Human Tissue in Research

HTA-CORE-SOP - Consent

1. Purpose

This standard operating procedure (SOP) aims to ensure that all individuals working with human tissue understand the requirements and procedures under the Human Tissue Act 2004 (HT Act) for obtaining consent for the storage of relevant material for the scheduled purpose of research.

2. Scope

This SOP forms part of Swansea University's Quality Management System (QMS) for the governance of the acquisition, storage, use and disposal of human tissue in line with the requirements of the HT Act and the standards set out by the Human Tissue Authority (HTA).

This SOP applies to all Swansea University (SU) staff and students involved in research projects intending to use human tissue considered relevant material under the HT Act. However, it can be applied to any type of human tissue sample, including material that is not considered relevant under the HT Act such as human DNA and RNA, acellular human biological fluids and human-derived cell lines.

Consent is a fundamental principle of the HT Act and relates to informing the donor or appropriate alternative of the purposes for which human material might be removed, stored or used. These purposes are set out in Schedule 1 of the HT Act and are called 'scheduled purposes'. The issues of consent that are central to the consent provisions of the HT Act are:

- Whether consent is required.
- Appropriate consent.
- Valid consent.
- Scope of consent.
- Duration of consent.
- Withdrawal of consent.

Broadly, the HT Act and HTA codes of practice stipulate that consent is legally required to undertake the following:

- Store and use dead bodies.
- Remove, store and use relevant material from a dead body.
- Store and use relevant material from the living.

Any individuals involved in seeking and receiving consent for the use of human tissue for research purposes must undertake appropriate training to do so. E.g. Good Clinical Practice training. Refer to Core HTA-SOP-Human Tissue Training.

Individuals involved in the removal, storage or use of human tissue under circumstances in which the HT Act requires consent must be satisfied that consent is in place and have full knowledge and understanding of the research including possible future use of the tissue. All individuals should be aware of the risks associated with the collection and use of the material for research.

3. Roles and Responsibilities

All SU staff and students who collect, use or store human tissue for the purpose of research have a responsibility to read and follow this SOP.

It is the responsibility of the Designated Individual (DI) to ensure that consent procedures and practices are appropriate, implemented and adhered to. The DI holds the responsibility of ensuring that those involved in human tissue research under a HTA licence are trained and that the conditions of the licence in relation to research are complied with.

The HTA Governance Officer (HTGO) is responsible for ensuring that the SOP remains fit for purpose.

4. Principles of Consent

4.1 Consent Requirements

The HT Act makes consent an underpinning principle for research. The HTA Code of Practice on consent sets out the requirements for seeking consent for the use of tissue from the living and deceased. Different consent requirements apply when seeking and obtaining consent for the use and storage of tissue from the living and tissue from the deceased.

Under the HT Act, consent is always required for the removal, use and storage of material from the deceased for ‘research in connection with disorders, or the functioning, of the human body’. The consent given must be appropriate and valid.

Consent exemptions exist for the use and storage of human tissue from the living in some circumstances. All SU researchers should be aware of additional legal requirements such as the data protection legislation and the common law duty of confidentiality.

4.2 Appropriate Consent

The HT Act defines appropriate consent in terms of the person who may give consent. This is either the person concerned i.e. the donor, their nominated representative (if

available) or a person in a 'qualifying relationship' with the donor immediately before they die. More information is provided in section 4.11.

4.3 Valid Consent

The giving of consent is a positive act. For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to agree to the activity in question. In research, this means that for the consent to be valid in the context of the HT Act, the person must understand the activity, what it involves and the potential associated risks.

Consent is only considered valid if proper communication has taken place. Consideration should be given to the needs of individuals and families whose first language is not English. Records should be kept of any communication difficulties encountered and how they were overcome (e.g. use of translator, pictorial representations). Individuals seeking consent should be experienced and trained and ensure that the consent obtained is appropriate for the intended purpose and scope of use.

If identifiable tissue (tissue linked to the donor) is to be used, the donor should be informed of any implications this might have (e.g. future contact by researchers, feedback). Within the consent process, donors should be asked to specify whether their consent is generic (i.e. for use in any future project) or specific to the individual study. If consent is specific, the donor should be informed of detailed information about the specific study.

The HTA encourages the seeking of informed and generic consent at the study's outset as the preferred position to facilitate the use of samples for different ethically approved research projects. If the intention is to store the tissue for as yet unspecified research or as part of a research tissue bank, this should be explained, setting out the types of research that it may be used for, as well as any wider or sensitive implications (e.g. genetic testing, animal research, commercial research, overseas research).

Researchers should consider how tissues will be handled should a participant lose mental capacity during a study.

4.4 Scope of Consent

Under the HT Act the scope of consent may be specific or generic. Specific consent imposes limitations on the use of the tissue for research. Generic consent typically only applies to research and involves obtaining consent to a broad remit of research allowing the tissues to be used for more than one research project. It is considered good practice by the HTA to obtain generic consent to avoid the necessity to obtain further consent in the future. Consent must still be valid whether specific or generic.

4.5 Duration of Consent

Consent may be enduring or time-limited. Enduring consent remains in force unless consent is withdrawn. A person may prefer to specify a time limit for the period they wish their consent to remain in force. Whether the consent is time-limited or enduring, the decision should be clearly documented in the donor's consent records.

4.6 Withdrawal of Consent

Consent may be withdrawn by an individual at any time, whether it is specific or generic.

Withdrawal of consent should be discussed at the point when consent is sought. The practicalities and implications of withdrawing consent should be discussed with research participants at the outset. Those giving consent should be informed of the limitations of withdrawing consent if samples have already been used.

Individuals giving consent for more than one scheduled purpose (e.g. Research, public display or anatomical examination) may withdraw consent for one of the multiple scheduled purposes at any time. In this situation, only the samples stored for the scheduled purpose they have been withdrawn from would need to be disposed of.

In addition, individuals giving consent can also withdraw their consent for future research projects but this does not mean that information or data should be removed from existing projects where consent remains.

Individuals approached for consent should feel at liberty to decline, this decision should be respected and the refusal to participate documented in the patient notes, laboratory records or both as appropriate.

4.7 Consent Exemptions

The HTA has stipulated exceptions to the requirement to seek consent for the use of human tissue for the scheduled purpose of research. However, the HTA Code of Practice on consent advocates the seeking of consent in all research as good practice.

In circumstances where relevant material is exempt from the consent provisions of the HT Act, it must still be stored on HTA-licensed premises when retained for unspecified future research.

4.7.1 Existing Holdings

It is not legally necessary to obtain consent to store or use an existing holding for research. An existing holding is defined as material from the living or deceased that was already held at the time the HT Act came into force on September 1st 2006.

Existing holdings should not be used freely and without regard to issues of consent or other ethical considerations. Where practical, the consent of the participant should be obtained retrospectively and where the wishes of the deceased or their relatives exist, these should be observed and respected.

Consideration should be given to:

- whether obtaining retrospective consent would cause undue distress.
- whether alternative tissues can be used for the research in question.
- whether the benefits of the research outweigh any potential harm to the donors of the samples.

4.7.2 Samples over 100-year-old

If more than 100 years have elapsed since the date of death, consent to undertake research is not required under the HT Act.

4.7.3 Imported Material

Consent for the use of imported material is not required under the HT Act. However, the HTA consider it good practice to implement mechanisms to provide assurance that the tissue has been obtained with valid consent. Imported samples are not exempt from HTA licensing requirements for storage or from the requirement to obtain ethical approval for their use in research. Human tissue must not be exported with the intention of re-importing as a mechanism of avoiding the requirement for consent.

4.7.4 HRA REC Approved and Anonymised Samples from the Living

Relevant material and DNA can be used for research without consent where all of the following apply:

- when collected, the material came from a living person.
- the material is anonymised.
- the material is used for a specific research project approved by an HRA REC or a Committee recognized by the UK Ethics Committee Authority.

***NOTE**: Review by University Ethics Committees does not constitute a recognised review committee under this exception. Approval must be obtained from an HRA Research Ethics Committee (REC).*

Anonymisation means that the donor is unidentifiable to the researcher. This may be achieved by a robust coding system where samples are uniquely identified. The links between donor information and tissue should be kept securely and under appropriate guardianship.

This exemption would apply if a clinician has access to an identifiable database of patient material which they utilise to support a research study, by collecting tissue samples from specific patients to transfer to a researcher. The HTA considers the tissue to be anonymised, providing the donor of the tissue is unidentifiable to the researcher and the researcher does not seek to link the patient to the sample. In this circumstance, where the research has been approved by a recognized REC the consent exception can apply.

4.8 DNA Theft

Consent is required for the storage of DNA and use of the results of DNA analysis in research unless an exemption applies (material is from the living, anonymised and approved by an HRA REC).

An offence will be committed where bodily material (including gametes and hair and nails from the deceased) is held with the intention to analyse DNA for research without consent for non-excepted purposes.

4.9 Seeking Consent and Consent Training

Under the HT Act, any individual seeking consent for the removal, storage or use of relevant material for a scheduled purpose must be trained in the process of obtaining consent.

Researchers collecting human material should also be trained in Good Clinical Practice (GCP) and those dealing with friends or relatives of the deceased should have bereavement training. Training on obtaining consent is covered in the GCP training course provided by the National Institute for Health and Care Research (NIHR). Completion of this course is sufficient evidence of receipt of training. A record of attendance should be maintained by the individual and the research project's principal investigator. Training records for obtaining consent should be available for internal audit by the DI, HTGO and PDs, as well as for external inspection by the HTA.

In an NHS setting, it is the clinician's responsibility to seek consent from a person, a person with parental responsibility or a relative. The clinician may delegate this task to someone else, usually another healthcare professional, as long as that person is suitably trained and qualified. In particular, they must know enough about the proposed treatment, the intended use of the tissue and the risks involved to adequately brief the person.

Seeking and obtaining consent is a sensitive issue, therefore, researchers and clinicians involved in obtaining consent should be trained in the process. They should be aware of the procedures involved in the proposed research and should be appraised of, and able to discuss, the possible risks and benefits to participants. Sufficient time should be allowed for potential participants to ask questions and engage in discussion if they wish to. The input of friends and family members should be encouraged if appropriate.

Consent is required under the HT Act but it is also a legal requirement under the common law (and the Mental Capacity Act 2005).

Local SOPs should be in place to detail the responsibilities of all those involved in seeking valid consent. Established procedures should be subject to periodic review to ensure they meet the HTA Code of Practice A on consent.

Template Patient Information Sheet (PIS) and Consent forms are available from SU's Research Governance webpage under Documents and Templates for adaptation in specific research projects.

4.10 Records of Consent

Researchers who are not directly involved in seeking consent must satisfy themselves that consent has been obtained. This may be evidenced by a letter or alternative documentation from the clinician, tissue bank or relevant organization supplying the tissues and responsible for obtaining consent.

Storage of consent records must be appropriate to the requirements for confidentiality, data protection and security. Records of consent should be kept onsite where possible, these would include:

- signed consent form.
- associated information sheet.
- records of consent training.

If consent records are stored at a location remote from the tissue, details of a named contact at the establishment, a blank consent form and an information sheet must be held with the tissue records.

If the material is imported, assurance of valid consent and evidence of appropriate ethical review from the source location must be in place. These may be set out in a material transfer agreement (MTA).

Record keeping and document disposal should be undertaken following SU's HTA-CORE-SOP-Management of Records.

4.11 Who can give consent for the storage and use of relevant material?

Consent can be provided by the donor or a nominated representative.

4.11.1 Human Samples from the Living

a) Competent adults

If an adult is competent i.e. has the capacity to make a decision, only they are permitted to give consent.

b) Adults lacking capacity

Guidance on research involving participants who lack capacity can be found in the Mental Capacity Act 2005 (MC Act) Code of Practice.

Researchers are legally required to have regard to the MC Act Code of Practice when carrying out research approved in accordance with the act. Researchers should assume a person has capacity unless there is proof that they lack the capacity to make a specific decision. An individual whose capacity is in question has the right to make decisions that may be considered unwise and has the right to refuse to participate in research.

Under the MC Act, a person aged 16 or over is unable to make a decision if they are unable to demonstrate that they can:

- Understand the information given to them, relevant to the decision.
- Retain that information long enough to make the decision.
- Use or weigh up the information as part of the decision-making process.
- Communicate their decision by any means.

Where there is doubt about whether an adult has the capacity to provide consent, they should receive help and support to make their own decisions before the conclusion that they cannot do so is reached. Some people may require help to communicate a decision, this does not necessarily mean that they lack the capacity to do so. Anybody who claims that an individual lacks capacity should be able to provide proof. Researchers seeking consent from patients whose capacity is in question must be aware of their own limits of practice and seek opinion and advice elsewhere as necessary.

Exemptions to consent stated in section 4.7.4 of this SOP where tissue is from the living, anonymised and used in ethically approved research (by a recognized committee) apply to adults with and without capacity. Research involving anonymised data is also exempt from consent for persons lacking capacity. Exemptions for research involving human tissue considered to be an existing holding applies to the use of material from individuals lacking capacity.

Researchers and recognized RECs both carry a responsibility for compliance with the MC Act's requirements. REC in this regard refers to HRA RECs or a Committee recognized by the UK Ethics Committee Authority.

Research covered by the MC Act involving people who lack capacity to consent can only proceed where it has the approval of a HRA REC or a Committee recognized by the UK Ethics Committee Authority.

Where lack of capacity is temporary such as where the person is unconscious, full consent must be sought as soon as capacity is regained.

c) **Children:** The HT Act defines children as being under 18 years old. Children may consent to the use and storage of their tissue if they are deemed to have sufficient intelligence and understanding to enable them to fully comprehend what is involved. Consent to a procedure by a child carries over into adulthood unless they withdraw it.

4.11.2 Human Samples from the Deceased

a) **Adults:** Where a living adult has given valid consent before death for any particular removal, storage or use of their body or tissue for research to take place after their death; that consent is sufficient to legally allow the activity to proceed. Should individuals who are close to the deceased at the time of death object to the consented activity, the matter should be discussed sensitively with them but they should be encouraged to accept the donor's wishes. It should be made clear that they do not have a legal right to veto the wishes of the deceased. Where conflict exists, all parties should be engaged in sensitive discussion and the impact of going ahead despite the strong feelings of individuals close to the deceased should be considered.

b) **Nominated Representatives:** An individual may, before death, nominate a person to make decisions regarding the removal storage or use of their body or tissues for research. If a deceased adult has not given consent or specific refusal before death, the individuals close to that person should be asked whether a nominated person was appointed to make those decisions. The nomination of such a representative can be made, and revoked, in writing or orally as set out in the HT Act. The decision of a nominated representative cannot be overruled by other individuals including family members.
   A nominated representative may not make decisions regarding anatomical examination or public display of relevant material.

c) **Qualifying Relationships:** If the deceased has not indicated consent or refusal for the use or storage of their tissue for research, and a nominated individual has not been appointed or is unavailable or unable to make a decision, then the appropriate consent may be given by someone who was in a qualifying relationship immediately before death.
   The qualifying relationship hierarchy (highest first) is defined in the HT Act, refer to Figure 1.

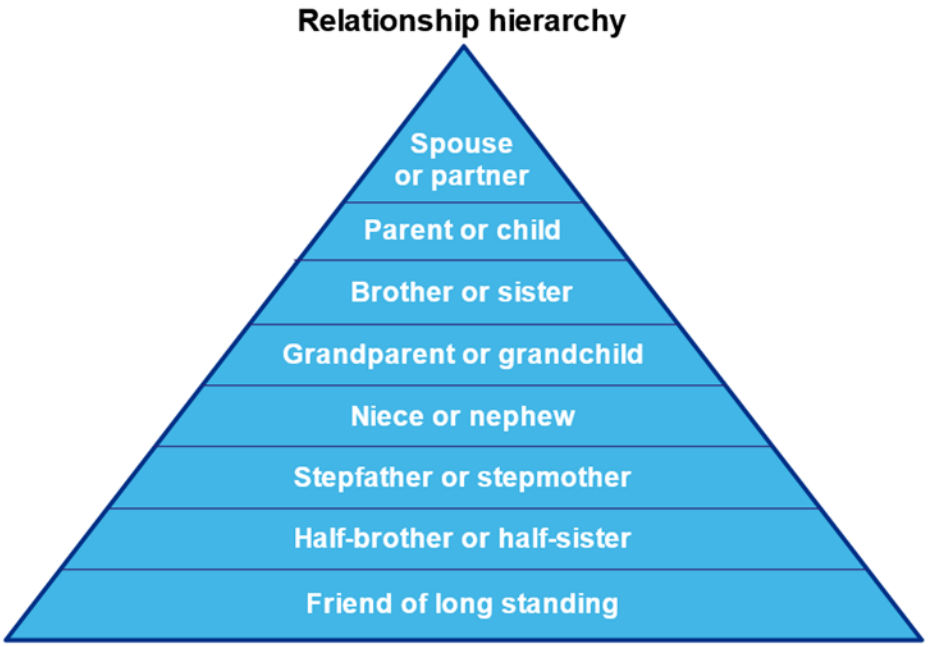

Figure 1. Qualifying relationship hierarchy pyramid

Spouse or partner includes same-sex or civil partners who live as partners in an enduring family relationship. Parent or child includes biological or adopted.

Consent is only required from one person in the hierarchy and should be obtained from the highest-ranking person. If a person higher up the list refuses consent it is not possible to act on consent from an individual further down the list.

d) Children: The HT Act defines children as being under 18 years of age. The consent of child who gave consent for the use of their body or tissue for research whilst alive and competent to do so is lawful for the removal, storage or use of tissue for that purpose.
If a child did not give consent or refusal for the removal, storage or use of their tissue for research, the consent of one person with parental responsibility is sufficient.
Children cannot appoint a nominated representative; therefore, in the absence of consent or refusal by the child or a person with parental responsibility, consent should be sought from the highest-ranking individual in a qualifying relationship with a child.

4.11.3 Fetal Tissue

The law does not distinguish between fetal tissue and tissue from the living and is therefore subject to the same consent requirements as all other tissue from the living. Consent for the removal, storage or use of fetal tissue for research should be obtained from the mother for the examination, storage and use of fetal tissue and non-fetal products

of conception (i.e. placenta, membranes, umbilical cord, amniotic fluid), even where the tissue is unidentifiable.

Consent should be in line with that required for the deceased, when using fetal tissue for research from:

- Stillbirths (babies born dead after 24 weeks of gestation).
- Neonatal deaths (babies or fetuses born showing signs of life and die before the age of 28 days).

4.11.4 Images of Human Samples

The making and displaying of images (including photographs, films and electronic images) is not covered by the HT Act. However, the HTA expect the DI to put into place systems that ensure that suitable practices are carried out, including the prevention of inappropriate use of images. The HTA offers guidance on "Filming or photographing of bodies or body parts that have been donated" and endorses guidance provided by the General Medical Council on "Making and using visual and audio recordings of patients"

4.12 Participant Information Sheets (PIS)

Information should be provided to the participant in writing so they can refer to it. The person seeking consent should also discuss the information sheet with the participant to ensure the consent is fully informed and that the participant has had the opportunity to ask any questions.

The level of detail contained within the information sheet should be proportional to the research activity, however, all information sheets should use simple, non-technical terms that a layperson would easily understand.

When collecting relevant material for use in research, the information sheet must contain the following information:

- Type of tissue to be collected, how much and by which method.
- Whether any identifying information will be affixed to the sample or if the samples will be anonymised / link-anonymised.
- What the material will be used for in the study.
- Whether any genetic testing will be carried out on the material.
- Whether the material will be exported.
- What will happen to the material at the end of the study, e.g. disposed of or retained for future use.
- What will happen to the material if consent is withdrawn.

4.12.1 Format of Information Sheets

The Health Research Authority (HRA) has provided guidance on Informing participants and seeking consent. Although aimed at projects seeking HRA REC approval, the format should be adopted for all studies involving human tissue.

A template for a consent form and PIS can also be found on SU's Research Governance webpage under Documents and Templates for adaptation in specific research projects.

Where the first language of the potential participant is not English, or where barriers to communication exist, the information sheet should be available in a suitable format (e.g. various languages, Braille) and/or an interpreter should be provided. In Wales, both English and Welsh versions of information sheets should be available by law.

4.12.2 Consent Form

The consent form should use a list of short but clear statements that the donor can demonstrate their agreement with, by writing their initials against each one. Followed by the date and signatures of both donor and researcher.

For NHS patients, the original consent form should be kept with the patient's medical notes and an additional two copies made; one for the patient and one to be retained by the researcher. For studies that have various consent options (e.g. multiple scheduled purposes), an itemised or hierarchical consent form may be needed to cover important issues, separating out the elements that are optional for the participant.

4.12.3 Basic Information

Basic information to be displayed at the top of the consent form includes:

- Study number.
- Title of the project.
- Name of the researcher.
- Donor ID number.
- Contact details.

4.12.4 Statements of Consent

Boxes for the donor's initials are located alongside written statements to encourage the donor to read each statement individually and facilitate a clear understanding of exactly what they are consenting to. They also allow the donor to consent to certain aspects of the study and not others if that is their choosing.

Mandatory statements need to appear on all consent forms, with additional statements to be included where necessary.

Mandatory statements ensure the donor:

- Confirms that they have read and understood the information sheet and that the patient/participant has had the opportunity to ask questions and these have been answered satisfactorily.
- Understands that participation is voluntary and they are free to withdraw at any time without giving a reason and, if applicable, without their medical care or legal rights being affected.
- Understands what samples will be collected and what will happen to their samples at the end of the study.
- Understands that their medical notes may be accessed by individuals associated with the project (if applicable).
- Agrees to their GP being informed of their participation in the study (if applicable).
- Agrees to take part in the study.

Additional statements will relate to the specific project and might include:

- Additional invasive tests or samples required for study purposes only.
- The scope of the future use of samples.
- Consent to use of audio/video-taping, with possible use of verbatim quotation or use of photographs.
- Export of samples to countries outside England, Wales and Northern Ireland.
- Transfer of data/samples to countries with less data protection.
- Consent to receive individual feedback from testing.
- Consent to being contacted for future studies.
- Consent for genetic testing sample storage.
- Consent for use in humans.
- Consent for use in animal testing.
- Consent for use in commercial research.
- ‘Given as gift’ - Some RECs have insisted on including a statement confirming that the tissue had been given as a gift and the donor would have no right to a share of any profits that might arise from research using it (e.g. as part of a new medical treatment or test).

4.12.5 Signatures

The signatories to consent should be those who are involved in the consent process, e.g. the participant or representative for the participant and the researcher or a representative of the researcher delegated to take consent. An independent witness is not routinely required but may prove useful in the case of consent by a participant who may be unable to sign personally.

4.12.6 Data Protection Act 2018

Any health-related records that identify the living individual who is the source of the tissue sample may constitute that individual's sensitive personal data. As such, the Data Protection Act 2018 will require that consent is sought for the processing of such data.

5. Procedure of Consent

Consent must be obtained in accordance with the requirements of the HT Act and as set out in the code of practice.

5.1 New Tissue Collections

For studies involving the acquisition of new tissue collections, consent requirements should be in line with the following steps:

1. Obtain appropriate ethical approval, either REC approval (when NHS patients are involved) or internal SU ethics.
2. Ensure that all members of the research team have been trained in obtaining informed consent under the HT Act and that the training is documented.
3. Consent procedures are documented in the study Protocol and SOPs using principles outlined in section 4.9.
4. Ensure all members of the research team have a good understanding of the study.
5. Written information in the form of a Patient Information Sheet (PIS) should be provided to those from whom consent is sought. Fundamentally, the PIS should be formatted appropriately to the situation and ensure the donor's comprehension, including language translations if necessary.
6. Template Consent form and PIS are available from SU's Research Governance webpage under Documents and Templates for adaptation in specific research projects.
7. When recruiting participants, engage each person in a comprehensive discussion of the research including risks/benefits and be prepared to provide answers to questions.
8. Copy of consent forms are provided to those from whom consent is sought and stored securely (refer to section 4.10 and HTA-CORE-SOP-Management of Records).
9. Once consent has been obtained, sample collection, labelling, storage and disposal must take place as documented in the study protocol and follow SU's QMS.
10. If consent is in place for future tissue use, ensure that the scope and any restrictions on the use are documented and retained with the material.
11. If the tissue is to be used for future research, ensure that:
    a. Evidence is retained and copies can be provided to the recipient detailing the scope of the original study and consent.
    b. A record is kept of the recipient, date of handover and name of future study.

12. Where applicable, MTAs should be in place with other parties to ensure that consent is obtained in accordance with the HT Act 2004 and the HTA's Codes of Practice.
13. If consent is withdrawn, follow the withdrawal protocol in the patient information sheet and ensure that all remaining identifiable tissue is disposed of appropriately in line with local policies.
14. Maintain records of:
    a. consent training
    b. consent form/location of consent form
    c. ethical approval
    d. tissue traceability records

5.1 Tissue from Research Tissue Banks or Collaborator

Tissue imported from a Research Tissue Bank (RTB) or from a collaborator still requires evidence of consent. To acquire tissue from a RTB or a collaborator use the following steps:

1. Obtain internal SU ethical approval for the use of imported tissue for your study.
2. Copy of blank consent forms, a copy of the PIS that was provided to donors and a copy of HRA REC approval should be obtained from RTB or a collaborator.
3. Create record(s) of all transferred tissue, including recipient, date and unique ID of tissue samples, tissue type and storage location.
4. If consent is withdrawn, follow the withdrawal protocol in the patient information sheet and ensure that all remaining identifiable tissue is disposed of appropriately in line with local policies.
5. Maintain records of:
    a. PIS & consent form
    b. Ethical approval
    c. Tissue traceability records

5.2 Existing Holdings (Pre 1st Sept 2006)

The HT Act indicates that existing holdings are exempt from its consent provisions. An existing holding is defined as the body of a deceased person or relevant material from a human body (whether living or dead) held before the day on which the HT Act commenced (1 September 2006) for use for a Scheduled Purpose.

The following steps should be taken and documented for the use of existing holdings for research purposes:

1. Obtain HRA REC approval for the use of existing holding in the proposed research project.
2. Ensure full traceability records are maintained with the original study. Evidence should be available detailing:

- To whom the material was released, when and for what study
- Whether the material was released anonymously or linked through unique sample identification numbers/codes.

3. Ensure full traceability records are maintained with the new study detailing:
    - Ethical approval of the new study.
    - Where the material was supplied from.
    - Date of receipt of the material.
    - Details of the unique sample identification numbers/codes for the original and new studies.

5.3 Existing Collections (Post 1st Sept 2006)

The following steps should be taken and documented as appropriate, for the re-use of relevant material collected after September 1st 2006 for research.

1. Establish whether the new study is in line with the original donor consent:
    a. If the new study is considered to be in line with the original consent, HRA REC approval is required for the new study and the original study records must be kept to demonstrate that the new study is within the scope of the original consent.
    b. If the new study is considered **not** to be in line with the original consent and the material was collected from the living:
        i. HRA REC approval can be obtained to use the tissue without consent but in this situation, the tissue must be supplied anonymously.
        ii. HRA REC approval can be obtained to use the tissue if new consent is collected from original donors.
    c. If the new study is **not** considered to be in line with the original donor consent and the material was collected from the deceased, the material must NOT be used without further consent from the relatives. The person's relatives must not be contacted unless they gave consent for contact or with HRA REC approval to contact them. Approval should be in place before any relatives are contacted.

2. Ensure full traceability with the original tissue collection to evidence:
    a. To whom the material was released, when and for what study.
    b. Evidence that the new study was within the scope of the original consent or that HRA REC approval has been obtained for the use of the material with or without consent (samples from living) or further relative consent (samples from deceased).

3. Ensure full traceability records are maintained with the new study to evidence:
    a. From where the material was supplied.

b. Date of receipt of the material.
c. A copy of the original information sheet, blank consent form and HRA REC ethical approval letter.
d. Details of the unique sample identification numbers/codes for the original and new studies.
e. That the new study is within the scope of the original consent or of HRA REC approval to use the material with or without consent (samples from living) or further consent from relatives (samples from deceased).

6 Transportation of Human Tissue

When relevant material is transferred in or out of the University this should form part of the information imparted to donors. Consent of the donor for the transportation of their tissue to collaborators or 3rd parties should be obtained and the transportation activities should be included in the REC submission and be covered by approval. Where relevant material is exported to a country outside of England, Wales or Northern Ireland, specific consent of the donor for international export of their tissue should be obtained. Please refer to HTA-CORE-SOP-Transportation for further guidance.

7 References

HTA Code of Practice A: Guiding Principles and the Fundamental Principle of Consent
Human Tissue Act 2004
Mental Capacity Act 2005
UK policy framework for health and social care 2023

8 Risk Assessment

A risk assessment for this HTA governance SOP is not required.

9 Definitions

A list of useful definitions of technical terms used within SU's HTA Core SOPs can be found in the HTA-Research Quality Manual.

10. Document History

Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	21/09/15	Removal of appendix to standalone template, update front page and footer, minor text review	1.0	Lisa Wakeman
3.0	01/09/16	Post-licence grant review, amendment from acting designated individual reference; minor text amendments	2.0	Lisa Wakeman
4.0	18/04/18	Amendments to reflect revised HTA Codes of Practice and Standards and UK policy framework	3.0	Lisa Wakeman
5.0	07/02/2024	Revised SOP to reflect the separation of the previous joint HTA licence between SU and SUHB and to establish new SU procedures moving forward. Appendix B was removed and adopted into the main document.	4.0	Bethan R Thomas & DI

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Approver	**Name and role**	Professor Catherine Thornton Designated Individual (DI)	
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