Human Application (Q&S Regs) sector Annex B Standard Conditions

The following standard conditions apply to licences for procurement, testing, processing, storage, distribution, import and export of tissues or cells intended for human application 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, and any relevant third party premises, or any premises proposed to be such premises; this includes inspecting any equipment or records and observing any activity.

2. A duly authorised person may require production for inspection of any records or documents required to be kept by, or by virtue of, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) ('the Regulations').

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 Human Tissue Act ('the Act') and Regulations.

4. Where tissues and/or cells are supplied to a person to whom another licence applies, or with whom the establishment has a third party agreement, that person shall also be provided with such information as the HTA may specify in writing or in Directions.

5. Where the Licence Holder or the Designated Individual proposes to introduce a licensable activity not specified in the licence (procurement, testing, processing, storage, distribution, import or export of tissues and/or cells for human application), this may not be commenced until an application for a licence variation has been made to the HTA, such information as requested by the HTA has been provided and until such a licence has been granted.

6. Where the Licence Holder or the Designated Individual proposes a licence variation in any 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 and any fee payable to the HTA has been paid.

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 activities or providing tissues and/or cells for use for the purpose of activities governed by the Regulations, 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 or any relevant third party premises; this should include provision of information about the contingency arrangement for services, for transfer and future storage of tissues and/or cells and for maintenance of records and provision for the return of any licence certificates and copies thereof.

10. The Designated Individual may not substitute or add a person or persons designated under section 17 (b) of the Act, as applied by regulation 8 of the Regulations, without first notifying the HTA in writing of the name of the proposed person or persons to be substituted or added.

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 activities 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 Designated Individual shall provide to the HTA such information regarding the type of tissues and/or cells procured, tested, processed, stored, distributed and/or imported/exported as required by the HTA from time to time.

14. Where a new type of tissues and/or cells is to be procured, tested, processed, stored, distributed, imported or exported by the establishment, or under a third party agreement, the Designated Individual must first notify the HTA and the new type of tissues and/or cells may not be procured, tested, processed, stored, distributed, imported or exported by the establishment (or the third party) until the HTA is satisfied that the establishment has suitable premises and employs suitable practices to carry out the proposed activity in respect of these tissues and/or cells.

15. The Licence Holder and the Designated Individual, shall comply with the HTA's Directions on the standards expected of establishments under the Regulations. It shall be the duty of the Designated Individual to ensure that all personnel directly involved in activities relating to the procurement, testing, processing, storage, distribution, import and export of tissues and/or cells intended for human application comply with the Regulations.

16. 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 and shall ensure that third parties are made aware of, given copies of, and comply with, any such Directions as may be applicable to them.

17. Where a third party agreement is entered into by the Licence Holder, or the Designated Individual on behalf of the Licence Holder following the grant of a licence, then the Licence Holder, or the Designated Individual must first notify the HTA and the HTA must be satisfied as to the suitability of the proposed relevant third party premises before any licensed activity is carried out by the third party on behalf of the Licence Holder.

18. The Licence Holder and the Designated Individual shall ensure that, in relation to import, only the activities prescribed in the 'scope of activities' as set out in the importing tissue establishment licence certificate are undertaken by the establishment. This certificate will accompany a licence as Annex E. Any variation to the scope of activities shall be considered a variation of this licence condition under Schedule 3 paragraph 8 of the Human Tissue Act 2004, as applied by Regulation 8 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).

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 the Regulations 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.

Condition 14 is being imposed to enable the HTA to satisfy itself as to the suitability of proposed significant changes of activities and to approve such changes as suitable under the licence.

Conditions 15 is being imposed to secure compliance with the standards expected of establishments to secure compliance with the Regulations.

In addition, condition number 16 is being imposed to secure compliance by the Licence Holder and/or the Designated Individual with their duties under the Act and the Regulations and in particular the duty of the Licence Holder under Regulation 6 of the

Regulations and the duty of the Designated Individual under Regulation 12 of the Regulations.

Condition number 17 is being imposed to enable the HTA to satisfy itself as to the suitability of proposed relevant third party premises and to approve proposed relevant third party premises where such premises are proposed following the grant of a licence.

Condition number 18 is being imposed to secure compliance with paragraph 5A of Schedule 1 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as amended, and give effect to the importing tissue establishment licence certificate. Establishments which hold a licence for import under the Regulations may only conduct import activities as set out in the certificate unless a variation of the licence condition is requested by the establishment and approved by the HTA.

Human Application (Q&S Regs) sector Annex C Statutory Conditions

Conditions on all licences imposed by Schedule 1 paragraph 5 of the Regulations and Schedule 3 paragraph 2(4)(c) – (f) of the Act as applied by Regulation 8 of the Regulations and Regulation 13 of the Regulations (General Conditions).

1. That the activity or activities authorised by the licence shall be carried on only on the premises specified in the licence, or, in the case of the activities of procurement, testing, processing, distribution or export of tissues and/or cells intended for human application, on relevant third party premises.

2. That the activity or activities 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 or activities 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 may be specified by the HTA in Directions.

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.

7. The Licence Holder, and, where different, the Designated Individual, any person to whom a licence applies, any third party with whom the establishment has a third party agreement, and any personnel of either the licensed establishment or third party, must secure that all necessary arrangements are made to ensure that all information which is collected in pursuance of the licence or a third party agreement in relation to the licence:

a. is available for the purpose of tracing donations;

b. is kept up-to-date and corrected without delay where any discrepancy relating to such information is identified; and

c. is held securely and subject to safeguards against unauthorised additions, deletions, modifications or transfer of information.

Human Application (Q&S Regs) sector Annex D Schedule of Definitions

Blood
References to blood mean whole human blood collected from a donor and processed either for transfusion or for further manufacturing.

Blood component
Blood component means a therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods, but does not include lymphocytes intended for use for the purpose of haematopoietic stem cell transplantation.

Cells
Cells mean individual human cells or a collection of human cells when not bound by any form of connective tissue, including cell lines grown outside the human body but not including:

a. gametes;

b. embryos outside the human body; and

c. blood and blood components.

Designated Individual
The individual designated in the licence as the person under whose supervision the licensed activity is, or licensed activities are, authorised to be carried on. A licence cannot authorise the licensed activity or activities to be carried on under the supervision of more than one Designated Individual.

This person is responsible for securing:

a. that other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity or activities;

b. that suitable practices are used in the course of carrying on the licensed activity or activities;

c. compliance with the conditions of the licence and the conditions of third party agreements in relation to the licensed activity or activities authorised to be carried on under their supervision; and

d. compliance with the requirements of Regulation 13(1) of the Regulations (Information and Confidentiality).

The HTA must be satisfied as to the suitability of this person, that they will perform their duty under Regulation 12 of the Regulations and have the necessary qualifications and experience required by the Regulations (Regulation 11(3)(c) and (d)).

Where a proposed Designated Individual is not the applicant for a licence, then they must consent to the application for the licence.

Duly authorised person
A duly authorised person means a person authorised by the HTA to act for the purposes of a particular provision or provisions of the Regulations.

Export
Export means export from the United Kingdom to a place outside the United Kingdom.

Human Application
Human application, in relation to tissue or cells, means use on or in a human recipient, including use in extracorporeal applications but not including use for autologous graft.

Import
Import means import into Great Britain from a place outside the United Kingdom and import into Northern Ireland from a country other than Northern Ireland or an EEA state.

Licensed premises
Where the licensed activity or activities (example storage of tissues and/or cells for human application) is authorised to be carried on. If the licensed activity or activities will take place at more than one place (other than relevant third party premises in the case of the activities of procurement, testing, processing, distribution, import and/or export where there is a third party agreement in force between the Licence Holder (or the Designated Individual on behalf of the Licence Holder) and the third party in respect of one or more of those activities), 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.

The HTA must be satisfied as to the suitability of any proposed licensed premises or proposed relevant third-party premises.

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

the storage of tissues and/or cells intended for human application
procurement, testing, processing, distribution, import, and/or export of tissues and/or cells intended for human application where there is no third party agreement in force between the Licence Holder (or the Designated Individual on behalf of the Licence Holder) and the third party in respect of such activities.

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.

The Licence Holder is required under the Regulations to enter into third party agreements where the third party:

a. carries on a licensed activity (other than storage), on behalf of the Licence Holder, or

b. supplies to the Licence Holder any goods or services which may affect the quality or safety of tissue or cells.

Where the applicant for the licence 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.

Relevant third-party premises
This is the premises (other than premises to which the licence relates):

a. on which a third party procures, tests, processes or distributes, or to which a third-party imports or from which a third party exports, tissue or cells on behalf of any person authorised by a licence to carry on that activity, or

b. from which a third party provides any goods or services which may affect the quality or safety of tissue or cells to any person in connection with licensed activities carried on by that person.

The HTA must be satisfied that any proposed relevant third-party premises is suitable for the activity or activities to be carried-on on behalf of the Licence Holder.

Storage
Storage means maintaining tissue or cells, whether by preservation or in any other way, for more than 48 hours.

Tissue (or tissues)
Tissue (or tissues) means all constituent parts of the human body formed by cells, but does not include:

a. gametes;

b. embryos outside the human body; or

c. organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body.

Third country
Third country means:

a. in relation to the import of tissues of cells into, or the export of tissues and cells from, Great Britain, a country other than the United Kingdom;

b. in relation to the import of tissues or cells into Northern Ireland, a country other than Northern Ireland or an EEA state; and

c. in relation to an export of tissues or cells from Northern Ireland, a country other than the United Kingdom or an EEA state.

Third party
A third party is a person with whom a Licence Holder, or a Designated Individual on behalf of the Licence Holder, has a third-party agreement.

Third Party Agreement (TPA)
A third party agreement is an agreement in writing between a Licence Holder, or the Designated Individual on behalf of the Licence Holder, and another person, which is made in accordance with any Directions given by the HTA for the purpose of securing compliance with the requirements of the Regulations, under which the other person:

a. carries on a licensed activity (other than storage or import from a third country), on behalf of the Licence Holder, or

b. supplies to the Licence Holder any goods or services which may affect the quality or safety of tissue or cells.