These notes refer to the Human Tissue Act 2004 (c.30)
which received Royal Assent on 15 November 2004

HUMAN TISSUE ACT 2004

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 1 - Removal, Storage and Use of Human Organs and Other Tissue for Scheduled Purposes

Section 1: Authorisation of activities for scheduled purposes

10. Section 1 is the foundation of the Act. It establishes that consent from an appropriate person ('appropriate consent' as defined in sections 2 and 3) 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 in these notes as 'scheduled purposes'. Relevant material from a human body is defined at section 53 as any material consisting of, or including, human cells, with the exception of gametes, embryos outside the body (as defined in, and separately regulated by, the Human Fertilisation and Embryology Act 1990), and hair and nail from a living person. Cell lines are also excluded by virtue of section 54(7), as is any other human material created outside the human body.

11. *Subsections (2) & (3)* deal with the special requirements for the lawful storage and use of a body for anatomical examination. These provisions are carried over from the Anatomy Act 1984.

12. *Subsections (4)* to *(9)* allow activities of the kind mentioned in *subsections (1)* to *(3)* to be done in certain cases without meeting the conditions for which those subsections provide. The exceptions relate to imported bodies and material and to bodies, and material from bodies, of persons who died before the coming into force of the new regime where there is a gap of more than 100 years between the date of death and the activity concerned. This will allow continued import of tissue for research and will exclude archaeological specimens from the consent provisions. There is also an exception for health-related research on material from living people where the material is not linked to an identifiable individual and the research has been ethically approved in accordance with regulations. It is anticipated that this ethical approval will be given by existing Research Ethics Committees.

13. *Subsection (10)* makes it lawful for relevant material, which has been obtained from a living person, to be stored and used for the limited purposes set out in Schedule 1 Part 2, without any consent. These purposes are ones considered intrinsic to the proper conduct of a patient's treatment (clinical audit, quality assurance and performance assessment - which could include evaluations of *in-vitro* diagnostic devices) or necessary for the public health of the nation (public health monitoring and health-related education and training).

14. *Subsection (11)* provides that the Secretary of State may vary, omit or add to the purposes set out in Schedule 1, by means of a statutory instrument, subject to affirmative resolution in both Houses. *Subsection (12)* excludes from the consent requirements of

section 1 the storage and use of relevant material in *in-vitro* diagnostic medical device testing where this is already regulated by Directive 98/79/EC. *Subsection (13)* is aimed at ensuring that bodies and relevant material are not exported and re-imported simply to get around the consent requirements.

Section 2: "Appropriate consent": children

15. Section 2 sets out the meaning of 'appropriate consent' in relation to activities regarding the body of a deceased child, or relevant material from living or deceased children. For the purposes of this section, children are people under the age of 18.

16. Living children who are competent to do so may give their own consent. If they are not competent or choose not to decide, appropriate consent will be that of a person with parental responsibility for them. Competence is not defined in the Act, but will be established according to common law principles (the 'Gillick test').

17. Where a child has died, if he or she was competent and made an advance decision (to give or refuse consent), that will apply. *Subsections (4)* to *(6)* provide that consent of a competent child to have his or her body used for anatomical examination or public display must be in writing and witnessed. No-one other than a competent child may give consent to the use of his or her own body for purposes of anatomical examination or public display. Anatomical examination is defined in section 54. *Subsection (5)* of this section provides that prior written, witnessed consent to anatomical examination is only necessary in relation to material which is not excepted material (as defined in section 12), that is, in relation to a whole body, or material which has come from a whole body during an anatomical examination. For other scheduled purposes, such as the carrying out of a *post mortem* examination or the use of organs for transplantation, the consent of someone with parental responsibility will be appropriate consent, but only if the child did not deal with the issue of consent. *Subsection (7)* provides that if a child has died and there is no-one with parental responsibility, someone in a 'qualifying relationship' may give consent to removal, storage or use of the child's body or material from the body. (The group of next of kin etc who qualify for these purposes is given at section 54(9) and dealt with further at section 27(4)).

Section 3: "Appropriate consent": adults

18. Section 3 sets out the meaning of 'appropriate consent', in relation to activities concerning the body of a deceased adult or relevant material from a person who is (at the time of the activity) a living or deceased adult. If the adult is alive his own consent is required. *Subsections (3)* to *(5)* provide that after death, the adult's consent, given in advance in writing and witnessed, is required for purposes of anatomical examination or public display. As explained in the previous paragraph, anatomical examination is relevant only in relation to a whole body or material which has come from a whole body during an anatomical examination. For other scheduled purposes, if the adult made no prior decision, a person nominated by him in accordance with section 4 to make decisions after his death or, failing that, someone in a 'qualifying relationship' (as listed in section 54(9) and dealt with further at section 27(4)) may give consent.

Section 4: Nominated Representatives

19. This section sets out how an adult aged 18 or over can make a valid appointment of one or more 'nominated representative(s)', who may give consent after the adult's death to storage or use of his or her body, or removal, storage and use of relevant material from his or her body for scheduled purposes. *Subsection (6)* says that where two or more people are appointed as nominated representative, they will be assumed to be able to act alone unless the appointment says they must act jointly. Unless they have been appointed to act jointly, the consent of one of several nominated representatives is sufficient to make the activity lawful, even if the others object.

Section 5: Prohibition of activities without consent

20. *Subsection (1)* penalises the carrying-out of any of the activities to which section 1(1), (2) or (3) applies if done without appropriate consent. This means that where there is consent to use material for one purpose, it may not be used for another. However, a person does not commit an offence if he reasonably believed that the appropriate consent was in place, or that the activity was not one in relation to which consent was required.

21. *Subsection (2)* penalises a person who knowingly makes a false representation to another person that appropriate consent has been given or is not needed. *Subsections (3) to (6)* relate to offences and penalties in connection with anatomical examination which have been transferred from the Anatomy Act 1984.

Section 6: Activities involving material from adults who lack capacity

22. This section enables the Secretary of State to specify in regulations the circumstances in which there is to be deemed to be consent to activities regulated by the Act in relation to adults who lack capacity to consent for themselves, where a decision of theirs about such matters is not already in force. It is envisaged that the regulations will provide for consent to be deemed to be in place where the activity would be in the adult's best interests - for example, it could be in their best interests to donate tissue to a close relative for transplantation. The regulations will also be able to provide that where consent has been given by a proxy in accordance with Schedule 1 to the Medicines For Human Use (Clinical Trials) Regulations 2004/1031, storage and use of material from the adult lacking capacity as part of the trial should be treated as done with consent. The regulations will also be able to take account of the Mental Capacity Bill, introduced in the House of Commons on 17 June 2004, in particular in relation to research involving those who lack capacity to consent, which will be regulated by that Bill.

Section 7: Powers of court to dispense with the need for consent

23. *Subsections (1) to (3)* of this section allow the Human Tissue Authority to give a direction deeming consent to be in place in relation to relevant material from a living person who is either untraceable, or who has not responded to requests for consent to use of his material, but where the material could be used to provide information which may be relevant to another person. These are expected to be rarely-used powers, but they may be important where valuable information could be obtained about the treatment and diagnosis of the applicant for the direction.

24. *Subsection (4)* enables the Secretary of State to make regulations which would provide a similar power for a court to deem consent to be in place where relevant material or a body could be used for health-related research. It is envisaged that this power would be exercised only in rare and unusual cases where the research would be in the overwhelming public interest, for example, where a person has died of an unknown virus which has the potential to spread among the general population.

Section 8: Restriction of activities in relation to donated material

25. This section provides that, where the body of a deceased person or relevant material from a human body is the subject of any consent under section 1, it may not be used, or stored for use, for purposes other than the following: (a) a purpose listed in Schedule 1, (b) medical diagnosis or treatment, (c) disposal or (d) another purpose excepted by regulations. It will be an offence to use such material for any other purpose. The offence will not apply where a person believes on reasonable grounds that the body or material is not relevant material which is the subject of appropriate consent. The regulation-making power is intended to be used to ensure that legitimate uses of tissue which may come to light in future will not be criminalised.

Section 9: Existing Holdings

26. This section deals with 'existing holdings', namely, a body, or relevant material, which is already held for use for a scheduled purpose when the new regime comes into force. In such a case, the effect of the section is that use, or storage for use, for a scheduled purpose is authorised under section 1(1) without the need for appropriate consent. However, this does not apply to storage and use of bodies or material in relation to which there is an authority under the Anatomy Act 1984 and where the anatomical examination is not concluded before the Act comes into force. Such bodies and material are dealt with in section 10. The code of practice to be issued by the HTA under section 26 will deal with the storage, use and disposal of existing holdings.

Section 10: Existing Anatomical Specimens

27. This section provides for what should be done, once the consent provisions of the Act take effect, about bodies and parts of bodies already donated for dissection under the Anatomy Act 1984, but where the anatomical examination of them has not been concluded. The Anatomy Act provides that bodies might be kept for up to three years with the donor's or his next of kin's authority and body parts might be kept for longer. This section provides that the terms of the authority given under the Anatomy Act 1984 are to be treated as 'appropriate consent' to anatomical examination. In addition, if the existing authority allowed parts of the body to be held after conclusion of the examination and the examination was not in fact concluded before the consent provisions in the Act came into force, the authority is to be treated as "appropriate consent" to storage for the purposes of education and research.

28. *Subsection (6)* is intended to ensure that, where authority under the Anatomy Act has been given on terms, the authority under the Act which is based on that authority is also subject to those terms.

Section 11: Coroners

29. In order to maintain the current legal position regarding coroners, this section exempts from the requirements of Part 1 of the Act anything done for the functions of a coroner or under his authority. This includes both his statutory functions and his common law authority. *Subsection (2)* provides that if a body or material from it may be needed for the purposes of the coroner, the authority conferred by section 1 to act in relation to the body or material does not apply.

Section 12: Interpretation of Part 1

30. This section defines 'excepted material' which is relevant to the references in sections 2 and 3 to anatomical examination.