Human Tissue Act 2004 Standard Form: UoL

Adverse Event/ Incident Reporting Form

For guidance on use of this form see SOP HTA-A1022-UoL

1. Reporting

|  |  |  |
| --- | --- | --- |
| AE/Incident reported to: | By: | On:  (dd/mmm/yyyy) |
| Person Designated |  |  |
| Designated Individual |  |  |
| Research Governance Office (RGO) |  |  |
| College of Life Sciences Human Tissue Governance Committee Meeting |  |  |
| Other personnel (Please Specify ) |  |  |

This form is to be completed within 24 hours of becoming aware of the Incident/Adverse Event

Type of Report (Select relevant type of Report box)

Initial

Follow Up

Final

Initial & Final

2. Adverse Event/ Incident

|  |
| --- |
| Date AE/ Incident occurred |
|  |
| Date DI or staff under PD’s supervision informed of/made aware of AE/ Incident |
|  |

|  |
| --- |
| Premise/site of AE/ Incident |
|  |
| Summary of AE/Incident |
|  |
| Severity/grade of AE/ Incident (Select relevant box) |
| Low  Minor  Moderate  Major  Catastrophic |

3. Initial action taken by DI and/or PD since being made aware of AE/ Incident

|  |
| --- |
| Initial action taken |
| Corrective |
|  |
| Preventative |
|  |
| Date of resolution, if applicable (dd/mmm/yyyy) |
|  |

4. Any other relevant information

|  |
| --- |
| Please provide any additional information relevant to the AE/ Incident |
|  |

|  |  |
| --- | --- |
| Report completed by: | Date report submitted: |
|  |  |
| AE/ Incident closed by: | Date closed: |
|  |  |