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| **Human Tissue in Research**  **Contingency Plan Template – Temperature Controlled Storage Units** |

**Purpose**:

This form should be used by Swansea University (SU) staff or students when storing human tissue considered relevant material which must remain within acceptable temperature limits to ensure the integrity of human tissue and therefore the reliability of data.

All temperature-controlled units storing relevant material should have a written contingency plan. The contingency plan should outline the actions to be taken in the event of failure of a temperature-controlled unit.

It is expected that this contingency plan template or similar be appended to storage units containing relevant material. It is encouraged at best practice that a QR code be created and linked to the contingency plan and appended to the storage. Refer to [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/).

**Scope:**

The contingency plan should be used for temperature-controlled storage units but could also be used for other critical equipment used within a human tissue study.

**Instructions:**

1. Tailor the template by adding specific details to the sections highlighted in yellow on the template.
2. Delete this cover page.
3. Save the contingency plan securely to a nominated Swansea University OneDrive account and permit viewing rights to all Swansea University Staff & students.
4. Disseminate the plan to all staff & students using the storage unit and any lab users. (All staff storing tissue in the freezer should contribute and agree to the contingency plan. Regardless of different research groups.)
5. Refer to [HTA-SOP-QR Code Labels](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/) and create a QR code link to the tailored Contingency plan.
6. Refer to [HTA-Template-Storage Sign](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/) and add the tailored Contingency plan QR code.

Alternatively, after step 3 you could print the tailored template and append it to the storage unit, however, this is not recommended.

# **Contingency Plan for [Add Fridge Freezer unique identifier]**

1. **Summary:**

This contingency plan outlines the actions to be taken in the event of failure of (describe storage facility/unit/equipment) located in (insert location details).

The tissue types covered in this contingency plan are:

* (insert details of all tissues at risk).

1. **Contact Personnel:**

The following persons are responsible for ensuring that this contingency plan is followed if Storage Unit / Equipment fails:

* Insert a hierarchy of contact details for personnel who can be contacted in the event of failure
* PI should always be named first as it is their responsibility to supervise contingency activities.
* Insert names - contact information.

1. **Procedure:**
   1. ***Existing Arrangements***

Describe the current arrangements for the storage of samples in the storage units for the project/tissue to which the contingency plan refers *e.g. Relevant materials are stored in 2ml Eppendorfs, in racks on shelves 1 and 2.*

* 1. **Location of the Contingency Storage Unit.**

Describe the exact location and unique identifier of backup facilities.

* 1. **Failure Conditions**

Describe the conditions for failure such as temperature deviation limits and duration outside limits requiring the contingency arrangements to be invoked.

e.g. This storage unit should be maintained at -80°C, with a minimum temperature of -90°C and a maximum temperature of -65°C.

If the temperature exceeds these limits and cannot be corrected within 30mins, all samples listed in the above summary must be moved to a contingency freezer.

If a **T-scan** monitoring system alarms and notifications are triggered to responsible individuals due to temperature failure, this contingency plan should also be invoked.

* 1. **Actions to be Taken in the Event of Equipment Failure**

Insert details of actions to be taken when equipment fails, including specific locations of designated contingency storage units.

Tissue transferred to temporary storage locations will be labelled in accordance with the Core HTA--SOP-Equipment Maintenance i.e.

**HUMAN TISSUE**

Human Tissue relocated from [insert fridge/freezer location and ID]

Date of transfer:

Name of Principal Investigator:

The temporary storage of tissues are located on shelves: XXX

* + 1. ***Recording an Adverse Event (HTA Relevant Material Only)***

Following the failure of the storage unit used to store relevant material or any instance where tissue integrity is compromised, an adverse event report must be completed in line with the [HTA-CORE-SOP-Adverse Event Reporting](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/).

**Review and Amendments**

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| **Document History** | | | | | | | |
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