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| **Adverse Event Reporting Form** |

**Purpose**:

This document should be completed by Swansea University (SU) research groups (staff and students) handling and storing human tissue.

All SU staff and students working with human tissue should have a good understanding of the Quality Management System in place to ensure human tissue is being handled in line with the Human Tissue Act (2007) legislation and the Human Tissue Authority’s Codes of Practice.

**Instructions:**

Remove this cover page from the document.

The Person Designated / Principal Investigator / Chief Investigator should email this form to the [Human Tissue Governance Officer](mailto:HumanTissueResearch@swansea.ac.uk) (HTGO) when completed.

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| --- | --- | --- | --- | --- |
| **Human Tissue Adverse Event Reporting Form** | | | | |
| **Principal Investigator** | |  | | |
| **Person Designate** | |  | | |
| **Adverse Event (AE) Details** | | | | |
| **Date of occurrence** |  | | **Time of occurrence** |  |
| **Date of observation** |  | | **Time of observation** |  |
| **Name of person reporting AE** | | |  | |
| **If the tissue is related to a specific study, please give the study title and any reference numbers (IRAS / REC)** | | |  | |
| **Location of adverse event (building, room, freezer/storage unit)** | | |  | |
| **AE type (please tick)** | | | **Consent** |  |
| **Governance and Quality** |  |
| **Tissue Tracking** |  |
| **Storage** |  |
| **Transportation** |  |
| **Disposal** |  |
| **Other – provide details** |  |
| **Description of adverse event** | | |  | |
| **Description of any immediate corrective actions already taken** | | |  | |
| **Root cause of adverse event if identifiable** | | |  | |
| **Did the AE result in loss of / damage to HTA relevant material?\* Where yes, please provide details.** | | | **Yes** | **No** |
| **Please provide details of tissue that has been lost / subject to loss of integrity including individual sample identifiers and total numbers of samples.** | | |  | |
| **Category (refer to table 1)** | | | **Serious** |  |
|  | | | **Moderate** |  |
|  | | | **Minor** |  |
|  | | | **Near miss** |  |
| ***For HTA Governance use only*** | | | | |
| Reference: | | | | |
| Date received | | |  | |
| *Please complete this form at the point of identification of a human tissue adverse event and submit to HTA Governance Officer.* | | | | |

**Table 1 - Examples of categorisation of adverse events are shown below:**

| **Category** | **Example** |
| --- | --- |
| **Serious** | * Conduct of non-licensed activities (e.g. storage of relevant material for research without NHS REC approval) * Non-recoverable loss of unique relevant material (e.g. through freezer/alarm failure) * Relevant material removed from a participant, stored or used without appropriate consent * Staff member seeking consent without appropriate training * Loss/compromise of relevant material and/or patient records during transportation * Relevant material used for a research study without NHS REC approval * Breach of data protection/confidentiality * Failure to dispose of material appropriately |
| **Moderate** | * Relevant material transported without appropriate transfer agreement (e.g. MTA, SLA) in place * Labelling error that led to the incorrect use of samples * Inappropriate transport of specimens |
| **Minor** | * Incorrect version of policy or SOP in use * Not registering new SOPs or updating existing SOPS to reflect changes in practice * Documentation temporarily misplaced |
| **Near Miss** | An adverse event could have occurred if intervention had not been made, e.g.   * Short term cold storage failure with no harm to tissue * Freezer failure leading to the requirement to transfer samples to alternative locations. * Alarm failure with no harm to tissue * Labelling error that was remedied * Unauthorised access to tissue under licence with no harm to tissue |