To ensure compliance with CUHNFT Human Tissue Act (HTA) Licence 12315 (ethics-expired research samples of 'relevant material') and HTA Licence 12318 (stored post-mortem material)

As Principal Investigator, I have 'relevant human material' in storage, which is covered by the Hospital **Human Tissue Authority research licence 12315** and/or **post-mortem sample licence 12318.** Therefore, I confirm that;

1) For individual samples newly collected or received under HTA 12315 or 12318 after 1st September 2006, I will keep copies of consent forms or can access them.

2) For individual samples newly collected or received under HTA 12315 or 12318 after 1st September 2006, where samples were obtained by third parties *(those who are not in possession of a Cambridge University Hospitals NHS Foundation Trust contract, or a University of Cambridge contract and based on CUNHFT site)* I will;

    a. store evidence of consent pertaining to each specimen OR
    b. archive a Supply/ Material Transfer Agreement (signed by both those collecting & those receiving the samples) which contains an example consent form including the standard statements required by the HTA.

3) For sample collections newly collected or received under HTA 12315 or 12318 after 1st September 2006, REC-approved documents (typical consent and Participant Information Sheets) are available which confirm that informed consent was obtained for the collection, storage and use in research of the specimens and that this conforms to the Human Tissue Authority (HTA) Code of Practice (Code 1; July 2006).

4) I have attended GCP training and have attached the evidence or will arrange attendance at such training within the next six months and will submit evidence to the Designated Individual (DI, Dr Jiminez-Linan, Pathology)

5) I agree to submit to an audit of all sample collections and records relating to material falling within the HTA, and of procedures ensuring compliance, by the DI or those working with the DI.

6) I will comply with any new procedures required to meet compliance with the HTA Codes of Practice.

7) I, and those supervising or controlling collection of tissues or cells will attend training on the HTA Act and Trust procedures.

8) I confirm that those delegated to handle samples, and with responsibility for risk management of samples regulated by the HTA, will additionally be required to attend any training sessions that are advised by the DI.

9) I will keep accurate records of where material is stored.

10) I will use documented procedures for creation, amendment, retention and destruction of records relating to samples regulated by the HTA (currently on *iPassport*).

11) I will ensure all paper and or computer records have a backup mechanism.

12) I will document the process by which tissues and cells are released to other organisations, & will keep a separate, auditable record of transfers, recorded

on a Material Transfer/Supply Agreement and will submit a record of transfers to the DI on an annual basis.

13) I will ensure, and document, that all tissues and cells are tracked and either used, according to the purpose allowed, returned or stored in compliance with HTA regulations (By another HTA Licensed establishment or as samples for a specific research project with ethical approval). This would generally be expected via a Material Transfer/Supply Agreement.

14) I will ensure donated tissues and cells are allocated unique identification codes.

15) I will use documented cleaning and decontamination procedures, which identify protective equipment and facilities required for handling tissue.

16) I will keep all relevant material falling under the HTA licence in locked storage (e.g. locked freezers), in areas that are locked out-of-hours.

17) I will ensure that the tissue or cell donor is not identifiable from information on the samples (post September 2006 samples, and where possible pre-2006).

18) I will ensure that freezers containing relevant human material have an alarm system which either links directly to (or via the hospital switchboard to) the phone numbers of at least 3 of people controlling my tissue collection(s) that may be called.

19) I will ensure that alarms monitor freezer temperature failure and power failure. Failures will be recorded and an adverse incident report will be made to the DI along with any relevant incident reporting through CUHNFT procedures. Any other adverse events that occur will be reported via the established Trust mechanism and will additionally be notified direct to the DI.

20) I confirm that freezer failure can be responded to within 4 hours, or 12 hours where liquid CO_2 backup is in place.

21) I confirm that backup freezer space is available for all samples regulated under the HTA licence.

22) I confirm that standard operating procedures (SOPs) are available for all equipment used in relation to the processing of ‘relevant material’ falling under the HTA Licence.

23) I will ensure that my staff will report any equipment problems to the Department of Medicine Laboratory Manager.

24) I agree to comply with, and document, any specific disposal arrangements that have been requested by consenting donors.