



# A guide to licensing for Designated Individuals and Licence Holders

March 2006  
(Produced with advice from Morgan-Cole Solicitors)



# Introduction

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1. This guide has been prepared for the benefit of Designated Individuals (DI), Licence Holders and Persons Designated by the DI as someone to whom the licence applies. It is also relevant to others working within the provisions of the Human Tissue Act 2004 (HT Act) and Regulations made under the HT Act and equivalent Scottish legislation, which are relevant to the Human Tissue Authority's (HTA) licensing function. The HT Act covers England, Wales and Northern Ireland. By agreement with Scottish Ministers, the HTA will act as the Competent Authority for Scotland in terms of the EU Tissue and Cells Directive, thereby achieving consistency of approach across the whole of the UK.
2. At the time of preparation of this guide, not all provisions of the HT Act have been brought into force. Even when fully in force, it will be necessary to regard the HT Act as providing a framework for a system of regulation that will continue to evolve. This guide will evolve in the same way to take account of developments such as the introduction of new Regulations.
3. In developing this guidance, the HTA has gathered evidence from a range of sectors and in a variety of ways. This includes information gathered during our Code of Practice consultation events; telephone interviews; workshops/meetings; letters/emails and extracts from Hansard. Significant legal advice and production of some of the content of this guide was provided by Morgan-Cole Solicitors.
4. This document supports a framework for governance focussed around the role of the Designated Individual. It is designed to cover the five broad sectors that HTA will license and to accommodate varying organisational structures both within and between sectors. The framework also recognises that there is a range of opinion within the sectors to be regulated about who should be the DI. We also acknowledge that one model does not fit all situations, so we are aiming for flexibility for each organisation and applicant supported by clear guidance to enable decision-making.
5. The framework is based on giving advice and guidance to the sector explaining the roles and responsibilities of the DI, licence holder, Person/s Designated by the DI, and others working to the licence. We will share this advice and guidance by providing written information such as this, running workshops and via e-learning packages.

6. The HTA framework provides for various models of governance around three key roles, as outlined in the Human Tissue Act. These three roles are:
  - DI;
  - Licence Holder (if different to DI); and
  - Person Designated as a person to whom the licence applies.

There is a fourth category as an adjunct to these roles and that is other persons working under the 'direction of' the DI or person designated by the DI. Each of these roles will be explored more fully in this guidance.

## Legislative background

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7. The HTA has a responsibility to regulate against the HT Act 2004 and is also one of two Competent Authorities for the implementation of the European Union Tissue and Cells Directive in the UK (EUTCD). (The Human Fertilisation and Embryology Authority is the other Competent Authority.)

### The Human Tissue Act 2004

8. The HT Act 2004 provides a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specified health related purposes and public display.
9. The HT Act makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue from the living or the deceased for specified health related purposes and public display.
10. The HT Act regulates the removal of such material from the deceased but does not cover removal of such material from the living, and this will continue to be dealt with under the Common Law. The HT Act regulates removal, storage and use of human tissue. This is referred to in the HT Act as "relevant material" and is defined as material that has come from a human body and consists of, or includes, human cells. (Cell lines are excluded, as are hair and nail from living people. Live gametes and embryos are excluded as they are already regulated under the Human Fertilisation and Embryology Act 1990.)
11. The HT Act lists the purpose for which consent is required in schedule 1 and they are referred to as "Scheduled Purposes" (Annex A). The consent required under the HT Act is called "appropriate consent", which broadly means consent from the appropriate person, as identified in the HT Act. Penalties of up to three years' imprisonment or a fine, or both, are provided in the HT Act as a deterrent for failing to obtain or to misusing consent.

12. The HT Act makes it an offence to have human tissue, which includes hair, nail and gametes in this context, with the intention of its DNA being analysed without the consent of the individual from whom the tissue came, or of those close to them if they have died.
13. The HT Act received Royal Assent on 15 November 2004.

## **European Union Tissue and Cells Directive (EUTCD) 2004/23/EC**

14. The EUTCD sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells intended for human application. The EUTCD makes the HTA one of the Competent Authorities for implementing the Directive in the UK. Establishments storing tissue for human application will need to be licensed by 7 April 2006.
15. During 2006, the HT Act will be amended by Regulations which transpose the detail of the Directive into UK law. For Scotland, the vehicle will be Regulations made under Section 2(2) of the European Communities Act 1972. The main substance of these Regulations derives from two technical annexes contained in Commission Directives. Once the detail of the relevant technical annexes is known, the HTA will be in a position to inspect against those standards. However, in the short term, a staggered approach to implementation is proposed. In March 2006, specific parts of the HT Act were commenced to allow the HTA to issue licences to establishments storing tissue for human application in compliance with the EUTCD.
16. HTA will issue Directions outlining the standards to be met within the first and second technical directives (TD1 and TD2) of the EUTCD. We will issue the first set in April/May 2006 and they will reference the standards required for TD1. If the second Technical Directive is agreed by August 2006 we will issue further Directions in September to summarise TD2. To assist the sectors we license the HTA aims to issue Directions at two points each year – either April or September.

## **Licensing framework**

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17. The role of the DI is central to the HTA's licensing framework. The DI has specific responsibilities as set out in Section 18 of the HT Act and summarised further in this document. Licence conditions represent an important regulatory tool. Section 18 of the HT Act makes it the duty of the DI to secure, amongst other things, that the conditions of the licence are complied with. The HTA has power under paragraph 7(2)(b) to revoke a licence if it is satisfied that the DI has failed to discharge, or unable because of incapacity to discharge, the duty under Section 18. Furthermore, wherever there is power to revoke a licence, the HTA may instead vary the licence.

18. There are three types of licence conditions: statutory, standard and additional.

## **Statutory licence conditions**

19. Paragraph 2 of Schedule 3 contains a number of conditions that must apply to all licences of a particular type. The conditions imposed by paragraphs 2, 3 and 4 of Schedule 3 to the HT Act apply to all relevant licences and cannot be varied by the HTA. However, under paragraph 5 of Schedule 3, the HTA has power to grant licences subject to any further condition as it thinks fit.

20. The statutory conditions that apply to all licences are as follows.

- (a) That the licensed activity shall be carried on only on the premises specified in the licence.
- (b) That the licensed activity shall be carried on only under the supervision of the individual designated in the licence as the person under whose supervision it is authorised to be carried on.
- (c) That such information about such matters relating to the carrying on of the licensed activity as may be specified in directions shall be recorded in such form as may be so specified.
- (d) That any record made for the purposes of the condition in paragraph (c) shall be kept until the end of such period as may be specified in directions.
- (e) That there shall be provided to such persons and at such intervals as may be specified in directions:
  - such copies of, or extracts from, any record to which the condition in paragraph (d) relates, and
  - such other information, as may be so specified.
- (f) 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.

21. Paragraph 4 of Schedule 3 contains further statutory conditions which apply to other licences including those relating to anatomical specimens.

## Standard conditions

22. The Authority will also develop “standard” conditions that apply to all licences of particular types. Such conditions are applied and varied at the discretion of the HTA. Some examples are standard conditions relevant to compliance with the EUTCD and about participation in HTA education and training workshops or other e-learning for DIs.

## Additional conditions

23. These are conditions which are specific to a licence and are imposed on the grant of a licence (subject to a centre’s right to make representations). These conditions can be written to help improve standards and the Authority’s approach is to draft additional conditions using the “SMART methodology”, that is the condition should be Specific, Measurable, Achievable, Relevant and Time bound. This will help to achieve compliance with our licensing requirements. Additional conditions may also be used to restrict the manner in which a licensable activity can be performed.

## Issuing General Directions

24. General Directions can be used by HTA to set standards or requirements that must be met by the licensed sector. The HTA will use its Direction making powers prudently to assist the sector to meet the standards required. Therefore we aim to issue General Directions at just two points each year: either April or September.

## Codes of Practice

25. The HTA has power under Section 26 to prepare and issue Codes of Practice for the purpose of:
- (a) giving practical guidance to persons carrying out activities within Its remit; and
  - (b) laying down the standards expected in relation to the carrying on of such activities.

26. Currently the HTA has prepared Codes of Practice as follows:

Code of Practice 1	Consent
Code of Practice 2	Donation of organs, tissues and cells for transplantation
Code of Practice 3	Post mortem examination
Code of Practice 4	Anatomical examinations
Code of Practice 5	Removal / collection, retention and disposal of human organs and tissue
Code of Practice 6	Donation of allogenic bone marrow, peripheral blood stem cells and donor lymphocytes for transplantation

27. Section 28 of the HT Act explains the effect of a breach of any of the Codes. A failure on the part of any person to observe any provision of a Code of Practice shall not, of itself, render the person liable to any proceedings. However, the HTA may, in carrying out its functions in respect to licences, take into account any relevant observance of, or failure to observe, a Code of Practice. So, failure to comply with guidance and standards provided in the Codes will not, of itself, represent grounds for revoking a licence. However, it may provide evidence of an unsuitable practice which, in turn, might amount to a breach of the duty of the DI under Section 18(b). Breach of the duty under Section 18(b) would be grounds for revoking or varying a licence.
28. However, it is important to remember that the Codes of Practice should not be treated as being equivalent to a statutory requirement and that the Codes contain guidance and standards. The key regulatory concept is whether “suitable practises” are being carried out. The Codes may be relied upon as evidence of an unsuitable practise but a breach of a Code is only part of the evidence to be considered.

## Licensable activities

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### Overview

29. Establishments will need to apply for a licence when Section 16 (Annex B) is brought into force because Section 16(1) prohibits a person from conducting an activity covered by Section 16 otherwise than under the authority of a licence granted by the HTA. This is reinforced by the fact that, under Section 25, a person who contravenes Section 16 commits an offence which is punishable with up to 3 years’ imprisonment.
30. Section 16 has to be read in conjunction with Schedule 3 to the HT Act. Paragraph 1 of Schedule 3 states that the Authority may on application grant a licence for the purposes of Section 16. The HT Act does not give the HTA power to issue licences for any activity other than one contained in Section 16.
31. The HT Act is also supported by Regulations which will include some exemptions to licensing. The Department of Health is due to publish these Regulations in spring 2006 and equivalent Regulations will be made for Scotland.
32. Section 16 should also be read in conjunction with Section 1 and Schedule 1 to the HT Act. Section 1 is the foundation of the HT Act. It establishes that consent from an appropriate person is required before certain activities can be undertaken for particular purposes. These activities are storage and use of whole bodies, removal, storage and use of relevant material from the body of a deceased person, and storage and use of relevant material from a living person. The purposes to be regulated are listed in Schedule 1 and are referred to as “Scheduled Purposes”.

## General exemption from Section 16(2)

33. An activity will be excluded from any part of Section 16(2) if:

- It relates to the body of a person who died before the day on which this Section comes into force or to material which has come from the body of such a person, and
- At least 100 years have elapsed since the date of the person's death.

## Premises where the licensed activity takes place

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34. Paragraph 2(3)(a) of Schedule 3 of the HT Act prohibits the HTA from granting a licence for an activity to be conducted on premises at different places. Place is not defined in the HT Act, however the HTA has taken the view that to enable accountability for any problems at particular premises, there should be clarity between the licensable activity and specific premises.

35. An application for a licence should specify the premises where the licensed activity is to take place. If the licensed activity will take place in premises 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 in the same place. The HTA will obviously have to consider this on a case by case basis dependent on the facts in each application.

36. If more than one licence is needed to allow for the definition of “premises at different places” as set out in the HT Act, the HTA has streamlined the process to assist licence applicants. This means that wherever possible a single application for multiple licences may be made. The ability to do this is reliant on the activities taking place at multiple premises falling under one governance structure, one set of standard operating procedures and being supervised by the same DI. This gives robustness to the licensing approach but also allows flexibility for the Licence Holder.

37. The governance framework for DIs includes the role of Person/s Designated (see below). So, a DI could identify Person/s Designated at different sites to “direct” the activities at those sites. As such the Person Designated assists in the governance of the activities authorised by the licence.

38. Where the above criteria are present we aim to produce licences simultaneously using a single set of documentation: this would allow a series of licences to be issued at the same time. Each licence will show what activities each premise is licensed for. The licence will also name the DI and this will be the same for each licence issued under a single application for multiple licences.

# The Designated Individual governance framework

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39. The HTA framework offers various models of governance around three key roles, as outlined in the HT Act. These three roles are:
- DI;
  - Licence Holder (if different to DI); and
  - Person Designated as a person to whom the licence applies.
40. Anyone acting under the direction of the DI or a **Person Designated in the notice given to the HTA** is a person to whom the licence applies.
41. The governance framework is supported by an HTA education and training programme and e-learning packages that we will provide for DIs, Licence Applicants and Persons Designated.
42. Each of these roles is explained below.

## Designated Individual

43. The DI in relation to a licence, means the person under whose supervision the licensed activity is authorised to be carried on.<sup>1</sup> The role of the DI is crucial to the successful implementation of the HTA's licensing systems.
44. Section 18 of the HT Act provides that it shall be the duty of the DI to secure:
- (a) that the other persons to whom the licence applies are suitable persons to participate in the carrying on of the licensed activity;
  - (b) that suitable practices are used in the course of carrying on that activity, and;
  - (c) that the conditions of the licence are complied with.
45. Before the HTA can grant a licence it must:
- (a) have an application for a licence from the DI or consent to the application from that individual, and;

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<sup>1</sup> Section 41(1)

(b) be satisfied that the proposed DI:

- is a suitable person to supervise the activity to be authorised by the licence; and
- will perform the duty under Section 18.

## Characteristics of the Designated Individual

46. The HT Act does not define what characteristics make a proposed DI a suitable person to supervise licensable activity. However in the Parliamentary debate on the Bill in the House of Lords, Lord Warner said:
47. “The Designated Individual will not be a person in a particular role within an institution; that is it almost certainly need not be the Chief Executive of a Trust, or the Dean or Vice-Chancellor of a University. The Designated Individual will be a person who in each case is in a position to ensure that the activities carried out under the licence complies with the regulatory requirements to which I have referred. Indeed.....before someone becomes a Designated Individual they would need to establish that they were able to bear and discharge the responsibilities which go with being such a Designated Individual. The system is constructed to ensure that people do not get into a situation where they become Designated Individuals who cannot discharge their responsibilities under the legislation.
48. The person might be a Head of Department of a clinician, a scientist or a manager. What is important is that it is a person who is in a position to secure that activities are conducted properly by people who are suitable to carry out those activities and that all the necessary requirements are complied with”
49. Accordingly, the HTA has taken the view that the DI needs to have knowledge and understanding of the HT Act and the relevant Codes of Practice. S/he should demonstrate managerial capability, ensuring development and implementation of quality management systems and supervising responsibility to effect change. This may be done via appropriate links to corporate / board level. Importantly, s/he should have time within their substantive role to carry out the responsibilities of the DI and ensure compliance with licence conditions.
50. Once the requirements of the EUTCD are transposed into UK legislation the DI for establishments affected by the Directive will need to fulfil the same criteria as those of the “Responsible Person” as described in the Directive. The EUTCD states that the Responsible Person should be in possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned. They should also have at least two years’ practical experience in the relevant fields.

51. The word “individual” means that the DI must be a specific human being (i.e. it cannot be a corporate body).

## **Licence Holder (formerly applicant)**

52. The term “Licence Holder” is not used or defined in the HT Act. However, paragraph 6(4) of Schedule 3 to the HT Act states that where the applicant for the licence is not the proposed DI, the HTA must be satisfied that the applicant is a suitable person to be the holder of the licence.
53. The applicant for the licence, (whether or not the applicant is the proposed DI), will become the holder of the licence, if the licence is granted.
54. The Licence Holder must have the consent of the DI to apply for the licence. Significantly, paragraph 8(1) of Schedule 3 permits the holder of the licence to apply to the HTA to vary the licence so as to substitute another individual for the DI. This would allow for circumstances such as the DI being unable or incapable of continuing in the role.
55. Where there is a Licence Holder separate from the DI, all relevant Notices of licence decisions have to be given to the licence holder in addition to the DI. The HTA must therefore receive a written acknowledgement from both before the licence becomes valid.

## **Characteristics of the Licence Holder**

56. Where the applicant is not the DI, the HTA has to be satisfied that s/he is a suitable person to be the Licence Holder. In order to be suitable, the proposed Licence Holder should be involved in some managerial capacity in the establishment concerned rather than someone who is entirely remote from it. However the Licence Holder is not under any duty comparable to those of the DI under Section 18 to supervise the activities concerned.
57. The licence holder can be an individual, for example a Chief Executive or somebody with managerial links to the establishment, or could be a corporate body, for example an NHS Trust. The latter may be preferable, as it requires less administration by the licensed sector when any changes occur in post holders. So, if the corporate body is the Licence Holder, the establishment would not need to apply to the HTA to vary the licence to change the name of the Licence Holder unless the corporate body itself changed.

## **Persons Designated as a person to whom a licence applies**

58. An establishment can designate particular individuals in a Notice to the HTA. They will then be regarded as Persons Designated as a person to whom the licence applies: to whom the authority conferred by the licence extends. However such Notice to the HTA does not constitute a licence application.

59. The names of persons to whom a licence applies should be provided in a Notice given by the DI to the HTA. The DI should take appropriate steps to record the consent of these individuals to this role. There is no requirement for the HTA to approve the names of individuals put forward. However if the HTA has particular concerns about the identity of any particular individual then the means of regulatory control would be under Section 18 of the HT Act (Duties of the DI).
60. Section 17 states that the authority conferred by a licence extends to:
- (a) the DI;
  - (b) any person who is designated as a person to whom the licence applies by a Notice given to the HTA by the DI; and
  - (c) any person acting under the direction of:
    - the DI; or
    - a Person Designated as mentioned in paragraph (b).

## **Characteristics of the Person Designated as a person to whom a licence applies**

61. Other people can work under the direction of Persons Designated as a person to whom the licence applies. Persons Designated do not have a legal duty comparable with those set out for the DI under Section 18 of the HT Act (i.e. to ensure that suitable practices are used and that there is compliance with licence conditions). However the role of Person Designated carries with it the ability to “direct” others in relation to the HT Act. The DI should have procedures in place to ensure that the requirements of the HT Act are met and Persons Designated could reasonably assist in developing and implementing these procedures as part of “directing”. For example a Person Designated could work at a satellite site offering advice and guidance to those at the site. This means other persons working under the direction of the Person Designated are advised about how and why they need to follow procedures and systems agreed by the DI to comply with the HT Act.
62. The word “direction” is not defined in the HT Act. The dictionary definition of the word includes “guiding, managing, instruction what to do, order” which envisages a range of different levels of supervision. It will not be sufficient for the individual merely to be authorised by the DI or Person Designated as Lord Warner explained during debates on the Bill in the House of Lords, “The effect of this would be to weaken the role and responsibility of the Designated Individual.....and to weaken the overall control of licensed activities. The problem with this is that we fully intend that the Designated Individual should be directly responsible for ensuring the proper conduct of the activities carried out under the licence”.

## Any persons carrying out licensed activity on licensed premises

63. It is not essential that an individual has to be named in a notice given to the HTA. This means that anyone acting under the direction of the DI or a Person Designated in the Notice given to the HTA is a person to whom the licence applies.

## Licensing process

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### Grant of licence

64. Paragraph 6 of Schedule 3 to the HT Act sets out a number of pre-conditions to the grant of a licence. The HTA may not grant a Licence in pursuance of an application unless the following requirements are met, namely:
1. The HTA must have received a licence application from the proposed DI or from another person but with the proposed DI's consent to the application.
  2. The HTA must be satisfied that the proposed DI:
    - (a) is a suitable person to supervise the activity to be authorised by the licence; and
    - (b) will perform the duty under Section 18.
  3. Where the applicant for the licence is not the proposed DI, the HTA must be satisfied that the applicant is a suitable person to be the holder of the Licence.
  4. The HTA must be satisfied that the premises in respect of which the licence is to be granted are suitable for the activity to be authorised by the licence.
  5. A copy of the conditions to be imposed by the licence must have been shown to, and acknowledged in writing by:
    - (a) the applicant for the licence; and
    - (b) where different, the proposed DI.
65. In practice, all of the above pre-conditions with the exception of 5 represent matters about which the HTA must be satisfied before it can offer a licence. Pre-condition 5 will become relevant if the HTA proposes to offer a licence. The licence is not actually valid until the HTA has received written acknowledgment of the proposed conditions from the DI and, if different, the applicant for the licence.

## Imposition of licence conditions

66. In addition to the statutory licence conditions as mentioned, the HTA has power to issue a licence subject to such further conditions as it thinks fit.<sup>2</sup> The proposed imposition of licence conditions on the grant of a licence will give rise to a right on the part of the applicant to make representations. Paragraph 10(1)(b) provides that before making a decision to grant an application for a licence subject to a condition, the HTA shall give the applicant notice of the proposed decision and the reasons for it.

## Offer of licence

67. It is essential that the terms on which the licence is to be issued (including all licence conditions) are acknowledged in writing by the licence applicant and if different the DI.

## Notification of licensing decision

68. Once a licensing decision has been made, (which includes where representations have been made and considered) the requirements of paragraph 11 of schedule 3 apply. In summary, where a decision is made to grant, revoke or vary a licence, notification of the decision has to be given to the DI or, where different, the applicant for the licence. The only exception to this as in the case of a decision to vary a licence on the application of the Licence Holder to substitute a different person as the Designated Individual. In this exceptional case, notification of the decision has to be given to the holder of the licence and the person who is to be the DI and not the existing DI.

## Refusal of licence

69. Paragraph 10(1)(a) of Schedule 3 to the HT Act further provides that, before a decision is made to refuse an application for the grant of a licence the HTA should give the applicant notice of the proposed decision and the reasons for it.

## Written acknowledgment of licence

70. Paragraph 6(6) of Schedule 3 makes it a pre-condition to the grant of a licence that a copy of the conditions to be imposed by the licence have been shown to and acknowledged in writing by:

- (a) the applicant for the licence; and
- (b) where different, the proposed DI.

71. The licence is not valid until the HTA receives written acknowledgment from both the applicant and, where different, the proposed DI.

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<sup>2</sup> Paragraph 5 of Schedule 3 to the HT Act.

# Right to make representations and appeal

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## Notice of intention to make representations

72. Where a relevant Notice is issued under paragraph 10 of Schedule 3 giving notice of the right to make representations, the holder of the licence and/or the DI have 28 days, beginning with the day on which the notice was given, in order to give notice of the wish to make representations. The HT Act does not specify how this notice is to be given. Accordingly, verbal notice (e.g. by telephone) to the Licensing Manager, Inspections Manager or Director of Regulation at the HTA will be sufficient to trigger the right to make representations. The member of staff receiving this request will make a written contemporaneous note of any such verbal request and then notify the Licence Holder and/or DI in writing of the receipt of that request.

## Representations

73. A person who has received a Notice confirming refusal of an application for the grant of a licence or the grant of a licence subject to a condition has the right to require the HTA to give him an opportunity to make representations.<sup>3</sup> Such representations may be:

- (a) oral representations made by him, or a person acting on his behalf;
- (b) written representations by him.

74. This right is exercisable by giving the HTA notice of exercise of the right before the end of the period of 28 days beginning with the day on which the notice was given.<sup>4</sup>

75. This right to make representations should not be confused with the right of an application to seek reconsideration of a decision, (which is considered further below). Reconsideration is, in effect, an appeal against a decision that has already been made. Representations are made prior to the initial decision being finalised. The HTA will make Regulations which set out a procedure for considering representations and for appeals. This will include a timetable within which representations should be heard.

## Reconsideration by an Appeal Committee

76. Section 19 of the HT Act sets out the right to reconsideration of licensing decisions. The right arises when an application for grant, revocation or variation is refused and also where the HTA, of its own volition, determines that the licence should be revoked or varied. The right to apply for reconsideration is given to the Licence Holder and the DI.

77. The right is exercisable by giving notice to the HTA before the end of the period of 28 days beginning on the day on which notice of the decision was given.

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<sup>3</sup> Paragraph 10(3) of Schedule 3 to the HT Act.

<sup>4</sup> Paragraph 10(4) of Schedule 3 to the HT Act.

78. The matter shall be referred for reconsideration by an Appeal Committee of the HTA. We will issue further specific information about how appeals will operate.
79. There is a right of further appeal to the High Court under Section 22, but only on a point of law.

## Revocation, variation of suspension of a licence

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### Revocation of licence

80. An application to revoke a licence can be made by the DI or the holder of a licence. This would happen where a DI and/or the licence holder decides s/he no longer wishes to carry on a licensable activity at the premises. The application is made so that the HTA can ensure that proper processes are in place to transfer any records or material to another licensed establishment so that they can continue to be stored in compliance with the HT Act. The HTA may also consider it necessary to revoke a licence itself – i.e. without prior application from the Licence Holder.
81. The HTA's powers to revoke a licence derive from paragraph 7(2) of Schedule 3. The HTA may revoke a licence if:
  - (a) it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading;
  - (b) it is satisfied that the DI has failed to discharge, or is unable because of incapacity to discharge, the duty under Section 18;
  - (c) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity;
  - (d) it ceases to be satisfied that the person to whom the licence is granted is a suitable person to be the holder of the licence;
  - (e) it ceases to be satisfied that the DI is a suitable person to supervise the licensed activity;
  - (f) the DI dies; or
  - (g) it is satisfied that there has been any other material change of circumstances since the licence was granted.

82. If the HTA wishes to revoke a licence then it must give Notice of the proposed decision<sup>5</sup> and the reasons for it before making that decision. Such notice has to be given to the holder of the licence and, where different, the DI. They then have the right to require the HTA to give them an opportunity to make representations as in the case of a proposal to refuse to grant an application for a licence. If, following the consideration of representations, a decision is made to revoke the licence, the HTA must again give notice to the holder of the licence and the DI. This again must set out the reasons for the decision. There is then the right to apply for re-consideration by an Appeal Committee.

## Variation of licence

83. The HTA may on application by the holder of a licence vary the licence so as to substitute another individual for the DI if:

- (a) the application is made with the consent of the other individual, and;
- (b) the HTA is satisfied that the other individual is a suitable person to supervise the licensed activity.

84. It is to be noted that the consent of the DI is not required. Indeed, there is no requirement on the HTA to give notice to the existing DI.

85. Apart from an application for variation by the Licence Holder to substitute another DI, there is a more general power to vary a licence on application by the holder or the DI.

86. In terms of the HTA's powers of variation, the HTA may vary a licence wherever it has power to revoke a licence.

## Suspension of licence

87. The HTA may suspend a licence where it:

- (a) has reasonable grounds to suspect that there are grounds for revoking a licence; and
- (b) is of the opinion that the licence should immediately be suspended.

88. It may by notice suspend the licence. The licence can only be suspended for up to three months at a time and this will be specified in the notice.

89. The effect of the suspension is that the licence will be of no effect while a notice of suspension is in force.

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<sup>5</sup> Paragraph 10(1)(a) of Schedule 3.

90. Although the power to suspend is only for a period of three months, the HTA has power to make a further order for suspension. The limitation is that each suspension order cannot exceed three months.

## Payment of licence fees

91. Paragraph 13(2) of Schedule 3 states that an application for a licence shall be accompanied by such fee (if any) as the HTA may determine. In addition to the payment of an initial licence fee, paragraph 2(4)(f) of Schedule 3 makes it a statutory condition of every licence issued by the HTA 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.**

92. Under this provision if such fees are not paid, then there will be a breach of licence condition and this would be grounds for revoking a licence.

# Annex A: Scheduled Purposes under the Human Tissue Act (Schedule 1)

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Schedule 1 consists of 2 parts, namely:

**Part 1** – purposes requiring consent: living and deceased persons:

- (a) anatomical examination;
- (b) determining the cause of death;
- (c) establishing after a person's death the efficacy of any drugs or other treatment administered to him;
- (d) obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person);
- (e) public display;
- (f) research in connection with disorders, or the functioning, of the human body;
- (g) transplantation.

**Part 2** – purposes requiring consent: deceased persons:

- (h) clinical audit;
- (i) education or training relating to human health;
- (j) performance assessment;
- (k) public health monitoring;
- (l) quality assurance.

## Annex B: Licensable activities under the Human Tissue Act (Section 16)

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1. Subject to Section 16 being brought into force by a relevant Commencement Order or Orders,<sup>6</sup> the following is a full list of the licensable activities contained within Section 16:
  - (a) **the carrying out of an anatomical examination.**
2. 'Anatomical examination' means macroscopic examination by dissection for anatomical purposes.<sup>7</sup>
3. 'Anatomical purposes' means purposes of teaching or studying, or researching into, the gross structure of the human body<sup>8</sup> references to the carrying-out of an anatomical examination are to the carrying-out of a macroscopic examination by dissection for anatomical purposes of the body of a deceased person, and, where parts of the body of a deceased person are separated in the course of such an examination, include the carrying-out of a macroscopic examination by dissection of the parts for those purposes.<sup>9</sup>
- (b) **the making of a post-mortem examination.**
4. Post-mortem examination is not defined in the HT Act. However, of necessity, the examination will have to be for a scheduled purpose.
- (c) **the removal from the body of a deceased person (otherwise than in the course of an activity mentioned in paragraph (a) or (b)) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;**
5. This part covers the removal of relevant material from the body of a deceased person other than in the course of an anatomical examination or a post-mortem examination.
6. Unsurprisingly, references to material from the body of a deceased person "are to material from the body of a person not alive at the point of separation".<sup>10</sup>
7. Relevant material" is defined in Section 53(1) as meaning material, other than gametes (i.e. sperm or eggs), which consist of or includes human cells. Section 53(2) specifically provides that relevant material from a human body do not include:
  - embryos outside the human body;
  - or hair and nail from the body of a living person.

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<sup>6</sup> Section 16 (2)(e) (ii) was brought into force on 1 March 2006.

<sup>7</sup> Section 54(1)

<sup>8</sup> Section 54(1)

<sup>9</sup> Section 41(1)

<sup>10</sup> Section 54(2)(b)

8. Removal must be for a scheduled purpose other than transplantation.

**(d) the storage of an anatomical specimen.**

9. "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).<sup>11</sup>

**(e) the storage (in any case not falling within paragraph (d) of:**

- the body of a deceased person;
- or relevant material which has come from a human body, for use for a scheduled purpose.

10. For the purposes of the HT Act, material shall not be regarded as from a human body if it is created outside the human body.<sup>12</sup>

11. The Secretary of State has power to make Regulations specifying the circumstances in which storage of relevant material by a person who intends to use it for a scheduled purpose is excepted from Section 16(2)(e)(ii).

Such Regulations have been proposed by the Secretary of State<sup>13</sup> and are due to be published during 2006. Regulation 3 of the proposed Regulations will provide that the storage of relevant material by a person who intends to use it for a scheduled purpose is excepted from Section 16(2)(e)(ii) in the following circumstances, namely:

**(f) 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.

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<sup>11</sup> Section 41(1)

<sup>12</sup> Section 54(7)

<sup>13</sup> The Human Tissue (Ethical Approval, Exceptions from Licensing and Powers of Entry and Search; Prescribed Information) Regulations 2006.

12. References to 'Public display' in relation to the body of a deceased person, do not include:

- display for the purposes of enabling people to pay their final respects to the deceased, or;
- display which is incidental to the deceased's funeral.<sup>14</sup>