**Adverse Event/Incident (AE/I) Report Form**

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| **Adverse Event/incident (AE/I) Report Form***To be completed by the Principal Investigator, with the assistance of the Person Designated for the area in which the AE/I occurred. A copy of the initial findings must be sent to the DI and Clinical Assurance Manager as soon as possible, and no later than 24 hours from the AE/I occurring or being known. A full report/update of the AE/I, action taken and further planned activities must be submitted to the DI and Clinical Assurance Manager within 5 working days of the AE/I occurring.* |
| **Type of report:** |  Initial / Follow-up / Final (**Delete as necessary**) |
| Date and time AE/I occurred: |  | Date and time AE/I observed (if different): |  |
| Name of person reporting initial AE/I  |  | Email address |  |
| Name of Principal Investigator (PI) |  | Email address |  |
| UEC or NHS REC number of study impacted (if more than one study, list all) |  |
| 1. **Reporting**
 |
| **AE/I reported to:** | **By:** | **Date (dd/mmm/yyyy):** |
| Person Designated (PD) |  |  |
| PI |  |  |
| Assurance |  |  |
| HTROG |  |  |
| DI |  |  |
| Other (please specify) |  |  |
| Name of PD notified |  | Email Address |  |
| 1. **AE/I details**
 |
| Location of AE/I (facility, room, freezer, database, off-site location etc.): |  |
| Type of AE/I: | [ ]  | Consent | [ ]  | Governance & Quality |
| [ ]  | Sample Taking | [ ]  | Sample Tracking |
| [ ]  | Storage | [ ]  | Transportation |
| [ ]  | Disposal | [ ]  | Other? |
| Where ‘Other’ has been selected, please provide further details: |  |
| Description of the AE/I (including the findings of any initial investigation): |  |
| Did the AE/I result in, or have the potential to result in personal injury? | [ ]  | Yes (complete separate accident/incident report form)  | [ ]  | No |
| Impact of AE/I – Please detail the impact of this event (e.g. on ethics, compliance, or storage of other samples): |  |
| 1. **Corrective Actions and Preventative Actions**
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| Has any immediate corrective action been taken – provide details: |  |
| (these points may be completed in a follow-up/final report if not available for the initial report) |
| Please detail any longer-term preventative or corrective action that will be taken (including planned completion dates): |  |
| Please provide any additional information relevant to the AE/I, including details of any meetings/discussions: |  |
| Report completed by: |  | Date completed |  |

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| 1. **To be completed by Assurance**
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| Severity of AE/I\* |  |
| Assurance to provide any additional information relevant to the AE/I, including details of any meetings/discussions: |  |
| AE/I closed by: |  |
| Date AE/I closed: |  |

\* Using the grading system below

**FOR RIGO USE: Grading of Adverse Events/Incidents for human tissue research activities**

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| **Severity Level** | **Description of Adverse Event / Incident (not exhaustive list)** |
| 5 Catastrophic | * Loss of unique human tissue that impacts on a study or potential future studies
* Loss of participant identification records in public area or during transportation
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| 4 Major | * Loss of human tissue not classed as unique
* Human tissue removed from a participant, stored or used without appropriate consent
* Staff member seeking consent who has not been appropriately trained
* Human tissue used for a research study which has not been approved by the appropriate Research Ethics Committee
* Breach of Data protection/confidentiality
* Incorrect type of specimen acquired or from wrong participant, specimen incorrectly labelled, specimen in wrong format
* Freezer/Nitrogen back-up and alarm failure resulting in destruction of material
* Unauthorised removal of material from a storage facility
* Human tissue placed with non-clinical or animal waste for disposal
* Quality of human tissue significantly compromised during transportation
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| 3 Moderate | * Human tissue transported to or from University of Surrey without appropriate contract/material transfer agreement (MTA) in place
* Labelling error that can be accurately rectified
* Not using a tracking system to record material acquisition, storage, use and disposal
* Inappropriate transport of specimens
 |
| 2 Minor | * Incorrect version of policy or SOP in use
* Not registering new SOPs or updating existing ones on the RIGO website
 |
| 1 Insignificant | * Incident occurred which resulted in no compromise of human tissue
 |
| 0 Near miss | * An AE/I could have happened if intervention had not been made
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