Department of Health

Use of Human Organs and Tissue: A Draft Interim Statement for Consultation by the Department of Health

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1. Human organs and tissue[1] can be used in a number of different ways that benefit the present and longer-term health both of individuals and the population as a whole. These purposes include some, such as quality assurance, that are essential for the maintenance of effective treatment of patients, and others, such as research, education and training, that have less direct, but no less important, implications.

2. Through these means, clinical care can be improved; clinical standards can be maintained or enhanced; and new diagnoses and treatments can be developed. Developments in the treatment of cancer and heart disease, in our understanding of AIDS and variant CJD, and in the clinical means of responding to germ warfare or bioterrorism would all have been seriously impaired if human tissue had not been available for the necessary investigation and research. Similarly, access to historic tissue (such as that held from the 1919 influenza pandemic) has helped us to respond to more recent challenges.

Purpose of this statement

3. The present law on the removal, retention and use of human organs and tissue contains many uncertainties. In particular there is limited existing law relating to the use of tissue taken from live subjects. Work is in hand to resolve these problems (see paragraphs 4 and 13). In the meantime the Department offers this statement, initially for consultation, as a guide for clinicians, researchers and others. In doing so, the Department appreciates that some of its conclusions imply the development of some new, possibly time-consuming, procedures. These issues are being addressed as part of a much broader programme of work. This statement has the more limited aim of conveying the Department's advice on whether, in the context of the existing law, particular uses of tissues should or should not be permissible and in what specific circumstances. This cannot of itself be a definitive statement of law, but the Department is seeking, through consultation, to achieve a statement that commands broad support.

How things are changing

4. In the past organs and tissue were sometimes removed, stored and used without the standard of consent that would be regarded as acceptable today. This has been a particular issue in circumstances where a death has occurred in hospital. In some instances, the deceased person might have expressed his or her wishes, or consent might have been obtained from relatives. But, in other cases, consent was not sought (or, at least, satisfactory evidence of this was lacking). As a result, the law in England and Wales on the taking and use of organs and tissue is currently being reviewed by the Department of Health[2], in consultation with the NHS Directorate of the National Assembly for Wales. There will be widespread

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1 For the purpose of this statement, "organs and tissue" includes whole organs, tissue blocks (see paragraph 6) and, in fact, anything that contains human nucleic acids. The statement does not extend to **photographs of tissue**, which, as records, should be treated in the same manner as other clinical data obtained from patients. Guidance on tissue photography is being formulated by the General Medical Council.

2 Rt Hon Alan Milburn, House of Commons, 30 Jan 2001; *The Removal, Retention and Use of Human Organs and Tissue from Post-Mortem Examination: Advice from the Chief Medical Officer* (DH, January 2001).

consultation on this early in 2002. In tandem the Home Office is leading a review of the coroners' system. In addition, a working group on human remains has been established by the Department of Culture, Media and Sport. Working links are being maintained between these projects to ensure consistency.

5. In the meantime, various developments have already influenced the climate of opinion and direction of practice. These include developments in case law, human rights legislation, the initiatives of key professional and research bodies, the patient-centred focus of the *NHS Plan* (2000)[3], the Department of Health's "Good Practice in Consent" initiative[4] and reports on past practice at Alder Hey[5], Bristol[6] and elsewhere.

General principles

6. **In general, human organs and tissue should be used only for purposes for which patients[7] have had the opportunity to give their valid consent.** This means

   - that patients must be provided with suitable information in a form that they can understand. For example, they need to know that small pieces of tissue may be placed in **blocks or slides** for examination under a microscope and possible retention with clinical records[8];
   - that they have the opportunity to ask questions; and
   - that they are able either to register their objection or to give explicit consent to particular tissue removal, storage or use.

7. It is axiomatic that the human body and its parts are treated with respect in all circumstances.

8. The principles at paragraph 6 have many similarities with those relating to consent to treatment. However, while organ or tissue removal may be a part of treatment, the consent aspects of treatment and those relating to the removal, retention or use of tissue for other purposes need to be addressed separately. A case in point would be the possible use in education or research of any **"surplus" tissue** (*ie* organs or tissue removed as part of ordinary clinical care or investigation).

9. **Where someone has died** without expressing any wishes as regards organ or tissue removal, retention or use, the responsibility for taking any decisions – including whether a hospital post mortem may take place[9] – rests with relatives or those closest to the deceased person[10]. A code of practice on communicating with families about these matters, together with model consent forms for hospital post mortems and the removal, retention and use of organs and tissue, are to be piloted as part of the

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3 *The NHS Plan* (DH, July 2000), Chapter 10.

4 *Reference Guide to Consent for Examination or Treatment* (DH, March 2001) and footnote 11.

5 *The Royal Liverpool Children's Inquiry Report* (Chairman: Michael Redfern QC) (House of Commons, 30 Jan 2001).

6 *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary* (Chairman: Prof Ian Kennedy) (Cm 5207, July 2001).

7 Parents or other relatives may be asked to give consent in the case of children under 16 who are unable to consent themselves or (see paragraph 9) where someone has died. Similarly the agreement of relatives may, in some circumstances, be sought if an adult is unable (eg through mental incapacity) to give consent him or herself, though there is currently no provision in English law for anyone to give consent on behalf of another adult. The current review of the law on organs and tissue is addressing the relevant issues.

8 See *Tissue Blocks and Slides: an information note* (Retained Organs Commission, April 2001).

9 A coroner's post mortem does not require consent, though the family should be told what this will involve and given the opportunity to consent to the retention or use of any organ or tissue beyond that necessary for the post mortem itself.

10 See Department of Health's draft code, *Families and Post Mortems*, to be issued for consultation, January 2002.

Department's broader consent initiative[11]. **The Department's view is that only by operating a policy of valid consent by relatives can the requirements of the Human Tissue Act 1961 properly be met**[12].

Organs or tissue taken in the future

10. It follows from paragraphs 6-9 that, provided the future removal, retention, storage and use of tissue are authorised by a valid consent[13], the practice will be lawful. However, there are particular considerations that apply to certain uses, including some (*i* and *ii*) which are so much a part of clinical procedures that – with some provisos – the Department considers that consent given for those procedures should of itself be sufficient.

(i) quality assurance and audit

With some clinical procedures or tests (*eg* cervical screening) some separate examination or testing of tissue is essential to ensure a high quality of service and hence the realiability of such procedures. The Department believes that tissue samples may be used for quality assurance and audit purposes without requiring specific patient consent. However, there need to be active local arrangements for informing patients of such use[14]. Wherever possible, such samples should be anonymised or pseudonymised.

(ii) in-service training

Qualified professional staff frequently contribute, as part of the normal clinical process, to in-service training: *eg* by providing a preliminary diagnosis of a tissue slide. Specific consent is not required for the use of tissue in these circumstances since it forms an integral part of patient care (and is also essential if NHS staff are to develop their professional skills and provide the high quality service that patients have the right to expect).

(iii) research

In the case of organ or tissue use for clinical research the Department endorses the following additional principles[15]:

- research should go ahead only if the potential benefits outweigh any potential harm (which will usually be minimal) to the donors of the samples;
- samples of human organs or tissue obtained for use in research should be treated as donations;

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11 Health Circular 2001/23 (October 2001).

12 Under section 1 of the Human Tissue Act parts of the body may be removed for medical purposes if "having made such reasonable enquiry as may be practicable", there is no reason to believe that the deceased person has expressed an objection or that the surviving spouse or any surviving relative objects.

13 Except any organs or tissue required by a coroner to be retained for post mortem purposes: see footnote 9.

14 An analogy is informing patients about uses of personal health information. This means that such arrangements should extend beyond the availability of publicity materials (newsletters, websites, notices in waiting areas, etc) that can help to reinforce a general approach. They should involve providing patients directly with suitable information and the opportunity to ask questions or to seek further details or reassurance (see Department of Health (1996) *The Protection and Use of Patient Information*). If a patient is unwilling for tissue to used for QA purposes it will be necessary to explain why this is important. If he or she continues to object, consideration may have to be given as to whether it is possible to proceed with a particular treatment or diagnostic test.

15 These draw in large measure on the Medical Research Council guidance, *Human Tissue and biological samples for use in research: Operational and Ethical Guidelines* (2001).

- the human body and its parts should not, as such, give rise to financial gain (though it is legitimate for suppliers to levy an administrative and/or handling charge for parts that have been acquired and stored in an ethical manner) ;

- patients should be asked whether organs or tissue left over following diagnosis or treatment may be retained and/or used for research;

- records of storage and use should be properly maintained and, where necessary, linked to (or unlinked from) relevant patient information systems;

- all research using samples of human organs or tissue must be approved by a properly constituted research ethics committee[16];

- researchers should treat all personal and clinical information relating to research participants as confidential[17];

- research participants, if they wish, should be able to know individual research results that affect their interests.

These principles should apply also to **student research**, even though the purpose of this is usually primarily educational (see *(iv)* below).

(iv) education

Tissue may be used, under proper supervision, in undergraduate teaching and post-graduate meetings and courses. As with *(i)* above, there must be an active local policy of informing patients of these activities and, wherever possible, tissue samples should be anonymised or pseudonymised. However, if a patient does object to his or her tissue being used in this way, that objection should be respected. The principles at *(iii)* above would apply to student research.

Existing stored tissue

11. More problematic than the future removal or use of tissue is any proposed use of existing stored tissue. **Here a decision will need to be taken as to whether consent (or further consent) needs to be sought**. Pending new legislation, the Department offers the following advice:

- ***valid consent may previously have been given*** to a particular use or uses, in which case it is lawful to use the organs or tissue as already authorised;

- ***where the donor's identity is known*** (or could be identified from records) and unambiguous consent has not already been obtained for the removal, storage or use of tissue, consideration should be given to whether it is possible (or, depending on the nature of the research, necessary) to seek consent from the person concerned (or, if he or she is no longer alive or cannot reasonably be traced, from a relative[18]). It is important to test assumptions about such prospects

16 See *Governance Arrangements for NHS Research Ethics Committees* (DH, July 2001).

17 See *Personal Information in Medical Research* (MRC, 2000).

18 This process will require the sensitive handling of any confidentiality issues, especially if the tissue donor is or may still be alive. It is possible that standards of consent applied when particular tissue was taken were less rigorous than they are now. This may raise certain ethical issues if the donor has since died and consent is being sought from a relative. However, the Department takes the view that this need not of itself preclude the use of that tissue provided that suitable consent can be obtained and there is no evidence of actual malpractice in the taking or storage of the tissue.

and not take for granted that organs or tissue obtained before a certain date are likely to have been "abandoned"[19]. However, logistical considerations may sometimes have to be balanced against other factors, such as the potential distress to those who might be contacted. Equally an intention to anonymise and unlink tissue is likely to strengthen the case for its ethical use. These are issues on which research ethics committees should be able to advise;

- ***where the identity of the donor is apparently unknown, or he or she cannot reasonably be traced (including where the tissue is simply too old for this to happen)***, there is, by definition, no prospect of obtaining contemporary consent. It is possible that consent was in fact given at some point in the past (maybe orally), even if there is now no evidence of this; and, indeed, the antiquity of some samples is such that their removal and storage would have been subject to a rather different legal and ethical framework. It would therefore be wrong to conclude that the use of unidentified tissue is necessarily unethical. **But equally such tissue should not be used without careful consideration**. The following principles should apply[20]:

  – tissue samples from established collections in museums and archives may be used for research provided that this has been approved by a local or multi-centre research ethics committee and (as will usually be the case) there is no potential harm to the donors;

  – if there is suitable tissue for which valid consent has been given or could be obtained, this should normally be used in preference to that for which the parameters of consent are inadequately recorded;

  – researchers should satisfy themselves that there is no evidence of samples having been obtained in an unethical manner, nor any ethical concerns about the propriety of a collection as a whole.

12. **Genetics research** arouses some particular concerns. Specialised guidance should be consulted[21].

13. The Retained Organs Commission is considering what should be done about organs and tissue whose return has not been sought by families once the current process of responding to families' enquiries about retained organs is complete. The Department is working closely with the Commission in this and other areas. **In the meantime it is important that organs and tissue that are not subject to a request for return or disposal are not destroyed.**

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19 Although not an exact parallel, the sensitivities are illustrated by recent instances in which organs and tissue taken from people without evidence of consent as long as 30 or 40 years ago have been traced following enquiries from relatives.

20 Again these draw strongly on MRC guidance (see footnote 15) and that of other bodies (eg Royal College of Physicians).

21 Advisory Committee on Genetic Testing (1998) *Advice to Research Ethics Committees:* Department of Health: London; Medical Research Council (2001) *Human Tissue and Biological Samples for Use in Research:* Medical Research Council: London.