Human Tissue Act 2004 Standard Form: UoL AE/ Incident Reporting Guidance
 For guidance on use of this form see SOP HTA-A1022-UoL

| Severity Level |  | 1 | 2 | 3 | 4 | 5 |
| --- | --- | --- | --- | --- | --- | --- |
| Descriptor | Subdescriptor | Low | Minor | Moderate | Major | Catastrophic |
| Failure to adequately manage health & safety including:* Exposure to biological agents or hazards
* Exposure to potentially infectious human samples
 | Injury tostaff orothers | Minimal injuryrequiringno/minimalintervention ortreatment.No time off work. | First aidtreatment<3 days absence<2 daysextended hospital staySemi-permanentharm up to 1 year. | Medical treatment<15 daysAbsence.Hospitalstay 4 to 14 daysPermanent harmRIDDOR incident | Major injuries,or long termincapacity /disability (lossof limb). RIDDOR incident | Death or majorpermanentincapacity.RIDDOR incident |
| Inadequate management of samples, sample storage and/or data including:* Loss of material due to inadequate labelling and tracking system
* Loss of material in transfer
* Loss of material due to storage equipment failure or security breach
* Loss of patient or sample data
* Material disposed of by an inappropriate method/route
* Disposal records not retained for audit.
 | Damage, loss or theft.Breach of security to premises.Breach of data confidentiality and anonymity. | Temporary loss of data recoverable via back-upCollection placed at risk due to storage/equipment failure but no losses occurred. | Minimal loss of material/data which does not compromise tissue collection. | Single failure to ensure specimen security and integrity and/or patient confidentiality. | Multiple losses of personal and or identifiable dataMultiple failures to ensure specimen security and integrity. | Total loss of collection due to security breach or storage failure without adequate back-up. |
| Breach of ethical standards including* Tissue collected, stored or used without appropriate consent.
* Tissue collected, stored or used for a purpose not covered by consent.
 | Inspection /Audit | Minorrecommendations/non-compliancewith relevant standards and regulations | Single failure toadhere to internalstandards, policies and procedures | Single failure toadhere to national standards, HTA Codes of Practice and regulations | Multiple failuresto comply with internal standards, policies and procedures | Multiple failuresto comply with national standards, HTA Codes of Practice and regulations |
| Interruption to/disruption of research  | Research targets | Loss / interruption/minor disruption to research in local laboratory | Loss / interruption/disruptionto research of other groups in multi-user lab | Disruption to research in acritical area | Disruption to research in oneor more critical areas | Disruption to research University-wide |
| AdversePublicity | Reputation oforganisation | Rumours:Minimal ImpactLocal Press  | Regular ConcernLocal Media 1 to | Moderate loss of confidenceNational Media  | Major loss ofconfidenceNational Media | Internationaladverse publicitysevere loss ofConfidence.Public inquiry |