**HTA-32: Human Tissue Adverse Event Reporting Form**

To be completed with reference to the standard operating procedure “*HTA-32: Reporting an adverse event*”

1. *Staff details*

|  |  |
| --- | --- |
| Individual reporting adverse event |  |
| Date of Report |  |
| Principal Investigator |  |

1. *Details of Adverse Event*

|  |  |
| --- | --- |
| Date of Adverse Event |  |
| Type of Adverse Event | *Delete as appropriate*  **Acquisition/Use/Storage/Disposal** |
| Details of Adverse Event |  |
| Immediate corrective or preventative actions taken |  |

**Part 2: To be filled in discussion with Human Tissue officer (HTO) or Persons Designated (PD)**

1. *Details of adverse event meeting*

|  |  |
| --- | --- |
| *Date of Meeting with HTO/PD* |  |
| *Staff members present* |  |

1. *Analysis of Adverse Event*

Refer to the guidance in the HTA-32 SOP. Considering the events running up to the adverse event, can problems be identified in any of the following areas?

|  |  |
| --- | --- |
| People | Yes / No |
| Management | **Yes / No** |
| Procedure | **Yes / No** |
| Equipment | **Yes / No** |
| Materials | **Yes / No** |
| Environment | **Yes / No** |
| Please provide further details on any aspect to which “Yes” was answered |  |

**Use the information here to complete Fishbone diagram below.**

**

*Action Plan*

Actions agreed to be taken by:

|  |  |
| --- | --- |
| Chief Investigator and Research Team |  |
| Human Tissue Officer |  |
| Designated Individual |  |

|  |  |
| --- | --- |
| **Date of follow-up meeting to review progress** |  |

|  |  |  |
| --- | --- | --- |
| **Chief Investigator** | **Signed** | **Date** |
| **HTO/PD** | **Signed** | **Date** |
| **Designated Individual** | **Signed** | **Date** |

Part 3: *Follow-up meeting*

|  |  |
| --- | --- |
| Chief Investigator and Research Team | Have all actions been successfully completed? Yes / No  If No – Please provide details and action to be taken below (including agreed timescales) |
| Human Tissue Officer | Have all actions been successfully completed? **Yes / No**  If No – Please provide details and action to be taken below (including agreed timescales) |
| Designated Individual | Have all actions been successfully completed? **Yes / No**  If No – Please provide details and action to be taken below (including agreed timescales) |

|  |  |  |
| --- | --- | --- |
| **Chief Investigator** | **Signed** | **Date** |
| **HTO/PD** | **Signed** | **Date** |
| **Designated Individual** | **Signed** | **Date** |