



## Registration and Storage of Human Tissue for the Purpose of Research Compliance with the Human Tissue Act (2004)

### 1. Human Tissue Authority Licence

The University of Bolton does not currently hold a Human Tissue Authority (HTA) licence. Therefore, no researcher at University premises can store human tissue (which may be body parts, organs, tissue, cells, bodily waste products, including blood, serum, plasma, etc.), unless one of the following exemptions apply:

- I. A research project using relevant material that has been approved by a recognised research ethics committee [(REC) e.g. Integrated Research Approval System (IRAS), local NHS REC] and the researcher cannot identify the individual from whom the material has come.

The relevant material may be stored without a license for the duration of the project and the end of the project, the relevant material must either be destroyed or returned to the licensed premises. A University REC is not considered to be a recognised research ethics committee for this purpose.

- II. A research project using tissue provided by a REC-approved bank, which has generic ethical approval. The recipients do not need to store relevant material under an HTA licence during the period of the research project. On completion of the research project, the researcher must return tissue to the bank or to an alternative HTA-licensed establishment, apply for project-specific approval by a REC or destroy it.
- III. Where relevant material is being held with the intention of processing to render the material acellular (e.g. extracted DNA, RNA, protein, metabolites) prior to research. Tissue may be stored without a licence providing that the processing takes a matter of hours or days and certainly no longer than a week. Please refer to University Policy for a list of relevant material.
- IV. A research project using cell lines. In this case, all the original cells from the person have been replaced by cells that have divided and therefore have been created outside the human body.

A research project using primary cell cultures that have divided to an extent that all the original cells have been replaced by new cells created within the culture.

- V. Storage of tissue that is incidental to transportation.

Principal Investigators (PIs) acquiring relevant material for use in research must ensure that all aspects of the process for use of human tissue in research are adhered to, in addition the requirements for storage as outlined in this Code.

## 2. Registration of Human Tissue at University of Bolton

For each sample acquired and stored at University premises, an entry must be made on the University register by way of completion of the appropriate information capture form. This is to be done by the PI of the research project. This form is available as an associated document to this Code. The information captured by the form will allow the HTA Compliance Officer (CO) to make an appropriate entry to the register of human tissue held at the University.

The Register will include details of:

- a) The project title,
- b) IRAS No or other REC No (if applicable),
- c) PI's details,
- d) Start date,
- e) Finish date,
- f) Sample receipt dates,
- g) Specific storage location,
- h) Scope of consent,
- i) Transfer of material,
- j) Dates of audit,
- k) Dates and means of disposal.

PIs must ensure samples are labelled to the standards set in this policy. Samples will not be accepted for storage unless all details are provided. In addition, any entry must be updated if the sample has been used/processed in any way.

## 3. Audit of the Material

An audit of the material held by the University will be carried out on a 6 monthly cycle. The PI must ensure that the information on the register of material held is kept up to date.

## 4. Storage of the Material

Samples will be stored in a separate, secure, designated facility. The HTA CO will allocate storage space to the PI.

The following will be available: room temperature, cold (2-8°C), and freezer (-20°C and -80°C). No cryostorage (liquid N<sub>2</sub> cooled vessels at -196°C) facility is available at the University.

For the University of Bolton, the HTA CO will oversee operational matters involving storage of human tissue at University of Bolton premises.

## 5. References

- <sup>1</sup> Quality Manual: University of Bolton policy for use of human tissue for research.
- <sup>2</sup> The University of Bolton Biomedical Sciences laboratory codes of practice and standards.