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| **Human Tissue in Research**  **Self-Traceability Audit Form** |

**Purpose**

In addition to organisational internal audit inspections by the Human Tissue Governance Officer (HTGO), Designated Individual (DI) or another appropriate individual, it is recommended that research groups and support staff conduct regular self-inspection to identify deficiencies in compliance with HTA standards.

This Self Traceability Audit form should be used as a record of self-inspection and aid research groups and support staff to identify deficiencies in sample traceability and take quick corrective actions when needed.

**Scope**

This form can be used by all Swansea University (SU) staff and students involved in research projects intending to use any type of human sample, to self-audit the traceability of each sample stored. This includes material that is considered relevant under the HT Act, non-relevant human material, human DNA / RNA and human-derived cell lines.

**Instructions**

Please ensure you have access to your database/spreadsheet of all human tissue samples stored within the unit you are auditing. Please ensure you have physical access to the storage unit you are auditing and all necessary PPE available to you.

You can now dispose of this cover page and follow the instructions on the following Self Traceability Form.

**Self Traceability Audit**

**Name of Study/Group/Facility................................................... Contact name..................................................**

**Specific unit being audited............................. Date of audit..............................**

**Part 1. Consent to Sample Location Check**

**Steps:**

1. Select three samples from the database/spreadsheet of human tissue samples stored in the unit.
2. Physically check the sample itself to verify that the sample location stated in the record matches the actual location of the sample in the storage unit.
3. Records should be selected from different databases when there is more than one and different sample types (e.g. urine and blood).
4. Check that consent forms are available for all three samples.

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| --- | --- | --- | --- | --- | --- |
|  | **Sample Type** | **Sample ID** | **Storage location stated sample database** | **Location of the sample found in the storage unit** | **Consent form viewed (Y/N)** |
| **1** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **3** |  |  |  |  |  |
| **Comments / corrective actions taken** |  | | | | |

**Note: If corrective actions are needed, please contact the** [**HTGO**](mailto:b.r.thomas@swansea.ac.uk) **and send a copy of this audit.**

**Part 2. Sample to Consent Check**

**Steps:**

1. Select three samples from a storage unit(s). Samples should be selected from different sections/shelves when there is more than one and different sample types (e.g. urine and blood).
2. Check the location against the database/spreadsheet.
3. Check that consent forms are available for all three samples.

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| --- | --- | --- | --- | --- | --- |
|  | **Sample Type** | **Sample ID** | **Location of the sample selected from the storage unit** | **The storage location is recorded in the sample database.** | **Consent form viewed (Y/N)** |
| **1** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **3** |  |  |  |  |  |
| **Comments / corrective actions taken** |  | | | | |

**Note: If corrective actions are needed, please contact the** [**HTGO**](mailto:b.r.thomas@swansea.ac.uk) **and send a copy of this self-audit.**

**Self Audit conducted by:……………………………………..**

**Signature:………………………………………………………..**

**Date:…………………….**