

I. Introduction

- I.1 The MRC issued its guidance *Human Tissue and Biological Samples for use in Research*¹ in April 2001, at a time when there was little such guidance available. It was aimed mainly at researchers, but was intended also to be useful to others such as those responsible for research governance and also for research ethics committees. The guidance states that the MRC would keep it under review.
- I.2 The Human Tissue Act² received the Royal Assent in November 2004, though most of its provisions will not come into effect **until 1 April 2006**. The Act was introduced largely in response to events at Alder Hey and the Bristol Royal Infirmary, both of which were subject to public inquiries, and in response to the Isaacs Report prepared by HM Inspector of Anatomy. The Act introduces new legislation covering the removal, storage and use of human organs and tissue. The Act lays down minimum legal requirements; best practice will often go beyond this. An update on the Act is available on the Department of Health website.³
- I.3 This clarification is aimed at providing some additional guidance as a consequence of the Act. **It is not intended to be comprehensive**. The Act itself, together with its Explanatory Notes, and the DoH guidance should be consulted for a comprehensive view.
- I.4 The Act does not apply in Scotland, except for section 45 and Schedule 4 (non-consensual DNA-analysis). Nevertheless, the MRC recommends that its guidance should be adhered to throughout the UK.

- 1.5 During passage of the Human Tissue Bill through Parliament, the MRC consulted its research community and, together with other research organisations, commented on various drafts of the Bill and provided briefing for parliamentarians.⁴
- 1.6 Other organisations are also planning to issue revised guidance, in particular the Royal College of Pathologists.⁵
- 1.7 The Act (Part 2) makes provision for the establishment of a Human Tissue Authority, which will issue Codes of Practice (Sections 26 – 29). The Authority is being established before April 2006 and this guidance may need to be updated again when its codes have been published.

2. Purpose of the Human Tissue Act

- 2.1 The purpose of the Act is to provide a consistent legislative framework for issues relating to whole body donation and the taking, storage and use of human organs and tissue. **It makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased persons.**
- 2.2 The Act, by establishing the Human Tissue Authority, will set up an over-arching body which is intended to rationalise existing regulation of activities like transplantation and anatomical examination, and introduce regulation of other activities like postmortem examinations, and the storage of human material for education, training and research. It is intended to achieve a balance between the rights and expectations of individuals and families, and broader considerations, such as the importance of research, education, training, pathology and public health surveillance to the population as a whole.

3. Summary of the main points of the Act, as they relate to research

- 3.1 Purposes requiring consent include (Schedule 1, Part 1):
- Research in connection with disorders, or the functioning, of the human body.
 - Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).
- 3.2 Storage for such purposes, as well as use, requires consent (Section 1 (d) and (f)).
- 3.3 Material covered by the Act is "material, other than gametes, which consists of or includes human cells". Embryos outside the human body and hair and nail from the body of a living person are excluded (Section 53). Other exclusions are listed below at 3.1.1. Blood, for example, is thus included.
- 3.4 Relevant material also includes left-over tissue taken from operations and for diagnostic purposes. Consent for treatment/diagnostic procedures is of course required outside the scope of the Human Tissue Act, but storage and use of tissue so obtained for the purposes covered by the Act does require **separate** consent.
- 3.5 The Act's requirement for consent applies to taking, storage and use of tissue from dead people, as well as to storage and use of tissue from living people (see 3.8, below).

3.6 Consent for research is not a legal requirement if the samples are anonymised to the researcher; ie, if i) the research "is to be, or is, carried out in circumstances such that the person carrying it out is not in possession, and is not likely to come into possession, of information from which the person whose body the material has come can be identified", **and** ii) the research has been approved by a Research Ethics Committee (Section 1 (9) and cross-references to it). If the clinician is the researcher, either consent must be obtained from the provider of the tissue and/or the samples must be anonymised such that the clinician, when doing the research or subsequently, does not know from whom they came.

It is not necessary that samples be irreversibly anonymised. During passage of the Bill, the Minister made clear that anonymisation would "not mean that the patient and the tissue would be permanently unlinked. Further information could be sought from the records, but the researcher should not get identifying information, and the ethics committees would be able to consider what arrangements were appropriate in each case".⁶ Situations where the "researcher should not get identifying information" equates with the "Coded samples" category in the MRC guidance (page 2).

3.7 During passage of the Bill, Ministers also made clear that under the Act consent is consent. It can be "broad and durable" or "limited in time and scope".⁷ That is to say that the Act sets a baseline requirement for consent so that it does not, for example, require consent to the use of tissue in research to be project-specific. Further guidance on consent will be provided by the Human Tissue Authority in a statutory Code of Practice.

3.8 The Act sets out requirements for obtaining consent:

- From children (less than 18 years) (Section 2).
- From adults who lack the capacity to consent (Section 6).
- Relating to people who have died (Section 3).

The details are complex, but briefly:

Children: from the child himself or, when the child is not competent to deal with the issue of consent, from the person who has parental responsibility for him.

Adults lacking capacity: such a person is only deemed to have given consent to an activity if it is done in "circumstances of a kind specified by regulations specified by the Secretary of State". (This was a holding position, pending passage of the Mental Capacity Act⁸; the Act, passed on 7 April 2005, now applies.)

Deceased people: ideally from the person himself before he died. If this is not available, from a person appointed by the deceased person or, if this is not available, from a person in a "qualifying relationship" to him immediately before he died. (Qualifying relationships are defined/listed in Section 54 (9) of the Act.)

3.9 A person does not commit an offence if he "reasonably believes" that appropriate consent had been given (Section 5 (1)).

3.10 It is illegal even to hold any material with the intention of undertaking DNA analysis on it without consent (Section 45).

3.11 The Act's requirement for consent does not apply to:

- Samples in existence on the day the Act comes into force – "Existing holdings" (Section 9).
- Cell lines – "material shall not be regarded as from a human body if it is created outside the human body" (Section 54 (9)).
- Surplus or "residual" material from living patients stored or used for education or training relating to human health (including training in research techniques) (Schedule 1).
- Imported material (Section 1 (5) and (6) and cross-references to them).

3.12 The Act provides for a licensing system, the details of which are under discussion (Sections 16 – 25). It may not necessarily be the case that all individuals storing or using human tissue will require a licence.

4. Implications for current MRC guidance

4.1 As indicated above, the Act sets out minimum legal requirements. In many respects the MRC's 2001 guidance already goes beyond this. Thus those who follow the MRC guidance should have little difficulty in obeying the law. However, researchers now need to take account of the following points.

4.2 Consent for research use; linking samples to consents and tracking samples

Under the Human Tissue Act, **unless the samples have been anonymised** and the research project has ethical approval (see 3.6, above), it will be illegal to use human material for research without consent. Note that **existing holdings are exempt**. Researchers are therefore advised to work with their clinical colleagues to ensure that **from now on** consents for all clinical procedures where tissue will be removed will be accompanied by consents for use of tissue in research, whether the sample is taken solely for a research purpose, or as a clinical procedure where surplus tissue may be used for research either immediately or at some time in the future. (see also 4.3, below). Consent must be recorded in writing, but it is not a legal requirement that it has to be signed by the participant. If consent for research use is not obtained and recorded with the sample, such samples may henceforth be used for research only after anonymisation. It is thus now of increased importance that mechanisms are in place that a) easily allow clinicians to link samples with the consents that were given when they were taken, and b) allow tracking of sample usage and transfer.

4.3 Use of material surplus to clinical requirements for research

The MRC's current guidance states that "The MRC recommends that wherever practicable individual consent should be obtained for the use for research of human material surplus to clinical requirements" (Paragraph 3.1); this remains good practice (if it is not done, such samples may only be used anonymously – see 4.2, above). The guidance also states that "there must always be explicit separation of the consent to the treatment or diagnostic test from the consent to the use of surplus tissue for research" (Paragraph 3.4). This remains the case.

4.4 Broad consent

Broad consent for research is not unlawful under the Act. Current MRC guidance states that where a sample or part of a sample is to be stored, a two-part consent process is recommended, the donor being first asked to consent to the specific experiment(s) already planned, and then to give consent for storage and future use for other research (Paragraph 6.2). Although current MRC guidance also states that it is not acceptable to seek completely unconditional blanket consent, for example using terms such as "all biological or medical research", it is now considered reasonable to request consent for example for "future medical research projects which would have to be approved by a properly constituted research ethics committee". It would be for the Research Ethics Committee subsequently to decide whether each new research project could proceed on the basis of such broad consent. The MRC plans to review the guidance again in the light of the Codes of Conduct to be issued by the Human Tissue Authority.

4.5 DNA analysis

The current MRC guidance addresses the issue of genetic research (Paragraph 8.5). There is now a new offence of holding any material with the intention of undertaking DNA analysis on it without consent. Thus if there is any intention of doing genetic analysis on identifiable material, consent for this must be obtained at the time the sample is taken (otherwise as soon as possible after the decision to do the analysis is taken).

5. References

- 1 Human Tissue and Biological Samples for use in Research, Medical Research Council, 2001 (www.mrc.ac.uk/pdf-tissue_guide_fin.pdf)
- 2 Human Tissue Act 2004:
See: www.legislation.hmso.gov.uk/acts/acts2004/20040030.htm
Explanatory notes:
See: www.hmso.gov.uk/acts/en2004/2004en30.htm
- 3 Human Tissue Act 2004 – new legislation on human organs and tissue
www.dh.gov.uk/assetRoot/04/10/36/86/04103686.pdf
- 4 See: www.mrc.ac.uk/public-human_tissue_consultation.htm
- 5 See: www.rcpath.org/index.asp?PageID=38#general
- 6 Hansard House of Commons, 28 June 2004, Column 97
- 7 Hansard House of Lords, 16 September 2004, Column GC 519
- 8 Mental Capacity Act 2005: See:
www.hmso.gov.uk/acts/acts2005/20050009.htm

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