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| **Human Tissue in Research**  **Maintenance Report** |

1. **Purpose**

This freezer audit record is to aid researchers and support staff in recording maintenance and monitoring of storage units housing human samples considered relevant material stored for research. These maintenance and monitoring records will form part of internal and external HTA audits.

1. **Scope**

The [HTA-CORE-SOP-Maintenance and Monitoring of Cold Storage Units](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/) describes all the requirements for the maintenance and monitoring of fridges and freezers used to store relevant material. Including temperature monitoring, alarm challenges and maintenance checks.

This form should be used to evidence regular maintenance and monitoring of fridges and freezers used to store relevant material held either under HTA licence 12651 for research purposes or stored for NHS REC-approved studies with planned storage under the licence at the end of the study.

***Exception:***

If storage units with relevant material are monitored using a digital system (e.g. **t-Scan**) and temperature is recorded onto a cloud database and maintenance checks are carried out and recorded through the FMHLS **iAuditor** system, you can substitute this digital record as evidence of monthly temperature recordings, maintenance and alarm checks, if requested for audit purposes.

If the digitally recorded temperature show fluctuations/trends that suggest a potential issue or maintenance checks highlight deficiencies with the storage units, you must complete and submit a “Near Miss” [HTA-FORM-Adverse Event Report](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-forms/) to the [HTGO](mailto:b.r.thomas@swansea.ac.uk).

1. **Instructions**

***Temperature monitoring audit instructions:***

* Monthly check for temperature fluctuations/trends approaching set limits.
* Annotate with comments and actions taken and signed and dated by the reviewer.

***Freezer Maintenance & Alarm Challenge:***

* Refer to the challenges that should be carried out found in ‘HTA-SOP-Maintenance and Monitoring of Cold Storage’.

You can now dispose of this cover page and fill in the following freezer monitoring record form.

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| **Laboratory / Location:**  **Contact name:**  **Fridge/Freezer under review:**  **Date of review:** |

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| **Type of maintenance undertaken:** | |
| Temperature Monitoring  Fridge/Freezer Maintenance  Alarm Challenge |  |

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| **Period reviewed:**  (insert dates) |

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| **Maintenance findings:** |

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| **Actions taken:** |

**Signature:…………………………**

**Name:………………………………**

**Date:………………………………..**