**Registering a Human Tissue study with the UoM**

**Research Governance, Ethics and Integrity Team**

On completion, please return this form to: [diane.escott@manchester.ac.uk](mailto:diane.escott@manchester.ac.uk)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | |  | | | | | | | | |
| **Faculty and School** | |  | | | | | | | | |
| **Email** | |  | | | **Phone** | |  | | | |
| Q1 | Are your tissue samples:   1. Relevant material as defined by the HTA?\* 2. Non-relevant material? 3. Both?   \*See HTA List of relevant material at the end of this document, or click on pdf link:  <https://www.hta.gov.uk/sites/default/files/List_of_materials_considered_to_be_relevant_material_under_the_Human_Tissue_Act_2004.pdf> | | | | | | | | | |
| Q2 | Will you be carrying out DNA (RNA) analysis on any of the samples you receive, either relevant material, bodily material or acellular material, either extracted or to be extracted? | | | | | | | | | Yes  No |
| Q3 | Are your tissue samples related to a clinical trial? | | | | | | | | | Yes  No |
| Q4 | If you have samples of relevant materials stored under the University’s Human Tissue Authority (HTA) research licence please state below the Person Designated for the licensed collection **and complete questions 7.1 – 7.4**  **Person Designated** | | | | | | | | | |
| Q5 | Do you have samples of HTA relevant material that are either NOT stored under the University’s HTA research licence or do not [have valid NHS REC approval?](http://www.hra.nhs.uk/research-community/applying-for-approvals/)  ***If ‘Yes’ please complete questions 7.1 - 7.4 and return the form immediately to*** [diane.escott@manchester.ac.uk](mailto:diane.escott@manchester.ac.uk) ***to make arrangements for the samples to be prepared for storage under the University’s HTA Research licence.***  ***If ‘No’ please continue to Q6*** | | | | | | | | | Yes  No |
| Q6 | Are you storing any human tissue samples with [current valid research ethics approval from an NHS REC](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/) (this includes tissue obtained from a research tissue bank)? *Please use an additional form if you need to report more than one study.*  Study PI  ***If ‘No’ please return the survey; otherwise please continue to Q7.1*** | | | | | | | | | Yes  No |
| **PLEASE COMPLETE ALL QUESTIONS IN SECTION 7** | | | | | | | | | | |
| Q7.1 | Title of Study | | | Ethics Ref    Sponsor | | Tissue Bank Name *if applicable* | | Date ethics expires | | |
| Will your tissue samples be retained for future use at the end of the study when ethics expires? | | | | | | | | Yes    No | |
| Approximate number of samples in storage? | | | | | | | |  | |
| Q7.2 | Are the samples stored on UoM HTA Licensed premises? | | Yes  No | | | | | | | |
| Q7.3 | If the samples are stored on UoM HTA Licensed premises, please provide the following: | | School  Building  Room number | | | | | | | |

|  |  |  |
| --- | --- | --- |
| Q7.4 | Have your samples been collected from living or deceased\* donors:  *(\*At the point of sample collection)*  Living  Deceased  Please indicate the types of samples stored *Tick all that apply* | |
| Organs, solid tissue, tissue biopsies,  Includes fresh, frozen, fixed and embedded tissues. |  |
| Tissue sections mounted on slides |  |
| Bodily waste products (including excretions and secretions) containing cells |  |
| Primary cells |  |
| Whole blood |  |
| Others (please specify) |  |

* Please note that cultured cells (after passage 1) and cell lines are not HTA relevant.
* Information for the [Research Sector](https://www.hta.gov.uk/regulated-sectors/research) with a set of [frequently asked questions](https://www.hta.gov.uk/faqs), information on licensing exemptions and consent exemptions is available on the [HTA website](https://www.hta.gov.uk/).
* Please refer to the Research Governance website for further information:

<https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/>

On completion, please return this survey to: [diane.escott@manchester.ac.uk](mailto:diane.escott@manchester.ac.uk)

Training - All staff using human tissue in research must complete the [MRC human tissue e-learning training](http://byglearning.co.uk/mrcrsc-lms/course/category.php?id=1). Once you are on the page choose Research and Human Tissue Legislation. You will need to either login or create a new account.

**List of materials considered to be ‘relevant material’ under the Human Tissue Act 2004**

This list is intended to supplement the HTA’s guidance on ‘relevant material’.

The list is not intended as exhaustive or exclusive, but is intended to provide guidance to stakeholders in respect of a number of materials that might be considered relevant material. The HTA will review the list periodically and update it as required.

Where a material is not included within the following list, stakeholders should use the information on our website to make their own assessment about whether it is relevant material, seeking advice from us where necessary.

Materials classified in the following list as relevant material are done so subject to the following general caveat that they are relevant material except where:

* They have divided or been created outside the human body
* They have been treated, processed or lysed through a process intended torender them acellular. This would include the freezing or thawing of cells onlywhere that process is intended to render the material acellular.

Although cell damage can be minimised by controlling the rate of temperature change and/or by adding one or more ‘cryoprotective’ agents, freezing/thawing can cause cell damage such that no whole cells remain. Centrifugation can be used to remove residual platelets from plasma, rendering it acellular, but the effectiveness is dependent on the protocol used. In either case, sufficient validation data (either in-house or published research) should be provided if the techniques are to be relied on to render samples acellular.

|  |  |
| --- | --- |
| **Material** | **‘Relevant material’ for the purposes of the Human Tissue Act 2004?** |
| Antibodies | No |
| Bile | Yes |
| Blood | Yes |
| Bone marrow | Yes |
| Bones/skeletons | Yes |
| Brain | Yes |
| Breast milk | Yes |
| Breath condensates and exhaled gases | No |
| Buffy coat layer (interface layer between plasma and blood cells when blood is separated) | Yes |
| Cell lines | No |
| Cells that have divided in culture | No |
| CSF (cerebrospinal fluid) | Yes |
| Cystic fluid | Yes |
| DNA | No |
| Eggs (ova)\* | No |
| Embryonic stem cells (cells derived from an embryo) | No |
| Embryos (outside the body)\* | No |
| Extracted material from cells e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids. | No |
| Faeces | Yes |
| Fetal tissue | Yes |
| Fluid from cystic lesions | Yes |
| Gametes\* | No |
| Hair (from deceased person) | Yes |
| Hair (from living person) | No |
| Joint aspirates | Yes |
| Lysed cells | No |
| Mucus | Yes |
| Nail (from deceased person) | Yes |
| Nail (from living person) | No |
| Nasal and bronchial lavage | Yes |
| Non-blood, derived stem cells (i.e. derived from the body.) | Yes |
| Non-fetal products of conception ( i.e. the amniotic fluid, umbilical cord, placenta and membranes) | Yes |
| Organs | Yes |
| Pericardial fluid | Yes |
| Plasma  (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and other blood cells. If any of these cells are present, then the plasma must be regarded as relevant material). | No |
| Platelets | Yes |
| Pleural fluid | Yes |
| Primary cell cultures (whole explant/biopsy present) | Yes |
| Pus | Yes |
| RNA | No |
| Saliva | Yes |
| Serum | No |
| Skin | Yes |
| Sperm cells (spermatozoa)\* | No |
| Sputum (or phlegm) | Yes |
| Stomach contents | Yes |
| Sweat | No |
| Teeth | Yes |
| Tumour tissue samples | Yes |
| Umbilical cord blood stem cells | Yes |
| Urine | Yes |

**Notes**

\* While outside the definition of relevant material for the purposes of the Human Tissue Act 2004, these materials fall within the remit of the Human Fertilisation and Embryology Act 1990, and are regulated by the Human Fertilisation and Embryology Authority (HFEA).