timescale will be explained to the Complainant, the Respondent and other involved parties in writing, presenting an estimated revised date of completion.
PROCESS: The required steps of this list fall into two categories: "Required actions" which relate to any use of the Procedure and "Actions required following [OUTCOME]", which relate solely to that particular outcome of the Procedure.
All "Required actions" should be taken, followed by those relating to the particular outcome in question.
Required actions: The Named Person working with the Research Integrity Manager, and with others as necessary, should take any further action(s) they deem necessary to: address any misconduct the investigation may have found; correct the record of research, and/or address other matters uncovered during the course of the investigation. Such recommendations might include but are not limited to:
a. whether following the conclusion of the operation of the Procedure, the matter should be referred to the Organisation's relevant disciplinary procedure; and/or
b. whether following the conclusion of the operation of the Procedure, the matter referred to another relevant Organisational process, such as the examination regulations, academic misconduct process or equivalent or the Organisation's financial fraud investigation process; and/or
c. what individuals and/or departments within the Organisation should be notified of the findings of the investigation, such as line managers, Human Resources and/or Student Services, a central committee with responsibility for research quality, or equivalents; and/or
d. what external organisations should be informed of the findings of the investigation, with appropriate confidentiality, such as statutory regulators, relevant funding bodies, partner organisations and professional bodies, the latter being particularly relevant if concerns relate to Fitness to Practise; and/or
e. informing research participants and other involved parties; and/or
f. whether any action will be required to correct the record of research, including but not limited to informing the editors of any journals that have published articles concerning research linked to an upheld allegation of misconduct in research and/or by a person against whom an allegation of misconduct in research has been upheld; and/or
g. whether procedural or organisational matters should be addressed by the Organisation or other relevant bodies through a review of the management of research and other measures

as appropriate; and/or
h. other matters that should be investigated, including allegations of misconduct in research which are either unrelated to the allegation in question or alleged to have been committed by persons other than the Respondent and/or other forms of alleged misconduct; and/or
i. communication of anonymised summary data on uses of this Procedure within a specific period. This includes reporting required in the Annual statement on research integrity required under The Concordat to support Research Integrity, reports to relevant central committees/ departments within the Organisation, and dissemination of anonymised learning points within the Organisation as appropriate.
When considering the above, the Named Person and the Research Integrity Manager should take into account any recommendations on such actions made by the Full Investigation Panel and any need to involve other elements of the Organisation (for example, line managers, Human Resources, committees/departments with responsibility for research quality, etc.) and/or external bodies (for example, partner research organisations, publishers, funders, regulatory bodies, etc.) in carrying out agreed actions.

31. Appeals stage:

The appeals process will be managed by an individual other than the 'Named Person' as they could be implicated in the substance of any appeal. An alternative designated individual who has not been involved in the matter previously will establish an Appeals Panel. At least one member of the Appeals Panel must be from outside the Organisation. The Appeals Panel has the power to uphold, reverse or modify the following outcomes of the Procedure, including the decisions and/or recommendations associated with them.
TIMESCALE: Any appeal should normally be heard within two months of the outcome of the investigation. Any delays to this timescale will be explained to the Complainant and the Respondent in writing, presenting an estimated revised date of completion.
Grounds for appeals: Appeals may be permitted on any or all of the following grounds:
a. Procedural irregularity in the conduct of the investigation up to and before the Appeal Panel that could have had a material impact on the outcome.
b. Fresh evidence becoming available which was not available to the Investigator and/or the Full Investigation Panel.
c. There was evidence of bias or unfairness in the process or decisions taken by the Named Person, Investigator and/or the Full Investigation Panel.
d. The recommendations made as part of an outcome of the Procedure/ subsequent actions taken are either excessive or inadequate concerning the misconduct found by the investigation.
Decisions that an appeal does not fall within one or more of the grounds for appeal should be taken carefully and an appropriate explanation of the reason behind the matter not proceeding further should be provided to the person(s) concerned. Whilst it may be clear to the Organisation that a concern does not fall within the grounds for appeal, this might not be equally clear to the person who has made the appeal, who may have raised their concerns after considerable thought and have strongly held views on the substance of the matter. Extra care should be taken also if this decision is being taken by one person without any advice. All people have their own unconscious biases and gaps in their expertise. Care must be taken not to dismiss on the basis of bias, or because of the way the matter has been presented, or because it appears to resemble previously seen matters.

The Appeals Panel will normally consist of three persons. Depending on the circumstances of the investigation and at the discretion of the Alternative Named Person, the Appeals Panel may consist of a greater number of persons, for example, to ensure that it contains sufficient expertise or diverse perspectives to reach a thorough and fair conclusion on the appeal. No individual involved in the Appeals Panel will have been involved at any stage previously as an Investigator or as a member of a Full Investigation Panel or the Named Person. One member of the Appeals Panel shall be from outside the Organisation. At the discretion of the Appeals Named Person, the Appeals Panel may include more than one external member. This may be advantageous where the appeal involves multiple disciplines and/or is especially complex and can help reassure involved parties that the process will be transparent rigorous and fair.

Resolution using informal measures:

One potential outcome of the use of this Procedure is a conclusion that the allegation(s) under investigation has some substance but, due to its relatively minor nature or because it relates to poor practice rather than to misconduct, will be addressed through education and training or another non-disciplinary approach. They may be used after the initial investigation or full investigation stage.

It is not recommended that they are used after the receipt of allegation stage, as an assessment of the substance of the allegation has not taken place at this point.

Informal measures can take many forms and some examples are given below.

This list should not be taken as exhaustive, and Organisations should devise and implement other informal measures as needed for the situation in question.

a. Education, training, and other development activities.
b. Enhanced supervision/ oversight of research activities.
c. Restriction of research activities.
d. Mentoring.
e. Mediation between involved parties.
f. Awareness-raising of relevant issues of good research practice.
g. Pastoral care and support.
h. Revision of relevant research practices, systems and/or policies relating to the allegation(s) in question. Such revision may be limited to a particular team or have a wider scope, covering a department or the entire organisation, and should be supported by appropriate training and awareness-raising.

IMPLEMENTING RESOLUTION USING INFORMAL MEANS:

Six key features of an effective system of resolution using informal measures are set out in the following paragraphs:

a. The nature and scope of the informal measures should be clearly defined.
b. A designated person should be responsible for carrying out the agreed measures.
c. Their duration should be clearly set out.
d. The designated person, working with the Research Integrity Manager and others, should ensure that the informal measures are delivered.
e. Appropriate documentation should record the delivery and outcomes of the informal measures, and any next steps.
f. Once completed, there should be discussion by the Research Integrity Manager and others about any learning points for the Organisation.

The person designated to carry out the informal measures can also request implementation of formal measures instead, and this should be considered by the Named Person as above.

DEFINED: the nature and scope of the informal measures should be defined in writing. This should be communicated by the Named Person or the Research Integrity Manager to the persons involved, in writing and including those who will be responsible for carrying out the informal measures. (e.g., "The Respondent should undergo training in authorship and publication ethics, including the norms of their discipline. The training will be sourced by the Organisation and the Respondent must provide evidence to their line manager that they have completed it."). If communications with external persons or organisations are required, this would normally be carried out by the Research Integrity Manager on behalf of the Organisation.

DESIGNATED PERSON: the Organisation should determine who will carry out and/or oversee the informal resolution, what resources will be made available to support them, and to whom they will give updates on the progress of the informal resolution. (e.g., The Departmental Head will liaise with the Research Integrity Manager to arrange awareness-raising activities on plagiarism, including discipline-specific information, within their department. The Research Integrity Manager will provide materials for these activities and, if possible, a speaker for an awareness-raising event.")

DURATION: the duration of informal measures should be set out at the onset, including a proposed start date, and communicated to all involved parties (e.g., "The process of mentoring for the Complainant will last for three months and then there will be a review by the line manager, with the mentoring extended for an additional three months if necessary"). The designated person should make the Named Person aware via the Research Integrity Manager if there is a significant delay in starting or completing the informal measures.

DELIVERY: Given their nature, informal measures can be vulnerable to delays and/or a lack of engagement from involved persons, whether an individual (e.g., Complainant and/or Respondent) or groups (e.g., a research team or a department within the Organisation). The aim is the delivery of the informal measures as defined (see above) and progress should be measured, in a light-touch way, against their agreed nature and scope (e.g., "We are undertaking the agreed course of mediation between the Complainant and Respondent to repair their working relationship. At the end of the mediation, they and their line managers will explore whether the Complainant and Respondent now both feel comfortable working together in the future or if they will no longer work in partnership.")

Care must be taken to ensure that agreed actions are delivered by the Organisation and the designated person must be given support by the Named Person, the Research Integrity Manager and/or others, as needed.

DOCUMENTATION: the informal nature of these measures does not mean that no records should be kept. Brief notes should be kept on:

- the nature and scope of the informal measures;
- who has responsibility for their delivery; the proposed and actual duration of the measures;
- and their delivery and associated outcome(s).

When informal measures are concluded, involved parties (e.g., Complainant and/or Respondent; Named Person and/or Research Integrity Manager; line managers/ supervisors; Human Resources or Student Services) should be informed in writing, summarising the

delivery and outcome(s) of the informal measures and any next steps (e.g., "The Respondent has now completed the six-month period of additional supervision of their research. They have outlined in writing key lessons learned during this period and the additional supervision will now cease. The Respondent has been reminded that they can seek advice from their supervisor, their line manager and the Research Integrity Manager on issues of consent and data management in the future."
If communications with external persons or organisations are required, this would normally be carried out by the Research Integrity Manager on behalf of the Organisation.
Records should be retained in line with the provisions given earlier in this Procedure normally by the Research Integrity Manager.
The Organisation should determine if records should also be retained by others within the Organisation (e.g., line managers; Human Resources or Student Services).

DISCUSSION: the conclusion of informal measures is an opportunity for review and learning, whether in relation to the persons involved; wider groups of researchers and/or professional services staff; or for the systems and practices as a whole. The Research Integrity Manager, working with others as necessary, can generate learning points for dissemination to appropriate members of the Organisation, supported by anonymised summary information, to safeguard and enhance good research practice within the institution.

Ref: UKRIO-Procedure-for-the-Investigation-of-Misconduct-in-Research-V2.pdf

Approved by University Research Ethics & Governance sub-committee: Feb 2020
Approved by University Committee for Research & Innovation Strategy: Feb 2020
Policy Approved by Senate: July 2015 and June 2020.

Section 9

POLICY ON PUBLIC DISCLOSURE (WHISTLEBLOWING)

1. Introduction

Swansea University is committed to the highest standards of openness, probity and accountability. It seeks to conduct its affairs in a responsible manner taking into account the requirements of the funding bodies and the standards in public life set out in the Nolan Principles. These are: selflessness, integrity, objectivity, accountability, openness, honesty and leadership.

The Public Interest Disclosure Act 1998 (amended 2013) gives legal protection to employees and workers who disclose confidential information about malpractice in the workplace, whether carried out by other employees/workers or the employer, these are concerns which are both serious and likely to be of wider public interest.

1.1 This policy applies to all employees, students, all lay members, contractors, consultants, officers, interns, casual and agency workers.

1.2 If you are an employee, this policy does not form part of your contract of employment.

1.3 This policy is not intended to be used as a substitute for other University's policies and procedures and the following should be raised in the usual manner:

1.3.1 This policy is intended to cover concerns of malpractice which are in the wider public interest.

1.3.2 Allegations of research misconduct - these should be reported using the University's Policy on Handling Allegations of Research Misconduct (link);

1.3.3 Matters which relate to an individual's complaint regarding their employment, or the way others are behaving towards them including any personal grievance or complaint they may have should be raised under the University's Grievance Ordinance (Ordinance-11.10---Staff-grievances.pdf (swansea.ac.uk)) or under the Dignity at Work and Study Policy (Dignity at Work and Study Policy - Swansea University) as appropriate.

1.3.4 In the case of students, concerns other than those falling under the categories set out above should be raised through the normal complaints procedures (Complaints Procedure - Swansea University);

1.3.5 Matters which relate to workplaces other than Swansea University, for example in hospitals, businesses, or other places where students or staff may be based or on placement/secondment. In such cases the University, Faculty, School or Department will ensure that students and staff are made aware of the relevant whistleblowing procedures in force at the other workplaces and, should it be necessary, will provide appropriate support to those seeking to follow other organisations' whistleblowing procedures;

1.3.6 Lay members should not view this procedure as an avenue to challenge or question business or financial decisions taken by the University; as an avenue of appeal to challenge decisions previously taken under other procedures of the University; or as a way of dealing with malpractice/wrongdoing of students;

1.3.7 Concerns which have been addressed under other internal procedures, where

decisions have been made and appeals processes exhausted should not be brought further under this policy.

2. What is whistleblowing?

The Department for Business, Innovation and Skills has developed Guidance for Employers and Code of Practice on Whistleblowing.

2.1 The University's aim is to maintain the highest standards of integrity in everything it does. However, all organisations can occasionally be affected by conduct that is dangerous, against the law or breaches ethical or professional codes. Should you have any such concerns, the University encourages you to report them immediately - this is called 'whistleblowing' (more formally known as making a disclosure in the public interest). You can be assured that the University will take your concerns seriously, they will be thoroughly investigated, and you can be confident there will be no reprisals. Details re protection for whistle-blowers can be found in para 5 below.

2.2 The types of concerns you may want to raise with the University by whistleblowing might include:

- any activity you suspect is criminal;
- any activity you suspect is fraudulent;
- any activity you suspect puts health and safety at risk;
- any activity you suspect may damage the environment;
- any activity you suspectas financial malpractice and impropriety (including but not limited to: financial irregularities, corruption, bribery and/or dishonesty);
- any activity you suspect falls under the Criminal Finances Act;
- any activity you suspect as a miscarriage of justice;
- any failure to comply with legal or regulatory obligations;
- any failure to comply with the University's Charter or Statutes and/or the Regulations of the University;
- any unethical behaviour;
- any failure to meet professional requirements; and/or
- any attempt to conceal one or more of these activities.

This list is not intended to be exhaustive, and members of the University are encouraged to utilise this policy on occasions where they believe they have discovered malpractice or impropriety.

2.3 If in doubt, speak to your line manager, tutor or other appropriate trained individual if you are not sure whether something you have become aware of is covered by this policy. Note that if your complaint is covered under an alternative University Policy you will be given guidance on how to proceed.

2.4 A disclosure under this policy may be made by an individual or jointly with others.

3. How to raise a whistleblowing concern

3.1 In cases where an individual intends to make a disclosure under this policy, it should normally be made to the University in the first instance. As stated in 2.4 above, should you require support or advice in raising a concern, you can speak to your line manager, tutor or other appropriate trained individual, in the first instance, who can further assist with the procedure below.

3.2 You should write to the Principal Officer under this Policy, being either the Registrar and Chief Operating Officer or the Provost. If your concern relates to the actions of the Vice-Chancellor, the Registrar and Chief Operating Officer or the Provost you should write to the Chair of the Audit, Assurance and Risk Committee.

3.3 Your letter should clearly state that you are raising your concerns under this Whistleblowing Policy and then explain what they are. Include all the key facts, dates, and the names of the people involved. On receipt of your letter, the Principal Officer will write to you acknowledging receipt within 5 working days.

3.4 You will be invited to a meeting to discuss your concerns, and you are entitled to be accompanied at this and any subsequent meetings by a colleague or trade union representative. If you bring a companion, you must both agree to keep your disclosures confidential before, and after the meeting and during any investigation that may follow.

3.5 After the initial meeting, you may be asked to attend further meetings, which could include specialists with particular knowledge or experience of the issues you have raised.

3.6 The Principal Officer will consider the information made available to him/her and decide on the form of investigation to be undertaken. This may be: a) to investigate the matter internally and to appoint an Independent Investigator; b) to refer the matter to the police; c) to call for an independent external inquiry.

3.6.1 If the decision is that investigations should be conducted by more than one of these means, the Principal Officer should satisfy him/herself that such a course of action is warranted.

3.6.2 Where the matter is to be the subject of an internal inquiry, the Principal Officer will then consider how to conclude whether there is a prima facie case to answer. This consideration will include determining: a) who should undertake the investigation (Independent Investigator); b) the remit of the Internal Investigator including the ability to make recommendations to the University regarding the actions to be taken c) the procedure to be followed; d) the scope of the concluding report. In the event that actions of the Vice Chancellor, the Registrar and Chief Operating Officer, the Provost or any other member of the Senior Leadership Team are the subject of whistleblowing the Principal Officer may wish to appoint an independent team to support the Independent Investigator to ensure complete independence.

3.6.3 The Independent Investigator appointed will be at the discretion of the Principal Officer, the Independent Investigator may be someone within the University who is considered to have relevant knowledge and expertise of the issues raised, or an appropriate individual external to the University. The Independent Investigator will undertake the internal investigation and will report his/her findings to the Principal Officer. The Principal Officer will be responsible for making any decision following the investigation and to fully consider any recommendations delivered within the report.

3.6.4 As a result of this investigation other internal procedures may be invoked by the Principal Officer. Reference to the police or other external bodies may also be made at this point.

3.6.5 In some instances it might be necessary to refer the matter to an external

authority for further investigation, e.g. the Higher Education Funding Council for Wales, or the bodies listed in Public Interest Disclosure Act.

3.7 Due to the concerns you have raised, other individuals are likely to be interviewed as part of your Whistleblowing Complaint, including but not limited to the individual who the concern have been raised against. Any individual interviewed under this process will be afforded equal support and are entitled to be accompanied at any meetings by a colleague or trade union representative and to reach out to any appropriately trained individual under this Policy. Any individual involved, including all those interviewed, and all companions, must agree to keep the disclosures confidential before, and after the meeting and during any investigation that may follow.

3.8 You will be kept informed about how the investigations are progressing and how long they are likely to take. Sometimes, however, the Principal Officer may be unable to give you details about the investigation (or any action it leads to) as the University needs to protect confidentiality and comply with legal obligations. It is understood that this may be frustrating and give you concerns about whether any action has been taken, and if this happens an appropriate individual will explain why the University is acting in this way. Also, due to the complexity of the concerns you have raised it may be impossible for the Principal Officer to provide you with a timeframe for such an investigation. The Principal Officer will however keep you updated as is felt appropriate within the circumstances of the investigation.

3.9 Your concerns will be addressed fairly, and the investigation will be thorough, however the outcome may differ from your expectations. If you are not satisfied with how the University has conducted the investigations, and your matter has been dealt with by either the Registrar and Chief Operating Officer or the Provost, you can take the matter to the Chair of the Audit, Assurance and Risk Committee for further consideration. If your original concerns were dealt with by the Chair of the Audit, Assurance and Risk Committee you may take the matter to the Chair of Council for further consideration. Where a whistle-blower is not satisfied, they also have the right to refer their concerns to one of the relevant bodies referred to in point 3.6.5.

3.10 An individual will not suffer any detriment at all for making a disclosure which falls under paragraph 2.2 above and the University actively encourages individuals to come forward if they have any concerns. Even if the disclosure is found to be incorrect, the individual making the disclosure will not suffer any detriment provided that they believed in what they were saying when they raised the concerns. Details re protection for whistle blowers can be found in para 5 below.

4. Confidentiality and anonymity

4.1 There is a significant difference between wanting to keep your concerns confidential and making a disclosure anonymously. While anonymous whistle blowing is actively discouraged, the University may use its discretion in exceptional circumstances.

4.1.1 In exercising this discretion, the factors to be considered will include: the seriousness of the issues raised; the credibility of the concern; and the likelihood of confirming the allegation from attributable sources.

4.1.2 Concerns raised anonymously are very difficult - and sometimes impossible - to investigate. The University can't properly establish whether your allegations are credible without being able to ask you for more details or for

clarification, and this makes it hard to reach an informed decision. This is why you are urged you not to report matters anonymously.

4.2 You are always encouraged to raise concerns openly, and if you prefer to do so in confidence, the University will do all that it can to ensure your identity remains hidden. The Investigator may want to disclose your identity to people involved in the investigation but will always discuss this with you first.

4.3 The University will treat all appropriate disclosures made in accordance with this policy in a confidential and sensitive manner. It will therefore endeavour to keep confidential the identity of the person who has raised the concern. However, it must be appreciated that the investigation process may reveal the source of the information and that a formal statement from the original complainant may be required as part of the investigative process.

4.4 You are protected from reprisals under this policy (see paragraph 5) but if you are still worried you are encouraged to discuss this with the Principal Officer, the Investigator or an appropriate individual and they will explore how far the investigation can go in keeping your concerns confidential.

5. How whistle blowers are protected

5.1 If you raise a concern under this policy, the University will support you fully even if it is found through the investigations that the concern was raised as a result of a genuine mistake or that there has been no breach of policy, legal obligation etc. However, if you feel you have been treated detrimentally as a result of raising a concern, you must tell the Principal Officer immediately. First inform your manager and, if the matter remains unresolved, you must follow the formal process under the Grievance Ordinance.

5.2 Victimisation or other detrimental treatment of an employee, student, or other member of the University, as a result of that person raising concerns under this policy, may be considered a serious disciplinary offence under the University's disciplinary procedure.

5.3 Victimisation or other detrimental treatment of an individual who has supported an employee, student, or other member of the University, as a result of that person raising concerns under this policy, may be considered a serious disciplinary offence under the University's disciplinary procedure.

5.4 All whistle-blowers are afforded the same protection, so individuals must not threaten others who have raised concerns or carry out reprisals against them. Individuals who do so may face disciplinary action which could include dismissal for gross misconduct, if we find they have. Individuals doing so may also face legal action from the whistle-blower in these circumstances.

5.5 Any individual within the scope of this policy who attempts to prevent an individual raising a concern under this policy may face disciplinary action which could include dismissal for gross misconduct. They may also face legal action from the whistle-blower in these circumstances.

5.6 It should be noted however that any disclosure made by anyone in the organisation in bad faith or maliciously will not be tolerated and could lead to disciplinary action. Such disclosures undermine the whole tenet of a whistleblowing policy.

6. Taking your concerns outside the University

6.1 This policy outlines the process for raising, investigating, and resolving wrongdoing or malpractice within the University. It is rarely necessary for anyone outside the University to become involved when a whistleblowing allegation is made.

6.2 In some exceptional circumstances, you may need to go to an external body or regulator.

6.3 This policy covers the actions of third parties such as suppliers, service providers, and clients, as well as our staff, students, and lay members. Should you have concerns about a third party, you are encouraged to raise these concerns with us before approaching anyone else. Your line manager, tutor, or appropriate person will be able to explain how you should proceed.

6.4 Alerting the media or an irrelevant third party to a concern - particularly before or during an internal investigation - is almost never justified or appropriate in any situation. We strongly discourage you from doing so and may consider contact with the press to be a disciplinary issue justifying dismissal unless exceptional circumstances exist. We would normally expect you to have taken all reasonable steps to deal with the matter internally or with an external regulator, and to have taken full independent legal advice before being justified in approaching the press or an irrelevant third party. You should also note that taking a matter to the press or an irrelevant third party may potentially affect your rights and protection under the Public Interest Disclosure Act 1998 (amended 2013).

6.5 In respect of external regulators mentioned above (6.2), this will depend on the nature of the concern. However, these may include but are not limited to:

- The Charity Commission
- Higher Education Funding Council for Wales (HEFCW)
- The Home Office
- The relevant Police Regulatory Authority
- The relevant Research Council
- External funding bodies

In line with clauses 2.3 and 2.4 above, if in doubt, you may seek advice and support from your line manager, tutor, or other appropriate trained individual.

7. Reporting of Outcomes

7.1 A report of all disclosures and any subsequent actions taken will be made by the Principal Officer who will retain such reports for three years. In all cases a report of the outcomes of any investigation will be made to the Audit, Assurance and Risk Committee, in detail as a means of allowing the Committee to monitor the effectiveness of the procedure.

Section 10

POLICY ON RESEARCH DATA PROTECTION & CONSENT

Summary:

Research and the General Data Protection Regulations (GDPR)
Some of the research undertaken by the University uses information about identifiable living individuals and uses personal information, which falls within the remit of the General Data Protection Regulations (GDPR) and Data protection Act 2018. GDPR adopts a 'broad' definition of research, encompassing the activities of public and private entities alike. **The GDPR aims to encourage innovation, with a number of exemptions applicable to research, as long as organisations implement appropriate safeguards**.

It is important that staff collecting data for research purposes process the data in line with the GDPR and the Data Protection Act 2018 as well as any University Guidance. Non-compliance may result in serious reputational and legal implications for the University.

If data has been truly anonymised, then GDPR no longer applies. Guidance on anonymization can be found on the Information Commissioners Office website:

https://ico.org.uk/for-organisations/guide-to-data-protection/anonymisation/

This policy summarises the main University Data Protection Policy and individuals must be aware of and adhere to this policy:

http://www.swansea.ac.uk/media/Data%20Protection%20Policy.pdf

Scope
This policy applies to:

- All members of the University involved in processing of personal data for research purposes.
- Personal data is defined as data relating to any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. Examples may include, but are not limited to, data obtained from surveys; access to medical records; photographs.
- Principles of the GDPR:
  - **Principle 1:** Personal data shall be processed lawfully, fairly and in a transparent manner.
  - **Principle 2:** Personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes.

- **Principle 3:** Personal data shall be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')
- **Principle 4:** Personal data shall be accurate and, where necessary, kept up to date.
- **Principle 5:** Personal Data processed for any purpose shall not be kept longer than is necessary for that purpose (data processed for research purposes may be kept for 'longer').
- **Principle 6:** Appropriate technical and organisational measures shall be taken to prevent the unauthorised or unlawful processing of personal data and the accidental loss, destruction of, or damage to, personal data.

Aims

This policy sets out how the University seeks to protect personal data of data subjects in the context of research and ensure that staff and students involved in the processing of data for research purposes understand the rules governing their use of personal data.

The University Data Protection Policy provides specific detail on Definitions; Conditions of processing; The rights of an individual; Accountability of the University; Policy Statements; Records of Processing activities; Children; Data Sharing; Data Protection Breaches; Responsibilities of Staff and Students and Data Protection Support.

GENERAL DATA PROTECTION REGULATIONS

When conducting research with human participants, researchers shall demonstrate compliance with GDPR and the main University Data Protection Policy, including but not limited to the following aspects:

- Commitment to protecting the rights and freedoms of individuals in accordance with the provisions of data protection legislation.
- Demonstrating compliance with the data protection principles.
- When collecting personal data for research purposes at least one of the conditions of the Regulations for the processing of personal data must be satisfied and the processing of this data must be fair. Those highlighted in bold are likely to be the conditions used for the processing of data for research purposes:
    - *The data subject has given his or her consent*
    - *The processing is necessary for the performance of a contract between the University and the Data Subject*
    - *To meet the University's legal compliance obligations*
    - *To protect the data subject's vital interests*
    - ***For the performance of a task in the public interest or for your official functions, and the task or function has a clear basis in law***
    - *To pursue the University's legitimate interests (this will not be used for research purposes as this condition can only be applied where processing does not fall within the University's core function).*
- Where the data includes special category data (for example racial or ethnic origin, political opinion, religious belief, trade union membership, genetic data or biometric data used in identification, health or sex life/sexual orientation), in addition to identifying one of the above conditions for lawful basis, one 'article 9' condition must

also be identified, further detail can be found in the guidance for researchers document provided in the appendices to this framework.

- All personal data held must be kept securely; and not disclosed to any unauthorised third party in any way, either accidentally or otherwise.
- Researchers using cloud-based services must ensure that they are compliant with the University's data protection and information security policies.
- In the event that the University engages in a third party as a 'data processor' for its personal data, a specific written contract with the supplier providing assurance of security provision will be in place. The University will not rely on supplier set 'terms and conditions'.
- Personal data must only be kept for the length of time necessary to perform the processing for which it was collected. Once information is no longer, needed it should be disposed of securely (truly anonymised data may be kept indefinitely and research data may be kept longer as long as safeguards are met).
- Consent should be obtained using an 'opt-in' by the data subject (research participant) rather than an 'opt-out'.
- Individuals providing their personal data to the University should be aware who the data controller is and what will be done with their data via GDPR compliant privacy notices.
- The University will manage the personal data it processes in a secure way. This applies to paper and electronic records systems. Systems should be access controlled, staff appropriately trained, and security processes should be developed and understood.
- Appropriate monitoring and reporting on data security risks, initiatives and developments will be undertaken by the Universities management groups.
- The University will consider the impact on data privacy during all processing activities. This includes implementing appropriate technical and organisational measures to minimise the risk to personal data and conducting data protection impact assessments where required.
- The University will implement privacy by design when processing personal data by implementing appropriate technical and organisation measures in an effective manner, to ensure compliance with data privacy principles.
- Personal data shall not be transferred to a country or territory outside the EEA unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.
- The GDPR lists the factors that should be considered to ensure an adequate level of protection for the data and some exemptions under which the data can be exported.
- Information published on the internet must be considered to be an export of data outside the EU. This covers data stored in the cloud unless the service provider explicitly guarantees data storage only takes place within the EU.
- The Information Commissioner's Office guidance on the use of cloud computing should be consulted before any use of external computing resources or services via a network which may involve personal data.
- Staff involved in transferring personal data to other countries should consult the Data Protection Officer

- Individuals must be given the opportunity to remove themselves from lists or databases used for direct marketing purposes. The University must cease direct marketing activity if any individuals request the marketing to stop.
- Processing personal data for direct marketing purposes must be in line with the GDPR and the Privacy and Electronic Communications Regulations 2003.

With specific reference to researchers:

- Researchers should be aware of and compliant with any specific legal requirements and data protection guidance from their subject area, for example, the Health Research Authority.
- Researchers should be aware that whilst consent may be required from the research participant, this might not form the lawful basis for processing under GDPR. The lawful basis for processing must be clearly communicated to the data subject.
- Where consent is relied upon for the lawful basis of processing, the research participant (data subject) must be given a number of rights linked to consent including the right to withdraw consent and the right to data portability, which may not be practicable for research. Guidance on consent can be found at: https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/consent/
- The processing of special category data (for example data revealing racial or ethnic origin; political opinions; religious or philosophical beliefs; trade union membership; genetic or biometric data; health or sex life and sexual orientation) is prohibited unless an alternative legal basis for processing is met. Where this is for research purposes, specific measures to safeguard the fundamental rights and interests of the data subject must be implemented.
- Where research exemptions outlined in GDPR are applied, namely in relation to the rights of: access; rectification; restriction of processing and to object then appropriate safeguards outlined in the guidance to protect the rights and freedoms of the individuals whose personal data is being processed must be in put in place.
- Where the processing of personal data for research purposes is considered to be high risk (for example evaluation or scoring; automated decision making; systematic monitoring; sensitive data; large scale processing; vulnerable data subjects; data transfer across borders); data protection by design and privacy impact assessments (PIAs) must be used in order to demonstrate that the risks are understood, mitigated and compliance is demonstrated.
- The University as the employer is the 'Data Controller' and as such, staff have no right to remove personal data obtained for research purposes after leaving the institution without the University's permission.
- Research subjects should not be identified in published research results or publicly available datasets unless they have consented to being identified, or if the information is already in the public domain.

If there remains uncertainty around roles and responsibilities in respect of data protection, advice may be sought from the University Data Protection Officer.

Specific guidance for Researchers
Specific detailed guidance related to this policy is available in the appendices to this framework:
GDPR & Research – A Practical Guide
GDPR Data Protection Impact Assessments – Guidelines
GDPR Data Protection Privacy Assessment - Template

Further guidance is available from the Information Commissioner's Office (ICO):
https://ico.org.uk/for-organisations/guide-to-data-protection/

For NHS related research, further guidance is available from:
http://hra-decisiontools.org.uk/consent/examples.html

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/

Related policies & procedures:
Our policies and procedures - Swansea University

CONSENT
As discussed in section above, consent should generally not be relied upon as the legal basis for processing personal data for research purposes under the General Data Protection Regulations (GDPR). However, ethically it is very important to gain informed consent from participants to take part in a research project. Gaining consent must be considered and implemented throughout the lifecycle of the research project.

Consent requires that research subjects should fully understand the purpose, methods and intended possible uses of the research, and its implications for them (including any risks). Conducting research in an open way, which respects the rights of research subjects and obtains their agreement, is a crucial part of conducting research in an ethical manner.

To be meaningful, consent must be informed and must be freely given. "Informed" consent means that research subjects understand what they are consenting to and receive comprehensive information about the project and in a language and vocabulary with which they are familiar. While this information will vary from project to project, and will have to be tailored to the culture or society in which the research is being conducted, it is recommended that it should include:

- the name of the project, its purpose and its objectives;
- the identities of the organisations or individuals who have funded the research and any interests they may have in the research;
- why the information was being collected, and why it was necessary for the project;
- the name and contact details of the person who will be responsible for gathering the data for the project;
- names of individuals with access to the data, including any organisations or individuals

outside the organisation who may be given access;
- special security measures that will be taken to protect the data;
- the countries to which the data may be transferred. Whether the data is gathered outside the UK and will be transferred into the UK and whether the data will be transferred outside the European Union;
- how the data will be published or made available, including whether research subjects will be identifiable in the published data, or whether the data will be published in anonymised form;
- steps which will be taken to archive the data;
- how the data will be used in future research projects; and
- how the research subject can withdraw their consent to participate in the project if they subsequently decide to do so.

Consideration should also be given to the extent to which the research subject is capable of giving consent. Every effort should be made to secure the informed consent of children and other vulnerable groups (e.g., adults with learning difficulties); although it is recognised, that informed consent may also require the involvement of a parent, guardian or other person with a duty of care. Parental consent should normally be sought for children under the age of 16. Consent given "Freely" means that the individual should not be under duress: there should be no adverse consequences for them from refusing to participate in the project, and no coercion (actual or implied) to participate in the project. Researchers should recognise that informed and freely given consent requires an on-going dialogue with the research subject and is not a one-off event.

Further information on gaining consent for research involving children or vulnerable adults can be found in the related policies on undertaking research with children and young people and undertaking research with vulnerable adults.

Consent may need to be renegotiated, e.g., if the aims of the research or the methods of disseminating its results change. Research subjects have the right to retrospectively withdraw their consent at any point in the process, including after the completion of the research.

How should consent be recorded?

Consent must be recorded in some way – for example in writing, orally or non-verbal. However, types of research study such as Clinical Trials of Investigational Medicinal Products (CTIMPs), consent must be recorded in writing to be considered legal.

Written consent is preferable as it may offer more protection for the researcher and participant if disputes arise; be more solid from a legal perspective; and offer consistency, but sometimes it may not be possible – for example the illiterate; informal research settings; participants wary of 'formal' documentation (e.g., in research regarding illegal activities).

Verbal consent however may create greater risk for the researcher, and it may be difficult to make all issues clear. Verbal consent would preferably be recorded via audio or video, therefore.

However, it should be noted that some committees and governance boards would require that written consent is mandatory, and researchers should check specific requirements relating to their project.

A signature on a consent form does not necessarily mean that it is valid – a person's agreement with statements contained in the consent form should be recorded for example via a tick box or yes or no statement. All parties involved in the consent conversation should sign the form.

The traditional and most straightforward way of recording consent is through a paper consent form signed by the research subject. The form should record the research subject's consent to their data being used in the manner and for the purposes described in the information given to them. It should also give the project copyright permission to use the research subject's contribution.

In some fieldwork situations, where use of a written consent form may be impractical or even harmful to the relationship between the researcher and the research subject, researchers should concentrate on the objective of ensuring the research subject's informed participation and adopt a method of achieving that which is appropriate to the project and the society where the research is taking place. Sensitivity should be shown to cultural differences in areas such as the concept of consent and the relationship between the individual and the group.

Any decision not to use written consent forms should take the following factors into account:

- There may be other, more suitable ways of directly recording the research subject's consent than a written consent form. For example, if data is gathered through audio-visual recordings of interviews, the recording of the first interview could start with the researcher explaining the nature and purpose of the project and how the data will be used and asking the interviewee to confirm that they agreed to participate in the project.
- A decision not to use a formalised method of recording consent does not remove the researcher's Data Protection and ethical obligations to provide research subjects with enough information for them to make a truly informed decision whether to participate. This should be done by whatever method is most appropriate in the research context. However, if research subjects were able to read, it would normally be expected that they should be provided with written information about the project so that they have a record of what they participated in. Where written consent forms are used, the research subject should be given a copy of the form to keep.
- The records of the project (e.g., project plan, field notes) should document the methods chosen by the researcher to obtain informed consent and how they were implemented. All documentation relating to the obtaining of consent (including consent forms and other written information provided to the research subject, where used) should be preserved for at least as long as the data is retained in non-anonymised form.

What does consent mean for audio-visual material and photographs?

Films, sound recordings and images will be personal data if they capture an individual with sufficient clarity to allow them to be identified. All of the considerations relating to consent outlined in the previous sections apply equally to AV material and photographs. Covert or "hidden camera" recording or photography (in which individuals are not aware that the process is taking place) raises serious ethical and legal concerns and should only be undertaken after full ethical review of the proposed research according to the Faculty Ethical review procedures. Consent for recording or photography may not always be necessary. In the UK, images of public spaces or public activities in which individuals are captured incidentally are not usually seen as raising privacy issues or requiring consent. For example, a photograph of a high street showing shoppers walking up and down, or news footage of a public demonstration. However, there are many legal uncertainties in this area; the courts have held that in some cases, individuals have a right to privacy in images of their activities carried out in public. Typically, this occurs where the image focuses on an individual, intrudes into their private life, is used without their consent, and there is no overriding public interest justification.

Researchers should also be wary of importing UK concepts of what is "private" and "non-private" into other cultural contexts. Activities performed by a group in its own group space may still be regarded as "hidden" or secret to the group, even if performed in the open. Researchers should always be transparent with research subjects about when recording or photography is taking place, and how the information will be used. When in doubt, following the recommendations for obtaining informed consent outlined above (see what the role of consent is? and how should consent be recorded?)

What does consent mean for surveys?

Surveys, which are entirely anonymous (i.e., the researcher has no way of knowing the identity of the respondent), will not gather personal data in the sense of the General Data Protection Regulations. Data Protection issues are not relevant, as there is no way of linking individuals to the data. However, it would still be good ethical research practice to provide respondents with information about the nature of the project and how their responses will be used. Survey data is personal data if respondents are identifiable, e.g., from information which they provide on the form or through other information which is available to the researcher. Respondents' informed consent must be obtained, but as previously noted; this is unlikely to be the lawful condition for processing the data, so it should be made clear to the participant that this is "***For the performance of a task in the public interest or for your official functions, and the task or function has a clear basis in law".***

The aim should be to cover, as far as possible, the points outlined in 'what is the role of consent?' The notice should also state that by completing the form, it would be assumed that the respondent consents to the use of their data for the purposes described. If a respondent will be contacted again (e.g., for a follow-up survey or to update them on the progress of the project), this should be explained, and the respondent told how they can opt out from future contact (e.g., by checking a box).

Signatures, while desirable as method of authentication, may be impractical in some situations (e.g., web-based surveys). Fair collection notices can be used to give respondents

a range of choices about how their data will be used, e.g., through check boxes. However, researchers should be wary of presenting respondents with too many options, as this may make it more difficult to manage the data.

How much data should be gathered?

The answer to this question will obviously depend on the goals and objectives of the research project. However, researchers should remember that the third Data Protection Principle requires that personal data should be **adequate, relevant, and not excessive** in relation to the purpose for which it was gathered. Avoid the temptation to collect more data about individuals than is necessary for the project: e.g., information which might possibly be of some use in the future, but for which no immediate use is envisaged.

How to keep data secure?

Good data security is an essential part of ethical research practice and is a requirement of the General Data Protection Regulations. Unauthorised access to personal data or accidental loss of data can have serious consequences for research subjects and may damage Institutional reputation and that of the individual researcher. Research that involves the use of IT systems must conform to the IT policies and procedures.

Where a project team involves more than one individual, one team member (usually the team leader) should be assigned responsibility for data security. The project team should agree and document the procedures, which they will follow to keep data secure.

The appropriateness of data security procedures will depend on the sensitivity of the information. Not all personal data is equally sensitive. Information about individuals, which has already been published or is publicly available, may need little or no protection. Similarly, information about individuals' public lives (e.g., their job title, office or rank, the identity of their employer) will generally be less sensitive than information about their private lives and may not require extensive protection. Conversely, strong security measures will be necessary for sensitive personal data, personal financial information, or information whose disclosure might cause individuals loss or harm. As a rule of thumb, it should be assumed that harm could result from any unauthorised disclosure of information, which relates to private life (e.g., home contact details, income, personal relationships, or beliefs).

Anonymization can play an important role in ensuring data security. As it is not personal data, an anonymised dataset can be used in a lower security environment than the version in which individuals are identifiable. Often, only the anonymised data is necessary for analysis purposes.

As far as possible, non-anonymised personal data should only be stored on Institutional server, where it will be backed up automatically and protected by security systems. Access should be restricted to those individuals who need access to the data for the purpose of the research project: for example, by restricting access to individual directories and/or password protecting individual files.

Most data security breaches occur when data is "on the move". As many high-profile cases demonstrate, laptops and storage devices such as data keys/flash drives, CDs/DVDs and portable hard drives are particularly vulnerable to theft and accidental loss. These devices

should only be used to transport non-anonymised personal data where necessary. Where they are used, individual files containing personal data on research subjects should be password protected and should be encrypted if the information includes sensitive personal data, financial information about individuals, or information whose disclosure could cause harm or loss to individuals.

The transmission of personal data on research subjects should also be avoided, unless necessary. Where transmission is necessary, emailing encrypted attachments is preferable to the post as a method of sending personal data. Email attachments, containing non-anonymised personal data must be password protected, and must be encrypted if the information could cause harm or loss to individuals. Passwords or pass phrases must be communicated separately from the data (preferably by telephone). If the postal service has to be used to transfer personal data, the data should be sent by recorded delivery and the storage media must be protected through encryption as outlined above.

Data is vulnerable when it is being used at home, because of the increased risk of theft and unauthorised access.

To prevent accidental loss of data, researchers should regularly back up personal data, which is not stored on the Institutional servers, and are referred to the university's Information Security policy:

Policy History

Version	**Author**	**Summary of changes**	**Approved by**	**Date**
1	Anjana Choudhuri/Bev Buckley (DP officer)	First version	*UREGSC*	July 2015
2	Corinna Summerill/Bev Buckley (DP officer)	Second version	*UREGSC*	February 2019

Swansea University
Prifysgol Abertawe

PARTICIPANT INFORMATION SHEET

[TITLE OF RESEARCH]

[SELECT AN APPROPRIATE WORKING TITE FOR YOUR PROJECT. PLEASE ENSURE THE TITLE YOU CHOOSE IS CONSISTENT ACROSS YOUR ETHICS DOCUMENTATION (CONSENT FORM, INFORMATION SHEET, DEBRIEF, ETHICS FORM)]

You are being invited to take part in some research. Before you decide whether to participate, it is important for you to understand why the research is being conducted and what it will involve. Please read the following information carefully.

What is the purpose of the research?
We are conducting research on… [INSERT A FEW SENTENCES DESCRIBING WHAT YOUR RESEARCH IS ABOUT. USE PLAIN ENGLISH]. The purpose of the study is to… [SUMMARISE THE RESEARCH AIMS. IF THERE IS MORE THAN ONE, EACH MUST BE SPECIFIED SO THAT EXPLICIT INFORMED CONSENT CAN BE OBTAINED.] Your participation in this study will take approximately [INSERT AN APPROXIMATE DURATION - This should be specific and contingent on how long the project is intended to take place. If it only comprises 1 interview, which is intended to take approximately 1 hour, then include this].

Who is carrying out the research?
The data are being collected by [Please include details of student name, details of Department within Faculty and if relevant also state Supervisors name, Department and Faculty at Swansea university] The research has been approved by the Faculty Research Ethics Committee.

What happens if I agree to take part?
[DESCRIBE WHAT THE PARTICIPANT WILL ACTUALLY BE DOING. USE PLAIN ENGLISH]
EXAMPLE: We will ask you to complete a 'values' questionnaire. In the values questionnaires we ask you to rate how important some values are to you as guiding principles in your life. Additionally, we will ask for some background information including your level of education, your age and sex.

Are there any risks associated with taking part?
The research has been approved by the Faculty of Committee. There are no significant risks associated with participation. [IF THERE ARE ANY SIGNIFICANT RISKS, THESE MUST BE SPECIFIED].

Data Protection and Confidentiality
Your data will be processed in accordance with the Data Protection Act 2018 and the General Data Protection Regulation (GDPR). All information collected about you will be kept strictly confidential. Your data will only be viewed by the researcher/research team. [IF THE DATA ARE TO BE SHARED WITH 3RD PARTIES YOU MUST DECLARE THIS HERE AND NAME THE PARTIES CONCERNED.]

All electronic data will be stored on a password-protected computer file [STATE WHERE]. All paper records will be stored in a locked filing cabinet [STATE WHERE]. Your consent information will be kept separately from your responses to minimise risk in the event of a data breach.

[ADD THE FOLLOWING STATEMENT FOR STUDIES WHERE THE DATA WILL BE MADE ANONYMOUS (WHICH WILL BE MOST STUDIES): Please note that the data we will collect for our study will be made anonymous, [PLEASE PROVIDE AN INDICATION OF WHEN ANONYMISATION WILL TAKE PLACE], thus it will not be possible to identify and remove your data at a later date, should you decide to withdraw from the study. Therefore, if at the end of this research you decide to have your data withdrawn, please let us know before you leave.

[ADD THE FOLLOWING STATEMENT IF INFORMATION IS BEING COLLECTED ONLINE E.G. ONLINE SURVEYS: Please note that if data is being collected online, once the data has been submitted online you will be unable to withdraw your information.]

[ADD THE FOLLOWING STATEMENT IF DATA WILL NOT BE ANONYMISED]: The lead researcher (or supervisor, if student research) will take responsibility for data destruction and all collected identifiable data will be destroyed on or before [ENTER DATE – note that data should be kept for a reasonable time - please therefore justify the period that you will be keeping data for, bearing in mind that data should not be stored unless for a valid purpose.]

International Data Transfers [ONLY REQUIRED IF APPLICABLE]
Your data may/will [DELETE AS REQUIRED] be stored and processed in [STATE LOCATION]]. Please note countries outside of the European Economic Area may not offer the same level of data privacy protection as in the UK. [NB: IF INTENDING ON SHARING PERSONAL DATA OUTSIDE THE EEA, PLEASE DISCUSS YOUR SITUATION WITH THE UNIVERSITY COMPLIANCE OFFICER FOR DATA PROETECTION AND FREEDOM OF INFORMATION. SEE University Governance - Swansea University

Conducting research overseas [ONLY REQUIRED IF APPLICABLE]
The researchers will abide by local data protection laws when collecting personal data.

What will happen to the information I provide?
An analysis of the information will form part of our report at the end of the study and may be presented to interested parties and published in scientific journals and related media. *Note that all information presented in any reports or publications will be anonymous and unidentifiable*.

Is participation voluntary and what if I wish to later withdraw?
Your participation is entirely voluntary – you do not have to participate if you do not want to. If you decide to participate, but later wish to withdraw from the study, then you are free to withdraw at any time, without giving a reason and without penalty.

Data Protection Privacy Notice
The data controller for this project will be Swansea University. The University Data Protection Officer provides oversight of university activities involving the processing of personal data and can be contacted at the Vice Chancellors Office.

Your personal data will be processed for the purposes outlined in this information sheet.
Standard ethical procedures will involve you providing your consent to participate in this study by completing the consent form that has been provided to you.

The legal basis that we will rely on to process your personal data will be processing is necessary for the performance of a task carried out in the public interest. This public interest justification is approved by the Faculty Research Ethics Committee, Swansea University.

The legal basis that we will rely on to process special categories of data will be processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

How long will your information be held?
We will hold any personal data and special categories of data for [HERE YOU WILL NEED TO SPECIFY

THE RETENTION PERIOD FOR WHICH THE PERSONAL DATA WILL BE STORED, OR IF THAT IS NOT POSSIBLE, THE CRITERIA USED TO DETERMINE THAT PERIOD. IT IS IMPORTANT TO BE AWARE THAT THE GDPR STATES THAT PERSONAL DATA MUST BE KEPT 'NO LONGER THAN IS NECESSARY FOR THE PURPOSES']

Automated decision making and profiling [only required if applicable]
[HERE YOU WILL NEED TO SPECIFY WHETHER OR NOT YOU USE AUTOMATED DECISION MAKING OR PROFILING. WHETHER THIS SECTION APPLIES WILL NEED TO BE DETERMINED ON A CASE-BY-CASE BASIS. IT WILL ONLY APPLY WHERE DECISIONS ARE BEING MADE ON INDIVIDUALS WIHOUT ANY HUMAN INTERVENTION]

What are your rights?
You have a right to access your personal information, to object to the processing of your personal information, to rectify, to erase, to restrict and to port your personal information. Please visit the University Data Protection webpages for further information in relation to your rights.

Any requests or objections should be made in writing to the University Data Protection Officer: -

University Compliance Officer (FOI/DP)
Vice-Chancellor's Office
Swansea University
Singleton Park
Swansea
SA2 8PP
Email: dataprotection@swansea.ac.uk

How to make a complaint
If you are unhappy with the way in which your personal data has been processed, you may in the first instance contact the University Data Protection Officer using the contact details above.

If you remain dissatisfied, then you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at -

Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF
www.ico.org.uk

What if I have other questions?
If you have further questions about this study, please do not hesitate to contact us:

[INSERT STUDENT NAME] Department of Swansea University [INSERT SWANSEA UNIVERSITY STUDENT EMAIL]	[INSERT SUPERVISOR CONTACT DETAILS – SEE EXAMPLE BELOW] Dr XXX Department of Swansea University. Email: XXX@swansea.ac.uk

Section 11

POLICY ON RESEARCH DATA

The University promotes the highest standards in the management of research data and records as fundamental to both high-quality research and academic integrity.

It acknowledges its obligations that sound systems should be in place to promote best practice, including through clear policy, guidance, supervision, training, and support.

The University recognises that accurate and retrievable research data are an essential component of any research project and necessary to verify and defend, when required, the process and outcomes of research. Research data are valuable to researchers for the duration of their research, and may well have long-term value for research, teaching and for wider exploitation for the public good, by individuals, government, business, and other organisations, as a project develops and after research results have been published.

Researchers should keep clear and accurate records of their research. This includes procedures, protocols, approvals, sources used, and results obtained, giving due consideration to the requirements of anonymity and confidentiality. Researchers must determine the retention requirements for their research data and records on a project-by-project basis or at least for clearly defined categories of projects, taking account of:

- the legal and regulatory framework for particular types of research.
- the terms and conditions imposed by external research sponsors/funders.
- the commercial, political, or ethical sensitivity of particular types of research, or any research for particular external sponsors.

Faculty's, Schools, Departments, Professional Services units and, where appropriate, research sponsors and external collaborators, need to work in partnership to implement good practice and meet relevant legislative, research funder and regulatory requirements.

Research data and records should be:

- accurate, complete, authentic and reliable;
- identifiable, retrievable, and available when needed;
- secure and safe;
- kept in a manner that is compliant with legal obligations and, where applicable, the requirements of funding bodies and project-specific protocols; and
- able to be made available to others in line with appropriate ethical, data sharing and open access principles.

11.1 How long should research records be kept?

It is important to protect the integrity and auditability of the research. Each research project is unique, and judgement is required to determine how long records should be kept. Research

data and records should only be retained for as long as they are of continuing value to the researcher and the wider research community, and as long as specified by research funder, patent law, legislative and other regulatory requirements. A Data Management Plan (DMP) should be established before the project starts, covering all project records and this is often required as part of a research funding application.

Data should normally be preserved and accessible **for a minimum of 10 years after completion of the research**. Records from studies with major health, clinical, social, environmental or heritage importance, novel intervention, or studies, which are ongoing or controversial, should be retained for at least 20 years after completion of the study. It may be appropriate to keep such study data permanently within the university, a national collection, or as required by the funder's data policy.

Where research is supported by a contract with or a grant to the University that includes specific provisions regarding ownership, retention of and access to data, the provisions of that agreement will take precedence.

If research data and records are to be deleted or destroyed, either because the agreed period of retention has expired or for legal or ethical reasons, this should be done so in accordance with all legal, ethical, research funder and collaborator requirements and with particular concern for confidentiality and security.

Research carried out for the NHS or under contract for a commercial organisation is subject to that body's own archiving, data protection and retention policies. For Clinical Trials of Investigational Medicinal Products (CTIMP) archiving needs should be undertaken according to the European Union Regulations and detailed requirements are given in the clinical trials toolkit which can be found at http://www.ct-toolkit.ac.uk

A data manager and/or data monitoring committee should be appointed for CTIMP studies and should consider the regulations. A Trial Master File should be set up at the beginning of a trial and maintained throughout the trial in accordance with Good Clinical Practice. There is more specific and detailed guidance at http://www.ct-toolkit.ac.uk/routemap/archiving.

Researchers should be aware of the archiving policies of other organisations involved in the research and are responsible for:

- managing research data and records in accordance with the relevant principles and requirements;

- developing and documenting clear procedures for the collection, storage, use, re-use, access and retention or destruction of the research data and records associated with their research. This will include, where appropriate, defining protocols and responsibilities in a joint or multi-institution collaborative research project. This information should be incorporated, where appropriate, in a research data management plan;

- planning for the on-going curation (at the University or using third-party services) of their data after the completion of the research or, in the event of their departure or retirement from the University, reaching agreement with the head of department/Faculty (or his/her nominee) as to where such data will be located and how this will be stored; and

- ensuring that any requirements in relation to research data and records management placed on their research by funding bodies or regulatory agencies or under the terms of a research contract with the University are also met.

The following should be noted:

- a custodian should be designated for any archived information.
- data should be stored in line with other policies.
- data should be stored in a way that permits a complete retrospective audit if necessary.
- data should be safely stored, with appropriate preservation and backup procedures in place.
- data, particularly personal data, should be treated in confidence, i.e. kept securely with no unauthorised access.
- should a research team cease to exist or the lead moves to another Institution, the expectation is that the responsibility for the information belongs to the University that hosted the original research.
- research hosted within the NHS should comply with the data retention policy of the host Trust, provided that the minimum requirements of this policy document are adhered to.

The University will be responsible for:

- providing access to services and facilities for the storage, backup, deposit and retention of research data and records that allow researchers to meet their requirements under this policy and those of the funders of their research;
- providing researchers with access to training, support and advice in research data and records management;
- providing the necessary resources to those operational units charged with the provision of these services, facilities, and training.

The University's Research Ethics & Governance Sub-Committee, a sub-committee of the University Research Committee, would be responsible for guiding the development and updating of the policy.

11.2 Process for handling of DBS certificates

Researchers at Swansea University who intend conducting research with vulnerable people are required to present a valid U.K Disclosure and Barring Service certificate (DBS) to help Faculty Research Ethics Committees assess the suitability of the researcher.
A researcher, working with children and vulnerable adults should familiarise themselves with the following University policies:

1. P1819-135: Policy on undertaking research with vulnerable adults and adults lacking capacity &

2. P1617-635: Policy of undertaking research with Children and young people.

The University complies fully with The DBS Government code of practice regarding the correct use, storage, retention, and disposal of certificates. The University also complies fully with its obligations under the General Data Protection Regulation (GDPR), Data Protection Act 2018 and other relevant legislation pertaining to the handling of DBS certificate information.

Storage

The code of practice states that information on DBS certificates should be kept securely, in lockable, non-portable, storage containers with access strictly controlled and limited to those who are entitled to see it as part of their duties. Electronic storage of information should also comply with the DBS guidance and the Data Protection Act. A copy of the certificate must be held on a secure, restricted access university computer drive.

Retention

The information revealed from a DBS check is considered only for the purpose for which it was obtained (the certificate copy should be destroyed after an ethical decision has been made. Ethics committees should not keep the certificate for more than 6 months).

Once the decision on the researcher's suitability has been made, any DBS certificate information should be immediately destroyed by secure means. No photocopies should be kept or any other image of the certificate or any copy or representation of the contents of a certificate. However, in the case of university staff the Faculty Research Ethics Committees (REC's) will pass details of the date of issue of a certificate, the REC reference, the type of certificate requested, the unique reference number of the certificates to the University's HR function (via Faculty HR business partner) to be recorded on the staff researcher's ABW record and will also retain the details of the ethics decision taken.

https://www.gov.uk/government/publications/handling-of-dbs-certificate-information/handling-of-dbs-certificate-information

Where researchers inform the Research Ethics Committee that they have subscribed to the DBS Update service with a check at the same level as that required, the REC (with applicant's permission) should refer to the following to undertake the required check via the on-line service:

https://www.gov.uk/government/publications/dbs-update-service-employer-guide/dbs-update-service-employer-guide

Recorded information will be handled in line with the University's Data Protection Policy and the Staff Privacy statement

In some cases, research staff need to keep the original copies of their DBS certificates as source data for audits by external regulatory bodies. In such instances, staff would keep their own certificates as part of their training files along with all other certification in a secure, restricted access location. The certificates would be kept for the duration of the project and possibly archived at the end of the project for the length stated on a REC form (i.e. as identifiable data). These should be kept by staff in their locked cabinets in a controlled access room for a stipulated *period of time (usually up to 10 years after duration of research).*

Non –UK domiciled researchers (incl. students)

All non-UK domiciled REC applicants are required to complete a DBS disclosure application.

Non-domiciled researchers should also provide the University with a Police check/Certificate of Good Conduct from their home country (with a certified translation into English if necessary).
https://www.gov.uk/government/collections/dbs-checking-service-guidance--2

11.3 Concordat on Open research data:

Published in July 2016, the 'Concordat on Open research data' has been developed by a UK multi-stakeholder group. The development of the Concordat is to help ensure that research data gathered and generated by members of the UK research community is made openly available for use by others wherever possible in a manner consistent with relevant legal, ethical, disciplinary, and regulatory frameworks and norms, and with due regard to the costs involved. The *Concordat* proposes a series of clear and practical principles for working with research data that cover the many roles needed to support the research process. The Concordat sets out ten principles with which all engaged in research can demonstrate that they:

- are acting in an appropriate manner concerning research data;
- conform to all ethical, legal and professional obligations relevant to their work;
- nurture a research environment that makes data open wherever practical and affordable;
- use transparent, robust and fair processes to make decisions concerning data openness;
- have appropriate mechanisms in place to provide assurances as to the integrity of their research data; and
- recognise the importance of data citation and credit acknowledgement.

The 10 principles of the concordat on Open access is as follows:

Principle 1:
Open access to research data is an enabler of high-quality research, a facilitator of innovation and safeguards good research practice**.**

Principle 2:
There are sound reasons why the openness of research data may need to be restricted but any restrictions must be justified and justifiable**.**

Principle 3:
Open access to research data carries a significant cost, which should be respected by all parties**.**

Principle 4:
The right of the creators of research data to reasonable first use is recognised

Principle 5
Use of others' data should always conform to legal, ethical, and regulatory frameworks including appropriate acknowledgement.

Principle 6
Good data management is fundamental to all stages of the research process and should be established at the outset.

Principle 7
Data curation is vital to make data useful for others and for long-term preservation of data.

Principle 8
Data supporting publications should be accessible by the publication date and should be in a citeable form.

Principle 9
Support for the development of appropriate data skills is recognised as a responsibility for all stakeholders.

Principle 10
Regular reviews of progress towards open research data should be undertaken.

Further information on the concordat on open research data can be accessed via the URL
UKRI-020920-ConcordatonOpenResearchData.pdf

Section 12

RESEARCH GRANT APPLICATIONS – GOVERNANCE PROCEDURES

The University has arrangements in place for managing key requirements relating to the development of research proposals and external funding applications. The ***Research Engagement & Innovation Services*** **(REIS)** Department is responsible for coordinating and monitoring all aspects of research grants received by the University.

12.1 RESEARCH DEVELOPMENT

Based in REIS, the Research Development team advises potential applicants of available opportunities for external funding. The team is located across the four Research Hubs and in the REIS section of the Talbot Building. The Research Development Teams advices Principal Investigators and their research teams of key legislative and sponsor requirements affecting external funding, highlights to them potential funding opportunities, assists them with the application and costing process and assists them with bid writing of research proposals. Further information on researcher support available from the research development team can be obtained from the URL below

https://www.swansea.ac.uk/research/undertake-research-with-us/

The Research Governance Manager, based in REIS is responsible for receiving and reviewing applications of research projects for the University to act as Sponsor.

Export control

The Government's Export Control legislation seeks to ensure that UK science and technology is not exported into the wrong hands. Export controls applies to physical goods or the transfers of software, data, technology, or know how which has a military application. The transfer can be physical or electronic. Distribution is from the UK to the destination outside the UK. The main areas of concern are military technology and technologies that can be used in nuclear, chemical, or biological weapons or their means of delivery.

Exports are controlled for various reasons, including:
- concerns about internal repression, regional instability, or other human rights violations
- concerns about the development of weapons of mass destruction
- foreign policy and international treaty commitments including as a result of the imposition of EU or United Nations trade sanctions or arms embargoes
- national and collective security of the UK and its allies

Export controls are not unique to the UK. All countries have some form of an export control policy, legislation, and enforcement mechanisms. The UK has a well-developed and coherent export control system based on EU and national legislation.
The Department for Business, Innovation & Skills (BIS) issues specific guidance for academics. More guidance on the conditions can be accessed through the following URL

Business and enterprise: Trade restrictions on exports - detailed information - GOV.UK (www.gov.uk)
https://www.gov.uk/guidance/beginners-guide-to-export-controls
https://www.spire.trade.gov.uk/docs/guidance/Goods%20Checker%20Guidance.pdf
Export Control Joint Unit - GOV.UK (www.gov.uk)

Please contact mailto:researchcontracts@swansea.ac.uk for any queries relating to Export Control

12.2 GOVERNANCE OF AWARDS

Based in REIS, the Project Services team (projectservices@swansea.ac.uk) is responsible for ensuring the establishment and monitoring of systems of control and accountability, including financial and operational controls and risk assessment. They work with Principal Investigators and the Faculty/Schools financial support teams to assist them discharge their funder obligations and responsibilities. The Projects, owned by the respective Faculty, form part of the overall business plan for the Faculty.

Projects are managed within a defined Legislative and Regulatory framework that includes:

- Sponsor terms and conditions established by contract and subject to UK contract Law.
- Sub-contracts, Collaborations, Partnerships, and other third-party agreements.
- Audit frameworks e.g., Welsh European Funding Office (WEFO), European Funds Audit Team (EFAT), UK Research & Innovation (UKRI), Swansea University internal audit.
- HMRC VAT – Finance department provides guidance on these issues and the project services staff communicate them to Principal Investigators and Faculty Finance Administrators.
- HESA statistical return – The Project Services team is responsible for providing datasets for these returns. The Finance department of the University have overall responsibility for the HESA returns.

REIS Project Services manages these responsibilities within the context of a mature and robust financial control environment. They conduct periodic reviews of project expenditure and highlight overspends to relevant Faculty. The Department produces an annual report to Finance Committee highlighting risks. The Department has the authority to approve staff expenditure and major non-staff expenditures of up to £25k/per item. The Department advises on eligibility and highlights any non-compliance issues or risks via a clear escalation process to the University Risk Manager and the University Senior Management Team.

Aside from the University internal and external auditors, UK Research & Innovation has its own audit regime and REIS plays a key supportive role in allowing access to financial and management systems and information to assist with the process. The Project Services team is also responsible for archiving of all project material on project completion.

Section 13

POLICY ON RESEARCH RELATED HEATH AND SAFETY

Health, Safety, and well-being of participants:

All researchers (including PhD students) in a research establishment must:

- take responsibility for their own health and safety and ensure that they don't compromise the health and safety of others by the things they do or fail to do;
- work safely and efficiently;
- follow the organisation's policy, guidance and safe systems of work;
- attend training and put it into practice in the workplace;
- risk-assess, or assist with the risk assessment of their work;
- use protective equipment as recommended;
- not change research or other work protocols without first discussing the change with their manager and specialist safety advisers as appropriate;
- report incidents that have resulted in, or could have resulted in, injury or damage;
- assist in the investigation of accidents with the aim of introducing preventative measures;
- report unsafe conditions or actions;
- work co-operatively to improve health and safety standards and performance;

As a rule, people participating in research should not be exposed to risks that are greater than, or additional to, those that they encounter as part of their normal lifestyles. Researchers have a responsibility to protect participants from any harm arising from research. If it is expected that participants may suffer harm, unusual discomfort, or other negative consequences, whether during the research or in the future, as a result of their participation in research, the lead researcher must, prior to any person's participation, obtain:

- approval of independent, accredited ethics reviewers (e.g., University ethics reviewers, an NHS Research Ethics Committee or the national Social Care Research Ethics Committee);
- obtain informed consent of the prospective participant.

Depending on the nature of the research, researchers have a responsibility to ask participants about any factors, such as pre-existing medical conditions, that might create risks to them if they participate in a given research project, and participants must be advised of any special action they should take to avoid risk.

Before participating, people should be informed of how to contact the lead researcher, the Head of Department, or, ultimately, the Registrar within a reasonable time, if, following participation they experience stress, harm, or have any other concerns about their research.

In the case of clinical trials, research should only take place where the foreseeable potential risks and inconveniences to the prospective participants (i.e. trial subjects and/or patients) are deemed likely to be outweighed by the potential benefits for them and for future patients. In certain cases, a patient may explicitly support a research project and support invasive treatment that may be very harmful if, due to the particular circumstances (for example, if s/he is terminally ill); s/he feels that it is worth taking a significant, potentially life-threatening

risk. This example represents the point at which participants may feel they have a right to participate as well as a right to withdraw, a right to be harmed, in exceptional circumstances, as well a right to be protected from harm.

In the case of non-invasive research methods such as interviews and questionnaires, the content and line of questioning may be highly sensitive, may raise confidential personal issues, and may intrude, or be perceived to intrude, upon a participant's comfort and privacy. The initial judgment about whether or not questions are sensitive and likely to cause harm or discomfort rests with the lead researcher. For advice in such cases, the lead researcher should initially consult the Faculty Research Governance Support Officer or Chair of Faculty Research Ethics Committee.

The Management of Health and Safety at Work Regulations 1999 requires employers to have suitable arrangements in place for "the effective planning, organisation, control, monitoring and review" of their risk identification and control systems. This approach is recommended by the HSE document *Successful health and safety management* (HSG65). In a system intended to manage the health and safety aspects of a research project, this means putting in place organisational health and safety policy and guidance and:

- planning the health and safety arrangements for the activity **(PLAN)**
- implementing the planned health and safety controls and carrying out the activity **(DO)**
- checking that the arrangements and controls put in place to stop injury, damage and ill health are working as planned **(CHECK)**
- reviewing the activity to ensure that the health and safety arrangements were adequate and proportionate and then feeding any changes into the next research activity **(REVIEW)**

The University, Principal Investigator or researcher should:

- identify potential health and safety implications of all research projects.
- undertake reasonable steps to ensure the health and safety of all research participants and researchers.
- where appropriate, obtain Occupational Health clearance for researchers entering health and social care environments.
- ensure that staff and students whose research involves the participation of vulnerable groups such as the old, the young and the sick have Criminal Records Bureau disclosure before their research commences.
- ensure that appropriate risk review methods are in place for any potential and on- going risks are appropriately addressed, including containment, shielding and monitoring.

For further information on how to conduct research safely please consult the document '**responsible research – Managing health & safety in research**: **guidance for the not-for-profit sector**' http://www.iosh.co.uk/ushaguide
While writing up a project funding proposal and prior to embarking on any research project, please consult the University's Health and Safety policies via the following link: Health and Safety - Swansea University

Section 14

POLICY ON IP AND PROCEDURES FOR IMPLEMENTATION OF IP

14.1 INTELLECTUAL PROPERTY

Introduction

The policy and rules of Swansea University in respect of:

- the ownership of Intellectual Property created by staff of the University ("University Personnel")
- the use and commercialisation of Intellectual Property; and
- the implementation and administration of the Intellectual Property Policy.

Policy on IP and Procedures for Implementation of IP

This policy may be supplemented from time to time by guidance, made in accordance with the Procedures.

- **to Commercialise means** to realise commercial or financial benefit through the exploitation of Intellectual Property, and **Commercialisation** shall be interpreted accordingly.

- **to Create** means to create, devise, design, invent, discover, be the author of or otherwise originate any Intellectual Property and **Creator** shall be interpreted accordingly.

- **Intellectual Property** ("IP") means (1) patents, copyright, database rights, design rights, trade marks, topography rights, plant breeders' rights and all other intellectual or industrial property rights whether registered or unregistered such as exist now or in future under the law of England and Wales, the law of the European Union or the law of any other jurisdiction throughout the world (2) the right to apply for, and applications for, such rights and (3) all extensions and renewals of such rights. Intellectual Property shall also include other intellectual assets such as inventions and discoveries and any other product or attribute of intellectual or academic activity (whether or not formal property rights subsist or are capable of subsisting therein) such as (but without limitation) know-how, knowledge and expertise, skills, techniques, and the results of experiments, tests, or calculations.

- **University Personnel** means any members of staff or employees of the University.

- **Procedures** means Swansea University's Procedures for Implementation of its Policy on Intellectual Property as amended from time to time in relation to the implementation and administration of this Policy.

General Principles

The general principles underlying this policy are:

- The University owns the Intellectual Property created by University Personnel, except to the extent this policy provides otherwise.

- University Personnel who have created Intellectual Property, which is commercialised, should receive a fair share of the commercial benefit, as should the University and the relevant University Faculty(s).

- Whenever University funds, facilities, personnel, or other resources are involved in (1) creating Intellectual Property, which is exploited commercially, or (2) undertaking other commercial activities, the University must obtain good value for its investment.

  This is because:

  As a charity, the University has a duty to ensure that the use of its resources is properly accounted for, and most of the University's activity and resources is funded by public money. In general, public money or resources cannot be used to confer a direct or indirect benefit on a business undertaking, because of the danger of unlawful state aid. Where there is unlawful state aid, it must be paid back.

  Nevertheless, where the use of University resources is insignificant in the creation of the Intellectual Property, the University may waive its ownership of the Intellectual Property having regard to guidelines established under the Procedures.

In respect of Intellectual Property, which the University determines not to commercialise or otherwise exploit, the University should have the right to use that Intellectual Property for its own purposes and to receive a share of any benefits of commercialisation but should not unreasonably refuse to license or assign the Intellectual Property to the Creator.

14.2 Ownership of Intellectual Property - University Staff

- By law, rights in any Intellectual Property created by an employee of the University during the course of his or her employment belong to the University.

- Intellectual Property created by a member of staff within his or her employed area of academic or research expertise during his or her period of employment with the University are presumed to have been created during the course of his or her employment, and so belong to the University.

- In any event, if University funds, facilities, personnel or other resources are used, the University makes it a condition of use that any resulting Intellectual Property belongs to the University.

- University Personnel have a duty to disclose to the University any Intellectual Property that they have created during their period of employment, which may reasonably be considered suitable for commercial exploitation. Subject to that duty, University Personnel must keep confidential at all times and must not publish or disclose any such Intellectual Property, except as expressly permitted by the University under this Policy or otherwise in writing.

14.3 Teaching materials and other Academic materials

The principle, which the University applies to Teaching materials and other Academic materials, is that the University should be entitled to use the IP for its own purposes and receive a share of any proceeds from commercialisation but does not insist on ownership.

The Creator shall own the copyright in teaching materials, academic and other publications (books, articles etc.), theses and dissertations, lesson plans and learning modules except where they are comprised of original computer software, details of an invention or other commercially exploitable information or know-how not in the public domain, or when the materials have been specifically commissioned by the University or in circumstances where Clause 6 is applicable and the University is contractually required to own the copyright.

The University shall be granted an unconditional, perpetual, and irrevocable non-exclusive right to copy, use and modify these materials for all purposes connected with the University and any affiliated or subsidiary institution. The license related to Academic materials shall be non-exclusive. The license for Teaching materials, lesson plans and learning modules shall be exclusive during the term of employment and non-exclusive thereafter. In its discretion, the University will provide reasonable and appropriate acknowledgement of the Creator.

The Creator shall not publish without the express written consent of the University commercially sensitive information of the University, details of any potentially patentable invention, or any information in violation of a Confidentiality Agreement between the University and a third party.

In the event the Teaching materials, other Academic materials, or any other material are commercialised, the University shall be entitled to receive 15% of any proceeds over £2000.

It is the obligation of the Creator to ensure that any license or assignment of the intellectual property rights in Teaching or other Academic materials or any other matter to a third party, such as an academic publisher, is made subject to the rights of the University to use and modify such materials.

The Creator(s) shall indemnify and keep the University indemnified against all costs, claims, damages, or expenses incurred by the University or for which the University may become liable arising out of or relating to any use or commercialisation of the Teaching materials or other Academic materials or any other matter by the author, including any tax, national insurance, and related interest and penalties.

14.5 Commercialising Intellectual Property

No University Personnel may, without express authority from the University, enter into any discussions, negotiations, arrangements or agreements with any person or organisation in relation to any Intellectual Property, which belongs to the University.

University Personnel must inform the University of any potential Commercialisation of Intellectual Property. Unless the University expressly authorises otherwise, Commercialisation shall only take place via the University. The University shall determine if and how the University shall Commercialise Intellectual Property that it owns in accordance with the Procedures, including any provisions for consultation, which are contained in the Procedures.

Generally, if the University decides that it does not wish to Commercialise Intellectual Property, the University will license or assign the Intellectual Property to the Creators where it can be shown to its reasonable satisfaction that assigning ownership or licensing will be on terms which are consistent with the University's obligations as a charity and the use of public funds. If the IP is commercialised by the Creator, the University will be entitled to a share of revenue in accordance with guidelines set out in the Procedures.

The University may, in accordance with the Procedures, issue disclaimers of ownership of Intellectual Property in appropriate cases or provide for a license or assignment of the Intellectual Property to the Creators.

14.6 Contract Research and Consultancy

Where the University enters into a contract for the supply of research or consultancy services, it is likely that there will be special provisions relating to IP generated in the course of supplying those services.

Any Intellectual Property generated by University Personnel in supplying those services will belong to the University and will be dealt with in accordance with the relevant contract.

14.7 Revenue Sharing

The University will distribute the net revenue or other tangible benefit received by the University (after recovery by the University of its reasonable costs and expenses in connection with the identification, protection, Creation or Commercialisation of such Intellectual Property) deriving from Intellectual Property created by University Personnel in accordance with the following formula. Where there is more than one Creator, they will share their entitlement between them equally, unless they otherwise agree among themselves.

A13OUNT	CREATORS	UNIVERSITY	
		SCHOOL	UNIVERSITY
First £ 2000	100%	0	0
Next £2000-	60%	30%	10%

£20000			
Next £20,000-£100,000	50%	35%	15%
Next £100,000-£250,000	40%	40%	20%
Additional counts	35%	35%	30%

The University's commitment is subject to and shall be modified to reflect:

any major overarching initiative(s) entered into by the University, following relevant consultations, which may have different reward models.

the Creator's right to receive other benefits through the Commercialisation process (primarily, equity ownership in a spin-out company, in which case if a creator accepts shares or options over shares in the Spin-Out, the Inventor will not be entitled to receive additional revenue from the University).

14.8 Breach of Policy or Guidance

Any breach by University Personnel of this policy or of any guidance made in accordance with the Procedures may amount to a disciplinary matter and / or an infringement of the University's rights, and consequently may lead to disciplinary or legal action being taken by the University.

14.9 Implementation and Dispute resolution

Responsibility for the implementation and administration of this Policy shall lie with the Vice Chancellor, who may delegate that responsibility to another person.

If the Vice Chancellor or Chair of Council is personally interested in any matter related to the University's IP or has some other conflict of interest with the University related to any commercial matter, then the functions of the Vice Chancellor and/or the Chair of Council (as the case may be) under this policy and the Procedures shall be exercised by such independent person or persons as the Council may determine.

The Procedures shall include an internal dispute resolution procedure.

In the event University Personnel alleges that the University has not complied with this Policy and its Procedures, he or she may request that the matter be resolved by an arbitrator to be agreed upon between the University and the University Personnel, of if they are unable to agree on the identity of the person within one calendar month of the request to arbitrate, by an arbitrator appointed by the President of the Law Society of England and Wales. The arbitration will take place in Swansea and be conducted according to laws of England and Wales. The decision of the arbitrator shall be binding on the University and the staff member

and the costs shall be borne as decided by the expert. Either Party would be free to bring proceedings in the courts in order to seek mandatory, declaratory, or other relief, which is not available from an arbitrator.

Section 15

PUBLICATION AND DISSEMINATION OF RESEARCH FINDINGS

15.1 Research Publication Integrity for Authors, Reviewers, and Editors

Researchers should be mindful of the ethics of publication, and seek to ensure that their authorship, publication, peer-review, editing, and related practices are undertaken with integrity. This is particularly important for collaborative authorship and publication where there is a significant difference between the status of the individuals involved (e.g., well established researchers and early career researchers; academic supervisors and postgraduate researchers).

Publication and Authorship

- Organisations and researchers should accept their duty to publish and disseminate research in a manner that reports the research and all the findings of the research accurately and without selection that could be misleading.

- Organisations should ensure that sponsors and funders of research: respect the duty of researchers to publish their research and the findings of their research; do not discourage or suppress appropriate publication or dissemination; and do not attempt to influence the presentation or interpretation of findings inappropriately.

- Organisations should provide training and support to guide researchers in the publication and dissemination of research and the findings of research that involves confidential or proprietary information; issues relating to patents or intellectual property; findings with serious implications for public health; contractual or other legal obligations; and/or interest from the media or the general public.

- Researchers should address issues relating to publication and authorship, especially the roles of all collaborators and contributors, at an early stage of the design of a project, recognising that, subject to legal and ethical requirements, roles and contributions may change during the time span of the research. Decisions on publication and authorship should be agreed jointly and communicated to all members of the research team.

- Authorship should be restricted to those contributors and collaborators who have made a significant intellectual or practical contribution to the work. No person who fulfils the criteria for authorship should be excluded from the submitted work. Authorship should not be allocated to honorary or “guest” authors (i.e., those that do not fulfil criteria of authorship). Researchers should be aware that anyone listed as an author of any work should be prepared to take public responsibility for that work and ensure its accuracy and be able to identify their contribution to it.

- Researchers should list the work of all contributors who do not meet the criteria for authorship in an acknowledgements section. All funders and sponsors of research should be clearly acknowledged, and any competing interests listed.

- Researchers must clearly acknowledge all sources used in their research and seek permission from any individuals if a significant amount of their work has been used in the publication.

- Researchers must adhere to any conditions set by funding or other bodies regarding the publication of their research and its findings in open access repositories within a set period.

- Researchers should declare any potential or actual conflicts of interest in relation to their research when reporting their findings at meetings or in publications.

- Researchers should be aware that submitting research reports to more than one potential publisher at any given time (i.e., duplicate submission) or publishing findings in more than one publication without disclosure and appropriate acknowledgement of any previous publications (i.e., duplicate publication) is unacceptable.

- Researchers who are discouraged from publishing and disseminating their research or its findings or subjected to attempts to influence the presentation or interpretation of findings inappropriately, should discuss this with the appropriate person(s) in their organisation so that the matter can be resolved.

The **Committee on Publications Ethics** (COPE) exists to promote integrity in research publication and aims to define best practice in the ethics of scholarly publishing to assist researchers, authors, editors, editorial board members, owners of journals, and publishers. The COPE website contains many resources, including:

- Principles of Transparency and Best Practice in Scholarly Publishing;
- How to Handle Authorship Disputes: A Guide for New Researchers;
- Ethical Guidelines for Peer Reviewers;
- Text Recycling (i.e. Publication Overlap) Guidelines;
- A Guide to Ethical Editing for New Editors;
- A Code of Conduct and Best Practice Guidelines for Journal Editors;
- A Code of Conduct for Journal Publishers;
- A series of Discussion Documents on publication ethics;
- Flowcharts for Dealing with Suspected misconduct (e.g. fabricated data, plagiarism, and duplicate publication); and
- Guidelines for Retracting Articles.

COPE website http://publicationethics.org/about

The **Council of Science Editors** (CSE) also provides a wealth of advice on integrity in research

publication. For example, the CSE ***White Paper on Promoting Integrity in Scientific Journal Publications*** includes detailed advice on:

- Authorship and author responsibilities
- Reviewer roles and responsibilities
- Editor roles and responsibilities

CSE website: http://www.councilscienceeditors.org

Please contact LibraryResearchSupport@swansea.ac.uk for any queries related to Research Publications Policy.

Section 16

POLICY ON CONFLICTS OF INTEREST IN RESEARCH, CONSULTANCY, AND IP COMMERCIALISATION ACTIVITIES

16.1 INTRODUCTION AND PURPOSE

ConflictsPolicy-090621.pdf (swansea.ac.uk)
Declarations-and-Conflict-of-Interest-Procedure.pdf (swansea.ac.uk)

Swansea University encourages its Staff members to engage in activities that go beyond the traditional academic role and to establish links with charitable institutions, government, commerce, and industry locally, nationally, and internationally. These external activities promote staff development and the reputation of the University and further advance regional economic development and public interest as a whole.

By performing external activities, a Staff member may be placed in a position in which an outside interest may conflict, or appear to conflict, with University duties. Such conflicts arise because of the situation, and even though the Staff member is acting objectively, neutrally and with professional integrity, it may still appear that, his or her decisions are influenced by personal or economic interests.

This Policy does not cast aspersions on Staff members but provides a mechanism to protect their reputation by establishing an objective set of principles regarding the management of conflicts.

The purposes of this Policy are to:

(a) assist Staff members in identifying Conflicts of Interest that arise in the areas of research consultancy and commercialisation of intellectual property;
(b) provide guidance to those who review and manage Conflicts of Interest; and
(c) incorporate transparency and probity in the management and resolution of Conflicts of Interest.

To accompany this Policy, Procedures have been established for reporting, assessing, and managing Conflicts of Interest and providing for oversight of the process.

The University has policies relevant to other types of Conflicts of Interest that may arise. The University's Policy on Personal Consultancy Services addresses conflicts of commitment that occur when the private interest of a Staff member may interfere with his or her responsibilities to the University, particularly in respect of the time and energy devoted to university activities. The University's "Code of Conduct on Personal Relationships" addresses conflicts that may arise because of personal relationships. Swansea University's "Research Committee Guidelines on Good Research Practice" provides a broad policy on research integrity. In its Fraud Policy, the University commits itself to openness, probity, and accountability. Staff members must comply with those policies in addition to this Policy.

This Policy applies to all Staff members and relates to Conflicts of Interest arising in connection with research, consultancy or the commercialisation of intellectual property of the University.

16.2 DEFINITIONS

"Authoriser" means the person identified in the table below:

Authoriser	**Staff member**
Chair of Council	Vice Chancellor
Vice Chancellor	Registrar and Pro Vice Chancellors
Pro Vice Chancellor, as appropriate	Dean of Faculty or Heads of Institutes
Registrar	Senior Administrators and Heads of Non-Faculty-based Departments
Heads of Faculty	Academic, academic-related, research or technical staff, or others line-managed by the relevant Head of Faculty
Heads of Institute	Those who are line-managed by the relevant Head of Institute
Senior Administrators	Those who are line-managed within the relevant administrative division

"Commercialise" means to realise commercial or financial benefit through the exploitation of intellectual property, and "Commercialisation" shall be interpreted accordingly.

"Conflict of Interest" means an interest that has the potential to compromise or bias the professional judgement or objectivity of the holder of the interest or has the appearance of having the potential to compromise or bias the professional judgement or the objectivity of the holder of the interest.

"Director" means the Director of the Department of Research and Innovation (or such other person as may be specified by the Vice-Chancellor from time to time).

"External Appointment" means any appointment which results in a Staff member or any Related Party of that Staff member holding office (whether pursuant to a contract of employment or otherwise) as a director, officer or trustee, or such similar position which gives rise to a fiduciary duty to act in the best interests of the external entity in which such an appointment is held.

"Financial Interest" means a financial interest of a Staff member in the form of Payments, Investments, or IP Revenue, or the expectation or possibility of future Payments, Investments or IP Revenue; or a similar financial interest of a Related Party of the Staff member which is known by the Staff member.

"Insignificant Financial Interest" means:

i. In respect of an Investment. Where a Financial Interest consists of an investment, the University will consider it as insignificant if all of the following conditions are met:

   (a) the Investment is in a company that is listed on a recognised stock exchange;
   (b) the value of the shares does not exceed £5000 of the Staff member's salary at any time; and
   (c) there is no relationship or connection, explicit or implicit, between the acquisition of the shares and any research to be conducted for that company.

ii. In respect of a Payment. Where the Financial Interest is in the nature of a payment, it will be treated as insignificant if the Payments are less than £5000 in any twelve-month period in the aggregate from all sources, and that the payment of the consultancy fee is not related or connected in any way on a proposed relationship between the University and the relevant undertaking. Gifts and hospitality expenses paid by a company may contribute to a Conflict of Interest.

"Investments" means any interest in shares, share options, warrants and other securities and interests in an external undertaking, and the term 'investment' shall be construed accordingly.

"IP Revenue" means revenue related to the commercialisation and exploitation of intellectual property such as licensing fees, royalties, and other types of revenue sharing arrangements (excluding those made pursuant to the University's Intellectual Property Policy).

"Payments" means payments for services including consulting fees, director's fees, stipends and honoraria, or payments in kind, forgiveness of debt, property, intellectual property, revenues derived from intellectual property such as licensing fees or royalties, or other items of value.

"Procedures" means the "Procedures for managing Conflicts of Interest in Research Consultancy and Commercialisation Activities."

"Related Party" means a Staff member's immediate family (i.e., spouse, parents, siblings or children); partner; close personal friends; and any other person with whom a Staff member has a relationship which is likely to appear to a reasonable person to influence the Staff member's objectivity.

"Staff member" means a member of University staff, including students when acting as a Staff member.

"University Spin-Out" means a company to which the University has assigned or licensed intellectual property and in which the University had an equity interest.

16.3 PRINCIPLES

The University expects Staff members to act, and believes that they do so, with probity.

It is recognised that the existence of an actual or perceived Conflict of Interest arises from a situation and is rarely the product of, or indicative of, any wrongdoing. However, it is important that Conflicts of Interests are disclosed and managed.

The University must deal with Conflicts of Interests in a prompt, fair, reasonable and objective manner, with due consideration of the impact on a Staff member's work, career and reputation.

A student's education must not be negatively impacted because of the interest of a research sponsor.

A Staff member has an obligation to act in the best interests of the University in performance of his or her University duties and activities, including research and consultancy.

A Staff member should only be compensated for research in his/her core area of research through the University and should not conduct research under circumstances in which a reasonable person could believe that the research is affected by an expectation of direct or indirect financial gain other than in accordance with the University's policies.

Staff members must publish their research results in a comprehensive, non-biased and timely manner.

University resources, including staff time, should only be used for University purposes and activities and not for personal businesses, commercial or consulting activities, save where otherwise agreed by the University in writing.

16.4 CONFLICTS OF INTEREST

A Conflict of Interest exists if a reasonable person (e.g., a manager, a student, a collaborator, a colleague, a member of the public, a research sponsor, or a regulator) believes that the actions and judgements of the Staff member are likely to be influenced by a Financial Interest or an External Appointment.

Areas impacted by Conflicts of Interest in research consultancy and commercialisation activities are:

The University's Educational mission
The principal mission of Swansea University is the education of its students. Staff members involved in the education, training, or supervision of a student, or the direction, evaluation or grading of a student's work ("educational activities") must ensure that these educational activities are performed to the best of their ability without any Financial Interest or External Appointment detracting from these educational activities.

Research Integrity
Staff members must adhere to the highest ethical standards of scientific integrity. If a researcher has a Conflict of Interest relating to research activities, integrity alone may be insufficient to protect the researcher and the University from suspicion and damage to reputation. Various aspects of the research may be impacted by a Conflict of Interest such as the choice of research, its design and protocols, the conduct of the research, the interpretation of results, or the publication and reporting of such results.

Public Accountability/ Use of Public Funding
The University as a public body receives public funding, and it is inappropriate to use its resources for the purposes of performing research, consultancy or commercialisation activities that will result in private gain to the Staff member except in accordance with University policy.

16.5 EXAMPLES OF CONFLICTS OF INTEREST

This Policy cannot address all conceivable Conflicts of Interest; however, some examples of actions that may typically give rise to a conflict are set out below:

i. Acting as an academic supervisor, either for students or post-doctoral candidates, in a research project where the research is sponsored by an external entity in which the supervisor has a Financial Interest or External Appointment.

ii. Performing educational activities for a student when the Staff member has a Financial Interest or External Appointment in an external entity which is owned or controlled by the student.

iii. Participating in research sponsored by an external entity in which the Staff member has a Financial Interest or External Appointment.

iv. Performing research which may affect the value of intellectual property owned by or licensed to the Staff member.

v. Conducting research externally that would normally be conducted by the University.

vi. Conducting research or consultancy on a private basis when that research or consultancy should be conducted by the University unless the University has indicated that it does not wish to engage in such research or consultancy.

vii. Performing research on intellectual property owned or licensed to an external entity if the researcher has a Financial Interest or External Appointment in the external entity.

viii. Agreeing to perform consultancy under terms and conditions that might preclude the Staff member or the University from working on related research or consultancy being conducted by the University.

ix. Engaging in consultancy work that might cause substantial absences from the University and increase the workload on other Staff members.

x. Using or disclosing confidential information of the University or a third party to other organisations that sponsor research or consultancy work for the Staff member.

xi. Performing research on behalf of an external entity in which a Related Party has an Investment or from which a Related Party receives Payments.

16.6 DISCLOSURES OF A FINANCIAL INTEREST AND EXTERNAL APPOINTMENT

A Staff member must make the following disclosures:

Annual Disclosures

All Staff members must complete the "Declaration of Outside Interests by Staff" (as it may be varied from time to time) annually and at such other times during the course of the year when necessary to reflect a significant change in a Staff member's circumstances.

Specific Disclosures

To ensure that any possible Conflicts of Interest are identified and managed at an early stage, each Staff member must make a Specific Disclosure of any Financial Interest and/or External Appointment that is relevant to proposed or on-going research, consultancy or commercialisation activity. A Financial Interest must be disclosed, regardless of whether it is deemed insignificant, under the provisions of this Policy. The Procedures will establish specific requirements related to specific disclosures.

Public Disclosures

A Staff member formally discussing or commenting on research results must disclose any Financial Interests or External Appointments in an external entity affected by the research. This requirement extends to any discussion or comments that may be publicly distributed in any media such as television or radio programmes, newspapers, or electronic media, or in discussions or comments made before the public.

A Staff member must comply with any specific requirements regarding Conflicts of Interest that may be imposed by a relevant third party (e.g. academic or professional publications, or conference organisers).

16.7 COMMERCIALISATION ACTIVITIES

Principles of Staff member Involvement in Commercialisation Activities

Commercialisation activities are particularly susceptible to Conflicts of Interest because of the possibility of direct financial benefits accruing to Staff members coupled with the potential use of public funding being used for improper personal gain. The following rules apply in commercialisation activities:

- Staff members may hold an Investment in a University Spin-Out and may receive Payments from the Spin-Out but must disclose them.

- Staff members may serve as a Director, hold other External Appointments of a non-executive nature, or serve as a consultant in a University Spin-Out with the consent of the Director, subject to any special conditions imposed by the Director, and in compliance with other relevant University policies.

- Full-time Staff members may not serve as senior managers of a University Spin-Out without the prior written consent of the Director.

An External Entity's Use Of University Resources

An external entity may not use University space, unless the space has generally been reserved for such use (for example, a business incubation centre).

In all cases in which University resources are used or research is performed on behalf of an external entity in which the Staff member has an Investment or External Appointment, the University shall be fully compensated for providing the resources.

Administrative Staff

Staff members involved in the negotiation and administration of research grants and contracts, consultancy contracts and commercialisation activities are subject to special, more stringent requirements. These Staff members (for example, members of the Department of Research and Innovation, or technology transfer or commercial officers of the Schools) must be able to negotiate and administer research, consultancy or commercialisation activities in the best interest of the University without Conflicts of Interest.

An administrative Staff member nominated by the University to an External Appointment shall be deemed to accept the nomination in the discharge of his or her duties as a Staff member of the University and shall not accept any Payments from the external entity unless authorised in writing by the Director.

An administrative Staff member shall not hold an Investment in, or receive Payments from, an external entity (1) which was established as a result of the administrative Staff member's work in the University, or (2) which has a contractual relationship with the University related to research, consultancy, or IP commercialisation. This prohibition does not apply to shares which are purchased subsequent to the listing of the external entity on a recognised stock exchange.

16.8 MANAGEMENT OF CONFLICTS IN RESEARCH, CONSULTANCY AND COMMERCIALISATION ACTIVITIES AND DISPUTE RESOLUTION

The Director has primary responsibility for the management of conflicts in research activity. The Director's responsibilities are established in the Procedures.

A Staff member shall have the right to appeal the Director's decisions to a panel composed of a lay member of Council, a representative appointed by the President of the University and Faculty Union, and a Pro-Vice Chancellor. The dispute and its resolution and justification shall be recorded. A generalised record shall be made available upon request of a University employee; however, the report shall be generalised so it will not disclose confidential information.

In the event a Staff member alleges that the University has not complied with this Policy and its Procedures, he or she may request that the matter be resolved by an arbitrator to be agreed upon between the University and the Staff member, or if they are unable to agree on the identity of the person within one calendar month of the request to arbitrate, by an arbitrator appointed by the President of the Law Society of England and Wales. The arbitration will take place in Swansea and be conducted according to laws of England and Wales. The decision of the arbitrator shall be binding on the University and the Staff member, and the costs shall be borne as decided by the expert. Either party would be free to bring proceedings in the Courts in order to seek mandatory, declaratory or other relief, which is not available from an arbitrator.

16.9 DEVIATIONS FROM THIS POLICY

The Vice-Chancellor may, upon request of the monitoring Panel, approve a deviation from this Policy when justified by the University's interests as long as the principles of probity and transparency are maintained.

16.10 IMPLEMENTATION

The Registrar shall have wide authority and discretion within the confines of (1) the University's Charter and any Regulations, Ordnances or other provisions made by Council, (2) this Policy, and (3) any directions given by or on behalf of the Vice-Chancellor to adopt administrative processes, guidance, forms, and interpretations necessary to effectively implement this Policy and the Procedures.

Section 17

POLICY ON RESEARCH RISK ASSESSMENT & SUITABILITY OF FUNDERS/COLLABORATORS

Researchers must consider the following prior to entering into a research collaboration.

- where is the funding coming from?
- what interests does the funder represent and whether those conflict with the researchers own ethical values or those of the University?
- who owns the research and what are the funders able to do with it?

Appropriate ethical or legal issues related to ownership of the research, new processes or technologies should be formally addressed in advance of commencing a new partnership. Any controls put in place must be reviewed and whether there are any restrictions to the use of the research.

In particular researchers should be aware of any potential for military use of their research.

The UK government has restrictions in place relating to the sharing of military and dual-use academic research with overseas partners.

The University has in place processes to help researchers meet export control requirements. Trusted Research and Collaborating Safely with International Research Partners - Swansea University

Information on the setting up of research contracts is available through the University's Research Engagement and Innovations Services (REIS) webpages. Researchers are encouraged to contact the Research Hubs within each Faculty or the central REIS team early in the process to raise any questions they might have on how to protect, develop, and disseminate the IP in order to maximise the impact of their research

Undertaking a liability risk assessment of research projects is an obligation of the University, and the lead Researcher must ensure that there is the necessary insurance cover in place prior to the start of their project. Authorisation may be required in certain instances and will need to be checked by the University's Insurance Officer. Examples include Clinical Trials and the use of drones in research.

The University's Insurance Officer is responsible for providing advice on all matters relating to the University's insurance policies, insurance claims, maintenance and administration of all records relating to the University's insurance policies.

Further information on the University's covers can be found within the University's Financial Policies and Procedures.

Suitability of funders/Collaborators

In line with its Research Integrity policy, the University does not knowingly collaborate with, or accept funding from:

- Tobacco industry.
- Gambling Industry;
- Organizations considered illegal under UK law;
- Organizations whose aims and objectives are contrary to objectives and principles of the University (Hostile Actors)

Any researcher concerned with the nature of potential funding or collaborator should raise their queries with researchcontracts@swansea.ac.uk or researchintegrity@swansea.ac.uk or with the Director of Research Engagement & Innovation Services.

Section 18

POLICY ON STUDENT RESEARCH

The same principles of research integrity, research ethics, and research governance should be applied to student research as they are to all other research. The same high ethical standards should also be expected of student research. It is important that student *research* is recognized as such, that it is screened to determine whether it requires ethical approval, that no such research proceeds without adequate ethical consideration and appropriate ethical approval, and students are sufficiently well equipped and effectively supported to ensure that all aspects of the research are undertaken with integrity and ethical probity. Faculty Research Ethics & Governance Committees are responsible for ensuring that student research is undertaken in accordance with this Framework.

Student research may present particular challenges with respect to ethical review because of the large numbers, short timescales, limited scope, and diversity of the projects involved. The knowledge, experience, and capability of students will also vary enormously. Faculty Research Ethics & Governance Committees should therefore establish procedures specifically for reviewing research projects undertaken by undergraduate students and students on taught postgraduate courses. The ESRC's Framework for Research Ethics (updated January 2015) notes that in many cases student research may be managed at subject/department level and overseen by a light-touch subject/departmental ethics committee using an initial checklist, referring applications to full ethical review when it is appropriate so to do. Established protocols for commonly occurring research can expedite the review process. In some instances, student research may be considerably constrained (e.g., restricted to pre-approved protocols or fully determined by the supervisor or module co-ordinator) or even proscribed (e.g., research with personal data that would fall within the scope of the Data Protection Act, research with children or vulnerable groups or research without informed consent). Research on sensitive topics (e.g., child abuse, domestic violence, bereavement, terrorist organisations), research involving vulnerable participants, and research which exposes the researcher or others to avoidable risks (e.g., involving data collection late at night, researching on security sensitive websites) should always be subject to careful ethical scrutiny by a committee or panel.

Students are individually responsible under the Data Protection Act for personal data which they gather and use in their studies. Students may take personal data gathered by them in their research with them when they leave the Institution, unless the research was conducted as part of an Institutional research project in which the student participated, or the agreement with the funder or sponsor of the research specifies otherwise. Students are reminded that they must continue to meet the requirements of the Data Protection Act and other legal and ethical requirements when using the data. (See Section I for fuller details.)

When a student (undergraduate or postgraduate) is undertaking research they should have a designated research supervisor, which may be the module co-ordinator in appropriate circumstances. Supervisors should work closely with their students in considering ethical aspects of proposed research in keeping with this Framework. This is especially important for

undergraduate and taught postgraduate research projects (e.g., Dissertations), as well as for postgraduate research students.
It is the research supervisor's responsibility to inform students about the circumstances in which ethical review of their research is needed, and also the process to be gone through.
The ethical review process should be clearly explained to the student and support should be provided to the student throughout the process of obtaining ethical approval to conduct the research. As this process may take some time, the supervisor and student should agree on a timetable to complete the work necessary to obtain ethical approval. This process should also be planned with awareness of submission deadlines for the student.

Any application for ethical review should be completed with the help and advice of the supervisor, who should also sign the application for ethical approval prior to submission to the relevant Faculty Research Ethics & Governance Committees.

After submission of the application for ethical approval, the student and supervisor should receive a prompt, clear response from the Committee. Where further work on the application is needed before approval can be granted, clear details should be provided to the student and supervisor regarding the shortcomings in the application, and how they might be addressed before approval is possible.

When the research is required to undergo external ethical review (e.g. via IRAS https://www.myresearchproject.org.uk/) internal ethical review should be conducted prior to this process.

Where students are conducting research outside the UK, ethical approval should be sought first internally through the Research Ethics Committee of the relevant Faculty. Approval may also need to be sought in the country in which the research is to take place (e.g., data collection). In the event of a conflict between Swansea University requirements, and local requirements, Swansea University requirements should prevail.

Faculty's should ensure that the training programmes they provide incorporate the range of issues addressed in this Framework document so that students embrace an ethics culture from the start of their research careers. Research integrity and research ethics should be an integral part of a student's programme.

All students undertaking research should be made familiar with the appropriate principles and practices of research integrity, ethics, and governance as part of their research training. For postgraduate research students, this is likely to be through a combination of subject-specific training, supervision, and the University's Research Skills Development Programme. For other students, this is likely to be embedded within their modules, and instilled during supervision.

Where the research undertaken by students leads to its publication – in academic journals for example – principles of publication ethics should not be contravened (e.g., regarding criteria for authorship). For further guidance, see for example: http://exchanges.wiley.com/ethicsguidelines

Students should declare any conflicts of interest that are relevant to their research (e.g., a student researching an organisation within which they are also employed), as should their supervisors.

Any alleged or suspected misconduct by a student when conducting or reporting their research will be subject to the appropriate investigatory and disciplinary processes.

Duty of care towards student undertaking research

Some types of research may put the researcher themselves in a position of vulnerability or involve the risk of potential harm or verbal abuse from participants. Research involving sensitive topics, or where participants have revealed distressing information, could also cause distress to the researcher. Consideration therefore also needs to be given to issues of researcher safety.

As there is a relationship between the University and the Student, it is likely that this relationship is sufficiently close enough for a duty of care to exist; and the University should work under this assumption.

As part of the duty of care relationship to the Student, the University needs to ensure that the Student's health and well-being are paramount. This would include ensuring that the student doesn't suffer with any psychiatric harm/negative mental impact or distress caused by carrying out his/her research e.g., viewing distressing images.

The University advises academic tutors to "offer a level of supervision appropriate to the work and student/s, based on a risk assessment approach. For student projects the academic tutor should organise a risk assessment approach and agree and write down relevant standards, guidance, and local instructions". Students must also take responsibility for their own health and safety.

Swansea University
Prifysgol Abertawe

SWANSEA UNIVERSITY'S POLICY
ON
INTELLECTUAL PROPERTY CREATED BY STUDENTS

1. INTRODUCTION AND DEFINED TERMS

1.1. This document sets out the policy and rules of Swansea University in respect of the ownership of Intellectual Property ("IP") created by Students of the University.

1.2. ***Except where they are defined differently in this document, words and phrases defined in Swansea University's "Policy on Intellectual Property" and Swansea University's "Procedures for Implementation of its Policy on Intellectual Property" shall have the same meaning in this Policy.***

1.3. **"Procedures"** means Swansea University's Procedures For Implementation of its Policy on Intellectual Property.

1.4. **"Staff IP Policy"** means Swansea University's Policy on Intellectual Property, as it may be amended from time to time.

1.5. **"Student"** means any person registered as an Undergraduate or Postgraduate Student of the University or following any course as if a Student.

1.6. **"Student IP Policy"** means this Policy.

2. GENERAL PRINCIPLES

The default legal position on student intellectual property is that the student will automatically own all the intellectual property rights in work done and results created by him/her during his/her research project/studentship ('student IPR's)

The student should retain ownership of student intellectual property rights except where there is a specific requirement for the University to take ownership of the IPRs. Examples of such instances are:

- The grant funding terms of the studentship requires the University to own the student IPR's
- The studentship is a collaborative one with industrial partners and the funding terms of the collaborative studentship agreement requires the University to own the student IPRs in order to grant licenses/options to the industrial party.
- The studentship project forms part of a larger project within the University for which the funding terms and/or research collaboration agreements require the University to own all IPR's

- The University requires to own the student IPRs in order to apply for patent protection.
- The University requires to own the student IPR's for some other commercialisation reason e.g., a spinout.

Accordingly, the requirement or otherwise for an assignation of student IPR's needs to be assessed in the context of each specific studentship project. In practice few studentships will involve the creation of commercially significant student IPR's but it does happen from time to time.
If there is a specific requirement for the University to own student IPR's, then the student should be asked to sign an assignation of his/her student IPRs to the University using the University assignation and confidentiality agreement. Such a document can be obtained by contacting the Contracts/IP team in the Research & Innovations Services department.

In return for the assignation of the student IPRs to the University, the University will give the student the same revenue sharing rights in respect of any interventions made by the student as it gives University employees. The rights of the student should be explained to them before she/he signs the Assignation and Confidentiality agreement.

3. **OWNERSHIP OF INTELLECTUAL PROPERTY OTHER THAN COPYRIGHT CREATED BY STUDENTS**

When a student acting as an employee creates IP, the Staff IP Policy applies. Subject to that, the following rules apply.

4. **<u>Undergraduate Students</u>**

4.1. As detailed under the general principles, IP created by an Undergraduate Student (UG Student) will be owned by the UG Student except when the Intellectual Property has been created in a project specifically funded or commissioned by the University or a third party, or where the UG Student makes significant use of University resources to create the IP. "Significant use of University resources" in this context means that the Student used resources to a greater degree than generally used or expected to be used by Undergraduate Students, and "University Resources" include intellectual supervision, human resources, laboratory or computer facilities, University background IP, or other resources.

4.2. The decision of whether there has been a significant use of University Resources shall be made by the Director of the Department of Research and Innovation (or such other person as delegated by the Vice-Chancellor) in consultation with the Head of Faculty and the research or supervisor of the student, and the student. Proof of 'excessive use' must be exhibited while making the claim for use especially in the absence of a written agreement.

5. **<u>Postgraduate Students</u>**

5.1. A Postgraduate Student (PG Student) are not considered as an employee of the University.

5.2.Frequently a PG Student is required to perform research or consultancy activities as a component of their studies ("Research Activities"). As a condition of participating in such activities:

- The PG Student must enter into a written agreement which establishes the ownership and the use of IP created in the Research Activities. The agreement will be fair and reasonable giving consideration to all relevant factors, including, but not limited to, whether the PG Student is bringing significant background IP to the project, or is self-funded. In the absence of such an agreement, IP will be owned by the University so it can comply with any research funding obligations.

- In all cases in which the Research Activities are funded by a third party, the PG Student must accept the IP and confidentiality provisions of the research agreement between the University and the third party. The Principal Investigator of a project shall notify the Student working on that project of any requirements imposed by the sponsor regarding ownership of IP.

- The PG Student must not disclose any confidential information or commercially sensitive information of the University or a third party and is deemed to have consented to any confidentiality obligation imposed by a relevant third party.

- The PG Student must act in a manner which is fully consistent with the University's obligations in respect of the Research Activities, must comply with all relevant contractual obligations, and is deemed to have consented to all obligations placed upon him or her by the research agreement, including those relating to confidentiality and ownership of IP.

- A PG Student will sign all documents and take other reasonable actions at the University's or a third party's expense that are required to confirm the University's or a third Party's ownership of the IP**.**

5.3.The University shall appropriately reference the Student IP Policy in recruitment documents and publish the Student Policy in the Student Handbook.

5.4.A Postgraduate Students enrolling in a postgraduate degree program will be required to complete and sign a form in which he or she:

- Acknowledges and accepts the provisions of this Student IP Policy.

- Agrees to disclose any invention work in progress or other Intellectual Property relevant to the Research Activities that he or she will be doing, including a disclosure of any third party that may have a claim to that IP.

- Accepts and agrees to abide by the confidentiality terms imposed by a third-party sponsor of the Research Activities in which the Student will be involved, and commits not to disclose the University's confidential or commercially sensitive information.

- Agrees to disclose IP which he or she creates in the Research Activities.

- Agrees to make relevant enquires into the requirements of the sponsor of the research project or of the University in which he or she will be participating.

- Agrees to enter into a written agreement with the University regarding the ownership and use of IP that he or she creates in the Research Activities.

5.5. It is the responsibility of each Principal Investigator to ensure that an IP agreement is entered into between the PG Student and the University. The Department of Research Engagement and Innovation Services (REIS) shall provide a template to the Faculty and approve any specific agreement reached with the Student.

6. **WORK BASED LEARNING**.

Intellectual Property created by a Student as part of a work-based learning experience will be owned by the company, unless otherwise agreed between the Student and the company.

7. **OWNERSHIP OF COPYRIGHT**

7.1. The general rule is that a Student shall own the copyright in materials, such as a thesis or other materials for course work that he or she has authored. The University shall have the absolute right (1) to use the materials for its own internal purposes of detecting plagiarism or cheating, and (2) to control the material on electronic media hosted on the University websites.

7.2. The University may use the materials, other than as specified in Clause 4.1, with the agreement of the Student.

7.3. If a Student produces written material (including a thesis) in a project sponsored by a third party or if the material was specifically commissioned by the University, the copyright shall be owned by the University or the third party unless there is an agreement to the contrary. This means that:

- Confidentiality requirements, restrictions on the right to publish, and restrictions on access to the thesis or other documents will be determined in accordance with any contractual obligations between the University and a third party.

7.4. Copyright in software that is or will be used by the University, and copyright integral to other Intellectual Property that is owned by the University or a third party, will be owned by the University or the third party.

7.5. When the University or a third party owns the copyright in materials produced by a Student pursuant to the terms of this Policy, the Student waives any moral rights in the work.

7.6. A Student, at the University's expense, will sign all documents and take other reasonable actions that are required to confirm the University's or a third Party's ownership of IP when such ownership is required under the terms of this Policy.

7.7. Although a Student may own the copyright in materials that he or she has produced, the Student must comply with University regulations regarding plagiarism and will not knowingly and wilfully assist others in plagiarising the work by allowing others to use their materials.

8. REVENUE SHARING

8.1. In all cases where a Student has created Intellectual Property that is commercialised by the University, the Student will be entitled to share in the benefits as though he or she were a Staff member.

8.2. In such cases, rules and procedures relating to revenue sharing, which are set out in the Staff IP Policy and Procedures, shall apply to the Student.

9. DISCLAIMERS

The University may, in accordance with the Procedures, issue disclaimers of ownership of Intellectual Property in appropriate cases or provide for a license or assignment of the Intellectual Property to the Student or Students who created it.

10. INTERNAL DISPUTE RESOLUTION.

If a Student disagrees with the decision of the Director, the Student may appeal the decision to a committee comprised of the Registrar (or such other person as delegated by the Vice Chancellor) who shall serve as Chairperson, the Head of the Faculty which administered the project in which the IP was created, and a Staff member or a Student nominated by the Student. Their decision shall be final.

11. **ARBITRATION.**

If after the decision of the committee, the Student alleges that the University has not complied with the Student IP Policy, he or she may request that the matter be resolved by an arbitrator to be agreed upon between the University and the Student, or if they are unable to agree upon the identity of the person within one calendar month of the request to negotiate, by an arbitrator appointed by the President of the Law Society of England and Wales. The Arbitration will take place in Swansea and be conducted according to the laws of England and Wales. The decision of the arbitrator shall be binding on the University and the Student and the costs shall be borne as decided by the arbitrator. Notwithstanding the provisions of this clause, both the University and the Student are free to bring proceedings in the courts in order to seek mandatory, declaratory or other relief which is not available from an arbitrator.

IMPLEMENTATION

The Registrar shall have the authority and discretion, within the confines of
(1) the University's Charter and any Regulations, Ordinances or other provisions made by Council,
(2) the IP Policy, and
(3) any directions given by or on behalf of the Vice-Chancellor to adopt administrative processes necessary to effectively implement this Policy.

The Department of Research and Innovation (legal contracts & IP) shall issue guidance and interpretations, and establish procedures and documents necessary to implement this Policy.

CODE OF PRACTICE ON AUTHORSHIP

Policy No. **P2122-959 (Version: 2)**
Effective Date: March 2019
Last Revised: December 2022
Review Interval: Biennial.
Review Date: October 2024.
Approval Body: University Research Integrity: Ethics & Governance Committee.

Policy Owner: Research Engagement & Innovation Services.
Policy Author: Anjana Choudhuri using various sources.

Summary:

The Code of Practice on Authorship aims to provide a framework within which decisions on authorship can be made, and disputes over authorship can be resolved.
The code has been developed in line with the guidance provided by:

1. the UK Research Integrity Office (UKRIO) Authorship - UK Research Integrity Office (ukrio.org)
2. the ICMJE criteria http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
3. and the COPE (Committee on publication ethics) https://publicationethics.org/files/Authorship_DiscussionDocument.pdf
4. For Medical research: The Vancouver Recommendations | Forskningsetikk

Some references have also been drawn from relevant international guidelines specific to student concerns where applicable.

Purpose:

Why does Authorship matter?
Correctly identifying authorship of research publications matters, because of the ethical requirement to acknowledge the ownership of intellectual property, and the associated academic, social, and financial benefits and burdens. Authorship also confers responsibility and accountability for the integrity of a published work. Research integrity is contravened when individuals who have not contributed to the research are unjustly included in the authorship list or when authors who have contributed are denied appropriate recognition.

Swansea University recommends that all researchers abide by the ICMJE and COPE guidelines and the CREDIT statement (https://www.elsevier.com/authors/policies-and-guidelines/credit-author-statement) on authorship which are based on the following criteria:

1. Substantial contribution made to the conception and design of the work, or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published.

By accepting authorship, each author is accountable for the veracity of contributions made and should be able to identify the contributions made by the co-authors to any piece of work. ICMJE/COPE recommends that any staff member, student, or collaborator who satisfy the above criteria should be included in the list of authors. Contributors who meet fewer than all of the above criteria for authorship should not be listed as authors but should be acknowledged either individually or as a group contributor. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are: general supervision of a research group or general administrative support; writing assistance, technical editing, language editing and proofreading.
In accepting authorship, each researcher takes responsibility to affirm that:

- they have read the final manuscript
- they are prepared to defend at least their component of the work, and preferably the entire manuscript against criticism

Authorship is a scientific decision for which an individual should be accountable. The University recommends that authorship is agreed by the lead author in line with this policy.

Scope and Exemptions

Promoting good practice in authorship
Standards for assigning authorship vary significantly between disciplines. It is therefore advisable that researchers follow discipline- and journal-specific conventions. Where no journal- or-discipline specific guidance is available, where possible, it is good practice to agree with co-contributors the criteria and order of authorship listing at the research planning stage. It is advisable to agree a publication strategy in the initial planning stages of projects and this should always be the case before the preparation of a manuscript. To avoid future disputes about authorship, ensure any documentation on authorship contributions/credit orders have been kept and ensure all those who have contributed to the work, are privy to these documents or any changes to the work as it proceeds.
The *Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations* advises that: 'Collaborating partners should come to agreement, at the outset, and later as needed, on standards for authorship and acknowledgement of joint research products. The contributions of all partners, especially junior partners, should receive full and appropriate recognition. Publications and other products should state the contributions of all contributing parties.

Determining authorship credit and order-Supervisor/Student authorship agreement
Publication reflects the culmination of efforts and contributions made by everyone involved in research. Authorship is often the primary way by which contributions of individuals involved in a project are acknowledged. For a student conducting research, it can be a rewarding

experience and achievement, to see one's name on a publication for the first time. Publication of a research student's work is an important part of their professional and career development. The process of developing a publication provides opportunities for students to learn new skills, network with other researchers and contribute to new knowledge in the field. Students have the same rights to authorship acknowledgement as other researchers and their contributions should be accurately reflected in the authorship list. Students may have greater difficulty in challenging authorship decisions where research supervisors are co-authors, due to the power imbalance of student / supervisor relationships. Relationship between students and supervisors should be the same as with co-authors. Strengthening relationships between students and supervisors rather than regulations would ensure that authorship dispute between the parties is avoided.

Policy Statement:

University disputes procedures concerning Authorship:
Disputes concerning authorship may come to the attention of the University through a variety of formal and informal routes. The University deals with authorship disputes on a case-by-case basis and may choose to instigate a process of arbitration (see below) to resolve a dispute. The University will ensure that anybody undertaking arbitration on authorship is impartial and is familiar with the area of work and the authorship conventions. Those selected to arbitrate an authorship dispute (see below) will be expected to declare any past, present, or future conflict of interest with any party or parties involved.
Junior researchers are requested to seek guidance from Chairs of Faculty or School Research Ethics & Governance committees or from the Research Integrity Manager if they feel unable to challenge authorship requests or decisions of more senior researchers. Researchers are advised to consult the Research Integrity webpages Research Integrity: Ethics and Governance - Swansea University for further information on available policies, guidelines and training options.

Practices:

Resolving authorship disputes procedure

1. Where a dispute relating to authorship, publication credit or right to publish arises, in the first instance the designated author will engage all co-authors (including those whose authorship right may be in dispute) in correspondence, with a view to finding a resolution. A record will be kept of all correspondence. No attempt to publish the disputed output can be made at this stage. If the designated author is a student, he/she may request the advice and assistance from the subject Postgraduate Director. Alternatively, junior researchers are requested to seek guidance from Chairs of Faculty Research Ethics & Governance sub-committees or from the Research Integrity Manager (researchintegrity@swansea.ac.uk) if they feel unable to challenge authorship requests or decisions of more senior researchers.

2. If such discussions are not successful in a timely manner, the designated author will request intervention of the Associate Dean of Research Impact & Innovation (ADRII's) for the Faculty, to review the documentation, discuss the issue severally and jointly with all co-

authors and arrive at an agreed solution which will allow publication to proceed. The ADRII's for the Faculty may seek independent expert opinion as part of this process. It is not intended that the Procedure should be used as part of any disciplinary or regulatory process.

3. If the matter remains unresolved, the Pro Vice Chancellor Research & Innovation will request intervention by the University Authorship Resolution Panel (comprising of /consisting of Senior Academics with relevant expertise in the area). The panel will review all documentation, relevant information and correspondence and will make a final decision.
4. A formal process of Research Misconduct may be initiated where allegations are of a serious nature, and where mediation and arbitration has been refused or proven unsuccessful or an arbitrator has concluded that the matter cannot be resolved through arbitration and that the institution should initiate a misconduct investigation.

Policy History

Document Name	Code of Practice on Authorship
Version Reference	Version 1 February 2019, Version 2 December 2022
Document Owner	Anjana Choudhuri
Approved by	UREGSC (Feb 2019), URIEGC (Feb 2023)
Date of Version 1	February 2019
Date of Version 2 (Revised)	December 2022 (Version 2)
Amendments	• Amendments to the reporting structures in line with new University Faculty Structures. • Inclusion of the Vancouver recommendation. • Removal of Authorship agreement template

(Adapted from various guidelines: Dublin City University (DCU) Code of practice on Authorship, UKRIO Good Research Practice 2017)

Section 20

POLICY ON UNDERTAKING RESEARCH WITH CHILDREN & YOUNG PEOPLE

Summary:

This policy is for Swansea University staff and students who undertake research with children under the age of 18 years, and young people who are vulnerable (within this context to mean young people who are more exposed to risks than their peers. For example, in terms of deprivation (food, education, and parental care), exploitation, abuse, neglect, violence, and disability).

The policy has been developed in line with the following:

- The National Society for the Prevention of Cruelty to Children (NSPCC) guideline on research with Children: ethics, safety and avoiding harm.
- Children Act 1989 and 2004
- All Wales Child Protection Procedures' (2008).
- HM Government (2015) 'Working together Guidance'.
- Social Services and Wellbeing (Wales) 2014 Act
- Welsh Govt. (2006) 'Working Together Guidance'
- The Medicines for Human Use (Clinical Trials) Regulations 2004, and the subsequent amendments

The policy identifies particular issues which must be taken into consideration when undertaking any research with children and it must be read in conjunction with the following:

- ESRC Research Ethics Framework[1]
- Swansea University's Safeguarding Vulnerable Groups Policy
- UN Convention on the rights of the Child (1989)
- Any discipline specific requirements to the area of work

In the context of this policy, the term 'researcher' includes students at both undergraduate and postgraduate level, salaried teaching, research, and project staff, including casual members of staff, who will have direct (or indirect) contact with children and young people throughout the course or period of their research. 'Researchers' (as defined above) who have subject access to children should have an enhanced DBS disclosure performed prior to undertaking any research. The researcher must also undertake a minimum Level 2 or equivalent, 'Regional Safeguarding Children Board training' which deals with recognition and referral of abuse or other safeguarding concern. The training will allow the researcher to understand and report any abuse identified during the process of a research interaction. The University offers and online training on Safeguarding Awareness training, which can be accessed via the URL https://www.melearning.co.uk/learning/swanseauniversity/

The guidance applies to all children who are contacted either through an organisation or body such as a school or club or contacted independently through their home and is designed to be used in conjunction with the All-Wales Child Protection Procedures [2] and Her Majesty's

[1] ESRC Framework for Research Ethics 2015, www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015

[2] All Wales Child Protection Procedures 2008 can be accessed as follows: http://www.childreninwales.org.uk/our-work/safeguarding/wales-child-protection-procedures-review-group/

Government (2015) Working Together Guidance.

The Children Act 1989[1] defines a 'child' as a person under the age of 18 years. The UN Convention of the Rights of the Child[2] defines a 'child' as a person below the age of 18, unless the laws of a particular country set the legal age for adulthood younger. The Committee on the Rights of the Child, the monitoring body for the convention, has encouraged States to review the age of majority if it is set below 18 and to increase the level of protection for all children under 18. In this Guidance, any reference to a child or children includes young persons' up to the age of 18 years.

Please note that specific regulatory requirements exist in UK legislation which should be followed while conducting clinical trials involving children. Further information is available from the Medicines and Healthcare products Regulatory Agency (MHRA).

Key Principles

Research involving children and young people should only be conducted to investigate issues that will likely benefit children in particular and society in general. The aims of research should contribute to present or future benefits for children (e.g., health, well-being, development). Research involving children is important for the benefit of all children, and a research procedure which cannot directly benefit the child, is not necessarily unethical, if the findings might benefit future generations of children. Research where there is no benefit to the individual child participant should be of minimal risk. Any research with children must be conducted in line within the Welsh legal and policy context. Outcome of the research should contribute to the evidence to promote rights of children and young people. Any research with children must be subjected to risk assessment. In the past, the concern to protect children from the potential harms of research may have denied them potential benefits. To ensure that this group are not exploited, it is important to carefully assess the potential benefits and harm to children at all stages of any research. As the benefits of research are not predictable, the researcher must be satisfied that the research is not contrary to the child participant's interests. The foreseeable risks should be kept as low as possible: the potential benefits from the development of furthering of knowledge must outweigh any foreseeable risks. Research needs should be based on clear ethical guidelines and measures must be in place to protect any children who are involved. Child protection concerns can be exposed when undertaking research with children and young people; ethically robust solutions and pathways must be identified to handle any such concerns. Researchers must ensure that children must be respected by providing the right support and by knowing who to contact with concerns.

This policy is aimed at ensuring that any researcher undertaking work with this vulnerable group think through the ethical issues and find ethically justifiable solutions.

Ethical guidance for researchers:

All proposals involving research on children must be submitted to the relevant College research ethics committee (CREC) for approval. Researchers and the Research Ethics Committees must assess whether the research or the inclusion of child participants is justified. Any research project must balance the need of the research with the rights, well-being, and safety of the children as participants. Having a clear ethics statement at the beginning of a

[1] Children Act 1989, Section 105 - http://www.legislation.gov.uk/ukpga/1989/41/section/105

[2] The United Nations Convention on the Rights of the Child (1989)

project can help researchers assess potential risks to a child or procedures to follow if abuse or safeguarding issues are disclosed, identified or if the researcher has concerns. Prior to embarking on a research project involving children and young people, a researcher needs to consider the following:

- How to obtain informed consent and assent
- How to manage the risk of potential harm to participants and themselves.
- What to do with the information gathered during the research.
- What to do if concerns are raised or abuse is identified or disclosed.

Further guidance and useful information on the ethical issues of conducting clinical trials involving children is also available from the World Health Organisation webpages.

- http://www.who.int/ictrp/child/en/
- and from the Nuffield Council on Bioethics
- http://nuffieldbioethics.org/wp-content/uploads/Children-and-clinical-research-full-report.pdf

(The following guidelines has been informed by the NSPCC guidance for applicants to the Research Ethics Committees, HM Government (2015) Working Together Guidance)

- Voluntary participation based on valid informed consent and assent: The key principle of ethical research is that the participants involved in research should agree to participation voluntarily, on the basis of full, detailed, and robust information. Consent is possibly the most important but most complicated issue for researchers hoping to involve children as part of their study. Consent should be obtained using an 'opt-in' by the data subject (research participant) rather than an 'opt-out'. Participants who have agreed to be part of the study can withdraw consent at any time. This is especially important in research that extends over time. A researcher should ensure that all research participants have a reasonable understanding of the research, so that they can give their permission to be part of it. An option of 'Proxy consent' (*the process by which people with the legal right to* ***consent*** *to for a minor or a ward delegate that right to another person*), who can act properly on behalf of children and young people should be considered. Even if formal consent for the whole process has been sought and given at the beginning, it would be appropriate to check that the participant is happy to take part if some time has passed between the interviews/contacts especially in instances where the research has extended over some time. Similarly, it should be made clear to participants that even if they have given consent at the beginning of the process, they are entitled to decline to answer any particular question (s) or to not participate in any particular part of the research, without giving a reason, and are entitled to decide not to take part at any point, again without giving a reason. Participants should have the right to withdraw from a study without fear of punitive measures, penalty, or threats etc. Participants can also ask for their data to be removed from the study where practical. The process of assent engages children and provides them with the opportunity to make their own decisions as well as ensuring their willingness to participate even where this has no legal force. Researchers are encouraged to refer to the 'Frazer guidelines', which, even though relates to sexual health, in practice are used to assess an individual's understanding in other contexts. Consideration must also be given to the capacity of a participant to consent; this will depend on their cognitive level of

understanding of the potential risks and benefits of taking part in research. Article 12 of the UN Convention on the Rights of the Child (1989) states that 'parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in matters affecting the child, the view of the child being given due weight in accordance with the age and maturity of the child'.

The following guidelines may be helpful but in all cases the researcher should justify the approach taken to obtaining consent:

- Whilst it is recognised that young people aged 16 years and over are able to consent, further good practice consideration should be given to also obtaining consent from the young person's parents. Each situation will have to be carefully considered and justified by the researcher in terms of both the complexity of the research goals and processes and the competence of the young research participant.
- For young people aged between 12 and 15 years, assent should be sought from the young person and consent from the parent, guardian, carer, or other appropriate adult with the duty of care. If the young person has accessed a service being evaluated or researched, independently, then it may be appropriate to seek the young person's consent only. Researchers will have to justify this and also establish that the young person is competent and has enough information to make this decision as part of this process the researcher will have to be satisfied that the young person is "Gillick" competent and follow Frazer Guidelines.

- For children younger than 12 years, consent should be sought from the parent, guardian, or carer. **Assent must also be sought from the child.** In research, the child's wishes should be paramount and therefore if a child does not assent to participate then this overrides the consent from parents, guardian, or carer. Researchers should be aware of the signs that a child does not want to participate. For example, a child may say 'no' or be non-responsive by 'pulling away' or ignoring. Depending on the group involved in the research, alternative ways of communicating the information should be considered e.g., a video accompanying a 'Patient information Sheet' for those parents/carers who experience difficulty with reading. Consideration should be given to the format of the information e.g., pictorial, braille etc. Rather than assuming that a child has read the patient information sheet, researchers must confirm by speaking to the child that the child understands what they are being asked to do. For younger participants alternative forms of communication, like use of cartoon books with no words but pictures to tell a story of what the child would be asked to do can be used. To psychologically prepare parents/carers and children understand the process and requirements of a treatment of background to the research, using an age-appropriate, interactive, and engaging NHS app called "Little journey" might be beneficial.

- Disclosure:
  Whilst maintaining confidentiality is a priority in research more generally, one of the key issues for researcher with children and young people is a proper consideration of disclosure, especially if issues of child protection or other safeguarding concerns arise in the course of the research. It is vital that the process of disclosure is made clear to the participants -and those who may legitimately consent for them - know what the boundaries

of confidentiality are. Guidance in line with the All-Wales Child Protection Procedures (2008) needs to be followed, alongside the mandatory reporting guidance as part of Social Services & Wellbeing (Wales) 2014 Act.

Researchers should also have a good grasp of when and how protocols concerning confidentiality may be overridden, including guidance about what constitutes information that should be discussed with a third party; what the researcher should do within a data collection setting if they become aware of information that should be passed on; whom they should be reported to; and what the processes are for deciding whether the information should be disclosed. Consideration regarding reporting issues to designated safeguarding lead (in case of concerns) should be considered.

- Consent process:

  Researchers should assess the most appropriate method of obtaining consent for their research project. It is normal practice to provide information leaflets about the research to participants. However, the material should be tailored so that they are appropriate to needs and capacities of the participants. The information should be in an easily understandable form that uses lay language rather than technical terms. Depending on the age and cognitive ability of the participants, it may sometimes be necessary to provide several versions including translated version of the information leaflets and forms to participants. Other forms and types should also be made available according to the child's cognitive ability and understanding. If incentives are used to thank participants for their time, this should not be set at a level which would risk skewing the results because people are taking part solely for the reward. Details of any incentives for participation must appear in the participant information sheet and should be made known to potential participants before they consent to take part. Ideally incentives should be in the form of high street vouchers and not money unless this can be specifically justified. If incentives are provided, participants must receive the incentives even if they withdraw early from the study. The consent process should always take into consideration local cultural values and privacy of individuals. Mechanisms should be put in place to remove participants data if they retrospectively withdraw their consent.

- Gatekeepers:

  In order to access research participants, the researchers may have to contact 'gatekeepers' to participants (e.g., teachers, doctors etc.), who may have a role in arbitrating access and / or the protection of participants. Parents should also be considered to offer a gatekeeping role for potential research participants and should be consulted with regards to planned research being undertaken with their children. Through parents being consulted and versed with the proposed study would enable them to consider the study and give due regard to providing consent for their child to participate.

  Excessive reliance should not be placed on gatekeepers to recruit participants to research studies. The position of 'gatekeepers' may vary enormously and where the gatekeeper is in a position of power with respect to the potential research participants, a situation may arise where the potential participant may feel coerced or pressurised to take part in research. Another problem could be that the 'gatekeepers' do not explain the research to the participant appropriately. It is the responsibility of the researcher therefore to ensure that potential participants do understand what taking part in the research involves, and

that they do so freely by going through a thorough process of voluntary and informed consent.

1. Identifying potential risks of harm to participants and researchers:

The research design and protocols must consider processes for reducing/minimising risks and harm to both participants and researchers. The research design and questions must have measures in place to address the impact of any harm or upset through provision of support services, advice, and guidance. For social research, the main risk to participants is causing emotional or psychological distress which can be linked to a number of issues including:

- Vulnerable individuals can find participating in research stressful.
- Research may 'reawaken' old feelings or memories or hidden or suppressed feelings or memories.
- Additional concerns may come up; and
- Participants may worry about what they have shared.

All those undertaking research with children must demonstrate that they have given due consideration to the above in the selection of their aims and research questions, in the methods they intend to use and the mechanisms for analysis, and reporting practices.
For research that requires physical exercise, the main risk to the participants will be, causing physiological harm or discomfort through the research methods or recovery from participating. All those undertaking such research with children must be able to demonstrate that they have chosen the most appropriate methodology which is as non –invasive as possible, and that they are fully trained to undertake such methodologies. First aider (s) must be available for all physical testing in case of adverse event.
All studies involving children should seek to be inclusive and accessible, and pay due regard to the child's best interests, especially with respect to safeguarding the health and wellbeing of the child participant now and in their future. Children who have been abused can be particularly vulnerable and researchers must consider the psychological impact of sensitive research on the participant. Researchers need to be clear with participants from the outset that confidentiality may have to be breached if there is a disclosure relating to serious harm, abuse and/or other child protection concerns. If a participant divulges any information that gives rise to child protection concerns, or where the researcher observes or receives evidence of incidents likely to cause harm, the researcher has a duty to take steps to protect the child or other children to protect both the children and themselves. Researchers must consider how participants are likely to cope with being asked to talk about their past experiences. Debriefing participants at the end of the study or a stressful situation in order to identify any participant needs and referring them to appropriate help should be built into the research design. Any participant information sheet or 'thank you leaflet' must take into consideration information and contacts for immediate help and support if participants are distressed post an interview, or interaction with the researcher. Any correspondence with participants should also consider the literacy levels, language, and cultural issues.
Undertaking qualitative research brings additional risks because of the nature of the data collection. The research design should take into consideration ways in which additional risks can be minimised. Interview schedules should be structured so that more sensitive material is in the middle of the interview and participants are given a chance to return to more 'normal' level of conversation at the end of the interview. The interview should remain focussed on

the research topic and difficult topics are given enough time so that they are not 'crowded' towards the end. Researchers conducting qualitative interviews also need to make sure that the boundary between a research interview and counselling is rigorously maintained, even when the researcher is also a trained counsellor.

Internet mediated research

When considering internet mediated research, researchers should give due consideration to recognised ethical guidelines such as those issue by the British Psychological Society[1] (2017), UKRIO[2] and the Economic and Social Research Council[3]. With specific reference to children and young people, validation of age when considering consent and whether to research or not research with children and young people online can be challenging. Consideration should be given to how such risks will be mitigated in the planning stage.

Consideration should be given to the type of research and whether or not DBS disclosures are required – for example, whether the researcher is directly interacting with the child via the internet through chat rooms or social media for example, or whether data is being sought via an anonymous online survey.

Risks to researchers:

Researchers should also consider their own physical safety, especially when working outside of the workplace, with human tissue, or at unsocial times. Furthermore, researchers should be mindful of the psychological burden that can be placed on researchers involved with clinical populations or with regards to certain, sensitive social research questions. The main ways in which this risk is mitigated is through having a robust risk assessment process that involves on-going risk assessment by the researcher, and by ensuring that an appropriate and adequate level of internal and external support is available for the researcher before, during and after the data collection.

2. Disclosure of identity and personal information:

A participant's personal information and their identity should remain confidential unless a child is at risk of harm. A researcher must include a confidentiality protocol that clearly sets out the circumstances when a researcher can and should break confidentiality. The procedures should also include reference to sources or places where a researcher or child can access further support if harm or distress arises in or after the research.

(HM Government (2015) Working together guidance and All Wales Child Protection Procedures (2008)

Complaints procedure:

Procedures should be in place to facilitate participants making complaints about the research in general and the researcher in particular. Ideally arrangements should include the ability to talk to someone not connected with the research, for example, the Chair of the College Research Ethics Committee or a substitute in case the Chair is involved in the research. Consideration should also be given to facilitating children to make complaints by identifying an appropriate adult (e.g., teacher, carer, or social worker) with a good relationship to the

[1] Ethics Guidelines for Internet-Mediated Research (2017), The British Psychological Society
[2] UKRIO guidance note: Internet-mediated research
[3] ESRC – Internet Mediated Research

child and discussing the issue with them so that children can talk to them if they are concerned.

Definition of Child Abuse and Neglect (in accordance with the All-Wales Child Protection Procedures, HM Government (2015) Working Together Guidance and as set out in Swansea University Safeguarding Vulnerable Groups Policy)

Child Abuse and Neglect occurs when somebody inflicts harm to a child or fails to act to prevent harm. Children may be abused in a family setting or in an institutional or community setting, by those who are known to them or, more rarely, by a stranger. A child or young person up to the age of 18 years can suffer abuse or neglect and require protection via an inter-agency Child Protection Plan.

Physical Abuse.

Physical abuse may involve hitting, shaking, throwing, poisoning, burning, or scalding, drowning, suffocating, or otherwise causing physical harm to a child. Physical harm may also be caused when a parent or carer feigns the symptoms of, or deliberately causes, ill health to a child whom they are looking after. This situation may be described as fabricated or induced Illness by carer.

Possible signs of physical abuse:

- Unexplained injuries or burns, particularly if they are recurrent.
- Refusal to discuss injuries.
- Improbable/inconsistent explanations for injuries
- Untreated injuries or lingering illness not attended to
- Admission of punishment which appears excessive.
- Shrinking from physical contact
- Fear of returning home or of parents being contacted.
- Fear of undressing
- Fear of medical help
- Aggression/bullying
- Over compliant behaviour or a 'watchful attitude'
- Running away
- Significant changes in behaviour without explanation
- Deterioration in work
- Unexplained pattern of absences which may serve to hide bruises or other physical injuries.

Emotional Abuse

Emotional abuse is the persistent emotional ill treatment of a child such as to cause severe and persistent adverse effects on the child's emotional development. It may involve conveying to a child that they are worthless or unloved, inadequate, or valued only in so far as they meet the needs of another person. It may feature age or developmentally inappropriate expectations being imposed on children. It may involve causing children frequently to feel frightened or in danger, for example by witnessing domestic abuse within the home or being bullied, or the exploitation or corruption of children. Some level of emotional abuse is involved in all types of ill treatment of a child, though it may occur alone.

Possible signs of emotional abuse:

- Continual self-deprecation
- Fear of new situations
- Inappropriate emotional responses to painful situations
- Self-harm or mutilation
- Compulsive stealing/scrounging
- Drug/solvent abuse
- 'Neurotic' behaviour – obsessive rocking, thumb-sucking and so on
- Air of detachment – 'don't care' attitude.
- Social isolation – does not join in and has few friends.
- Desperate attention-seeking behaviour
- Eating problems, including overeating and lack of appetite
- Depression, withdrawal

Sexual Abuse

Sexual abuse involves forcing or enticing a child or young person to take part in any sexual activity, whether or not the child is aware of what is happening. The activities may involve physical contact, including penetrative or non-penetrative acts. It may include non-contact activities, such as involving children in looking at, or in the production of, pornographic material or watching sexual activities, or encouraging children to behave in sexually inappropriate ways.

Sexual abuse is not solely perpetrated by adult males. Women can also commit acts of sexual abuse as can other children.

Possible signs of sexual abuse:

- Bruises, scratches, burns or bite marks on the body.
- Scratches, abrasions, or persistent infections in the anal or genital regions
- Pregnancy (particularly in the case of young adolescents who are evasive concerning the identity of the father
- Sexual awareness inappropriate to the child's age – shown for example in drawings, vocabulary, games and so on
- Attempts to teach other children about sexual activity.
- Refusing to stay with certain people or go to certain places.
- Aggressiveness, anger, anxiety, tearfulness
- Withdrawal from friends

Possible signs of sexual abuse in older children:

- Promiscuity, prostitution, provocative sexual behaviour
- Self-injury, self-destructive behaviour, suicide attempts
- Eating disorders
- Tiredness, lethargy, listlessness
- Over-compliant behaviour
- Sleep disturbances
- Unexplained gifts of money
- Depression
- Changes in behaviour

Neglect

Neglect is the persistent failure to meet a child's basic physical and/or psychological needs, likely to result in the serious impairment of the child's health or development. It may involve a parent or carer failing to provide adequate food, shelter, and clothing, failing to protect a child from physical harm or danger, or the failure to ensure access to appropriate medical care or treatment. It may also include neglect of, or unresponsiveness to, a child's basic emotional needs. Neglect may occur during pregnancy as a result of parental substance misuse.

Possible signs of neglect:

- Constant hunger
- Inappropriate clothing
- Untreated medical conditions
- Compulsive stealing or scrounging
- Frequent lateness or non-attendance at school
- Poor personal hygiene
- Low self-esteem
- Poor social relationships
- Constant tiredness

Safeguarding

The welfare of children is everyone's responsibility (Laming; 2009). The researcher may have limited, yet regular, contact with children allowing them to become aware of possible areas of concern. Additionally, the subject matter being discussed may lead to disclosure of matters of concern. As such, the researcher has a duty to safeguard children and to protect them from harm.

The Government requires that any organisation, whether statutory, voluntary, or other, that has contact with children must have a Child Protection Policy. In addition, all representatives are required, by law, to report any suspicions or concerns about a child's welfare to the social services department at the local authority.

The Children Act 2004, HM Government (2015), Working Together & All Wales Child Protection Procedures (2008), places a clear responsibility of safeguarding children on all agencies who have contact with children and families in their routine work. There are several ways in which the researcher may become aware that a child has been or is being abused and/or neglected including:

a. An allegation made by the child directly (a disclosure).
b. Through reports or allegations made by another person.
c. Through observing signs or indicators of abuse.
d. Through an admission from an abuser.

The suspected abuse of a child must be reported to social services or to the police. They are the agencies with statutory powers to investigate suspected abuse. Other agencies/organisations **must not** undertake their own internal child protection enquiries as there are mandatory reporting procedures under Social Services & Wellbeing (Wales) Act 2014.

It would be useful to draw up a pathway or a protocol of what to do if concerns are raised.

General Responsibilities of the Researcher

All researchers working with children and young persons should:

- Be fully trained in the methodologies and techniques intended to be used.
- Treat the children and young person's rights and well-being with the utmost importance.
- Be alert to potential indicators of abuse and neglect.
- Be alert to the risks which individual abusers, or potential abusers, may pose to children.
- Be aware of the effects of abuse and neglect on children.
- Contribute as necessary to all stages of the safeguarding process.
- Respond positively in every case understand his/her role and responsibilities to safeguard and promote the rights and well-being of children.
- Be familiar with and follow the University's Child Protection Policy and Safeguarding protocol and /or that of the host organisation (e.g., school, youth club/group) and should seek training.
- Any researcher with access to children must undergo level 2 recognition and referral training, so that they know what to do, should a disclosure be made to them. (Rationale: significant subject access).
- Additionally Enhance DBS disclosure or similar appropriate international equivalent should be undertaken prior to commencing data collection/research with the child.
- Have access to and be familiar with HM Government (2015) Working Together Guidance
- Have access to and comply with the All-Wales Child Protection Procedures (2008);

Have received child protection training commensurate with his/her role. Safeguarding Awareness training, which can be accessed via the URL https://www.melearning.co.uk/learning/swanseauniversity/

- **Ensure that they have been subject to, and cleared by, an up-to-date Disclosure and Barring Service (DBS) check. You will need to contact Swansea University's HR department or Student Services to arrange this.**
- Know the protocols around raising concerns.

Know the named safeguarding lead officer in the College/School. The Director of Student Services is the Lead Safeguarding officer for the University. The University Safeguarding policy can be accessed through Safeguarding Awareness training, which can be accessed via Research Integrity - Swansea University

- The researcher is legally obliged to report any issues of concern to his or her line manager and/or safeguarding officer in the first instance. Where these concerns are not appropriately addressed, safeguarding concerns should be reported to the authorities.
- with regards to the physical and emotional health and well-being of the children with whom he/she works. It is the responsibility of the researcher to ensure that he/she is aware of the appropriate avenues to follow in reporting any concerns.
- The researcher must ensure that he/she responds appropriately to a disclosure or suspicion of child abuse.
- In the case of immediate danger to the child, the researcher should contact the police or social services directly.
- **Under Duty of Care good practice, the researcher must recognise his/her individual responsibility to his/her own safety and that of others with whom he/she works.**

Note: the researcher should not be:

- Responsible for assessing the accuracy of an allegation.
- Held personally responsible for the physical and/or emotional welfare of any child with whom he/she work.

Dealing with Disclosures and /or Recognising a Concern

When dealing with a disclosure from a child or recognising a concern the researcher should:

a. Listen to the child. If you are shocked by what they tell you, try not to show it. Take what they say seriously. Children rarely lie about abuse and to be disbelieved adds to the traumatic nature of disclosing. Children may retract what they have said if met with revulsion or disbelief.
b. Accept what the child says. Be careful not to burden them with guilt by asking "why didn't you tell me before?" Show the child that you have heard what they are saying, and that you take their allegations seriously.
c. Encourage the child to talk, but do not prompt or ask leading questions. Do not interrupt when the child is recalling significant events.
d. Do not make the child repeat his/her account.
e. Stay calm and reassure the child that they have done the right thing in talking to you. It is essential to be honest with the child, so do not make promises you may not be able to keep, like "I'll stay with you" or "everything will be alright now".
f. Do not promise confidentiality as you are under a duty to refer a child who is at risk. Reporting concern is not a betrayal of trust.
g. Try to alleviate any feelings of guilt that a child displays. For example, you could say: "you're not to blame" or "you're not alone, you're not the only one this sort of thing has happened to."
h. Acknowledge how hard it must have been for the child to tell you what happened.
i. Empathise with the child – do not tell them what they should be feeling.
j. Explain what actions you must take in a way that is appropriate to the age and understanding of the child.
k. Make a record of what you have been told, using the exact words, if possible, as soon as possible, and no later than 24 hours after the event.
l. Do not destroy your original notes in case they are required by a court.
m. Record the date, time, place, any noticeable non-verbal behaviour, and words used by the child. If the child uses their family's own private sexual words, record the actual words used, rather than translating them into proper words.
n. Draw a diagram to indicate the position of any bruising.
o. Be objective in your recording: include statements and observable things rather than your interpretations or assumptions.
p. ***Make sure that you provide immediate support at the time of disclosure and provide details of organisations that can provide further help.***
q. Get some support for yourself, without disclosing confidential information about the child to colleagues.

r. If you require advice or support, contact your Safeguarding Lead or NSPCC helpline (see annex for contact details). The need to seek advice however, should not delay any emergency action needed to protect a child.
s. If you are unable to contact your Safeguarding Lead for advice, you should report your concerns to Social Services or the Police in emergency situations.
t. Report any concerns to the Safeguarding Lead or team member with responsibility for child protection within the research team or, if appropriate, to the member of staff of the host organisation with designated responsibility for child protection.
u. Do not confront the alleged abuser. All concerns reported to social services are taken seriously. It is better to have discussed it with an expert who has experience and responsibility to make an assessment.
v. Make a note of the date, time, place, and individuals who were present at any discussion you have.

Specific Circumstances

A child or young person discloses a child protection concern in a formal setting (school/youth club etc.).

If you have any reason for concern, you must inform the Safeguarding Lead and the lead individual for child protection within the setting (frequently the manager/ head teacher etc.). It will be the responsibility of this lead individual to contact social services and you should confirm that this has been done. If you are not satisfied with the lead contact's response, you should inform the person with responsibility for child protection within the academic College who should inform social services.

A Child or young person discloses a child protection concern outside of a formal setting (within the home or in community context)

If you have any reason for concern, these should be raised with the Safeguarding Lead / person responsible for child protection within the project, who should pass on these concerns to Social Services. .

A child or young person raises a concern during a focus group/group discussion

A child or young person may choose to disclose concerns during a focus group or group discussion. In such circumstances, the limits of confidentiality should be restated, and the child should be asked to speak to the researcher after the session. If the child becomes distressed, it is best to terminate the group session and seek support from other staff. Follow-up will be as set out above.

The child or young person is at immediate risk of harm.

In the event that the researcher suspects that the child or young person is in immediate danger, the situation should be treated as an emergency. In such circumstances the researcher should:-

a. Should contact Social Services or the NSPCC to seek advice on the action to take in an emergency situation. If you are unable to make contact, do not delay reporting your concerns by contacting the Police (999) and informing the Safeguarding Lead.
b. The researcher should not under any circumstances, confront or contact the accused, or talk to friends and/or family of the abused.

Responsibilities of the Principal Investigator

General Responsibilities of the Principal Investigator

a. The Principal Investigator is responsible for ensuring that the researcher working with children and young people is familiar with appropriate child protection procedures and is equipped with appropriate knowledge and skills.
b. The Principal Investigator is responsible for ensuring that the researcher working directly with children and young people has an up-to-date DBS check.
c. The Principal Investigator should follow local child protection procedures for communicating child protection issues to the appropriate authorities, whilst keeping the best interests of the child and the researcher as the primary focus.

Responsibilities of the Principal Investigator in the event of a child protection concern

A phone call/written referral to social services should be made as soon as a problem, suspicion or concern becomes apparent, and certainly within 24 hours.

During office hours, referrals may be made by telephone to the local social services office. Outside of office hours, a referral should be made to the Social Services Emergency duty team. Social services should acknowledge the referral within one working day of receiving it. Social services should be contacted again if a response has not been received within 3 working days. Any discussion about a child's welfare should be recorded in writing by the Principal investigator, including a note of the date and time, and details of the individuals participated in the discussion.

At the end of any discussion there should be clear agreement about what actions will be taken and by whom, with details disseminated to the relevant parties.

If the decision by social services is that no further action is taken, this should be recorded in writing, including the reasons for that decision.

It is mandatory under the Social Services & Wellbeing (Wales) Act 2014 that any concerns are referred to social services, even if one may think it to be unimportant or that the cultural context is not fully understood. The information provided could be crucial in a broader context.

There is no restriction stated in the General Data Protection Regulations (GDPR) or other legislation that prevents concerns being shared for the purpose of protecting children. Therefore, the facilitation of information-sharing during the enquiry is to be encouraged (Ref: Laming 2009)

Wherever possible, consent should be obtained, but the public interest in child protection always overrides the public interest in maintaining confidentiality or obtaining consent. A child's safety is always of paramount consideration.

- **Other Responsibilities**

Responsibilities of the University

The University is responsible for ensuring that all research involving children and young adults is undertaken in compliance with these procedures. The University should ensure that all staff and students undertaking research with children and young people receive appropriate child protection training and DBS checks.

- **Abuse by a Professional Person**

It is best practice to avoid misunderstandings and to be clear about the correct procedure

when working with or having contact with children. Staff should be advised to avoid any physical contact with a child or young person that could be construed as over-familiar and to be aware of the implications of lone working. It is important that any disclosure made by a child is passed to social services or the police and at no time should an adult agree with a child to keep secrets.

If the behaviour of a member of staff causes concern with regard to his/her relationship with children:

- do not dismiss these concerns or suspicions.
- discuss the concerns with the named person who has responsibility for safeguarding children.
- if the above is inappropriate, or it is the felt that the concern has not been taken seriously, social services should be contacted.
- social services have a protocol for responding where there are allegations regarding a professional, and the University should expect to be involved in a subsequent strategy discussion.

Conducting Clinical Trials Involving Medicinal Products with children

(It is expected that any such studies would obtain approval from NHS REC and local Research & Development offices)

If you are undertaking a Clinical Trial of an Investigational Medicinal Product (CTIMP) involving with a new medicines or a current medicine without a waiver you may need to carry out a paediatric investigation plan (PIP). The Paediatric Regulations 2006 provide additional protection for a minor who is being considered for a clinical trial i.e., a person under the age of 18 years. They regulations require, among other provisions, that:

- the Medicines and Healthcare products Regulatory Agency (MHRA) will require advice from an Expert Advisory Group under the auspices of the Commission on Human Medicine before an application for a Clinical Trial Authorisation can be considered.
- an ethics committee considering the trial must receive advice on the relevant field of paediatric care; and
- a person with parental responsibility or a legal representative must give informed. consent and may withdraw the young person at any time; and

In relation to the young person:

- Staff with knowledge of the trial and experience with young persons must inform him/her of the risks and benefits of the trial according to his/her capacity to understand.
- The researcher must consider the young person's explicit wish to refuse to participate or to be withdrawn from the trial at any time.
- The clinical trial must relate directly to an illness from which the young person suffers or that
  can only be carried out on minors; and
- The trial must aim to provide some direct benefit for this group of patients.

Researchers and trial sponsors have a responsibility to follow the regulations regarding these

types of research projects and to ensure that all required authorisations are in place prior to recruitment beginning.
Further information on CTIMPs can be found on the MHRA webpages:
https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk
and also, in relation to the requirements for a paediatric investigation plan (PIP):
https://www.gov.uk/government/publications/legal-requirements-for-childrens-medicines/legal-requirements-for-childrens-medicines

Policy History

Version	Author	Summary of Changes	Approved By	Date
Version 1	Anjana Choudhuri, Jeanette Hewitt, Llewellyn Morgan, Alyson Davies, Julia Parkhouse, Jane Williams, Pamela Ugwudike, Victoria Jenkins	First draft	UREGSC	May 2017
Version 2	C. Summerill, S. Snelgrove; A. Davies; A. Smith; J. Parkhouse, A. Choudhuri.	Addition of roles and responsibilities; internet mediated research and definitions.	UREGSC	Feb 2019.
Version 3	A. Smith & A. Choudhuri	Page 4 (Assent) and various forms and appendices.	URIEGC	Feb 2023

National Mental Capacity Forum

EAP
Essex Autonomy Project

Supported Decision-Making Toolkit for People with Communication Difficulties

Developed by Hannah Atkinson, Dr Mark Jayes and Dr Anna Volkmer[1]

1. **Do your research**: Find out what helps this person to communicate and what doesn't help:

- Check for any written recommendations (e.g., in a "communication passport" or advance care plan, from a Speech & Language Therapist (SLT), from carers)

- Ask people who know the person (e.g., the service-user themselves, carers, family, members of the health and social care team)

- Gather information on whether the person might need support/adjustments in any of these areas of communication:
  - Attention, listening and looking.
  - Understanding the situation and others (understanding verbal and nonverbal information)
  - Expressing themselves (verbally and non-verbally)

2. ***Check you have the basics in place:***
   - Quiet, private, and distraction-free environment
   - Person is well-positioned and comfortable.
   - Person has working glasses and hearing aids.
   - Person has dentures in situ (if this person will be required to speak)
   - Pen and paper (for writing or drawing)
   - Photos or images (e.g., photos of their home or specific equipment)
   - The person's Augmentative and Alternative Communication (AAC) equipment (if they have any)

3. ***Plan:***
   - Think about the language you are going to use beforehand (see 'Four tips for simplifying language on pages 2-3)
   - Think about non-verbal communication strategies e.g., gesture, videos, pictures. What could you prepare in advance to help represent key words/ideas? Does your service already have some appropriate resources you could access?

4. ***Keep track:*** *document how you supported the person's communication needs to decide. What information did you communicate to the person and with what supports? How did the person communicate back to you and what did they express?*

Four tips for simplifying language:

1. Choose **familiar words** to the person. These tend to be words used regularly in daily life (high frequency words). Avoid professional jargon or words that are less commonly used in everyday life (low frequency words).

Example:

Accommodation	versus	Home/house
Prescribe medication	versus	Give medicine/tablets

2. Use **active sentences** instead of passive sentences. Put the 'do-er' of the action at the start of the sentence.

Example:

Active sentence: "The doctor will check your heart."
Passive sentence: "Your heart will be checked by the doctor."

3. Avoid using **too many pronouns** such as 'he', 'she', 'they', 'us', 'this', 'that'. Use the person's name or title instead (e.g., doctor).

Example:

Lots of pronouns: "**They** will scan your heart. Then **they** will tell **us** your results." Reduced use of pronouns: "**The heart doctors** will scan your heart. Then **the heart doctors** will tell **your GP** your results."

4. Avoid sentences with multiple parts (clauses). Try to make one point per sentence.

Example:

A multiple-part sentence: "Your swallowing impairment, which is a result of your brain injury, poses risks to your health, including weight loss and pneumonia."

The same concept expressed in several simpler sentences: "Your brain injury has caused swallowing problems. Swallowing problems can cause health problems. Swallowing problems can cause weight loss. Swallowing problems can cause chest infections."

Suggested reading:

- NHS England (2017) 'Accessible Information Standard' Available at: https://www.england.nhs.uk/about/equality/equality-hub/patient-equalities- programme/equality-frameworks-and-information-standards/accessibleinfo/
- Department of Health (2010) 'Making written information easier to understand for people with learning disabilities' Available at: https://www.gov.uk/government/publications/making-written-information-easier- to-understand-for-people-with-learning-disabilities-guidance-for-people-who- commission-or-produce-easy-read-information-revised-edition-2010
- Stroke Association (2012) 'Accessible Information Guidelines: Making information accessible for people with aphasia' Available at: https://www.stroke.org.uk/sites/default/files/accessible_information_guidelines.pdf 1_.pdf

Guidance on supported decision-making:

- Section 1.2 in NICE guideline (2018) 'Decision making and mental capacity' Available at: https://www.nice.org.uk/guidance/ng108
- Chapter 3 in MCA Code of Practice (2007) 'How should people be helped to make their own decisions?' Available at: https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice
- Chapter 3 in DRAFT MCA Code of Practice (2022) 'How should people be helped to make their own decisions?' Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attac hment_data/file/1080137/draft-mental-capacity-act-code-of-practice.pdf

*Approval sought from Ministry of Justice in Feb 2023 for use of the toolkit

GATEKEEPER CONSENT GUIDANCE

Title of Project:
Name of Researcher and School/Faculty:
The following questions can be headings in your information sheet and beneath each you should add text that is relevant to your study:

1. **What is the reason for this letter?**
2. **What is the purpose of the study/rationale for the project?**
3. **What are we asking you to do?** (be explicit about access and what role the gatekeeper will be taking)
4. **Why do we need access to your facilities/staff/students?**
5. **If you are willing to assist in the study what happens next?**
6. **How will we use the Information/questionnaire?**
7. **Will the name of my organisation taking part in the study be kept confidential?**' (The gatekeeper must be told in simple terms how their confidentiality is being safeguarded during and after the study)
8. **What will taking part involve? What should I do now?**
   - Sign and return the **Gatekeeper Consent Form** provided.
   - **For participants who are aged under 16 only**, please make sure **Signed Parental Consent Forms** are collected back **BEFORE distributing the questionnaire.**

Should you have any comments or questions regarding this research, you may contact the researchers: *(insert names & contact details)*
This study has received ethical approval from Faculty of xxxxx Research Ethics & Governance Subcommittee *(insert FREGSC reference number and date of approval)*
Contact Details of Researcher
Contact Details of Academic Supervisor *(student studies only)*

If you have any concerns regarding your involvement in this research, please discuss these with the researcher in the first instance. If you wish to make a complaint, please contact researchintegrity@swansea.ac.uk and your communication will be re-directed to an independent person as appropriate.

In the interests of safety for the researcher, Swansea University Research Integrity: Ethics & Governance Committee would advise researchers not to include home addresses or personal telephone numbers (mobile or home) as contact details for participants.

Guidance Note: In order to access research participants, the researchers may have to contact 'gatekeepers' to participants (e.g., teachers, doctors etc.), who may have a role in arbitrating access and / or the protection of participants. Parents should also be considered to offer a gatekeeping role for potential research participants and should be consulted with regards to planned research being undertaken with their children. Through parents being consulted and versed with the proposed study would enable them to consider the study and give due regard to providing consent for their child to participate. Excessive reliance should not be placed on gatekeepers to recruit participants to research studies. The position of 'gatekeepers' may vary

enormously and where the gatekeeper is in a position of power with respect to the potential research participants, a situation may arise where the potential participant may feel coerced or pressurised to take part in research. Another problem could be that the 'gatekeepers' do not explain the research to the participant appropriately. It is the responsibility of the researcher therefore to ensure that potential participants do understand what taking part in the research involves, and that they do so freely by going through a thorough process of voluntary and informed consent.

GATEKEEPER CONSENT FORM

Title of Project:
Name of Researchers:

Please tick to confirm your understanding of the study and that you are happy for your organisation to take part and your facilities to be used to host parts of the project.

Please add some brief information about your project here that clarifies exactly what the gatekeeper is agreeing to

1. I confirm that I have read and understand the information provided for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that participation of our organisation and students/members in the research is voluntary and that they are free to withdraw at any time, without giving a reason and that this will not affect legal rights. ☐

3. I understand that any personal information collected during the study will be anonymised and remain confidential. ☐

4. I agree for our organisation and students/members to take part in the above study. ☐

5. I agree to conform to the data protection act ☐

Name of Gatekeeper:Date:Signature:

Name of Researcher:Date:Signature:

Name of Person taking consent:Date:Signature:
(if different from researcher)

Swansea University
Prifysgol Abertawe

Participant Consent Form

(If necessary, include name of target group to which this consent form will be administered. Also note that for those under the age of 18 it may be appropriate for minors to consent without parental agreement and this form can be used. The rationale for allowing them to consent should be explained in the application. In other instances, children should give their assent and parents should also consent to their child participating. Please see separate form if this applies. Please refer to Swansea University Policy on undertaking research with children and young people and in particular pages 4 and 5 on consent/assent).

Project title……

(Select an appropriate working title for your project. Do not state your hypothesis as your project title. Please ensure the title you choose is consistent across all of your ethics documentation e.g., PIS, Debrief etc)

Name and Contact details of the principal researcher (Please also include details of supervisor if relevant).

		Participant initial
1.	I (the participant) confirm that I have read and understand the information sheet for the above study (dated) which is attached to this form.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons. (You will need to consider and amend here if information is to be anonymised and therefore people will only be able to withdraw until a certain point in time. This needs to be aligned with withdrawal that you also refer to in the PIS)	
3.	I understand what my role will be in this research, and all my questions have been answered to my satisfaction.	
4.	I understand that I am free to ask any questions at any time before and during the study.	
5.	I have been informed that the information I provide will be safeguarded (You may need to insert a clause here stating that confidentiality may not be guaranteed if certain information is divulged. Again, this would need to align with the PIS).	
6.	I am happy for the information I provide to be used (anonymously) in academic papers and other formal research outputs (Please note that these statements are examples only. You will need to consider whether your research data will be anonymised or pseudonymised, and explain this to participants in this section)	
7.	I am willing for my information to be audio/video recorded.	

8.	I have been provided with a copy of the Participant Information Sheet.	
9.	I agree to the researchers processing my personal data in accordance with the aims of the study described in the Participant Information Sheet.	

(For paper consent use the following):

Thank you for your participation in this study. Your help is very much appreciated.

_____ _____ _____

Print name of participantSignatureDate

_____ _____ _____

Print name of researcherSignature Date

This study is being conducted by Swansea University.
When complete: Original copy for participant, one copy to be retained by researcher if paper copy.

(For electronic consent use the following):

If you agree with all statements listed above, click **YES**.
If you disagree with any of the statements above, click **NO** and you will be taken to the end of this survey.
This study is being conducted by Swansea University

Thank you for your participation in this study. Your help is very much appreciated.

Section 21

POLICY ON RESEARCH WITH VULNERABLE ADULTS AND ADULTS LACKING CAPACITY

PURPOSE

The purpose of this policy is to outline the policy of Swansea University in relation to responsibilities of researchers when conducting research with potentially vulnerable adults.
The following policy has been developed in line with guidance from the following sources:

- Economic and Social Research Council
- Safeguarding Vulnerable Groups Act (2006)
- mental Capacity Act (2005)
- Health Research Authority
- medical Research Council
- Welsh Assembly Government – mental Capacity Act 2005 and consent for research
- General medical Council

SCOPE

This policy relates to conducting research with vulnerable adults (over the age of 18), and people over the age of 16 who lack capacity. Research involving children, under the age of 18, is covered in the separate policy, 'undertaking research with children and young people'.
This policy makes specific reference to legislation in England and Wales in relation to the Safeguarding Vulnerable Groups Act (2006) and the mental Capacity Act (2005).
Specific information relating to legislation in Scotland and Northern Ireland can be found at http://www.hra-decisiontools.org.uk
If research is to be undertaken with adults that lack capacity in other countries, researchers should seek guidance and adhere to local legislation.

POLICY STATEMENT

Researchers will be aware of and abide by the laws outlined in the Safeguarding Vulnerable Groups Act (2006); mental Capacity Act (2005) and Clinical Trials regulations for research involving participants in England and Wales. For research in other countries, researchers will make themselves aware of the local legislation in place relating to research with vulnerable adults and adults who lack capacity.
Researchers should be knowledgeable on and abide by specific guidance of the relevant funding bodies and regulatory authorities relating to their research and the involvement of vulnerable adults or adults who lack capacity.
Researchers will be aware of potential vulnerability within groups that may not be considered 'vulnerable' within the terms of the Safeguarding Vulnerable Groups Act but may become vulnerable within the context of the research and give due consideration to obtaining specific informed consent; use appropriate research methods and plan for circumstances where the researcher may find themselves in a position of increased responsibility or expected

responsibility.

VULNERABILITY

Safeguarding Vulnerable Groups Act 2006

There are a number of activities that are regulated by law under the Safeguarding Vulnerable Groups Act 2006, and as such the persons undertaking such regulated activity will require a Disclosure and Barring Service (DBS) check. People may be considered vulnerable adults if they:

1. Are 18 years or older and;
2. The subject of a regulated activity:
   a. Provision of health care by or under the direction or supervision of a health care professional.
   b. The provision of relevant personal care.
   c. A social care workers provision of relevant social work to a client or potential client
   d. The provision of assistance in relation to general household matters which is required by reason of age, illness or disability.
   e. The provision of any relevant assistance in the conduct of an adult's own affairs.
   f. The conveying of adults who need to be conveyed by reason of age, illness or disability by prescribed people in prescribed circumstances.
   g. In addition, any activity which consists of, or involves the day to day management or supervision of a person carrying out a regulated activity on a regular basis is in itself a regulated activity.

Therefore, if research involves unsupervised provision of any of the regulated activities, then a DBS check may be required. Further detail on DBS can be found at:
DBS Application Guidance - Swansea University
https://www.gov.uk/government/organisations/disclosure-and-barring-service/about#disclosure-checks-dbs-checks

Other vulnerabilities

Even if the research does not require provision of a regulated activity, consideration should still be given to potential vulnerability within the context of the research, in relation to potential harm from participation or a lack of positive impact where it is needed or expected by the participant. Being in a dependent or unequal relationship may limit the potential for freely given consent by the participant.

There is no definitive list of people or groups that may be considered vulnerable, and vulnerability is a complex, dynamic state that may be defined in different ways, and may arise for many reasons, for example as a result of (list not exhaustive):

- Being the subject of a regulated activity (see above)
- Being in an abusive relationship
- Potential vulnerability due to old age
- Potential marginalisation
- Disability
- Learning difficulties or mental illness
- Disadvantageous power relationships within personal and professional roles

- Being in a dependent relationship that means they feel coerced or pressured into taking part
- Patients in care
- People in custody or on probation
- People engaged in illegal activities (e.g., drug abuse)
- Language barriers between researcher and participant

Every effort should be made to secure freely given, informed consent that the participants have actively provided, whilst this is important in all forms of research, it may be more difficult to ascertain for potentially vulnerable groups. Researchers should ensure that participants have the time and opportunity to access support in their decision making if needed. Passive assent (such as group assent) and consent given by a gatekeeper should be avoided. methods of seeking consent should be appropriate to the groups studied using expert advice and support where necessary. Vulnerability should be considered on a case-by-case basis and many people not traditionally considered vulnerable could be exposed to issues as a result of participating in research, that may make them vulnerable.
Researchers should consider the following:

- Participant's vulnerability.
- Potential negative consequences or lack of personal benefits from their involvement in research where these are expected.
- Providing appropriate information to elicit freely given information consent for participation as well as information regarding data deposit and data re-use (where deposit is possible).
- Limits of confidentiality.
- Potential vulnerabilities and the impact that selected research methods may have.
- Extra care should be given to considering the use of incentives and rewards to ensure that participants are not considered coercive and are proportional to the risk involved.

Some groups or individuals may expect help and assistance as part of participation. Consideration should be given to what action should be taken if the researcher finds themselves in a position of increased responsibility or expectation even if these do not fall into the scope of the research project, for example if during an interview it is revealed that the participant is in significant danger. Advice and guidance should be sought from the research ethics committee where such situations may be anticipated.

ADULTS LACKING CAPACITY

Research involving people who lack capacity is governed in England and Wales by the mental Capacity Act 2005. The term 'capacity' is legally defined under the terms of the Act and applies to people over the age of 16 who 'lacks capacity in relation to a matter if at the material time they are unable to make a decision for themselves in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain'.

The Act also specifies that the impairment or disturbance may be permanent or temporary and that a lack of capacity cannot be established merely by reference to a person's age or appearance, or a condition of their behaviour, which might lead others to make unjustified assumptions about their capacity.

A person is unable to make a decision if they are unable to:

- Understand the information relevant to the decision
- Retain that information
- Use or weigh that information as part of the process of making the decision or
- Communicate their decision (whether by talking, using sign language or any other means)

The Act makes specific reference to research, stating that intrusive research carried out on or in relation to a person who lacks capacity to consent is unlawful unless it is carried out in accordance with sections 31-33 of the mental Capacity Act 2005. 'Intrusive' procedures are those that require consent in law, including the use of personal information.
Research involving adults who lack capacity must only be conducted if the research is related to their impairing condition or its treatment – i.e., you must not involve adults who lack capacity if the same or similar research could be conducted with people who have capacity.
Adults who lack capacity should only be involved in research projects (including clinical trials) if the expected benefit to them outweighs the risks.
Adults who lack capacity **may** be involved in other research projects (not including clinical trials) if:

- the research is not expected to provide a direct benefit to them but is expected to contribute to the understanding of their incapacity, leading to an indirect benefit to them or others with the same incapacity, and,
- if the risks are minimal (the person should not suffer harm or distress by taking part).

Research involving such participants must be reviewed by a recognised research ethics committee (REC) operating under the Governance arrangements for research ethics committees (Faculty ethics committees are not sufficient for this approval).
Researchers should assume that a person has the capacity to make a decision unless there is proof that they do not; a prospective participant must receive support to try to help them make their own decision. The researcher should ensure that what capacity and adult has is optimised as far as possible to enable that individual to make a decision for themselves.

- A person must be assumed to have capacity unless it is established that they lack capacity.
- A person must not be treated as unable to make a decision unless all practicable steps to help them to do so have been taken without success
- A person is not to be treated as unable to make a decision merely because they make an unwise decision
- Any act done or decision made, for or on behalf of a person who lacks capacity must be done, or made, in their best interests
- Before any act is done or decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.

The person assessing capacity must have sufficient training and experience to be able to assess the individual concerned under the specific circumstance.
Assessment of capacity should be a two-step process:

1. Consider whether there is an impairment of, or disturbance in the functioning of the person's mind or brain. Capacity may fluctuate and be temporary or permanent, for example as a result of heart attack; learning disability; serious pain; unconsciousness; concussion etc.
2. Determine whether, as a result of the impairment or disturbance, a person is unable to make that particular decision. In order to make that decision the person must be able to understand; retain; critique and communicate their decision.

The Participant has the right to disagree with the decisions that others might make (e.g. relatives or carers) and the interests of the person must be assumed to outweigh those of science and society. Researchers should consult with carers and take note of any signs of objection or distress from the participant and consider withdrawing the participant in the event of objection.

Clinical Trials of Investigational medicinal Products (CTIMPs):

In Clinical Trials of investigational medicinal products, you must get consent from a legal representative, who will be asked to give consent on behalf of an adult lacking capacity to do so themselves.

The legal representative must be told that they are being asked to give consent on behalf of the adult lacking capacity and that they are free to decide whether they wish to make the decision or not and that they are being asked to consider what the adult would want and set aside their own personal views.

The representative should be given sufficient information about the trial to make an informed decision and the participant must also receive information according to their capacity of understanding about the trial and its risks and benefits.

A CTIMP trial with adults that lack capacity can only be initiated if the trial is directly relevant to a life threatening or debilitating clinical condition that directly affects the participant. The expected benefit must outweigh the risks to the participant; no incentives or financial inducements should be given to people lacking capacity or their representatives.

Non-CTIMPs (other intrusive research):

If the participant does not have the capacity to give consent to participate then the researcher must consult with a specified consultee.

This should be a personal consultee where possible, this should be someone who knows the participant well (but is not a professional or paid care worker) whom the person that lacks capacity to decide would trust with important decisions about their welfare such as a family member or close friend.

If a personal consultee cannot be found then a nominated consultee should be proposed by the researcher who is prepared to be consulted but has no connection with the project, for example a professional care worker, member of a relevant charity or a professional care worker, providing they have no connection with the research project.

Consultees are not asked to give consent on behalf of the adult but to provide an opinion on the views and feelings of the potential participant and advice should be sought on whether they feel the adult lacking capacity would wish to be included in the research or not. Such advice should be recorded on a consultee declaration from rather than a consent form.

The consultee must be given sufficient information to enable them to provide the researcher

with informed advice. They must be told that they are being asked to advise and they are free to decide whether to provide the advice or not.
The participant must also receive information according to their capacity of understanding about the trial and its risks and benefits

Adults that have lost capacity to consent throughout the course of the project.
If a participant loses capacity during the course of a CTIMP then the consent to participate is presumed to remain legally valid after loss of capacity (provided that the protocol does not change significantly).
For other intrusive research, If consent has been obtained prior to a loss of capacity then the researcher will need to consider if this consent remains valid following the loss of capacity – there are only a limited set of circumstances where an earlier consent at common law endures loss of capacity.
Consideration should be given at the beginning of the study to what steps would be taken in the event of a participant losing capacity to consent during your study – in particular to whether these participants would be withdrawn from or remain in the study.
If the intention is that the participant would remain in the study and would be required to undergo further interventions and procedures, then this constitutes 'intrusive research' and would require approval by an appropriate research ethics committee and advice sought from a consultee.

You have a legal obligation to carefully consider a request made by a representative to withdraw someone from a study, after they have lost capacity. You must consider their current situation, including possible benefits and harms that might arise as a consequence of their continued participation.

In situations where the potential for losing capacity was discussed as part of the original consent you should still review how best to proceed if the participant does subsequently lose capacity. The original consent given by participants should not automatically be considered absolute. The current circumstances of the participant must be considered (see above).

Where consent to use data or tissue samples was given prior to loss of capacity then continued use of that material will not be considered intrusive research, however collection of new samples would be considered intrusive research and require additional consent. New uses of existing data would only be lawful if it falls within the terms of the original consent.
Where data or samples have been truly anonymised, the consent of a person with capacity is not required and therefore is not considered intrusive research.

Adults who gain capacity during the course of the study
If it is possible that an adult that lacks capacity could regain capacity during the course of the study, then the researcher must plan on how to involve them in the ongoing consent process. In most cases it would be appropriate to ask the participant to give their own consent once they are able. The legal representative or consultee should be made aware of this at the outset. The researcher should prepare an appropriate participate information sheet and consent form that explains what has happened so far and what you are seeking consent for. The researcher should also plan how they will handle a participant wishing to withdraw

consent at each stage of the study.

Research into treatments used in emergencies

The UK law allows adults not able to consent for themselves to be recruited into CTIMPs without prior to consent in emergency situations if:

- Treatment needs to be given urgently
- It is also necessary to take urgent action to administer the drug for the purposes of the trial;
- It is not necessary practicable to obtain consent from a legal representative;
- The procedure is approved by a NHS Research Ethics Committee
- Consent is sought from a legal representative as soon as possible

In England and Wales, the law allows adults not able to consent for themselves to be recruited into other intrusive research without prior advice from a consultee, in emergency situations if:

- Treatment needs to be given urgently
- It is also necessary to take urgent action to administer the drug for the purposes of the trial;
- It is not necessary practicable to obtain consent from a consultee;
- The procedure is approved by a NHS Research Ethics Committee
- A consultee is consulted as soon as possible to seek advice on the participant's likely views and feelings.

SUMMARY

Researchers need to consider:

- Is the research a Clinical Trial of Investigational medicinal Product (CTIMP) or other invasive research.
- Whether the research project will involve the provision of a regulated activity, and seek guidance on whether a DBS check is required.
- Will the research involve adults that lack capacity or adults that may lose capacity during the course of the research – if so, consider the actions needed to demonstrate consent.
- Additional potential vulnerabilities of adult participants and plan for unforeseen responsibilities.
- Will the research take place outside of England and Wales – if so, local guidance and legislation should be consulted.
- Plan for the above, consider related risks and seek appropriate approval from appropriate ethical committees.

RELATED LEGISLATION AND DOCUMENTS

- Policy on undertaking research with children and young people
- Policy on research data protection
- mental Capacity Act 2005
- mental Capacity Act (2005) Code of Practice
- Safeguarding Vulnerable Groups Act 2006

- Clinical Trials regulations
- The Care Quality Commission (CQC)
- Equality Act http://www.legislation.gov.uk/ukpga/2010/15/contents
- Welsh Assembly Government – mental Capacity Act 2005 and consent for research
- HRA decision tool: http://www.hra-decisiontools.org.uk/consent/principles-ALC-EnglandandWales.html

Section 22

TRAINING ON RESEARCH INTEGRITY

In conformity with its obligations as described in the ***Concordat to Support Research Integrity*** (2012, p.14), the University is committed to providing staff and students engaged in research with training, in order to maintain excellence in research integrity.

An online training on research integrity (Epigeum) https://staff.swansea.ac.uk/reis/research-integrity/research-integrity-training/ is provided for all research active staff and research managers.

A separate training programme for specialist areas of research integrity is offered through the Staff Development and Training services and REIS. The University expects all research active staff and supervisors of research students to undertake training. The University also expects all staff and students to have a working knowledge of this Framework.

The lead Researcher or Principal Investigator of a research project is expected to be responsible for, and encouraging to, all members of the research team in developing their skills, and to lead and foster an open exchange of research ideas. A PI must ensure that appropriate direction of research and supervision is provided at all stages of the research process, including the preparation of funding applications in accordance with the University's financial regulation, data collection, data storage, and data analysis and publication and dissemination.

All researchers should ensure that they have the necessary skills, training, and resources to carry out research to the required standards and that any gaps are filled by appropriate training. Researchers should be sufficiently well informed of the appropriate sponsor, funder, Institutional, legal, ethical, and moral obligations, and requirements to enable compliance.

All students undertaking research should be made familiar with the appropriate principles and practices of research integrity, ethics, and governance as part of their research training. For postgraduate research students, this is likely to be through a combination of subject-specific training, supervision, and the University's Research Skills Development Programme. For other students, this is likely to be embedded within their module, and instilled during supervision.

It is essential that members of Faculty Research Ethics & Governance Committees attend training sessions, and that Committee Chairs have regular training and professional development opportunities. If Faculty's are providing 'Discipline specific' training events then they should cover the various aspects of this Framework, including:

- principles of research ethics (e.g., publication ethics and informed consent);
- relevant aspects of law (e.g., concerning data protection);
- guidance on data management (e.g., secure storage of data);
- guidance on procedures for applying for ethical approval both within the University and externally (e.g., through IRAS);

- guidance regarding insurance and sponsorship;
- guidance regarding handling of conflicts of interest; and
- procedures for dealing with misconduct in research.

The University is committed to providing regular 'update' sessions on research integrity, ethics, and governance as new guidelines and relevant documentation emerge.

Section 23

Guidance on Ethical Approval of Pedagogic Research

1. What is Pedagogic Research?

Pedagogic research is a form of research involving critical reflection of teaching practices to help develop new knowledge or new curriculum. Pedagogic research offers an opportunity for academics to refine teaching practices and generate an understanding through evidence of what works and what doesn't in student learning. Pedagogic research has the goal of improving the quality of education locally and further afield, through dissemination of best practice. It requires a systematic and evidence-based study of student learning, often through research projects engaging students. Pedagogic research is as important to a University as traditional research areas, and demonstrates active engagement with the Teaching Excellence Framework (TEF).
Good practice for pedagogical research is that it is:

- Focused on student learning;
- Grounded in context;
- Methodologically sound;
- Conducted in partnership with students; and
- Appropriately public.

(*Felten, 2013*)

The Higher Education Academy defines Pedagogic research as research into the processes and practices of learning, teaching and assessment, which may involve systematic empirical research as well as contributions to pedagogic theory (https://www.heacademy.ac.uk/blog/higher-education-teachers-pedagogic-researchers).
In Universities, Pedagogical research usually falls into three categories:

- Analysis that makes use of data that has already been collected within university processes: For example, grades, attendance, module evaluation, engagement, VLE analytics for which students are not currently approached to provide further consent.
- Research that examines a specific teaching intervention: Here the evaluation would take the form of further qualitative or quantitative instruments and students would be asked to participate and provide consent.
- Macro level teaching research that may compare experiences from Swansea with other institutions and may involve researching teaching experiences external to the university.

2. Granting ethical approval to Pedagogic Research

Pedagogic research should undergo an ethical review to protect the researcher and the research participants and support the professional conduct of the research endeavour (*Cousin 2009*). Normally Pedagogical research is considered 'low risk'; however, particular attention should be paid to the power dynamics in the *teacher/researcher* and *student/participant* relationship. The ethical approval process is not a hurdle and approval can be granted by a Chair's review. Undergoing an ethical approval is an opportunity to reflect on the research design and receive pre-study peer review; embracing thereby a more constructive approach

to instil confidence and compliance with the process.
Ethical approval of any Pedagogic research must be undertaken before the commencement of the project but should also form part of the project monitoring Pedagogical research that requires ethical approval would require the principal investigator to complete an ethical review form as per other forms of research. The researcher also needs to consider their own position, values, and beliefs and how these might inform their interpretations.
Before commencing any pedagogic research, staff must discuss the research question and methodology identified, with the appropriate Director of Learning and Teaching to determine appropriateness of the proposed research. If the research goes beyond module evaluation, following approval from the Director of L&T, ethical approval must be sought through Faculty/School/Faculty Research Ethics Committees.
Staff undertaking activities with their students in their own modules which would be seen as either formal or informal module evaluation (i.e., evaluation of existing teaching methods or content) or strategic program level evaluation should not need additional ethical approval. However, if staff wish to use the results of such activities beyond the usual reasons of module evaluation/improvement or HEA fellowship applications, for example using the information in conference papers and journal articles, then ethical approval must be completed.

3. Consent and Data Protection of Pedagogic Research

As part of the application process a participant information sheet and consent form needs to be produced if participants are being recruited to a study/project. Students should not be disadvantaged in any way through either their participation or non-participation in a study, and all participation should be voluntary. Any research project that requires ethical approval will have to address data protection requirements. If researchers are collecting identifiable data, then they should take all the necessary steps for data collection and data processing in line with the University's obligations under the data protection legislation.
Even if a research project does not require an ethical review, necessary steps should always be taken to ensure that data collected and retained is GDPR compliant.

4. Timing and burden of Pedagogic Research involving students:

Other than existing module evaluation during the NSS survey period, there should be no pedagogic research involving 3rd year/Final year students. If students are being used as research participants in a piece of pedagogical research beyond module evaluation, then best practice would be that each cohort should not be subject to more than one study in any one semester. Faculties should operate a recording process so that pedagogical research participants can be easily identified. Exceptions may be made on a case-by-case basis when, for example, research operates at different scales. Priority should be given to research that is either externally funded or seen as a strategic priority for the University and/or being used for a staff members HEA membership.
In order to decrease the burden on students, many Universities allow Pedagogic Research to be undertaken on students only in the First year. Faculty/School/Faculty Research Ethics and Learning & Teaching Committees are requested to be mindful of requests from academics and abide by the above-mentioned protocols for Pedagogic Research.

https://www.heacademy.ac.uk/does-pedagogic-research-require-ethical-review
https://www.bera.ac.uk/publication/ethics-and-educational-research

Section 24

Guidance on Service Evaluation

The following is the Swansea University guidance for Ethical Review of Service Evaluation**.** It is primarily for Swansea University staff and students who intend conducting a service evaluation. The information provided draws on, and is supported by
https://arc-w.nihr.ac.uk/training-and-capacity-building/evaluation-best-practice-and-guidelines/
https://www.hqip.org.uk/wp-content/uploads/2017/02/guide-to-managing-ethical-issues-in-quality-improvement-or-clinical-audit-projects.pdf
https://www.weahsn.net/wp-content/uploads/Best-practice-in-the-ethics-and-governance-of-service-evaluation.pdf

Defining Service evaluation, Audit and Research
Service evaluation may be defined as "A study in which the systematic collection and analysis of data is used to judge the quality or worth of a service or intervention, providing evidence that can be used to improve it"[1]
In comparison, audits are commonly viewed as measuring a service against set standards or criteria not requiring ethical approval. Audits usually involve analysing existing data with results disseminated locally.
Research may be defined as "the attempt to derive generalizable or transferable new knowledge to answer clearly defined questions with scientifically sound research methods. This excludes audits of practice and service evaluations (UKPFH&SCR 2017). Research usually, but not always, requires ethical approval.

Service Evaluation
A service evaluation is part of quality Improvement (QI) and is crucial to ensuring those who use a particular service (patients/clients/ students) get the best care or service. It can be used for new or existing services to evaluate effectiveness, safety, efficacy, experience. It may be used for innovation to support the evidence base for commissioning or service development [1]. Ultimately it is an activity which aims to improve service, bring about positive change in a particular setting.
Examples of a service evaluation
The following list is not exhaustible. These examples are provided by https://arc-w.nihr.ac.uk/Wordpress/wp-content/uploads/2020/02/Full-guidelines-for-Best-Practice-in-the-Ethics-and-Governance-of-Service-Evaluation-Final02.pdf

- Aims to judge a service's effectiveness or efficiency through systematic assessment of its aims, objectives, activities, outputs, outcomes and costs.
- Asks questions such as - "has this service been a success?" or "how satisfied are patients /clients with the service being provided?"
- Are often specific to a department or clinical area.
- Never involves allocating service users randomly to different treatment groups.
- May also be used to compare the effectiveness or efficiency of a new practice/service (where supported by evidence) with an existing one - however this would be for the

purpose of local comparison, i.e. not with a view to derive generalizable or transferrable results (which would be research).
- Whilst benchmarking may be used to compare services, the evaluation will not involve measurement against agreed standards (which would be clinical audit).
- Generates evidence of effectiveness of a service which may lead to service redesign.

Service Evaluations and Ethical Review

It is commonly thought that service evaluations do not involve ethical review. Although service evaluations and audits fall outside the Research Ethics System, ethical issues may be embedded in a project with possible risk of psychological or physical harm to participants and therefore should have ethical review or oversight depending on the project evaluators themselves, academic supervisors and/or REC Chairs.

Role of the University

It is the role of the University to ensure that there are processes, or forms of approval, in place to ensure that ethical protection is afforded to participants in any research or evaluation study. While service evaluations may not require full ethical review, all service evaluations should be screened for potential ethical consideration by the evaluators themselves, and if necessary reviewed by a third party to identify and address ethical issues and risks and monitored throughout the evaluation process. This need not be an external body such as NHS Research Ethics Committee or a full University committee review but could be an ethical overview conducted by Peers, Faculty, School or Faculty REC Chair, designated committee or Research or Clinical Director against an agreed checklist assessing risk, ethical issues and governance arrangements (see below).

How to determine whether the project is service evaluation, audit or research?

If you are unsure whether your study is a service evaluation, research or audit then please seek advice from your Faculty/School/Faculty Research Ethics Chair or it may be helpful to consult 'The Health Research Authority (HRA)' which provides a tool for those working in an NHS setting to help decide whether or not a study is research, evaluation or audit. (http://www.wales.nhs.uk/sites3/Documents/952/RES_Defining_Research_Sept_2013.pdf
There is no service evaluation department at Swansea University. If service evaluations are undertaken as a stand-alone project or as part of an audit or as preparatory work for a grant application and you are unsure whether you require independent ethics oversight, then please consult your Faculty/School or Faculty Research Ethics Chair. If you are a student or postgraduate, then your supervisor should provide the necessary support. For NHS applications please consult resgov@swansea.ac.uk

Are the appropriate skills, knowledge and information available to conduct a service evaluation?

Those conducting service evaluations should make a judgement about whether they or the evaluator are suitably qualified to conduct the evaluation with the population under study. For example, taking account of issues such as independence, political interest and conflict of interest. They should also decide on whether they require any of the following:

- a professional registration,

- a Disclosure and Barring Service (DBS) checks,
- a research passport or
- suitable references.

What kinds of Ethical Risks may be encountered? How can I monitor them?
The kinds of ethical issues that arise in research may also arise in service evaluations:

- Recruitment and selection of participants
- Procedures for seeking consent
- Anonymization of data
- Confidentiality
- Risk to participants
- Data protection
- Data storage and data management
- Data sharing and archiving
- Data disposal
- Conflicts of interests

When does an evaluation study require ethics review or oversight?
Evaluators should conform to their own professional or Institutional guidelines to assess whether a service evaluation needs ethical consideration
If in doubt, researchers should consult the Faculty/School/Faculty Research Ethics Committee Chairs. In the case of student projects, Academic Supervisors should make the final decision on whether or not to ask Research Ethics Committee Chairs for ethical oversight or whether to undertake the ethical review themselves.
The following questions have been adapted from the HQIP (Healthcare Quality Improvement Partnership https://www.hqip.org.uk/ who propose the following questions to screen for possible ethics questions in service evaluations:
If the answer to any of these questions is **yes** then the study will need ethical oversight/ consideration

Does the evaluation	**Yes**	**No**
Infringe on individuals' rights?		
Risk breaching patient /client confidentiality or privacy?		
Place any extra burden on the individual beyond usual care or activity		
Involve any significant departure from usual clinical care or service		
Allocate any interventions differently among groups of service users?		

Involve a potential conflict of obligation, for example, a trade-off between quality and cost, to patients, clients, staff		
Involve the use of any untested clinical or systems intervention		
Provide no direct benefit to care of patients, service users, or their care or improving the service		
Is there risk to physical, psychological, emotional, social or financial risk		
Are there any conflicts of interest (E.g. a Manager conducting an evaluation who may have a conflict of interest)		
Seek out data or human tissue not usually collected		

When does a project not require Ethical Approval (If in doubt, please consult your Research Ethics Committee Chair. In the case of student projects, Academic Supervisors would make the final decision on whether or not to consult the Research Ethics Committee Chair for ethical oversight):

- If there is a firm **no** to all the above questions.
- If the evaluation uses existing personal data in a way which complies with the University's Data Protection policy then no ethics is required https://www.swansea.ac.uk/about-us/compliance/data-protection/
- If the Data is completely anonymous;
- If the use of the data does not cause substantial distress or damage;
- If the data collected is to be used for evaluations of educational modules that does not collect personal data and is used to enhance curriculum development;
- If it involves routine audit and evaluation, within the established management procedures of the organisation;

- If the data collected is to be used for evaluation of teaching methods already within University processes. E.g., figures for grades, attendance, module evaluation and engagement etc. for which students would not normally be approached to provide for further consent;
- If the data collected is for the development and evaluation of teaching materials that does not embody original research. [ef1:] https://arc-w.nihr.ac.uk/Wordpress/wp-content/uploads/2020/02/Full-guidelines-for-Best-Practice-in-the-Ethics-and-Governance-of-Service-Evaluation-Final02.pdf

Guidance on Welsh Language Standards for research activities

What are the Welsh Language Standards?

The Welsh Language (Wales) Measure 2011 established a legal framework to impose a duty on some organisations to comply with standards of conduct in respect of the Welsh language. **With effect from 1 April 2018, the** Welsh Language Standards **replace the University's Welsh Language Scheme**.

Students and members of the public have specific rights to use the Welsh language as they interact with the University.

The duties outlined within the Standards stipulate that organisations should not treat the Welsh language less favourably than the English language, and lay out requirements to promote and facilitate the use of the Welsh language (making it easier for people to use the language in their day-to-day-life).

The Welsh Language Commissioner has a statutory duty to monitor organisations' compliance with the Welsh Language Standards, and investigate complaints and breaches in compliance. It is within his power to impose enforcement action, county court judgements and fines.

While the Welsh Language Standards do not apply to research activities per se, the list of activities to which the Standards apply (see 'Scope of the Standards') can sometimes overlap with the output of research activities. Particularly, "information provided to students and prospective students about the body" could include research outputs in the form of websites, marketing material relating to student recruitment, social media and so on.

What is the advice for anyone undertaking research at the University?
It is difficult to provide definitive advice for anyone undertaking research in view of the complexity and range of possible scenarios. The University's Welsh Language Policy Officers are at hand to provide tailored advice on a case-by-case basis (see contact details below).
Their advice to you as a researcher will take into account the following:

- **Funding structure** - considerations will include whether the funder has requirements for anything to be undertaken bilingually as outlined in the funding agreement (e.g. Welsh Government). If bilingual content is required, the cost of translation must be factored into the project budget from the start, or a Welsh speaker be employed to work within the project team if the content is going to be ongoing/significant. If Swansea University is the main funder, use of the internal translation team may be possible free of charge. Otherwise, an external translator should be sourced and the costs should be split between the partners and ideally built into the project funding from the start.

- **Branding**- if Swansea University branding is prominent and we are not just listed as one of many partners, consideration must be given to the University's Welsh Language Standards. Unless the academic(s) are particularly prominent/ they're the lead academic(s), and if the activity doesn't fall within the scope of the Standards (see above), Swansea University does not need to provide translation (however it could contribute a proportion if the Welsh Language Standards apply and the partnership as a whole decides that they will translate some public-facing content e.g. web content, letters to participants etc).

- **Audience/Reach** - Is the research output of immediate interest to the public as opposed to other academics only (e.g. development of COVID-19 vaccine versus the intricacies of an engineering process)? If it is likely to be of interest to the general public, then Welsh language considerations will be more relevant.

- **Participants** - Will members of the public be called upon to participate in any study in writing? If so, depending on the other factors above, and in particular how prominently it appears to be Swansea University as an institution who is requesting their assistance, we are more likely to need to produce material bilingually. If we are asking for participation in a study, best practice suggests that participation rates may be higher if the material is available bilingually.

- **Events** – Any conferences and events with other academics, which are not open to the public, would generally not need to comply with the Standards in terms of the event itself. However, signage and general marketing of the event (but probably not abstracts etc.) should be bilingual. For events involving the general public, careful consideration will be given to the nature and content of the event in order to decide whether or not interpretation will need to be available for anyone attending who wishes to use the Welsh language as they contribute (interpreting will be into English so that other participants can understand spoken Welsh).

- **Press coverage** - press releases produced by the University must be produced bilingually. The press office at the University can advise further on this.

Frequently Asked Questions

We have started to compile a list of FAQs based on past queries. These will continue to develop, but should you have any examples you wish to add to the list, please let us know.

Contact details

The Welsh Language Policy Officers (Nia Besley and Emily Hammett), based in the University's Legal and Compliance team, are at hand to offer tailored guidance based on the above. Please contact welshlanguageoffice@swansea.ac.uk, giving as much information on the above points as possible.

Guidance for Staff & Students accessing security sensitive material online

Universities play a vital role in carrying out research which provides solutions to various issues, including those in the society. In order to undertake such research, accessing security sensitive material occasionally, is sometimes a requirement. There is a vast amount of security sensitive material which could be highly relevant to many kinds of perfectly legitimate academic research. If circulated carelessly, such material can be open to misinterpretation to the authorities and can put the author(s) in danger of arrest and prosecution under the counter-terrorism legislation. Prosecutions under counterterrorism legislation in the UK, have sometimes been brought on the basis of an accumulation, on personal computers, of downloaded material and other data. This happens due to police not being unable to distinguish between the accumulation of such material for legitimate research purposes, and the accumulation of material for terrorist purposes. Certain procedures for independently registering and storing security sensitive material, and its regulation through the research ethics processes is therefore an absolute necessity.

Researchers should not download any material that is security sensitive, and should not visit security sensitive websites, as such visits, may be interpreted by police as evidence of sympathy for, and perhaps even willingness to collude with, terrorism. Students who visit extremist sites out of curiosity, aside from research, could be interpreted as contravening counter terrorism legislation. It is acknowledged however that University researchers trying to carry out security sensitive projects which are highly attuned to the demands of counter terrorism, need, where possible, protection from intrusive and excessive oversight. This could be achieved by a legitimate oversight process within the Faculty/University which reveals people as researchers. An example of a legitimate research project would be, where a postgraduate research project involving terrorism related material is agreed by a Faculty Research Ethics & Governance Committee and the Head of Faculty/Director of Research, and the University Research Ethics & Governance Sub Committee has been made aware.

The general ethical justification for doing this is straightforward: unauthorised acquisition and use of security sensitive information can carry risks to the public, and the researchers can be suspected of obtaining and using it in ways that can be harmful, with costs to themselves and the Institution. For a student or member of academic staff to declare that they are using security sensitive information is in keeping with openness in research and helps reduce misidentification of information gathering as a suspect or criminal.

Besides requiring the declaration, itself, the University may provide secure storage of security sensitive material on a University server overseen by the University IT department, a Faculty Research Ethics Chair or a suitable counterpart. Central and secure storage, and a convention amongst researchers of not exchanging files for this store with others, would keep security sensitive material off personal computers and would shield the material from unjustified external scrutiny and misinterpretation.

Central and secure storage would involve researchers maintaining record of the material that they provide students and those records being made available for audits. Faculty Research Ethics Committee Chairs or Faculty/School Ethics officers or their counterparts overseeing the store would only know the document titles on the server and names of researchers. The

method would enable research material to be kept secure and perhaps away from legal jurisdiction. Home Office 'Prevent Duty guidance' for England and Wales states the following: *'Universities are expected to carry out a risk assessment for their institution which assesses where and how their students might be at risk of being drawn into terrorism. This includes not just violent extremism but also non-violent extremism, which can create an atmosphere conducive to terrorism and can popularise views which terrorists exploit'.*

Any institution that identifies a risk should develop a Prevent action plan to set out the actions they will take to mitigate this risk. Compliance with the duty will also require the institution to demonstrate that it is willing to undertake Prevent awareness training, and other training that could help the relevant staff prevent people from being drawn into terrorism and challenge extremist ideas which risk drawing people into terrorism.

Home Office expect appropriate members of staff to understand the factors that make people support terrorist ideologies or engage in terrorist-related activity. Such staff should have sufficient training to be able to recognise vulnerability to being drawn into terrorism and be aware of what action to take in response.

In terms of accessing security sensitive material, students and staff must comply with the:

- Prevent Duty guidance – Home Office guidance clarifies new legal duty on Institutions to help tackle radicalisation https://www.gov.uk/government/publications/prevent-duty-guidance/revised-prevent-duty-guidance-for-england-and-wales
- Terrorism Act 2006 – sections 2 and 3 of chapter 11 outlaws the dissemination of terrorism publications (which has a wide definition)
- University regulations and Policy. (e.g. Digital Technology Acceptable Use Policy) (https://www.swansea.ac.uk/media/Digital-Acceptable-Use-Policy-V1.0-October-2019.pdf)
- University Prevent Policy https://staff.swansea.ac.uk/media/Swansea-University-Prevent-Policy.pdf
- and consult the IT services web pages as per URL http://www.swansea.ac.uk/iss/mits/computer%20regs/

Discussing with Police and/or Security Services

South Wales Police are the Constabulary responsible for the Swansea area. They have dedicated Counter Terrorism Security Advisors (CTSAs) who are coordinated, trained, and tasked by National Counter Terrorism Security Office, a specialist police organisation co-located with the Security Service within the Centre for Protection of National Infrastructure. However, for non-urgent crime prevention advice, organisations can contact their local Crime Prevention Tactical Advisor as a starting point.

Anyone planning to undertake security sensitive research must contact one of the following individuals:

1. Director of Student Services (campuslife@swansea.ac.uk) or
2. University IT Risk & Security Manager or
3. University Research Integrity Manager (researchintegrity@swansea.ac.Uk)

To seek advice on:

- how best to safely protect the student if terrorists were able to contact him/her
- how to access information safely without contravening any laws.

Section 27

Guidance on Ethics Review

The purpose of a research ethics review is to protect the dignity, rights, safety and well-being of the participant(s), the researcher(s) and the reputation of the University. An ethics review confirms, amongst other things, that any research participants have provided informed consent to participate in the research, without inappropriate inducement, and are free to opt out at any time without redress.

Ethical practice in the management of such work requires a body that is independent of the research team to examine the research design. There are three important obligations placed on the ethics committee.

Firstly, and most importantly, the ethics committee must ensure that the rights of research participants are protected. This is achieved by ensuring that individuals receive sufficient information, which can be easily understood, and ensuring that appropriate strategies are in place to protect participants from potential adverse consequences of the research.

Secondly, the research ethics committees have an obligation to society which provides the resources for research and will ultimately be affected by the results.

Thirdly, the research ethics committees have an obligation to the researcher. The research proposal should be treated with respect and consideration. The research ethics committees should strive to meet each of these obligations.

It is therefore important that:

(a) the University and its Faculty Ethics Sub-Committees operate in accordance with ethical principles which are explicitly communicated.

(b) the University and its Faculty Ethics Sub-Committees operate in accordance with ethical practices which are followed.

(c) ethics reviewers understand their role and are guided by policies and regulations.

A robust ethics review:

- must be well-reasoned, structured, supportive, and balanced.
- must be consistent, coherent, and well-informed, so that the benefit of the research outweighs any associated risks.
- should provide appropriate positive feedback as well as any necessary constructive criticisms. Such an approach would allow researchers to improve the quality of the project. Ethics review and other supporting processes must make the facilitation of ethically sound research a priority. This will be evidenced by researchers viewing engagement with institutional research ethics processes as positive and valuable for all phases of their research.
- should be clear and defensible and only comment on methodology if it raises ethical issues of the research.
- must, in respect of its decisions and advice, be open to public scrutiny, and responsibilities must be recognised and discharged consistently. The reviews must always justify opinions, providing clear rationales.
- must acknowledge that some ground-breaking, highly innovative research may necessarily contain risks and/or could be considered intrusive and should suggest how it can be best accomplished.

- should be risk aware without being risk averse.

An ethics review should not:

- focus on matters of methodology and design unless they raise ethical issues such as exposing participants to avoidable risks and burdens.
- prevent sound research from taking place.
- be overly or inappropriately critical.
- provide legal or policy review. For example, matters such as lawful processing and storage of data should lie within the purview of research data governance.
- provide a proof-reading service; a review should comment on matters of language and layout only if participant documents are so badly constructed that they don't serve the purpose for which they are designed. Otherwise, the ethical review should avoid reference to matters of spelling, grammar, and syntax.
- check compliance with internal or external policy; this is a matter for research integrity and governance.

General principles of research ethics applications and reviews:

(Documents to consult: University Policy on Assessing Ethical Risks of Research & UKRIO Checklist for REC review panel)

1. Researchers are responsible for identifying potential ethics issues that may arise within a project and ensuring that it receives an appropriate level of ethical scrutiny.
2. A researcher should be guided by the standards set by their professional societies, disciplinary bodies, and the University research policies.
3. Research Ethics applications, submitted via the online system, should be considered in relation to the nature and context of the outlined research.
4. An ethics review must be proportionate to the potential risk or harm that the research imposes.
5. Risks should be balanced against benefits and, where possible minimised.
6. A light-touch review is justified in cases where there is a minimal risk of serious harm.
7. Research involving individuals or groups who come under the remit of the **Mental Capacity Act 2005** should be reviewed by the appropriate Research Ethics Committee (REC). Normally this will be a REC recognised by the Secretary of State and Welsh Ministers and operating under **Governance Arrangements for Research Ethics Committees (GAfREC)**.
8. Research conducted in Scotland should be reviewed by the **Scotland 'A' REC** which is operating under the **Adults with Incapacity (Scotland) Act 2000**.
9. Researchers should avoid duplication of an ethics review.
10. In collaborative research involving more than one organisation or multidisciplinary research, a single review process as agreed by the University should be used.
11. The principal investigator must ensure that participating organisations and collaborative researchers are satisfied that the research proposal has received adequate ethics review, and that regular monitoring of the conduct of the research takes place and is promptly reported to all organisations and researchers involved.
12. Research proposals involving human participants and personal data will require a full review by the appropriate research ethics committees (REC) that operate in accordance with the principles and guidelines set out in the University Research

Integrity Policy Framework. All data collection and analysis involving human participants or personal data should receive an ethics review before the research can commence.

13. The research ethics review must be conducted in a manner that is independent, competent, and timely. The ethics review should strive to notify researchers of their decision **within a month** of receiving a submission, and researchers and the research process should not be disadvantaged by RECs which are not sufficiently resourced to comply.
14. Ethics review timeframe **should not exceed 60 days maximum** unless there are circumstances beyond the control of the University.
15. Research Councils expect research on a funded project to commence within three months following the formal notification of funding to allow for recruitment of staff and ethics review. In the majority of cases research proposals should be submitted for an ethics review immediately after notification of funding, but it could also be prior to a pilot study so that participants' interests are protected, and prior to seeking the agreement of potential research sites and gatekeepers, so they can be assured of its good standing, or prior to the main data collection.

<u>The online ethics review system at Swansea University</u>

The online ethics review system introduced in 2022/23 is designed to facilitate ethics reviews by implicitly addressing all the above issues. The questions and guidance were developed by administrators and academics from across the institution, with the aim of accommodating to the greatest degree possible the cultures and conventions of all constituent Faculties and research areas while providing one unified system for assessing and recording research ethics applications from all researchers, staff and students of the University. Applicants and reviewers/assessors should refer to the templates and guidance provided as part of the system, under 'Help' and in the requisite information bubbles.

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Reviewing an approved application where the research has been led by another organisation.

All research led by a third party needs to go through a committee and is subject to review and an approval by a Chair.
The reviewer should have the approval letter from the lead organisation, the application, and the supporting documents.

The review is slightly different in that it is addresses the following 2 questions:

3. **Is the review process as rigorous as /equivalent to that of Swansea University?**
   No – go to 2
   Yes – recommend application approval
4. **Is there a significant risk of non-trivial harm or moderate or high reputational risk to Swansea?**
   No - recommend application approval
   Yes - recommend reject the application.

Once the review is complete and the reviewer is satisfied with the ethical review undertaken by the lead organisation, the reviewer will allocate a risk level.
The application will then be sent to the Chair/delegate chair to finalise the risk level and generate the approval /rejection letter.

The same approval/rejection letter will be provided to the applicant as for all applications.
If further information is required, the application would be sent back to the applicant to supply clarification of minor points by using the general comments box on the application.
If the application is deemed to be unacceptable, the risk will be accessed by the reviewer and a timeline note added to reject the application.
The chair will comment on the application in general comments, finalise the risk, and reject the application.

Section 28

Security Sensitive Research Policy

(Separate document: - Available on request).

Section 29

UK Research & Integrity Office Recommended Checklist for Researchers

The Checklist lists the key points of good practice in research for a research project and is applicable to all subject areas. A PDF version is available from www.ukrio.org

(Before conducting your research, and bearing in mind that, subject to legal and ethical. Requirements roles and contributions may change during the time span of the research):

1. Does the proposed research address pertinent question(s) and is it designed either to add to existing knowledge about the subject in question or to develop methods for research into it?

2. Is your research design appropriate for the question(s) being asked?

3. Will you have access to all necessary skills and resources to conduct the research?

4. Have you conducted a risk assessment to determine:

- Whether there are any ethical issues and whether ethics review is required;
- The potential for risks to the organisation, the research, or the health, safety and well-being of researchers and research participants; and
- What legal requirements govern the research?

5. Will your research comply with all legal and ethical requirements and other applicable guidelines, including those from other organisations and/or countries if relevant?

6. Will your research comply with all requirements of legislation and good practice relating to health and safety?

7. Has your research undergone any necessary ethics review (see 4 above), especially if it involves animals, human participants, human material, or personal data?

8. Will your research comply with any monitoring and audit requirements?

9. Are you in compliance with any contracts and financial guidelines relating to the project?

10. Have you reached an agreement relating to intellectual property, publication, and authorship?

11. Have you reached an agreement relating to collaborative working, if applicable?

12. Have you agreed the roles of researchers and responsibilities for management and supervision?

m. Have all conflicts of interest relating to your research been identified, declared, and addressed?

14 Are you aware of the guidance from all applicable organisations on misconduct in research?

When conducting your research:

- Are you following the agreed research design for the project?
- Have any changes to the agreed research design been reviewed and approved if applicable?
- Are you following best practice for the collection, storage, and management of data?
- Are agreed roles and responsibilities for management and supervision being fulfilled?
- Is your research complying with any monitoring and audit requirements?

When finishing your research:

- Will your research and its findings be reported accurately, honestly and within a reasonable timeframe?
- Will all contributions to the research be acknowledged?
- Are agreements relating to intellectual property, publication and authorship being complied with?
- Will research data be retained in a secure and accessible form and for the required duration?
- Will your research comply with all legal, ethical, and contractual requirements?

Appendix 1

Acknowledgements:

Swansea University would like to gratefully acknowledge consulting and adopting policies and guidelines in the development of this Framework on work undertaken by other Institutions, including:

1. **University of Aberdeen**
2. **University of Bristol**
3. **Cardiff University**
4. **City University London**
5. **University of Oxford**
6. **University of London**
7. **University of Manchester**
8. **University of Nottingham**
9. **Northumbria University**
10. **University of Sheffield**
11. **Queen's Belfast University**
12. **Canterbury Christ Church University**
13. **School of Oriental & African Studies**

14. **UK Research Integrity Office** (www.ukrio.org)
Code of Practice for Research: Promoting good practice and preventing misconduct
http://www.ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf

15. **Procedure for the Investigation of misconduct in Research**
http://www.ukrio.org/what-we-do/procedure-for-the-investigation-of-misconductin -research/

16. **Singapore Statement on Research Integrity**
Singapore Statement on Research Integrity
http://www.singaporestatement.org/

17. **European Science Foundation** (www.esf.org)
European Code of Conduct for Research Integrity
The European Code of Conduct for Research Integrity - ALLEA

18. **Government Office for Science** (www.bis.gov.uk/go-science)
Rigour, Respect, Responsibility: a Universal Ethical Code for Scientists
http://www.bis.gov.uk/assets/goscience/docs/u/universal-ethical-code-scientists.pdf

19. **UK Research & Innovation**
Research integrity – UKRI

APPENDIX 2

Useful resources:

For more detailed guidance the following links provide useful information.

- The World medical Association's Declaration of Helsinki https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/
- The National Research Ethics Service (NRES) http://www.hscbusiness.hscni.net/services/1983.htm
- NHS Health Research Authority (HRA) http://www.hra.nhs.uk
- The medicines and Healthcare Products Regulatory Agency (mHRA)

  https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- UK Research & Innovation Policy and Guidelines on Governance of Good Research https://www.ukri.org/about-us/policies-and-standards/research-integrity/
- The Human Tissue Act 2004

  http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1
- Safeguarding Vulnerable Groups Act 2006 http://www.opsi.gov.uk/acts/acts2006/ukpga_20060047_en_1
- The medicines for Human Use (Clinical Trials) Regulations 2004 http://opsi.gov.uk/si/si2004/20041031.htm
- Universities UK Concordat to Support Research Integrity https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2019/the-concordat-to-support-research-integrity.pdf
- Framework for Research Ethics (FRE) https://esrc.ukri.org/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/
- The British Psychological Society www.bps.org.uk
- The British Sociological Association http://www.britsoc.co.uk
- The General medical Council (Research Guidance) https://www.gmc-uk.org/-/media/documents/good-practice-in-research-and-consent-to-research_pdf-58834843.pdf
- Nursing & midwifery Council www.nmc-uk.org search under 'Research and audit'
- An overview of the Freedom of information Act can be found here: http://www.shef.ac.uk/polopoly_fs/1.119826!/file/FOIOverview.pdf
- For guidelines regarding publication ethics: https://authorservices.wiley.com/ethics-guidelines/index.html
- UK Research Integrity Office http://www.ukrio.org/

- Integrated research application system IRAS - single system for applying for the permissions and approvals for health and social care / community care research in the UK https://www.myresearchproject.org.uk/
- UK Clinical Research Collaboration (UKCRC) http://www.ukcrc.org/regulation-governance/
- National Institute for Health and Social Care Research (NISCHR) ethics and governance sections of the website at http://www.wales.nhs.uk/sites3/page.cfm?orgid=952&pid=57178
- Committee on Publication Ethics (COPE) http://publicationethics.org/resources/code-conduct
- Counter terrorism Advisors, South Wales Police
- Search | South Wales Police (south-wales.police.uk)
- Oversight of security-sensitive research material in UK universities: guidance, Universities UK. https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2019/Oversight-security-sensitive-research-material-guidance-3.pdf
- Centre for Protection of National Infrastructure

APPENDIX 3

Glossary of Key Terms

The following is largely drawn from the ESRC's Framework for Research Ethics.

Assent: Agreement from an individual not able to provide free and informed consent to take part in research.

Authorship: According to the Committee on Publication Ethics (COPE), Authorship refers to the creator or originator of an idea or the individual or individuals who develop and bring to fruition the product that disseminates intellectual or creative work. Authorship conveys significant privileges, responsibilities, and legal rights; in the scholarly arena, it also forms the basis for rewards and career advancement. At a minimum, authors should guarantee that they have done the work as presented and that they have not violated any other author's legal rights (e.g. copyright) in the process.

Biobank: (research tissue bank) (http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-tissue-banks-biobanks/): A collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project.

Broad consent: has been seen as essential to facilitating biobank research. Participants are asked to consent to the use of samples and data within a biobank, at the time of collection rather than to a specific project or types of research. Broad consent means consenting to a framework for future research of certain types. Included in this framework is ethics review of each specific research project by an independent ethics committee as well as strategies to regularly update the biobank donor and ongoing withdrawal opportunities. If anything in the framework changes, the participant should re-consent.

Coercion: For consent to participate in research to be ethically sound any possibility that the consent is the result of coercion must be excluded. The presence of coercion invalidates the consent of the participant.

Confidentiality: Normally, information gathered about a research participant should be protected, for example by anonymisation or other strategies that obstruct the identification of participants. Information about participants that is kept either electronically or in hard copy should be stored securely and protected prior to its disposal. Participants should be made aware of the limits of these protective strategies in keeping with the terms of the Data Protection Act (1998) and the Freedom of Information Act (2000).

Conflict of Interest: A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgement and objectivity. Conflict of interest may involve individuals as well as institutions and is broadly divided into two categories: **intangible** – those involving academic activities and scholarships; and **tangible** – those involving financial relationships.

Controlled data: are data which may be identifiable and thus potentially disclosive but to which access may be granted to users who have been accredited and their data usage has been approved by a relevant Data Access Committee. Data service providers may provide details of their policies regarding access to controlled data, for example the UK Data Service (http://ukdataservice.ac.uk/get-data/data-access-policy/controlled-data.aspx).

Cultural sensitivity: Diversity enriches and strengthens the research culture and performance of any organisation. Diversity means that research may differ widely from one context to another. Thus the ethical issues relating to human participation in research may also differ considerably from one academic discipline to another. This therefore suggests that formal ethical review of research proposals involving human participants, personal data or human tissue is probably most effectively carried out within subject areas, according to the parameters provided by the Institutional Framework.

Data Custodian (Data Controller): is a person who determines the purposes for which and manner in which any personal data are to be processed in line with the Data Protection Act (https://ico.org.uk//for-organisations/guide-to-data-protection/).

Data Depositor/Data Producer: A data depositor/data producer is an individual or organisation who is named on a license as having sufficient responsibility to grant particular rights on behalf of a data collection. The depositor/producer may be the principal investigator, creator, or the copyright owner of a data collection, but does not have to be.

Deception: Deception runs counter to informed consent and deprives the participant of information that would allow them to make decisions affecting their participation under conditions of reasonable understanding of the research context, aims, and scope. It is normally unacceptable in research conduct. The use of placebo, however, in randomised controlled trials is not typically thought of as deceptive, even though the participant may not know whether they are being subjected to interventions or not. There may on occasion be good reasons to withhold reasonably full information to the participant, but these must be specified prior to approval, making clear why the knowledge gained is valuable and why it may only be generated under conditions of partial (e.g., misleading information, incomplete information, partially true information) or full deception. Where deceptive methods are approved, debrief is thought to be important to retain trust in the research community.

Dignity & Respect: Researchers should not design research that threatens the dignity of the research participant and should avoid methods that may embarrass or compromise the dignity of the participant. One way of failing to respect the dignity of a participant is by using them simply as a means to one's own ends (goals) as a researcher. Typically, the researcher has more to gain from the research than the research participant. Debrief and feedback to participants is thought to be a clear token of respect. Research involving animals, the environment, and cultural objects should be undertaken with due care and respect.

Enduring consent: This is where there is no time limit on consent given unless consent is withdrawn. Human participants do not need to be re-contacted should any of their personal data be reused for further research. Securing enduring consent may be essential in

longitudinal studies. It may also be important for data for which access is provided by the UK Data Service. Principles of preserving confidentiality apply.

Ethics protocols: The use of approved protocols for commonly occurring situations such as research with normally developing children in schools. These can expedite ethics review as principal investigators can confirm in a light-touch review to their REC that there is an approved protocol that appropriately covers the ethics issues raise by their research. It will be the responsibility of the Faculty REC to approve the suggested protocol for the work.

Excellence: Excellence in research is work that demonstrates originality and has an observable impact on the subject. Researchers must strive for excellence when conducting research and seek to produce and disseminate work of international (or, where appropriate, national) quality.

Expedited review: In exceptional circumstances, it may be necessary for a proposal involving possible risk of harm to receive a full review at short notice. An expedited review is carried out by one or more members of a Research Ethics Committee (REC), commonly its chair, and not by a member of the department due to carry out the research.

Freely given informed consent: Informed consent entails giving sufficient information about the research and ensuring that there is no explicit or implicit coercion so that prospective participants can make an informed and free decision on their possible involvement. Typically, the information should be provided in written form, time should be allowed for the participants to consider their choices and the forms should be signed off by the research participants to indicate consent. Where participants are not literate, verbal consent may be obtained but this should wherever possible be witnessed and recorded. In other circumstances, for example telephone interviews, written or witnessed consent may not be possible, but verbal consent should be secured. Where consent is not to be secured, a full statement justifying this should be submitted to the REC for review. In longitudinal research it may be necessary to explain the need for (and limitations of) enduring consent. The primary objective is to conduct research openly and without deception. Deception (i.e., when participants are intentionally not fully informed or are misinformed about the purpose of the research for methodological reasons) should only be used as a last resort when no other approach is possible. Any research involving deception should be submitted to the REC for review. This principle also requires that research staff need to be made fully aware of the proposed research and its potential risks to them.

Human participants: Human participants are defined as including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and foetuses, human tissue and bodily fluids, and human data and records (such as, but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements).

Informed consent: Normally, the informed consent of the research participant is a requirement of ethically sound research. The participant should be informed of the nature and duration of the research in clear terms and given sufficient time to decide whether or not

to take part. Also, the participant should be made aware that they can opt not to continue to participate in the research at any time (or at least up to the point of anonymisation of data) without fear of duress or penalty. Some inducements may be thought to compromise informed consent, undermining the voluntariness of the consent. A failure to express the aims, methods, and scope of the research to the participant may also undermine the possibility of informed consent.

Integrity: Research integrity refers to the active adherence by researchers and research organisations of the ethical principles and professional and legislative standards essential for the responsible practice of research. Researchers should present their work accurately, respect the principles described in the Framework, make known any conflicts of interest, and respect recognised criteria for authorship.

Lay member (of a REC): This person should have no affiliation to the research organisation apart from membership of the REC and may provide the perspective of the research participant to the REC.

Light-touch review: Light-touch reviews identify those projects where the potential for risk of harm to participants and others affected by the proposed research is minimal. In many cases this is the only ethics review necessary. An ethics checklist should be completed. RECs need to confirm that only a light-touch review is justified.

Nonmaleficence: Participation in research should not normally harm the participant or compromise their interests.

Personal data: Under the Data Protection Act 1998 'personal data' is defined as data which relates to a living individual who can be identified a) from those data or, b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual. Under this act, personal data consists of information as to (a) the racial or ethnic origin of the data subject, (b) his/her political opinions, (c) his/her religious beliefs or other beliefs of a similar nature, (d) whether he/she is a member of a trade union (within the meaning of the [1992 c. 52.] Trade Union and Labour Relations (Consolidation) Act 1992), (e) his/her physical or mental health or condition, (f) his/her sexual life, (g) the commission or alleged commission by him/her of any offence, or (h) any proceedings for any offence committed or alleged to have been committed by him/her, the disposal of such proceedings or the sentence of any court in such proceedings.

Privacy: Research methods should not normally violate the privacy of participants. Researchers should be sensitive to contexts where people might reasonably expect to have their behaviour observed, or not, and recorded for research purposes.

Research Ethics Committee: A Research Ethics Committee (REC) is charged with reviewing research for ethical approval. The independence of a REC is founded on its membership, on

strict rules regarding conflict of interests, and on regular monitoring of and accountability for its decisions.

Research ethics: Research ethics refers to the moral principles guiding research, from its inception through to completion and publication of results and beyond – for example, the curation of data and physical samples, knowledge exchange and impact activities after the research has been published.

Research project lifecycle includes the planning stage, the period of funding for the project and all activities that relate to the project once funding has ended. The research lifecycle also includes knowledge exchange and impact realisation activities, the dissemination process and the archiving, future use, sharing and linking of data.

Research: Research is defined as any form of disciplined inquiry that aims to contribute to a body of knowledge or theory.

Responsibility for the ethical conduct of research, including its presentation and publication, lies with the researcher. The researcher should consider their project design against standard ethical guidelines for the conduct of research (see below for links to relevant documents), as well as the regulations in this Framework document.

Results & methods: Research is ethically justified to the extent that the aims and the methods employed are ethically sound. So even if a research project could generate results which might benefit thousands of people, if the methods proposed to generate those results were not ethically sound, the research would only be approved under exceptional circumstances.

Student research: Normally, the aim of research is the generation of new knowledge. But in student-level research part of the value of the research process lies in its educative value, in training new generations of researchers. Thus, the generation of new knowledge is not a strict requirement for ethical approval of student research. It should be stressed, however, that the same ethical principles that constrain research generally also apply to student research.

Transparency in research ethics: The full, accurate, and open disclosure of relevant information is always important. Where the research involves new and innovative methodologies which raise distinctive considerations (e.g., online research), this is especially important.

Trusted Research: Trusted Research aims to support the integrity of the system of international research collaboration, which is vital to the continued success of the UK's research and innovation sector. It is particularly relevant to researchers in STEM subjects, dual-use technologies, emerging technologies, and commercially sensitive research areas.

Valid consent: Consent is valid if it meets three conditions: participant has capacity to decide; the process is free from coercion; and the consent is informed. For consent to be 'valid' the participant must be capable of understanding all the potential risks involved. Where this may be in doubt, the mental Capacity Act 2005, and Adults with Incapacity (Scotland) Act 2000 may apply.

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Accessible Participant Information Sheet

*Please read the following information carefully***.**

You are being invited to take part in some research.

Before you decide whether to join in, it is important for you to understand why the research is being conducted and what it will involve.

What is the aim of the research?

……

We want to interview people who …….

The interview could last about ……

You will need to read and sign the consent form and send this to …… by email, by post or online.

We will then get in touch with you to find a time that suits you to have an interview, which will probably be online using Zoom or Microsoft Teams.

We can provide and pay for an English interpreter if we need one for the interview.

Who is doing the research?

Add photo of researcher

The researcher is ……

The project has a steering group made up of …….

The research has been approved by the Research Ethics Committee, ……., Swansea University and funded by …… (add website)

What happens if I take part?

If you take part, we would like to interview you about your experiences of ……..

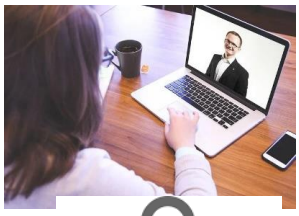
The interview will be led by you. We want to know about your experiences.

The information you share will be kept confidential.

We will make a recording of our discussion so that I can make sure that I have a good record of what we have talked about. The recording will be audio and visual.

We will ask you for some background information, so we can describe in general the people who took part.

We can do this research interview using an internet video programme called Zoom. We can send you details.



The findings from the project will be shared, but the information from the interviews will be anonymous meaning you will not be recognised.

To take part <u>you</u> must be over the age of 18.
and be happy to talk about your experiences of …….
If you want more support, we can make suggestions and give contact details about people who can help

Are there any risks associated with taking part?

There are no major risks with taking part. But sometimes when people talk about difficult times they might get upset. If this happens, we can stop the interview and we can contact someone you know on your behalf to support you.

Data Protection and Confidentiality

Your data will be kept safe and confidential, as long as your safety or others' safety is not involved. Your data will only be viewed by the researcher, with anonymous parts to the supervisor and project steering group.

If malpractice, harm, or unprofessional behaviour were raised, confidentiality may need to be broken.

All electronic data will be stored on a password-protected computer file with Swansea University. All paper records will be stored in a locked filing cabinet in Swansea University.

What will happen to the information I provide?

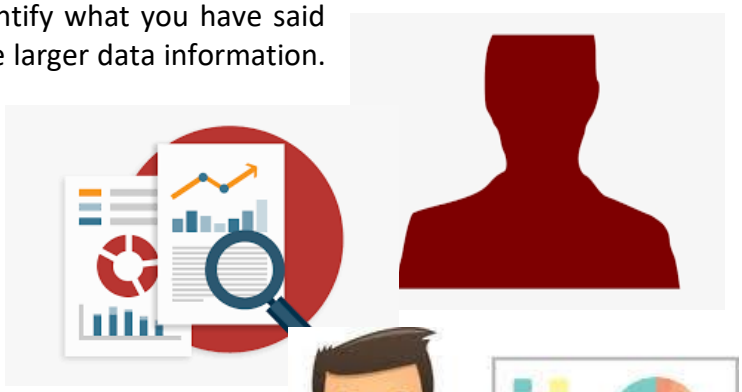
The information from the project will stay anonymous. This means that any names or places that people say will not be present in reports. What you say will be anonymous.

Findings and recommendations will be made into a final report and an easy-to-read summary that can be shared with people, as well as a short film.

Do I have to take part? And what if I change my mind?

Only take part if you want to. If you want to take part, and then later change your mind, that's okay, and we can stop the interview. If you decide not to take part, you do not have to give a reason. Taking part, or not taking part will not affect the services you receive. If you are interviewed, but decide to withdraw, you need to email us within two weeks of the interview date, so we can remove your data.

After the interview it will be difficult to identify what you have said because it will be anonymous and part of the larger data information. It will be hard to take out what you've said later on.



Data Protection Privacy

The data controller for this project will be Swansea University. The University Data Protection Officer looks at all university activities that include data and can be contacted at the university. Your personal data will only be used for the reasons given in this information sheet.

Data will be kept safe for a minimum of 10 years after the project finishes.

What are your rights?
You can stop being part of this study at any time. We will keep information about you that we already have. We will manage records carefully, so the research is reliable.

You can find out more about how your information is used by emailing:
……

What if I have other questions?
If you have further questions about this study, please do not hesitate to contact me:

Work address ……..
Email ……

How to make a complaint
If you are unhappy you can complain:

1. Data - GDPR IOC contact details dataprotection@swansea.ac.uk.
2. Research Integrity

   researchintegrity@swansea.ac.uk