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.