Human Application (HT Act) sector Annex B – Standard Conditions

The following standard conditions apply to licences for:

- the storage of relevant material which has come from a human body for use for a scheduled purpose

and have been agreed and validated by the HTA in granting this licence.

1. A duly authorised person, on production of appropriate identification, shall at any reasonable time or times be permitted to enter and inspect any premises to which the licence applies which includes inspecting any equipment or records and observing any activity.

2. A duly authorised person may require production for inspection of any records required to be kept by, or by virtue of, the Human Tissue Act 2004 ("the Act").

3. The HTA shall be provided, within fourteen calendar days of a request in writing being made (or within such other period as the HTA may determine), with such information as is specified in the written request or in Directions, to enable it to undertake its regulatory functions and duties and to enable it to exercise its powers under the Act.

4. Where relevant material is supplied to a person to whom another licence applies, that person shall also be provided with such information as the HTA may specify in writing or in Directions.

5. Where the Licence Holder and/or the Designated Individual proposes to introduce a licensable activity not specified in the licence, this may not be commenced until an application has been made to the HTA for a licence relating to this additional activity and such a licence has been granted.

6. Where the Licence Holder and/or the Designated Individual proposes a licence variation in a material respect, such as a major or a minor variation, this may not be undertaken until an application has been made to the HTA for a licence variation and such a variation has been granted and any fee payable to the HTA has been paid.

7. In consideration of the grant of the licence, the Licence Holder agrees that he will pay to the HTA any relevant licensing fee as determined by the HTA from time to time and within such time or times as the HTA may specify in writing or in Directions.

8. A copy of the Certificate of Licence (first page of the licence) describing the activity authorised by the licence must be displayed at the premises to which the licence relates in a position or positions in which it can be read easily by persons who are involved in the carrying out of the licensed activity or providing relevant material for use for the purpose of activities governed by the Act, or who may wish to do so.

9. The Designated Individual shall advise the HTA immediately should he become aware of any proposal or decision to close the licensed premises; this should include the provision of information about the arrangements relating to the transfer and storage of any relevant material and related records and provision for the return of any licence certificate(s) and copies thereof.

10. The Designated Individual may not substitute or add a person or persons designated under section 17 (b) of the Act, without first notifying the HTA in writing of the name of the proposed substituted or added person or Persons Designated.

11. The Designated Individual shall provide the HTA with regular information about compliance with the HTA's licensing standards, with any additional conditions and such other information or updates about its licensable activity as the HTA may specify from time to time and within such time and in the format as may be specified by the HTA in writing or in Directions.

12. The Licence Holder and the Designated Individual shall ensure that the HTA is informed as soon as possible of any changes to the contact details of the Designated Individual, the Licence Holder, any named persons working under the licence, and any named contact at relevant third party premises.

13. The Licence Holder and the Designated Individual shall comply with any and all Directions issued by the HTA which are applicable to the activities under its licence.

Reasons for Standard Conditions

These standard conditions are attached to licences issued by the HTA to ensure compliance with the provisions of the Act and to ensure a consistent set of standards are established and maintained by establishments in the conduct of licensed activities. This is to secure consistency of approach and application of good practice across all licensed establishments.

Human Application (HT Act) sector Annex C – Statutory Conditions

Conditions on all licences imposed by Schedule 3 paragraph 2 of the Act (General Conditions)

1. That the activity authorised by the licence shall be carried on only on the premises to which the licence relates.

2. That the activity authorised by the licence shall be carried on only under the supervision of the Designated Individual.

3. That such information about such matters relating to the carrying on of the activity authorised by the licence as may be specified in Directions shall be recorded in such form as the HTA so specifies.

4. That any record made for the purposes of Condition 3 above shall be kept until the end of such period as may be specified by the HTA in Directions.

5. That there shall be provided, to such person or persons and at such intervals as the HTA may specify in Directions:

    a. such copies of, or extracts from, any record to which Condition 4 relates, and

    b. such other information,

    as the Directions may specify.

6. That there shall be paid to the HTA at such times as may be specified in Directions sums of such amount as may be so specified in respect of its costs in connection with superintending compliance with the terms of licences.

Conditions on all licences authorising the storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose, imposed by Schedule 3 paragraph 4 of the Act (Conditions of certain storage licences)

7. That any former anatomical specimen which is stored at the premises specified in the licence shall be released from storage at the premises only into the possession of a person who is authorised in writing by the Designated Individual to have the specimen in his possession.

8. The condition in paragraph 7 above does not apply to the release from storage of a specimen for the purpose of its decent disposal.

9. That the Designated Individual shall give authority for the purposes of the condition in paragraph 7 above only if he is satisfied:

    a. that the person to whom authority is given is a suitable person to have the specimen in their possession, and

    b. that the person intends to use the specimen only for the purpose of education, training or research.

10. That any authority given for the purposes of the condition in paragraph 7 above shall specify:

    a. the person to whom the authority is given;

    b. the specimen to which the authority relates;

    c. the purpose for which the specimen may be used; and

    d. the duration of the authority.

11. That the Designated Individual shall give such notice of any authorisation for the purposes of the condition in paragraph 7 above as may be specified in directions by the HTA.

12. That such information about authorisations for the purposes of the condition in paragraph 7 above, as may be specified in directions by the HTA, shall be recorded in such form as may be so specified.

Human Application (HT Act) sector Annex D – Schedule of Definitions

Anatomical specimen
Anatomical specimen means:

- the body of a deceased person to be used for the purpose of anatomical examination, or
- the body of a deceased person in the course of being used for the purpose of anatomical examination (including separated parts of such a body).

Former anatomical specimen
Former anatomical specimen means a deceased body, organ or body part donated for anatomical examination which is held once the examination is completed.

Designated Individual (DI)
The individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on. This person is responsible for securing that other persons to whom the licence applies are suitable persons; that suitable practices are carried out in the course of carrying on the licensed activity and for compliance with the conditions of the licence. The HTA must be satisfied as to the suitability of this person.

Licensed premises
Where the licensed activity (e.g. storage, or making of a post mortem) takes place. If the licensed activity will take place at more than one place, a separate licence will need to be issued. Premises in different streets or with different postal codes will be considered as being in different places. In contrast, different buildings on a hospital site could be regarded as the same place.

Licensing
A number of activities can only be carried out where the establishment is licensed under the Act by the HTA for that purpose. The activities are:

- The carrying out of an anatomical examination
- The making of a post mortem examination
- The removal from the body of a deceased person (otherwise than in the course of the activities mentioned above) of relevant material of which the

body consists or which it contains, for use for a Scheduled Purpose other than transplantation

- The storage of an anatomical specimen
- The storage (other than of an anatomical specimen) of the body of a deceased person or relevant material which has come from a human body for use for a Scheduled Purpose
- The use, for the purpose of public display, of the body of a deceased person, or relevant material which has come from the body of a deceased person.

Licence Holder
The person who applies for and is granted a licence who can be, but is not necessarily the Designated Individual. The Licence Holder is responsible for the payment of any fees charged by the HTA including fees charged in respect of superintending compliance with licences and any other fees as specified by the HTA from time to time. The Licence Holder can be a corporate body. Where the applicant is not the proposed Designated Individual, the HTA must be satisfied that the applicant is a suitable person to be the holder of the licence.

Public display
An exhibition, show or display in which a body of a deceased person or relevant material which has come from the body of a deceased person is used for the purpose of being exposed to view by the public.

Relevant material
Relevant material is defined by the Act as material other than gametes, which consists of or includes human cells. In the Act, references to relevant material from the human body do not include:

- embryos outside the human body, or
- hair and nail from the body of a living person.

Scheduled purposes
Scheduled purposes are the activities relating to the removal, storage and use of human organs and other tissue, listed in Schedule 1 of the Act that require consent.

The Purposes are divided into two parts:

Part 1: Purposes Requiring Consent: General

- Anatomical examination

- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or other treatment administered to them
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
- Public display
- Research in connection with disorders, or the functioning, of the human body
- Transplantation

Part 2: Purposes Requiring Consent: Deceased Persons

- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance