## UCL Guidelines for Working with Human Tissue and Patient Information

**Please also see the Document 'UCL Working with Human Tissue and Patient Information including Checklist of Requirements'**

**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 derived from a human being including blood and blood products, tissue, cells, urine, sputum, faeces etc. The HTA regulates all cellular material with the exception of gametes, which are regulated by the 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 when and how their research is regulated under the Human Tissue Act. The MRC Regulatory Support Centre Learning Management System provides an e-learning course, 'Research and Human Tissue Legislation', at http://www.byglearning.co.uk/mrcrsc-lms/course/ for which registration is required and assessments are available.

Equally important is awareness of the rules governing **the confidentiality around information about patient and volunteers involved in research**. Courses and online training in information governance are provided by SLMS at https://www.ucl.ac.uk/isd/itforslms/services/handling-sens-data/training-and-awareness.

Access to clinical information for research purposes is only permitted with 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 to 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 with human samples, it is necessary for the project to have received Ethical Approval from an appropriate body. 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 NHS Trusts.

**It is the Principal Investigator's responsibility** to ensure that all research 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.

**It is the researcher's responsibility** to ensure that the project on which they are working has received ethical approval.

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 still recognizable, 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 (for those working at, for instance, Institute of Child Health / GOSH or Institute of Ophthalmology / Moorfields. Details of the human tissue legislation can be found at https://www.hta.gov.uk/guidance-professionals/codes-practice.

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 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 breach of regulations unless the ethics is 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. Contact details of Designated Individuals in UCL can be found at https://www.ucl.ac.uk/biobank.

Ethical approval is always required before tissue and / or data can be accessed for research purposes. Once the Health Research Authority 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.

There are a number of Human Tissue Authority-Licensed Biobanks at UCL: information is available at http://www.ucl.ac.uk/biobank. The 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.

**Ethical Approval** for research on human tissue and or clinical information is given by the Health Research Authority (HRA), formerly known as the National Research Ethics Service (NRES) although the Health Research Authority can authorise a local Biobank Ethics Committee to grant ethical approval.

**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 from a Local Ethics Committee which has been authorized by the Health Research Authority to give ethical approval. However, 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 See https://www.ucl.ac.uk/biobank.

A2. Ethical approval for access to human tissue from a HTA-licensed Biobank which is *not authorised* by the Health Research Authority to grant ethical approval for research projects, can be obtained by applying to the Health Research Authority. Once Health Research Authority 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 Health Research Authority for a project-specific ethics approval (http://www.hra.nhs.uk). 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-licenced premises.

For further information, please refer to http://ethics.grad.ucl.ac.uk/

**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.

All MTAs involving the movement of human tissue should be arranged by UCL Business (UCLB). Further information can be found at http://www.uclb.com/what-we-do/are-you-a-ucl-researcher/material-transfer-agreements.

**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 also refer to the UCL document on Working with Human Tissue and Patient Information including a checklist Of Requirements v1 held on the UCL Biobank website (https://www.ucl.ac.uk/biobank) 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.