



WORKING WITH HUMAN TISSUE AND PATIENT INFORMATION - UCL GUIDELINES

Please also see the Document 'Checklist of Requirements and Responsibilities for Working with Human Tissue and Patient Information – UCL Biobanks v.4-A. *'

Do you know the rules governing how to work with human tissue and patient data?

Training on the Human Tissue Act and working with clinical information

All staff using human tissue must be aware of the rules governing the use of human tissue, set out in the Human Tissue Act, and be competent to work to the HTA (Human Tissue Authority) Standards for Research. Research staff, students and newly appointed Principal Investigators must provide evidence that they have undertaken training in the Human Tissue Act, if they are performing research involving human samples. Human tissue includes anything from a human which contains whole cells including blood and blood products, tissue, cells, urine, sputum, faeces etc., or tissue sections. The HTA regulates all cellular material with the exception of gametes, which are regulated by the UK fertility regulator HFEA. For example, blood is regulated by the HTA and deemed to be 'relevant material' however some blood derivatives, such as plasma and serum, provided they are processed appropriately, are not regulated by the HTA as they are considered to be acellular.

It is vital that researchers are aware of how their research is regulated under the Human Tissue Act. *An overview of human tissue legislation with practical tips for compliance is given in the MRC e-learning module "Research and human tissue legislation". Scroll down to this module on the [MRC Regulatory Support Centre e-learning page](https://www.mrc.ac.uk/learning-centre/e-learning-modules). Registration is straightforward, and a number of other helpful e-learning modules are also listed on this page.*

Equally important is awareness of the rules governing **the confidentiality around information about patient and volunteers involved in research**. Information on Data Protection can be found at <https://www.ucl.ac.uk/data-protection/data-protection-overview/understanding-data-protection-ucl>, and **UCL Data Protection Online Training is available for Staff and Students at <https://www.ucl.ac.uk/data-protection/data-protection-overview/online-training/data-protection-online-training>.**

Access to clinical information for research purposes is only permitted with ethical approvals and informed consent from the patient. Access to human tissue without informed consent can only be permitted in certain circumstances and must be specifically approved by a recognised ethical committee.

Risk of infection while working with human tissue

All human tissue, such as blood, blood products, urine, solid tissue and aerosols from tissue are potentially infectious. People who work with human tissue but particularly those using needles, and other sharp instruments are at risk of exposure to blood-borne viruses (BBVs), but also infections from other pathogens depending on the type of tissue, e.g. respiratory pathogens associated with lung disease. Cuts and punctures with contaminated sharps and splashes



to mucous membranes such as the eye or mouth should also be considered as a route for accidental exposure. Every effort must be made by staff and students to avoid accidental exposure to any infectious agent. All staff and students must follow safe working practices when working with human tissue, such as gloves, lab coats, and safety goggles, etc..

If you have been or think you have been exposed to blood or body fluids, the following procedures should be followed, please see **'What do I do if I have a needle stick injury or other accidental exposure to blood or body fluids?'** which is under 'Workplace' on the UCL HR Health site on the UCL HR Workplace Health webpage at <https://www.ucl.ac.uk/human-resources/health-wellbeing/workplace-health/faqs#About-OHW>. You should also inform your line manager/DSO.

There is a requirement to be vaccinated for Hepatitis B 8 weeks before commencing any work using unfixed human tissue samples, including blood, blood products and tissue (**'Do I need to be vaccinated against Hepatitis B?'** under 'Workplace' on the UCL HR Health webpage at <https://www.ucl.ac.uk/human-resources/health-wellbeing/workplace-health/faqs>). There are several other infectious agents for which there are not vaccinations such as hepatitis C and HIV. Please contact your local Health and Safety lead in the first instance, to complete a Job Hazard Form arrange for a referral to UCL Occupational Health & Wellbeing for vaccination or confirmation of immunity prior to starting your laboratory work (<https://www.ucl.ac.uk/human-resources/files/job-hazard-formdoc>).

Ethical approval for your research

Before carrying out any research on human samples, it is necessary for the project to have received Ethical Approval from an appropriate body. A specific project-based research study utilizing human samples and data needs to have obtained NHS Health Research Authority (HRA) Approval. For information on how to prepare and submit an application for HRA ethical review please refer to the [IRAS Website](#) which is used to apply for ethical review for project based research, research databases and research tissue banks.

In most cases, approval from the Study Sponsor is also required. For UCL sponsorship, contact the UCL/UCLH Joint Research Office <http://www.ucl.ac.uk/jro> or your local R+D office for work linked to other is NHS Trusts.

It is the Principal Investigator's responsibility to ensure that all research on human samples performed under their direction has received ethical approval, and that those performing the work have had appropriate training in 'working with human tissue', health and safety issues, and Information Governance. All researchers involved in a project must be listed as investigators on the project delegation log. The name must be removed when a researcher terminates their research.

If research involves the use and storage of human tissue in a cellular form, that is any material consisting of human cells other than gametes and immortalised cell lines, in a form where cells are whole or are in tissue sections, ethical approval and R&D approval must be obtained to ensure that your work complies with the Human Tissue Act 2004. R&D approval should be obtained from the UCL/UCLH Joint Research Office <http://www.ucl.ac.uk/jro> or your local equivalent. Details of the human tissue legislation can be found <https://www.hta.gov.uk/guidance-professionals/codes-practice>.



Please be aware of the following information:

1. In most cases undertaking research on human samples requires ethical approval and requires the patient's consent. However, in some cases where samples collected from a living patient as part of clinical care are surplus to clinical requirement, and can be anonymised so that the researcher cannot identify the donor, the samples may be studied without consent from a patient. However, ethical approval is required for this.
2. All ethical approvals are time-limited, and project restricted. When approval expires you need to apply to the relevant ethics committee to extend the study.
3. You should be aware that continued storage of designated material after an ethical approval expires is in breach of regulations unless the ethics are renewed or the samples are transferred to a Biobank. The latter requires discussion with the relevant Biobank lead and is not always feasible. To facilitate the potential for transfer it is optimal to discuss procedures for retrieving, storing and documenting tissue with the relevant Biobank lead before the project starts.

Biobanking and Human Tissue Authority Licences

A **Biobank** allows for storage of human tissue for future unspecified research. Such tissue can only be stored on Human Tissue Authority (HTA)-licensed premises although short-term (7 days) storage in a non-licensed premises is permitted. The nature of the research that can be undertaken on biobanked samples and related personal data depends on what patients and healthy volunteered consented to. The Designated Individual for each HTA licence can provide details on their Research Tissue Bank approvals and criteria for access. The contact details of biobanks in UCL can be found at <https://www.ucl.ac.uk/human-tissue/hta-biobanks/UCL-HTA-licensed-Biobanks>.

Ethical approval is always required before tissue and / or data can be accessed for research purposes. Once the HRA has approved an application for undertaking research, there is no requirement for tissue to be held on HTA-licensed premises although those undertaking the researcher must work to HTA standards.

Information on HTA-licensed premises in the UK are available at <https://www.hta.gov.uk/professional/establishments>.

The type of HTA licence required must permit the storage of human tissue samples for the scheduled purpose of research.

Approval for research on human tissue and or clinical information may be obtained via the following routes:

A1. Ethical approval to access human tissue stored within a Human Tissue Authority-Licensed Biobank for research purposes can be obtained through the [IRAS Website](#). Most biobanks within or external to UCL are not regulated by a local ethics committee but one such biobank is the [UCL/UCLH Biobank for Studying Health and Disease](#).

A2. Ethical approval for access to human tissue from a HTA-licensed Biobank which has been authorised by the HRA to be a Research Tissue Bank (RTB) which can grant ethical approval for research projects, can be obtained when applying to the RTB for tissue samples for research studies.. Once HRA ethical approval has been granted, tissue does not have to be held on a HTA-licensed premises although those undertaking the researchers must still work to Human Tissue Authority Standards.



B. Ethical approval for using human tissue which is not stored in a HTA-licensed Biobank is obtained by applying directly to the HRA for a project-specific ethics approval. Such applications are required to specify what samples are to be collected, stored and what research is planned to be undertaken. These samples do not need to be held on HTA-licensed premises although those undertaking the researchers must still work to Human Tissue Authority standards.

C. The UCL Ethics Committee provides ethical approval for research involving volunteers who may not be NHS patients; for example cohorts who answer questionnaires, give blood samples to be used as control material. Any tissue approved for such studies must be used for research purposes within 7 days or stored on a HTA-licensed premises.

For further information, please refer to <https://www.ucl.ac.uk/human-tissue/ethics>.

Transferring Human Tissue and patient data from one institution to another

A Material Transfer Agreement (MTA) must be in place for the movement of human tissue transferred from one institution to another for research purposes. This is required **even if** ethical approval has been obtained for use of tissue for research. Human tissue stored under a HTA licence should be transferred to a location also holding a HTA licence although this is not required if ethical approval has been given to use the tissue for a specific research project (see section on ethics).

Tissue collected for biobanking at a site which does not have a HTA licence is required transfer the material to a HTA licenced premises within 7 days, or to process and / or render the material acellular within that time frame. Local policies should be in place to ensure that the recipient institution has ethical approval for the research or a HTA licence to store the samples; this and any additional limitations, such as further distribution or return of unused material, should be documented in the MTA.

MTAs involving the movement of human tissue should be arranged with the help of your group Administrator.

Working with NHS Patients

For UCL students and staff to undertake research with patients in the NHS, they must have an honorary contract or observership status with the NHS Trust with which they engage; this includes UCLH. Such research includes any direct patient contact, direct access to patient medical records, taking informed consent from patients, interviewing patients or completing patient questionnaires and/or taking tissue samples directly from the patient, such as blood, sputum, urine etc. Obtaining an honorary contract or observership status with an NHS Trust should be through the human resources department of the relevant NHS Trust. The process would generally be initiated with the clinical lead of the unit in which the patients of interest are based. Compliance with local NHS governance standards is required.

* Please see the UCL document '**Checklist of Requirements and Responsibilities for Working with Human Tissue and Patient Information – UCL Biobanks v.4-A**' on the right side of the [UCL HTA Biobanks](#) Web page for more detailed information, including a **Checklist that is required to be signed off** by your supervisor or delegated signatory prior to starting any research on human samples.