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| **Human Tissue in Research**  **HTA-Template-Risk Assessment** |

1. **Purpose**

All procedures involving the acquisition, storage, use and disposal of human tissue must be risk-assessed to comply with HTA requirements. This document provides a suitable template for a Risk Assessment to support compliance with the Human Tissue Act.

1. **Scope**

This risk assessment (RA) ensures that individuals undertaking research involving human tissue understand the possible hazards to the integrity of the tissue(s) and understand the steps to be taken to minimise these risks, they must carry out a risk assessment (RA), before the activity commences.

For compliance with the HTA Codes of Practice, all studies or collections of relevant material must be risk assessed for the risk to the human tissue rather than risks to researchers/handlers.  This RA should focus on identifying and minimising the risks to the integrity of tissue and respect for the donor first.

The health and safety of handlers is a secondary focus, as RAs for health and safety should already be in place for usually laboratory activity. Any SOPs involving laboratory safety (e.g. biological, chemicals or equipment) should have a separate assessment of risk that complies with the university’s laboratory safety policies. Information on laboratory safety, training and RA templates can be found [here](https://myuni.swansea.ac.uk/living-in-swansea/health-and-safety/postgraduates/policies-and-procedures/laboratory-safety/#bbq=on).

A risk assessment should accompany an SOP describing the manual, technical and scientific procedures involving human tissue within a study. If multiple SOPs exist for the various procedures they should all be risk assessed separately also.

1. **Guidance notes for tissue risk assessment:**

The risk assessment should consider the risks of all tissue-related activities including, but not limited to the risks listed below:

***Risk 1 - Consent Process***

* Consider your process of obtaining consent.
* Training for obtaining consent.
* Management of consent forms.
* Whether consent covers all possible future plans for the tissue to avoid unnecessary disposal at the study end e.g.
  + Genetic testing
  + Commercial use
  + Export
  + Retention under a licence for future use
  + Use in animal testing

***Risk 2 - Tissue Handling***

* Consider if sample anonymisation processes are sufficiently robust.
* Are all sample collection supplies available and are there any special requirements e.g. formalin/culture media?
* Are there any risks associated with the collection?
* Consider training requirements.

***Risk 3- Security/Facilities***

* Consider if samples are securely stored. What measures are in place to ensure that samples are secure from theft or damage?
* Are consent forms and personal data stored securely?
* Are the facilities suitable for your study?
* Do you have contingency plans for failure of critical equipment?

***Risk 4 - Tissue Traceability***

* Is there a documented sample labelling procedure for labelling secondary samples processed from the primary sample?
* All secondary samples should be uniquely identified from the primary sample and each other (e.g. primary sample identifier followed by “1 of 3”,”2 of 3” etc).
* Is there a mechanism in place for ensuring sample traceability and maintaining sample identification throughout analysis?
* Is any tissue being disposed of at this point – how will it be documented?

***Risk 5 - Tissue Storage***

* What measures are in place to avoid sample contamination?
* Are storage arrangements suitable?
* Are storage units linked to temperature monitoring systems where storage temperature is critical?
* Are storage units subject to regular, documented cleaning and maintenance procedures?
* Are there contact details and contingency plans available in the event of storage unit failure?

***Risk 6 - Tissue Transportation***

* Do sample packaging arrangements comply with [HTA-CORE-SOP-Transportation](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/)?
* A risk assessment must be completed when researchers plan to transport human material in private vehicles. Does the RA consider:
  + Contingency arrangements in place in case of a breakdown?
  + Requirements for transport e.g. specific area of the vehicle where samples should be placed?
  + Making drivers aware that they must not leave the vehicle unattended during transportation?
* Is there a chain of custody for recording sample dispatch and arrival?

***Risk 7 - Tissue Disposal***

* Consider the risk of accidental disposal of samples.
* Are staff/students aware of the procedure for tissue disposal including completion of disposal records and logs throughout the study and at the study end?

***Risk 8 - Training***

* Consider if all research staff and students involved in the study are trained appropriately (GCP, human tissue in research training)
* Is all training documented and periodically reviewed?
* Are all members of the research team familiar with the study protocol?

1. **Instructions:**

This risk assessment should be read and signed by all members of the research team to evidence that they have seen the assessment and it should be available for inspection on request.

The focus of this risk assessment process should be on the possible risks to tissue integrity. Human tissue is donated to research altruistically and as such researchers have a responsibility to take all reasonable steps to avoid damage or loss.

Where possible the risk assessment should be based on a study SOP or group of SOPs relating to a specific activity within the study.

Risk assessment and adverse event reporting are linked. Where investigations into adverse events highlight previously unconsidered issues of risk, these should be incorporated into a revised risk assessment to be read and acknowledged by all relevant personnel. Refer to [HTA-CORE-SOP-Adverse Event Reporting](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/) for definitions of adverse events relating to human tissue research.

Contingency plans detailing actions to be taken in the event of storage unit failure should be in place for all human tissue stored for research at Swansea University (SU). Such plans should be robust and cover failure outside of core hours unless documented risk assessment details why this is not required.

For queries contact the Human Tissue Governance Office (HTGO): [B.R.Thomas@swanse.ac.uk](mailto:B.R.Thomas@swanse.ac.uk).

**Warning!**

**The hazards and/or existing control measures already written into the following RA template may not apply to all collections of relevant material.**

* **Modify all text highlighted in yellow.**
* **Please ensure that hazards not applicable are removed.**
* **Please ensure that the existing control measures written are modified specifically for your study/collection.**

**It is your responsibility to identify and add hazards not already identified in grey.**

**The severity rating must reflect the impact to the donor and/or samples under the Human Tissue Act, hazards that could result in a critical or major shortfall must receive a high severity rating.**

**You may delete all pages before and including this page when saving your modified RA document.**

# **[Title of Risk Assessment here e.g. Study / Collection] - RISK ASSESSMENT**

**Title/File Name:**

Electronic location:

Hard copy location:

|  |  |
| --- | --- |
| **Faculty/School/Department/Group:** | **Study/collection IRAS/REC ref:** |
| **Building:** | **Room/Laboratory:** |

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| --- | --- |
| **Details of Risk Assessor:** | |
| **Name:** |  |
| **Position:** |  |
| **Date of Assessment:** |  |

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| **Brief Description of Study:** |

**Risk Rating:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Likelihood Rating | x | SeverityRating | = | Risk Rating Number |

**Likelihood of Hazards and Risks causing shortfall/damage:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1** | **2** | **3** | **4** | **5** |
| **Rare** | **Unlikely** | **Possible** | **Likely** | **Certain** |

**Severity / Consequence of outcome should hazard(s) come to fruition:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1** | **2** | **3** | **4** | **5** |
| Event that might be considered a shortfall under non-HTA regulation | Unexpected event that does not result in a shortfall due to effective contingency plans. | Deviation from expected standards. Partial sample loss that does not impact the donor or study. Incomplete or missing consent form identified early through routine process checks. | Unintentional: permanent loss of samples. No evidence of consent. Samples collected/used without/inappropriate consent. Multiple errors in the completion of consent forms. Repeated freezer failure (minimal sample loss). Repeated minor shortfalls in the same study/group. | Intentional actions that are known and understood to be in breach of the HT Act Intentional failure to declare samples that must be held under the HTA Licence. |

**Review period:**

**Risk assessments should be reviewed regularly, especially when a procedure changes significantly. The frequency of review of unchanged processes can be based on the level of estimated risk:**

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| **Risk Rating:** | **Categorised as:** | **Actions to be taken:** | **Review Period:** |
| 1-5 | Low risk | No further action is needed. | Review every 3 years |
| 6-10 | Medium risk | Appropriate control measures must be implemented. | Review every 2 years |
| 12-25 | High risk | Appropriate control measures must identified and implemented before work begins. The frequency of the review period should be increased to assess whether control measures are sufficient and followed closely. | 3-6 months |

**Part 1: Risk Assessment:**

***Refer to guidance notes for examples of risks to be considered.***

|  | **Identified Risks** | **Mitigation/Control Measures** | **Severity (1-5)** | **Likelihood (1-5)** | **Risk Rating** | **Further mitigation/actions required?** |
| --- | --- | --- | --- | --- | --- | --- |
| **Consent:** | Failure to obtain valid informed consent:   * Intentionally * Unintentionally | All SU staff & students taking consent receive appropriate training, as detailed in the [HTA-Core-SOP-Human Tissue Training Human](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/), before recruitment of participants and the principal investigator retains copies of the training certificates. | 5  4 | 1  2 | 5  8 |  |
| Failure to store consent or consent forms lost/damaged. | Consent is taken according to [HTA-Core-SOP-Consent](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/) and the consent forms are [stored in a locked cabinet in a locked room / stored in a password-protected digital folder]. Access is limited to those detailed in the study protocol and information sheet. | 4 | 2 | 8 |  |
| Insufficient training for obtaining informed consent.  Or  The person (s) taking consent do not have sufficient knowledge of the study. | All SU staff & students taking consent receive appropriate training, as detailed in the [HTA-Core-SOP-Human Tissue Training Human](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/), before recruitment of participants and the PI retains copies of the training certificates.  All persons taking consent must familiarise themselves with the study before they are permitted to take consent. Evidenced by reading all study-related documentation:   * Ethical application. * Study protocol. * Local SOPs and RAs related to the study. * HTA-CORE-SOPs and Quality manual. | 4 | 1 | 4 |  |
| Incorrect version of consent form/information sheet used | The PI is responsible for ensuring that any superseded versions of PISs and Consent forms are replaced by the updated amended version that includes an effective from date. PI is responsible for recording all superseded versions in the study site file. The effective from date can be cross-checked against the sample collection date to maintain a linkage between the documentation version and samples. | 3 | 2 | 8 |  |
| Samples used for purposes outside of consent  e.g. DNA Theft   * Intentionally * Unintentionally | All SU studies should use the recommended  [PIS and Consent form Templates.](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/documents-and-templates/) The customisable template consent form and PIS encourage PIs to consider consent appropriate for their current study and potential future studies to avoid unnecessary disposal at the study end and use outside of consent given.  PIs will maintain a record of which study samples were collected under and a copy of the study’s PISs and Consent forms will be recorded and maintained throughout the study and retained if there is an intention for re-use of tissue samples. The PIS will ensure the scope of the consent is clear. Any limitations placed on the use of the material are also recorded on consent forms.  As part of human tissue training and GCP all staff & students should understand the consent considerations that must be made before any new analysis is carried out on the samples, or if samples are used in a new study. Researchers must check the scope of the consent to ensure the new use is in line with the original consent. | 5  4 | 1  2 | 6  8 |  |
| Storage and/or use of samples after consent is withdrawn   * Intentionally * Unintentionally | The consent withdrawal procedure detailed in the [HTA-Core-SOP-Consent](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/) [and study protocol/PIS/local SOP…] will be followed and the sample disposed of as soon as consent withdrawal has been confirmed.  PI is responsible for ensuring that participant withdrawal confirmation is disseminated to authorised personnel directly involved in the study ensuring corresponding samples are destroyed, sample logs are updated, and a disposal record is completed. | 5  4 | 1  2 | 5  8 |  |
| Add all other consent risks identified specifically to your study | Add all other mitigations you have in place specifically to your study | ? | ? | ? |  |
| **Handling:** | Untrained staff or students | All staff & students handling human tissue samples received a laboratory induction and must complete human tissue training as outlined in HTA-Core-SOP-Human Tissue Training Human and read all local SOPs. | 4 | 2 | 8 |  |
|  | Human error (e.g. sample spillage) | The PI/Lab technician/Lab manager ensures that all staff & students receive the appropriate training in safe working practices. All staff & students working with human tissue will be familiar with how to report an adverse event. | 4 | 2 | 8 |  |
|  | Equipment failure  e.g. power outage, centrifuge breakdown, pipette inaccuracy | Emergency backup power supply is available through the red sockets in the lab.  Equipment is calibrated regularly as required. Technical staff closely monitor equipment for accuracy and consistency. This should minimise the risk of sample loss.  In the event of equipment failure alternative processing facilities may be used in a different area of the Building/ School/Campus, [insert details of backup equipment locations]. | 4 | 2 | 8 |  |
|  | Contamination of sample | Work areas/equipment are cleaned and maintained regularly and decontaminated after use using appropriate methods.  Refer to [insert your local SOPs for cleaning/decontamination]. This will help prevent sample cross-contamination.  The PI/Lab technician/Lab manager ensures that all staff & students receive the appropriate training in safe working practices. All staff & students working with human tissue will be familiar with how to report an [adverse event](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/). | 4 | 2 | 8 |  |
|  | Add all other handling risks identified specifically to your study | Add all other mitigations you have in place specifically to your study | ? | ? | ? |  |
| **Security**  **/Facilities:** | Samples are not stored securely resulting in theft. | There is a minimum of two Salto locked doors between the general public and stored human tissue samples. Only authorised personnel can open the Salto-locked doors located [insert locations of restricted access corridors].  All human tissue samples stored under a REC-approved study and all collections stored under the SU’s HTA research licence are also kept in locked storage units. With key access restricted to the research group. | 5 | 1 | 5 |  |
| Samples are not stored securely resulting in damage. | Staff & students trained in storage procedures and adverse event procedures. | 4 | 2 | 8 |  |
| Add all other Security/Facility risks identified specifically to your study | Add all other mitigations you have in place specifically to your study | ? | ? | ? |  |
| **Traceability:** | Untrained staff or student | All staff & students handling human tissue samples received a laboratory induction and must complete human tissue training as outlined in HTA-Core-SOP-Human Tissue Training Human and read all local SOP, [insert name/ref of your local sop here]. | 3 | 1 | 3 |  |
| Miss-management of samples leading to incorrect identification of samples | To avoid misidentification, human tissue samples are assigned a unique identifier.  All aliquots are also given a unique identifier that contains the original sample ID.  Sample IDs take the format [insert sample identification format] as per [insert your local SOP for labelling].  If samples are transferred between establishments staff or student responsible will follow all relevant procedures described in HTA-Core-SOP-Transportation.  They will communicate to ensure the receiving laboratory/facility are aware of sample transfer details.  Materials transfer agreements are in place and procedures are followed correctly to minimise sample loss. | 4 | 2 | 8 |  |
| Corruption of electronic records | All sample logging and tracking information are digitally saved on OneDrive Business through the SU staff/student accounts. All documents are stored securely on the Microsoft Cloud infrastructure and are geographically located at data centres within the European Union. All documents even if deleted can be recovered for up to 90 days. | 4 | 2 | 8 |  |
| Add all other Traceability risks identified specifically to your study | Add all other mitigations you have in place specifically to your study | ? | ? | ? |  |
| **Storage:** | Failure to control the temperature of storage units due to power supply e.g. fridges/freezers | Freezers are plugged into red sockets with backup electrical supply in the event of a power outage. T-Scan temperature monitoring systems have a battery supply (UPS), ensuring alerts can be sent to all responsible personnel when the temperature of the Freezers/ Fridge/ Cold-room storing human tissue exceeds temperature limits.  Contact details and contingency plans are available on the front of storage units. | 4 | 2 | 8 |  |
| Failure to control the temperature of storage units due to excessive environmental/room heat compromising fridges/freezers. | Storage units are placed in areas controlled by air handling units, these room temperatures are controlled by the BMS system and remotely monitored by estates. | 3 | 2 | 6 |  |
| Failure of the cold storage units. e.g. fridge freezer | Freezer units are regularly inspected, e.g. alarm and seal checks, are performed by a Technical and Compliance Officer (TCO) and recorded on the iAuditor system/insert responsible person here and how it is recorded. Freezers are de-iced when required in line with [HTA-CORE-SOP-Maintainenance of Cold Storage](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/).  Temperature checks are recorded manually/electronically.  Contact details and contingency plans are available on the front of storage units. | 4 | 1 | 4 |  |
| Failure to maintain temperature due to human errors. E.g. not closing the door correctly. Samples racks left outside the fridge/freezer too long. | The PI/Lab technician/Lab manager ensures that all staff & students receive appropriate training in safe working practices and storage procedures. | 4 | 2 | 8 |  |
| Failure to maintain temperature due a planned electrical shutdown. | Persons using the laboratory are informed of the dates that equipment will be out of action.  Experiments and incoming samples are rearranged to a different date or location. Emergency contact is available during planned power outage. T-Scan active to monitor the temperature of the freezers. Freezers should be kept shut to conserve the low temperatures.  If necessary, any potentially affected samples are temporarily moved as per the contingency plan [insert your contingency name/ref]. | 4 | 2 | 8 |  |
| Add all other Storage risks identified specifically to your study | Add all other mitigations you have in place specifically to your study | ? | ? | ? |  |
| **Transport:** | Failure to package human tissue appropriately for transport:   * Between buildings/Labs on the same campus * By Car/ Between campuses * By Royal Mail * By Courier   Resulting in a failure to deliver or a delay in delivery. | All staff & students involved in human tissue research must read the [HTA-Core-SOP-Transportation](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/), which covers appropriate packaging for all modes of transportation.  PIs must ensure that staff & students involved in human tissue research evidence that they have reviewed all [HTA-Core-SOPs](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/) by signing a “ [Read & Understood Form](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/)” before they are permitted to work with relevant material.  Local SOP [insert name] located [add location] has been developed specifically for this study's transportation requirements to ensure staff & students involved can maintain the integrity of samples in transit. | 4 | 2 | 8 |  |
|  | Transport  Traceability  e.g. Sample records do not match samples received | Local SOP for receiving samples [insert reference] followed.  Sample numbers were checked prior to packing and sample records were sent with the package and emailed to the recipient.  Packaging is checked by the recipient and samples are checked against record when removed from the packaging. | 4 | 2 | 8 |  |
|  | Add all other Transport risks identified specifically to your study | Add all other mitigations you have in place specifically to your study | ? | ? | ? |  |
| **Disposal:** | Material disposed of by an inappropriate route, or in error | All staff/students involved in human sample research will be trained in sample disposal procedures as defined in the [HTA-Core-SOP-Disposal](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/), local SOP [insert local SOP ref] and study protocol. All samples are to be disposed of correctly via incineration. | 4 | 1 | 4 |  |
|  | Records not kept for all disposal | Sample tracking database to be kept up to date and to include the number of individual samples/vials used and remaining, and which particular box/location each sample is stored in.  Record of samples used/disposed of to be kept up to date on the disposal column in the sample log along is a disposal record for study. | 4 | 2 | 8 |  |
|  | Add all other Disposal risks identified specifically to your study | Add all other mitigations you have in place specifically to your study | ? | ? | ? |  |

**Part 2: Actions arising from risk assessment**

| **Further mitigation actions required following a review of RA:** | **Person responsible:** | **Target Date** | **Done Yes/No** | **Included in new RA Version No.?** |
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**This Risk Assessment [Insert title and version] has been issued to and read by:**

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| **Document History**  *(To be completed by the research team whenever the risk assessment is reviewed)* | | | | | | | |
| **Version** | **Review Date** | | **Comment** | | **Replaces** | | **Reviewed by** |
| 0.1 |  | |  | | N/A | |  |
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