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 | Sub  descriptor | 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 to  staff or  others | Minimal injury  requiring  no/minimal  intervention or  treatment.  No time off work. | First aid  treatment  <3 days absence  <2 days  extended hospital stay  Semi-permanent  harm up to 1 year. | Medical treatment  <15 days  Absence.  Hospital  stay 4 to 14 days  Permanent harm  RIDDOR incident | Major injuries,  or long term  incapacity /  disability (loss  of limb). RIDDOR incident | Death or major  permanent  incapacity.  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-up  Collection 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 data  Multiple 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 | Minor  recommendations  /non-compliance  with relevant standards and regulations | Single failure to  adhere to internal  standards, policies and procedures | Single failure to  adhere to national  standards, HTA Codes of Practice and regulations | Multiple failures  to comply with internal standards, policies and procedures | Multiple failures  to 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/disruption  to research of other groups in multi-user lab | Disruption to research in a  critical area | Disruption to research  in one  or more critical areas | Disruption to research University-wide |
| Adverse  Publicity | Reputation of  organisation | Rumours:  Minimal Impact  Local Press | Regular Concern  Local Media 1 to | Moderate loss of confidence  National Media | Major loss of  confidence  National Media | International  adverse publicity  severe loss of  Confidence.  Public inquiry |