**DIVISION OF RESEARCH AND INNOVATION**

**Joint Research and Development Office**

**Human Tissue Act Compliance Leaflet**

(This document forms part of your conditions for R&D approval for study **<R&D number>)**

In compliance with the research licences issued by the Human Tissue Authority, ICH (UCL)/GOSH R&D office expects all researchers who use human tissue to be suitably informed of requirements of the Human Tissue Act and to seek to comply with all Codes of Practice issued by the HTA.

**As Lead investigator for this study it is your responsibility to:**

1. Ensure that you and your research team have completed relevant Human Tissue Act training. A recommended e-learning course for this purpose is: [www.rsclearn.mrc.ac.uk/](http://www.rsclearn.mrc.ac.uk/). A copy of the training certificates should be kept by the researcher and in the research site file.
2. Retain copies of signed consent forms or have access to the consent forms of the samples originating from an institution with which ICH has an appropriate agreement.
3. Indicate to the holders of diagnostic archive samples – at the time that you obtain the samples - if you plan to dispose of or return any excess material once your research project ends.
4. Ensure that where samples are to be sent to third parties, a Material Transfer Agreement or Service Level Agreement will be in place for the samples and that safe receipt of transferred samples is acknowledged from the receiving licensed organisation. You will need document the process by which tissues and cells are released to other organisations and keep a separate, auditable record of transfers.
5. Ensure that all materials falling under the HT Act will be kept in suitable labelled storage in rooms that are locked out-of-hours. You will need to keep accurate records of where material is stored.
6. Ensure that donated tissues and cells are allocated unique identification codes and that the tissue or cell donor is not identifiable from information on the samples.
7. Report any equipment problems or adverse events (e.g. loss of tissue) to the Unit HTA representative, Person Designate (PD), Laboratory Manager or Designated Individual (DI).
8. Indicate, when the R&D office contacts you approximately six months before the end of your study, what you intend to do with any human tissue samples that will remain on completion of the research. You will need to complete a human tissue registration form.
9. Comply with, and document, any specific disposal arrangements that have been requested by consenting donors.
10. Agree to audit (annually) all sample collections and records relating to relevant material, and of procedures ensuring compliance.
11. Comply with any new procedures required to meet compliance with the HTA Codes of Practice. (http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm)
12. Read the ICH HTA policies and procedures relating to human tissue storage which are available on the ICH/GOSH intranet.