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| **Human Tissue in Research**  **HTA-FORM- Before Study Checklist** |

# Purpose

The purpose of the checklist is to facilitate good document management and quality control for compliance with Human Tissue Authority (HTA) standards on Governance and Good Clinical Practice.

This form should be used by the Chief/Principal investigator (CI/PI) before starting any research study involving the use and storage of human tissue, defined as relevant material by the Human Tissue (HT) Act 2004.

# Scope

To be used by the CI/PI for every study involving the collection, use, storage or disposal of relevant material.

You will be expected to retain and maintain the following documentation & facilities (where relevant) to demonstrate compliance with the Human Tissue Act 2004. Evidence will be requested at internal audits.

All documents and forms referred to in this list can be found [online](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/).

1. **Instructions**

Before commencing your study ensure you have:

* Read and understood the HTA Code Of Practice A and E
* Read and understood all SU’s HTA Core SOPs
* Undertaken required training
* Gained ethical approval (or evidence of lead organisation’s ethics)
* Put Material Transfer Agreements (MTAs) in place
* Used the following checklist to ensure you are retaining and maintaining all documentation relevant to your study.
* Created a site file for document management

# Before study checklist

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| **Training** | | | |  |
| All persons involved in the research to complete the required human tissue research training: refer to [HTA-CORE-SOP-Human Tissue Training](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/). | | |  |
| All persons involved in the research must sign the “[HTA-FORM-Read and Understood](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)” and signed forms are to be retained in the site file. | | |  |
| **Ethical Approval** | | |  |
| For NHS REC-approved study you should add evidence of favourable opinion and all approved documentation, including original submission and any amendments to your site file. | | |  |
| For SU internal projects state the ethics application reference number | | |  |
| For NHS REC-approved study you should have a list of members of your research team involved in study activities (staff and students) and create a Delegation Log. | | |  |
| Justification and evidence for not seeking ethical approval (if applicable) | | |  |
| **Risk Assessment, Contingency and Local SOPs** | | |  |
| Undertake a Risk Assessment (RA) for the human tissue covering consent, storage, handling, traceability, transport (if applicable), security, facilities and disposal. Complete the [HTA-FORM-Risk Assessment](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/) and add it to the site file. | | |  |
| RA must reference local SOPs being developed to support risk mitigation | | |  |
| The RA must show a planned review. Following a review ensure you maintain all previous and current RAs in the study site file. | | |  |
| Create a contingency plan based on your RA. Use the [HTA-TEMPLATE-Contingency Plan](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/) for guidance. | | |  |
| Evidence of staff/students having read risk assessment and contingency plans. | | |  |
| Create local study-specific / lab-specific SOPs. You can use the [HTA-TEMPLATE-SOP](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/) and ensure you identify the individuals responsible for the processes described.  **Common local SOPs are listed below:** | | |  |
|  | Process of collection. | |  |
|  | Procedures for checking imported sample numbers against the record provided by the sender. | |  |
|  | How to anonymise the samples. | |  |
|  | How to use a standardise labelling format for all samples. | |  |
|  | Preparation/processing specimens before storing | |  |
|  | How to access your sample log and what details must be captured for each sample. | |  |
|  | How you will record sample disposal (e.g. use of a sample log column and/or [Disposal Record Form](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)) | |  |
|  | How will storage temperature be recorded (e.g. T-scan or other). | |  |
|  | How to calibrate or carry out maintenance of relevant equipment if required by staff or students | |  |
|  | How to record a calibration/maintenance check | |  |
|  | A system for reporting equipment problems. | |  |
|  | If required, how will transport arrangements be made and tracked. | |  |
| Evidence of staff/students having read all local SOPs | | |  |
| All local SOPs must show a planned review. Following a review ensure you maintain all previous and current SOPs in the site file. | | |  |
| **Traceability** | | |  |
| Name of Chief/Principal Investigator, project title, REC number (NHS or SU Internal), added to site file. | | |  |
| Evidence of chain of custody, if applicable. (e.g. [HTA-FORM-Tissue Transfer Record](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)) | | |  |
| A **sample log** of donated material and associated products with a unique sample ID reference ([HTA-TEMPLATE-Sample Log](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)). The log can be an electronic log stored on OneDrive and password protected. Ensure easy access to all users. | | |  |
|  | **The sample log/record must show for each sample:** | |  |
|  | Unique sample ID reference | |  |
|  | ID reference for any daughter samples (split) must be unique and containthe original sample ID | |  |
|  | Sample type (if more than one type is stored/used) | |  |
|  | Date of receipt | |  |
|  | Date sample labelled (if different from the date of receipt) | |  |
|  | Consent distinctions (if applicable) | |  |
|  | Where multiple MTAs are in place, samples must be linked to a specific agreement. | |  |
|  | The exact storage location of each sample to include the storage unit (e.g. Freezer), shelf, rack, sample box and position. | |  |
|  | Columns within the sample record to log details of withdrawal, even if withdrawal is not anticipated | |  |
|  | Columns within the sample record to log details of disposal, even if disposal is not anticipated | |  |
| Signed consent forms detailing the donor and unique sample ID link and any other donor-linked documents **MUST** be held securely and separately from all other tissue logs/records that denote the sample ID only. *We suggest storing signed consent forms in your Master site file and this should be securely locked either digitally on OneDrive and password protected or a hard copy in a locked drawer*.  See the **Consent Records** section below. | | |  |
| **Material Transfer Agreement Records** | | |  |
| Signed Material Transfer Agreement for any incoming or outgoing samples. | | |  |
| Evidence of ethical approval and consent for incoming samples.  (E.g. Source Organisations' ethical approval letters, a copy of their blank consent form and participant information sheet (PIS)). | | |  |
| **If Importing Relevant Material:** | | |  |
|  | An authorised (signed) Importation Justification Form.  (For all incoming samples from outside England, Wales & Northern Ireland) including Scotland) | |  |
|  | Assurance of consent and ethical approval at the source location.  (This may be in the MTA). | |  |
|  | Blank copies of the partPIS and consent used to consent donors whose samples have been received; translated where documentation is not in English | |  |
|  | Any restrictions or limitations on the use of the relevant material recorded | |  |
| **Consent Records** | | |  |
| Location of consent forms (Master Site File recommended). At least two locks between the general public and the Master site file.  *If digital the computer must be kept in a limited access office or room and stored on OneDrive with password protection or a hard copy in a limited access office or room and locked in a drawer.* | | |  |
| If the consent records are held at a different location/s (e.g. health board) details of a named contact at the establishment. | | |  |
| Justification for not obtaining consent and evidence of a legitimate exception from consent (if appropriate). | | |  |
| Blank copies of all versions of the consent form and associated PIS and date range for use. | | |  |
| All signed consent forms  (*Not required if samples are sourced from another establishment but MTA would be required to evidence consent was taken*) | | |  |
| The consent form must show: | | |  |
|  | The version number of the consent form and version of the corresponding PIS | |  |
|  | Who gave and who took consent | |  |
|  | The date of consent | |  |
|  | Donor decision for all options presented in the consent (the options on the use of the material must match the details in the corresponding PIS) | |  |
| Where applicable, use a record summary of any restrictions on the use of donor’s material as detailed in their consent form (e.g. samples will not be used by the commercial sector). | | |  |
| **Storage and Maintenance** | | |  |
| Documented cleaning and decontamination processes (e.g. local SOPs) | | |  |
| Documented contingency plans in case of failure of storage area & equipment, including location of backup storage equipment ([HTA-TEMPLATE-Contingency Plan](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)) | | |  |
| Evidence that staff have received training on contingency plans | | |  |
| Contingency plans are displayed on the storage unit. Use [HTA-SOP-QR Code Labels](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/) and [HTA-TEMPLATE-Storage Sign](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/). | | |  |
| Name and contact details of the CI/PI displayed on the storage equipment | | |  |
| Evidence of a system for reporting equipment problems (e.g. local SOP) | | |  |
| Evidence of systems to deal with emergencies on a 24-hour basis (e.g. local SOP or T-Scan) | | |  |
| Documents for recording storage conditions and temperature monitoring, including room temperature storage. e.g. [HTA-TEMPLATE-Temperature Log](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/). | | |  |
| Documents to record regular challenges to cold storage alarm systems e.g. [HTA-FORM-Freezer Maintenance Report](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)  Or iAuditor reports | | |  |
| Documents to record calibration, validation and maintenance of equipment used for the project including storage equipment and alarm systems  Or iAuditor reports. | | |  |
| **Transportation / Export of Relevant Material** | | |  |
| Evidence of the organisation's HTA licence.  *(If transporting relevant material outside SU but within England, Wales and Northern Ireland and the transfer is not part of an ethically approved study)* | | |  |
| RA for transport of samples (if not already covered in the study’s Human Tissue RA) | | |  |
| Evidence of a system to maintain traceability during transport (e.g. local SOP in line with Core SOP on Transportation) | | |  |
| Records of agreements with couriers or transport companies (invoices, confirmation emails etc) | | |  |
| Copy of [HTA-FORM-Tissue Transfer Record](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/), ready for use.  (If transporting outside SU but within England, Wales and Northern Ireland) | | |  |
|  | * The name of the CI/PI responsible for sending and receiving relevant material * Addresses from where relevant material was sent and received * The date of transport including date sent and date arrived if different * Method of transport including details of courier used and tracking reference or Air Way Bill (AWB) if appropriate * Traceability information relating to samples including ID numbers for samples sent, amount of each sample and type of sample * Information on whether relevant material will be returned or disposed of by the recipient. * If relevant material is to be returned, details of what, when, how much, by what method and who the sender and recipient will be | |  |
| **Disposal** | | |  |
| A copy of the [HTA-Form-Disposal Record](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/) ready for use if: | | |  |
|  | | * A sample is damaged, contaminated or fails quality assurance tests upon receipt. * The donor withdraws consent for the use of the sample in research. * The sample is found to pose a health and safety risk to the research staff. * At the end of the study if stored material is surplus to requirement. |  |
| Sample Log ([HTA-TEMPLATE-Sample Log](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)) must record when stored relevant material has been used up, divided or rendered acellular. | | |  |
| **Adverse Event** | | |  |
| Copy of [HTA-FORM-Adverse Event Report](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/) readily available for use if needed. | | |  |
| **Quality Management System** | | |  |
| All training requirements are met and updated every 3 years (e.g. MRC Human Tissue in Research and GCP) | | |  |
| Review dates set for all local SOPs and RAs | | |  |
| Change control management for any local documents | | |  |
| Self-audit schedule | | |  |
| **Premises, Facilities and Equipment** | | |  |
| At least two locks between the general public and samples. | | |  |
| Human Tissue and any derivatives must be stored separately from non-human material. | | |  |
| At least two locks between the general public and the Master Site File. | | |  |
| Monitoring alarms on controlled temperature storage, records to be reviewed regularly to predict when cold storage equipment may be about to fail.  (If not using T-Scan and iAuditor systems for fridge/freezers, see [HTA-CORE-SOP-Maintenance and Monitoring of Cold Storage](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/)) | | |  |
| Back-up facilities for controlled temperature storage | | |  |
| A programme of planned preventive maintenance.  (If not using T-Scan and iAuditor systems fridge/freezers, see [HTA-CORE-SOP-Maintenance and Monitoring of Cold Storage](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/)) | | |  |
| HTA licence is displayed on the storage unit if the material is held under the HTA Licence. | | |  |
| **Biobanking / Re-Use of Stored Samples for a New Study** | | |  |
| Refer back to the Transportationsection above for all transfer records to be used. | | |  |
| ***To be held at the original location of the samples, a record of:*** | | |  |
| Who the material was released to, when and for what study.  (Note any REC references if applicable) | | |  |
| Whether the material was released anonymously | | |  |
| ***To be held at the new location of the samples (even if still SU), a record of::*** | | |  |
| Where does the material come from | | |  |
| When the material was received and by whom | | |  |
| The original sample ID alongside the new sample ID (if applicable) | | |  |
| Ethical approval for the new study | | |  |
| **Consent and/or Ethical Approval Evidence** (*collected post 1st Sept 2006*)**:** | | |  |
| Any limitations on the use of the material | | |  |
| Evidence that the new use of the relevant material was within the original donor's consent | | |  |
| OR | | |  |
| Evidence that ethical approval was in place specifically for the use of anonymised relevant material from the living without consent (where this aligns with the HTA consent exception, see [HTA-CORE-SOP-Transportation](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/) for further details) | | |
| OR | | |  |
| Evidence that ethical approval and appropriate consent were in place to contact the donor or relatives of the deceased to use the relevant material for purposes outside the original consent | | |