25th June 2004

Human Tissue Bill

Views of the Medical Research Council

Updated at the time of the Report Stage in the House of Commons

Introduction

The Medical Research Council (MRC) has provided comments at earlier stages during the passage of the Human Tissue Bill:

- In advance of the Committee Stage (dated 26 January 2004)
  www.mrc.ac.uk/pdf-positioning_paper_htb.pdf
- In a letter to Ms Winterton (dated 25 March 2004). This followed a meeting with Ms Winterton, held on 9 March, which focused on the use of remnant tissue.
  www.mrc.ac.uk/pdf-human_tissue_bill_letter.pdf


The Report Stage is scheduled for Monday 28 June

The present comments are based on a briefing note on the amendments, provided by the Department of Health on 16 June. (Numbering follows that in the DH Note). Those in bold are the most important ones, which may require further amendments to the Bill itself.

The MRC broadly welcomes the proposed amendments, in particular those that remove the requirement for consent for the use of residual tissue for research. However, a number of other aspects remain of concern and have the potential to inhibit medical research of value to the human health. Where possible, these should be accommodated in the Bill itself; where not possible, the intention of Parliament should be made clear during subsequent debates (i.e. in Hansard) or in revised Explanatory Notes to be issued when the Act is passed.

1. Education and Training

MRC welcomes the amendment that will make it possible to carry out education or training relating to human health and to disorders and functioning of the human body using tissue from living patients, without the need for consent. (And that therefore references to education and training will be moved from Part 1 to Part 2 of Schedule 1). (And amendments to Clause 8. Schedule 5).
However, we understand that where the education or training is in research techniques, it is proposed this will remain a Part 1 purpose requiring consent from living patients. This distinction may be difficult to make in practice. For example, a diagnostic test may be used for diagnosis or for estimating the amount of a substance as part of a research project. There seems no rationale for making this distinction, and we urge strongly that it should be removed – i.e. that all education or training using tissue from living patients should be permissible without the need for consent.

2. Research

MRC very much welcomes the amendment to the Bill that will allow research using material from living patients without consent. This will avoid the imposition of additional bureaucracy and burdens on NHS staff, and permit much useful research to be undertaken in the future. MRC also recognises the need to have safeguards and notes that the Government has endorsed MRC’s own view that the research must be approved by a research ethics committee (REC).

(Amendments to Clause 1, Clause 53 and Schedule 5).

However, the new amendments require that the researcher must not possess any information that might allow identification of the individual whose tissue it is. While this will not be a difficulty in most cases, there may be instances where the research requires linkage back to information about the individual and it is therefore important that this can be allowed to happen. This will require the data not to have been irreversibly anonymised at source. In these cases it will be necessary for someone (not necessarily the researcher) to have newly-obtained information and information about the individual. The key issue is that the outcome of the research should safeguard the interests of the individual(s) by guarding against deductive disclosure, and this guiding principle should be what is made clear in the law or its interpretation.

We therefore repeat our earlier suggestion that the Bill should be re-drafted to permit the use of tissue for research, without re-newed consent, where anonymisation has not occurred, if the results cannot affect the person’s or the family’s interests, and where the patient has been informed at the time the sample was taken that their material might be used for research, for example by clearly displayed notices, by distribution of leaflets, or on the clinical consent form itself. Again, this should be permitted only if approved, project-by-project, by a Research Ethics Committee. Clear guidance will need to be provided by the HTA on the process of de-identification, anonymisation and linkage. See also our comments in 14 below.

3. Trafficking

MRC welcomes these amendments that will remove any doubt that certain clinical research activities, at present legitimately carried on for profit, will remain lawful following the passage of the Bill. (Clauses 29 and 55).
4. **Extension of consent offence**

MRC recognises the need for these amendments (to make it an offence for a person falsely to represent that the necessary consent has been given, or that it is not needed). (Amendments to Clauses 5 and 7).

5. **Court order where relatives are untraceable**

The Government proposes an amendment that would allow a Court order to be sought in cases where an existing stored sample needs to be tested in order to help diagnose or treat a relative, but where consent to such use of the sample was neither given nor refused, and where efforts to trace the original person have failed. (A new Clause, and consequential amendments to Clause 60 and to Schedule 5).

We note that, as described, this is a fairly narrow issue ("in order to help diagnose or treat a relative"), and will probably occur only very rarely. However, this would pertain to samples originally taken for a research purpose (as well as to those taken for clinical diagnosis/treatment). This potential problem supports the case in certain circumstances (see 7(iv) and (v), below) for 'opt-out' consent – i.e. where absence of evidence of agreement may be assumed to mean that consent has been given. It is beholden on researchers to ensure that appropriate information is recorded at the time the sample is taken, and to retain records so as to increase the likelihood that (if necessary) the donor may be traced.

[But see also 14 below].

6. **Mentally incapacitated adults**

MRC welcomes the amendments that allow regulations to set out what is required before tissue from those who lack capacity can be used for purposes regulated by the Bill (pending passage of the Mental Capacity Act). i.e.:

- In the case of incapacitated adults, appropriate consent will be considered to be in place where storage or use would be in the adult’s best interests.
- Provide for research using the tissue of incapacitated persons where the adult’s participation in a clinical trial is authorised in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.

(A new Clause, and consequential amendments to Clauses 53 and 60 and Schedule 5).

7. **Code of Practice on consent**

We welcome the proposal to make it explicit in the Bill that the Human Tissue Authority will provide a Code of Practice giving guidance on obtaining consent from living patients. (Amendments to Clauses 23 and 24). However, in our earlier comments we raised concern in several areas, which we re-iterate here:

1) **Definition of “Appropriate consent”**

The scope and specificity of “appropriate consent” should be more clearly defined, at least in terms of the minimum requirements, and with an emphasis on minimising bureaucracy. The terms of this should be sufficiently broad to allow for use of tissue for new and unforeseen projects, with ethical approval, without having to trouble patients or relatives again for further consent. The Codes of Practice should not be too restrictive;
some details should be left to the discretion of Local Research Ethics Committees (LRECs). In this way, if public attitudes change, these changes can be more readily reflected in the interpretation of the Act.

ii) Broad consent
We welcome the fact that the Bill leaves open the possibility of the donor being asked to give broad consent to the use of their tissue, at least within one of the categories in Schedule 1, part 1. During the second reading, Dr Ladyman said that the Bill “does not limit the duration and breadth of the consent, so we would not expect patients to have to be revisited for further consents” (Hansard, column 1044). The Bill should state this explicitly.

iii) Conditional consent
It remains unclear whether a donor will be able to give conditional consent in any sense: for research into certain disorders, say, but not others. Again, the Bill should state explicitly that this would not be possible, as how this is interpreted will currently be left to the HTA and LRECs. We doubt whether conditional consent would work in practice, as it would be too difficult to ensure that this level of detailed information could accompany all organs/tissues (especially if they are further subdivided).

iv) Written consent
Where there is already a mechanism for obtaining written consent (e.g. for surgery), we agree this should be expanded (as usually occurs now) to cover consent for other purposes, such as research. This reinforces the importance of obtaining consent and of the knowing (and usually very willing) participation of patients in research; a point often made by patient groups. However, in cases where there is currently no requirement for written consent to be provided by the patient, we hope that it will not be introduced (because of bureaucracy). However, there will need to be some record of consent (or decline or opt-out – see below), provided by the health professional.

v) Opt-in or opt-out
There is the question of whether the consent should be opt-out or opt-in. We would argue that it should be opt-out – i.e. that there should be a box on the form that the patient or health professional should tick if the patient does not want their tissue used for research, and that the record that accompanies the sample should state only whether the sample should not be used. This is on the basis a) that in benefiting from the NHS, patients should be encouraged to give something back for the public good, and b) that if there is no record of consent attached to a sample, it should be reasonable (i.e. lawful) for the researcher to assume that consent had been given for its use in research.

8. In Vitro Diagnostic (IVD) kits
No comment

9. Definition of Child
No comment
10. Definition of Anatomical Examination

We welcome the clarification of the definition of, and references to, anatomical examination to ensure that they include only dissection of parts of a body where the part has been derived from a whole body of a deceased person which has itself been used for anatomical examination. (A new Clause, and amendments to Clauses 2, 3, 7, 23, 43 and 55).

11. Archaeology

No comment

12. Cold Perfusion

No comment

13. Parliamentary scrutiny of Codes of Practice

We agree that the Codes of Practice should be subject to a process of Parliamentary scrutiny, and that those approved by the Secretary of State should be laid before Parliament and subject to approval by the negative resolution procedure before they may be issued. (Amendments to Clauses 23 26).

14. Court order to waive consent in the public interest

The Government has noted the concern about the need for a ‘last resort’ mechanism to waive the requirement for consent to use tissue from persons living or deceased, in the public interest. (For example, in a case where a person has died of a new virus and relatives cannot be found who may be asked for permission to take tissue for testing). The Government therefore proposes to include a power for the Secretary of State to make regulations which could enable the High Court to waive the need for consent to use tissue for health-related research, in cases where appropriate consent cannot be obtained; with the expectation that the regulations would provide for the court to waive the need for consent in rare and exceptional cases where the public interest justified it. (A new clause and consequential amendments to Clauses 53, 60 and Schedule 5).

We agree this is an important issue, but believe that this solution is too stringent. Unlike the case in paragraph 5, above (which pertains to diagnosis/treatment), for possible research uses there are Research Ethics Committees, and we therefore propose that this power be invested in Ethics Committees, not with a Court. [An additional safeguard would be to include a requirement that the RECs inform the HTA. The HTA could then satisfy itself that such waivers were not being over-used].

15. Best regulatory practice

We agree that the HTA should adhere to best regulatory practice, minimising burdens and costs etc., and welcome an amendment to this effect. (A new Clause to go immediately after Clause 36).
Other issues (raised previously)

i) Definition of “Relevant material”

The inclusion of blood under ‘relevant material’ conforms with MRC guidelines. However, this does have implications for licensing, since blood for research is frequently collected outside hospital settings (eg in General Practice and in Medical Schools).

ii) DNA analysis

The clauses concerning non-consensual analysis of DNA (46 and 47) do not fit well with the rest of the Bill, and would better be covered by other legislation.

The term “DNA analysis” is not clearly defined and is of uncertain validity as a concept. There are a number of genetic tests that do not involve analysis of DNA but which yield similar results. Also, DNA is mentioned, but there seems no logical reason to omit RNA.

The offence described here is to have any bodily material intending to analyse human DNA without qualifying consent. While it may be difficult to bring a prosecution proving intention beyond reasonable doubt, to create an offence of intention does not provide the clarity we would have wished. If this is to be included, the offence should be to do the analysis (however that term is defined), to cause an analysis to be done, or to disseminate the results without qualifying consent.

iii) Licensing

We are concerned that the licensing system has the potential to become over-bureaucratic and too demanding on researchers. It would be undesirable if the HTA took on roles that duplicated those of others (eg Research Ethics Committees) and/or which micromanaged. For example, the HTA should be able to carry out its role without the need to know of every research project being carried out in the specified premises. It should establish a mechanism by which it is able to focus on deviations from accepted or approved practice, in particular those where the public may have sensitivities. The HTA will have a lot of work to do during its first couple of years; but after this, it will probably not need to maintain the same level of activity.

The Bill and Guidance Notes are not clear about the numbers of licences that may be issued and the likely number and extent of specified premises. While this may not be feasible in a Bill, there is a risk that the premises may be too tightly defined (so that moving tissue a short distance breaks the law), or too loosely defined (so that one licencee cannot reasonably be expected to have responsibility across a whole campus).

iv) Human Tissue Authority

In view of the MRC’s leading role as public funder of medical research, we will request that MRC has observer status on the HTA. We think it is vital that the research perspective is taken into account in developing an appropriate balance between addressing public concerns and ensuring that important research to improve health is not impeded.
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