|  |  |
| --- | --- |
| Loughborough University | **HTA Training Record** |
| **The Centre for Biological Engineering** |
| Document Ref: HTA-RM-FORM/005 | Version No: | 2.0 | Issue Date: |  |
|  |  |
| **HTR No: CBE-HTA/TR/000** |  | **Working with HTA Licensable Material** |

**Part 1A: Standard Operating Procedure (SOP) Sign-off**

This section is to certify that you have:

* Read the SOPs relevant to your role
* Understand how to apply the SOPs to your work
* Know where to locate a copy of the current SOPs

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SOP Number** | **Title** | **Version** | **Date Read** | **Signature** |
| HTA-QS-SOP001 | Production & control of SOPs applied to activities involving HTA licensable material |  |  |  |
| HTA-QS-SOP002 | Change control for work activities involving HTA licensable material |  |  |  |
| HTA-RM-SOP003 | Induction and training for HTA compliance |  |  |  |
| HTA-PR-SOP004 | Receipt and storage of HTA licensable material |  |  |  |
| HTA-PR-SOP005 | Setting up and editing projects in the Procuro database |  |  |  |
| HTA-PR-SOP006 | Acquisition, transfer and transport of HTA licensable material |  |  |  |
| HTA-PR-SOP007 | Disposal of HTA licensable material |  |  |  |
| HTA-MI-SOP008 | Reporting of adverse events relating to HTA licensable material |  |  |  |
| HTA-MI-SOP009 | Self-inspection audit of research activities involving HTA licensable material |  |  |  |
| HTA-MI-SOP010 | Risk management and contingency planning |  |  |  |
| HTA-PR-SOP011 | Freezer Maintenance Schedule and Manual Challenge of Freezer alarms. |  |  |  |
| HTA-PR-SOP012 | Obtaining Informed Consent from Human Participants  |  |  |  |
| HTA-PR-SOP013 | Withdrawal of consent for using human material for research  |  |  |  |

**Part 1B: Relevant Reading Material Sign-off**

|  |  |  |  |
| --- | --- | --- | --- |
| **Document Title** | **Version** | **Date Read** | **Signature** |
| HTA Code of Practice for Research  |  |  |  |
| University HTA Compliance Quality Manual  |  |  |  |
| CBE Quality Manual  |  |  |  |

**Part 2: Local HTA Compliance Training**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Training Event | Date | Certificate attached | Trainee’s signature | Trainer’s signature |
| **1** | Medical Research Council e-learning course on Research and human tissue legislation\*\*. |  | [ ] Yes[ ] No |  |  |
| **2** | University HTA Training \* |  | [ ] Yes[ ] No |  |  |
| **3** | Local CBE HTA induction training |  | [ ] Yes[ ] No |  |  |
| **4** | Local sample tracking training session (Procuro database) |  | [ ] Yes[ ] No |  |  |

*\*Certificate/evidence of completion required*

*\*\*Competency assessed*

**Declaration**

I believe that I have received adequate information, instruction and training to be able to carry out my work with HTA licensable material safely and in accordance with the Human Tissue Act (2004) and the local SOPs. In the event of any situation arising where I am not sure about the appropriate action to take I will seek advice before proceeding. Where appropriate I will bring to the attention of my supervisor and/or Principal Investigator for the research project any concerns that I have in relation to my work with HTA licensable material

**Researcher**

|  |  |
| --- | --- |
| Name:  |  |
| Signature: | Date: |

**Principal Investigator or Person Responsible (where applicable)**

I confirm that I accept overall responsibility for the involvement of the above named researcher on research projects involving HTA licensable material that I am custodian for.

|  |  |
| --- | --- |
| Name:  |  |
| Signature: | Date: |

**Approval**

**Departmental Person Designate**

I confirm that the above named researcher is registered for working with HTA licensable material in the CBE.

|  |  |
| --- | --- |
| Name:  |  |
| Signature: | Date: |