

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

**Research Governance, Ethics and Integrity team**

The Human Tissue Act (HT Act) 2004 requires that HTA relevant human tissue samples for research must be stored either under the authorisation of an active project with ethical approval from an NHS Research Ethics Committee (which includes Tissue Banks) or under the University research licence (12172) from the Human Tissue Authority (HTA). **This is a statutory requirement; non-compliance is a criminal offence.** [Relevant material under the Human Tissue Act 2004 | Human Tissue Authority (hta.gov.uk)](https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004)

**Why do I need to register my human tissue study?**

The University of Manchester is legally required to keep a comprehensive database of human tissue holdings that are considered **HTA relevant material**, for research purposes, on its licensed premises. This includes human tissue stored under the HTA licence and human tissue stored under NHS Research Ethics Committee approval.

**Who does this apply to?**

Individuals (irrespective of whether they are University Staff) using and storing human biological samples (samples which consist of or include human cells) on **University of Manchester premises, including MIB and WMIC**.

For non-University sites, please ensure that you inform the Designated Individual at that site of your use/storage of human tissue samples for research purposes.

For samples stored on Manchester Foundation Trust premises please contact

 Dr Jay Brown (Jay.Brown@mft.nhs.uk).

For samples stored on Christie Hospital premises, Paterson Building, Alderley Park and the Oglesby Cancer Research Centre, please contact

 Ms Basia Hunt (the-christie.HumanTissueResearch@nhs.net).

For samples stored at Salford Royal Hospital please contact

 Dr Rob Oliver (Rob.Oliver@manchester.ac.uk).

**Who should complete this form?**

The form should be completed by individuals who have the primary responsibility for the use and storage of biological samples. This will typically be the **Principal Investigator**, but may include:

* Custodians of tissue banks/holdings
* Other staff (e.g. clinicians) storing tissues for research purposes

**What information should I include?**

You should provide information about all human biological samples (human tissue and cell samples, other than gametes, cell lines and embryos) that you use or store for research purposes.

**What if I have several research projects that involve human biological samples?**

It may not be straightforward for you to complete a single form that covers all the studies and samples that you utilise. In this case you may complete a separate form for each study.

**What are the consequences of failure to register my human tissue study?**

If you are in possession of human tissues that constitute relevant materials under the HT Act and which are stored as part of an active project with ethical approval from an NHS Research Ethics Committee, but fail to inform us of these tissues, it will not be possible to retain those samples on UoM premises after ethical approval expires.

If you are in possession of human tissues that constitute relevant materials under the HT Act and which are not stored as part of an active project with ethical approval from an NHS Research Ethics Committee, or as part of a collection under the University’s Human Tissue Authority research licence, failure to inform the University of these tissues by completing this form and initiating the process of storage under the University human tissue research licence, is a criminal offence and will leave you liable to prosecution in the event that your possession of such materials becomes known to the University.

**What happens next?**

If you are in possession of human tissues that should be stored under the University’s human tissue research licence, the HTA Designated Individual will contact you. Your laboratory will be assessed to determine whether it complies with the standards required and assistance given to reach compliance where appropriate.

**What should I do if I have any questions?**

Contact Diane Escott, email diane.escott@manchester.ac.uk

Thanking you in advance for your prompt attention to this matter.

Yours sincerely

**Dr Andrew Povey Professor Nalin Thakker**

Designated Individual for HTA Research Licence VP for Social Responsibility

**Please open in the Desktop App and then click View / Edit to use the checkboxes**

**You will need to File/Save your changes, as the document will not automatically save**

On completion, please return this form to: diane.escott@manchester.ac.uk

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| **Name of person completing the form** |       |
| **Faculty and School** |       |
| **Email** |       |
| Q1 | Are your human tissue samples:1. Relevant material as defined by the HTA?\* [ ]
2. Non-relevant material? [ ]
3. Both? [ ]

**\*List of materials considered to be ‘relevant material’ under the Human Tissue Act 2004**[Relevant material under the Human Tissue Act 2004 | Human Tissue Authority (hta.gov.uk)](https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004) |
| Q2 | Will you be carrying out DNA (RNA) analysis on any of the human tissue samples, either from HTA relevant material, bodily material or acellular material (either extracted or to be extracted)? | Yes [ ]  No [ ]  |
| Q3 | Are your human tissue samples related to a clinical trial? | Yes [ ]  No [ ]  |
| Q4 | If you already have samples of HTA relevant materials stored under the University’s Human Tissue Authority (HTA) research licence 12172, please state below the Person Designated for the licensed collection.**Person Designated**                  |
| Q5 | Are you storing any HTA relevant material 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 survey form if you need to report more than* ***one*** *study.*Study PI            NHS REC reference            IRAS           ***If yes,*** *please complete questions 7.1 to 7.7****If no,*** *please complete question 6* | Yes [ ] No [ ]  |
| Q6 | 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 - 7.7 and return the form immediately to* 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 return the form to* *diane.escott@manchester.ac.uk* | 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 the human tissue samples be retained at the end of the study when ethics expires, for use in future research? | Yes [ ]  No [ ]  |
| Do you have consent to retain these human tissue samples?  | Yes [ ]  No [ ]  |
| Approximate number of human tissue samples currently in storage? |       |
| Q7.2 | Are the human tissue samples stored on UoM licensed premises? This includes main campus, MIBand WMIC.  | Yes [ ] No [ ] If no, where are the samples stored      |
| Q7.3.1 | If the human tissue samples are stored on UoM licensed premises, please provide the following: | School      Building     Room number       |
| Q7.3.2 | How do you store the human tissue samples?Tick all that apply | ambient temperature [ ] refrigerator [ ] -20 freezer [ ] -80 freezer [ ] -150 freezer [ ] Liquid nitrogen [ ] Other       |

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| Q7.4 | Have your human tissue samples been collected from living and/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)                |  |
|  | **Plasma:** Please note that 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. |
|  | **Sebum:** Please note that recent advice from the HTA states that if the method used to collect sebum also collects human cells at the same time then, the sebum sample must be regarded as relevant material if you are storing the sebum for research related to understanding the connection between it and disorders or the functioning of the human body. If the work will store material to solely undertake research into the sebum (and it is not related to any research on disorders or functioning of the human body) then it may be exempt from the licensing requirement. |
| Q7.5 | Consent for the storage and use of HTA relevant human tissue must be obtained in accordance with the requirements of the Human Tissue Act 2004 and as set out in the Code of Practice. |
|  | Do you keep copies of consent forms on UoM premises? | **Yes No N/A**[ ]  [ ]  [ ]  |
|  | Where human tissue samples are sourced from a third party (research tissue bank, NHS Trust etc) do you have the necessary assurance that appropriate consent was taken? | **Yes No N/A**[ ]  [ ]  [ ]  |
| Q7.6 | Are any human tissue samples imported from outside the UK? | **Yes No N/A**[ ]  [ ]  [ ]  |
| Q7.7 | Will you be exporting any samples outside of the UK?  | **Yes No N/A**[ ]  [ ]  [ ]  |

* Please note that cultured cells (after passage 1) and cell lines are not HTA relevant.
* Information for the Research Sector is available on the HTA website here

[Research | Human Tissue Authority (hta.gov.uk)](https://www.hta.gov.uk/guidance-professionals/guidance-sector/research)

* Please refer to the UoM Research Governance, Ethics and Integrity website for further information: <https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/>

**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) which is found here <http://www.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 an account.

Research Staff must be trained in the seeking and taking of consent for research purposes. This may be GCP (Good Clinical Practice) training for NHS REC approved studies or for UREC approved studies Faculty specific handbooks can be found which offer guidance on consent.

The GCP training can be found here : [Good Clinical Practice (GCP) | NIHR](https://www.nihr.ac.uk/health-and-care-professionals/training/good-clinical-practice.htm)

The Faculty handbooks provide an introduction to ethics and guidance on consent and can be found here: <https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/events-training/>

For NHS REC approved studies, where consent is taken by local site staff, ie not UoM staff or students, the UoM CI should satisfy them self that competence for taking consent is in place, as in line with HRA advice: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/>

**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 to render them acellular. This would include the freezing or thawing of cells only where 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.

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| **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 Sebum (please note: Recent advice from the HTA states that if the method used to collect sebum also collects human cells at the same time then, the sebum sample must be regarded as relevant material if the sebum sample itself is to be used for research on disorders or functioning of the human body)  | Yes No |
| 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