End of Study Sample Application Form

Any relevant material being stored at the end of the study on University premises must be notified to the HTA Monitoring Officer and the DI to the HTA Research Licence (12384) **in advance** of the ethics expiry date.

In addition, there should be the following documentation available: i) the ethics approval the samples were collected; ii) a copy of the PIS, and iii) a copy of the written consent form. This will ensure we remain compliant with the Human Tissue Act, 2004.

Failure to follow this could mean that your material is confiscated due to non-compliance with the Human Tissue Act.

# Section A

|  |  |
| --- | --- |
| UoL study number: |  |
| IRAS reference: |  |
| REC Reference: |  |
| Date of favourable ethical approval: |  |
| Date of original ethics expiry: |  |
| Study / Project / Collection Name: |  |
| CI /PI: |  |
| Samples manager name |  |
| Contact email: |  |

# Section B

|  |  |
| --- | --- |
| Are your samples:\* See HTA List of [*relevant material.*](https://www.hta.gov.uk/sites/default/files/List_of_materials_considered_to_be_relevant_material_under_the_Human_Tissue_Act_2004.pdf) | Relevant material as defined by the HTA?\*  Non-relevant material?  Both? |
| If non-relevant samples are to be stored, what are these | DNA  Plasma  Serum  Primary cell cultures  Supernatants  Other |
| If other, please give details: |  |
| What are your plans for the remaining samples? | Storage by research team under the UoL Research Licence 12384 pending ethical approval for use in another project.  Storage by research team under the UoL Research Licence 12384 as part of a new research tissue bank.  Storage by research team under the UoL Research Licence 12384 and transferred into an active research tissue bank.  Transferred to an alternative HTA Licence.  Storage by research team of biological material which is “not relevant” for the purposed of the Human Tissue Act.  Disposal in accordance with the Human Tissue Code of Practice.  Other.  If Other, please state: |
| Are these arrangements the same as declared in the IRAS form? | Yes  No |
| Has the end-of-study documentation been sent and original REC notified about the transfer and storage under the UoL Research Licence 12384 | Yes  No |
| Have your samples been collected from the living or deceased donors? | Living  Deceased |
| Are your tissue samples related to a clinical trial? | Yes  No |

# Section C

|  |  |  |
| --- | --- | --- |
| Number of samples | Type of Sample (e.g., whole blood, plasma, biopsy etc.) | Relevant Material |
|  |  | Yes  No |
|  |  | Yes  No |
|  |  | Yes  No |
|  |  | Yes  No |
|  |  | Yes  No |
|  |  | Yes  No |

**Please note that long term storage of any relevant material must be in a HTA licensed area and follow the HTA Licence SOP for storage**

# Section D

|  |  |
| --- | --- |
| Long Term Storage Room Temperature / Freezer Location | |
| Location of samples: | Glenfield General Hospital (GGH)  Leicester Royal Infirmary (LRI-RKCSB)  Leicester General Hospital (LGH)  University of Leicester - Adrian Building  University of Leicester - Maurice Shock Building  University of Leicester - Henry Welcome Building  University of Leicester - Hodgkin Building  Other  If other, please give details: |
| Freezer Asset ID / Location: |  |
| Does this freezer have a freezer monitoring system: | Yes  No |
| Details of freezer monitoring system: |  |

# Section E

|  |  |
| --- | --- |
| Are consent forms available for the samples? | Yes  No |
| Location of the consent forms? |  |
| Do you have a Sample Storage Log? | Yes  No |
| If yes, please confirm location of the Sample log: |  |
| Do you have full temperature logs for the duration of the sample storage? | Yes  No |
| If no, please give details. |  |
| Have there been any temperature excursions or freezer breakdown that may have compromised the integrity of the samples? | Yes  No |

# Section F

|  |  |
| --- | --- |
| I confirm that the above information is accurate: | |
| CI Name: |  |
| Signed: |  |
| Date: |  |

|  |  |
| --- | --- |
| Copy sent to Departmental PD | |
| PD Name: |  |
| Department: |  |
| Date: |  |

|  |  |
| --- | --- |
| Review by Research Governance Office | |
| Print Name |  |
| Signature |  |
| Date: |  |
| Has a full consent audit taken place: | Yes  No |
| Date consent audit undertaken: |  |
| Consent audit undertaken by: |  |

* Please note that cultured cells (after passage 1) and cells lines are not HTA relevant materials.
* For further information regarding the Research Sector, please refer to [Code E](https://www.hta.gov.uk/sites/default/files/Code%20E.pdf) of the HTA codes of practice. The [HTA Standards](https://www.hta.gov.uk/sites/default/files/Code%20E%20Research%20Standards%20and%20Guidance.pdf) are also available. Information on [licensing exemptions](https://www.hta.gov.uk/policies/licensing-exemptions)is also available on the HTA website.
* Please refer to the Research Governance Office webpages for further information and HTA standard operating procedures.

On completion, please return this to [*HTAenquiries@leicester.ac.uk*](mailto:HTAenquiries@leicester.ac.uk)