Sample Application Form for Imported Samples

Any relevant material being imported to the University premises must be notified to the HTA Monitor and the DI to the HTA Research Licence (12384) in advance of the transfer-taking place.

In addition, there should be a corresponding MTA to go alongside this document that details;

1. the ethics approval the samples were collected
2. whether study participants gave written informed consent, and
3. what the tissue can be used for as guided by i) and ii).

A patient information sheet and blank consent form should also be provided. 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

|  |  |
| --- | --- |
| MTA reference: |  |
| IRAS ref (if applicable): |  |
| Date of favourable ethical approval: |  |
| Date of original ethics expiry: |  |
| REC Ref (if applicable): |  |
| Project / Collection name: |  |
| CI / PI for imported tissue collection: |  |
| 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? |
| Material Description: | Blood or blood Derivatives  FFPE Blocks  Frozen Blocks  Glass Slides  Other |
| If other, please give details: |  |
| Are the samples: | From a current ethically approved study.  Part of a collaboration agreement.  Being imported from Scotland.  Being imported from outside the UK.  Storage by research team as material which is “not relevant” for the purposed of the Human Tissue Act.  Other. |
| If other, please give details: |  |
| Are these arrangements the same as declared in the IRAS form? | Yes  No  Not applicable (due to outside of the UK) |
| 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**

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 all of the samples? | Yes  No |
| Location of the consent forms? |  |
| If you cannot have copies of the consent forms, do you have a blank template of the consent form? | Yes  No |
| Do you have a full sample log? | Yes  No |
| If yes, please confirm location of the Sample log: |  |

# 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: |  |
| Documents available: | MTA  Patient information sheet  Consent form template  Ethics approval (UK) |

* 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 of the HTA codes of practice. The HTA Standards is also available. Information on licensing exemptions is also available on the HTA website.
* Please refer to the RGO website for further information and HTA standard operating procedures.

On completion, please return this to:

[HTAenquiries@le.ac.uk](mailto:HTAenquiries@le.ac.uk)