



Response to the Department of Health Consultation on Regulations to be made under the Human Tissue Act 2004

Executive Summary

The Academy of Medical Sciences welcomes the opportunity to comment on the Regulations to be made under the Human Tissue Act 2004. This response is supported by the Council of Heads of Medical Schools.

Human biological material is an invaluable resource for medical research and contributes to the development of new medicines for patients and society. Regulation of its use therefore has important implications for the health of the nation.

Broadly, the Academy welcomes the Regulations. However, while recognising that many related issues were addressed at an earlier stage when the Human Tissue Bill went through Parliament, the Academy believes the Regulations leave some matters unresolved.

In summary, key issues are:

Regulation A: Licensing

The Academy is concerned that the requirement for licenses for the storage of material for unspecified research purposes will place excessive administrative and financial burdens on researchers. This will disadvantage patients and ultimately stifle wealth creation. The Academy, therefore, urges a 'light touch' approach to licensing. In addition, it would seem sensible to extend the Regulations so that storage licenses would not be required if explicit consent to storage has already been obtained.

Regulation B: Mentally incapacitated adults

Inconsistencies remain between the terms of the draft Regulations B and the Mental Capacity Act. For example, the terms for lawful storage, and use of relevant and bodily material from persons who lack capacity to consent, are narrower, in some respects, in the former than the latter. It is vital that Regulations B should be harmonised unambiguously with the Mental Capacity Act to permit research on similar terms.

General: Terminology

Whilst the Regulations are more consistent than the Codes of Practice, inconsistencies remain between the two that need to be resolved. For example, draft Regulations C and paragraphs 60-62 of the transplantation Codes supply different definitions of the term 'paired donations', while the term 'pooled donations' in section four of Regulations C is not found in the transplantation Code at all.

These and other issues are discussed below in more detail.

1: Introduction

1.1 The Academy promotes advances in medical science and campaigns to ensure that these are translated as quickly as possible into benefits for patients and society. The Academy closely followed the progress of the Human Tissue Bill through Parliament (Academy, 2004a). The final form of the Human Tissue Act and the resulting Regulations and Codes of Practice are of great concern to the Academy in its aim of promoting medical science.

1.2 In its response to the Department of Health's 'Choosing Health?' consultation, the Academy made the following statements (AMS, 2004b):

'there is a need to streamline current research regulation...'

'Regulation and legislation such as the Human Tissue Bill and Data Protection Act can, sometimes inadvertently, be an impediment to research in the public health sciences. Under the current framework vital research can be delayed a year or more...[W]e reiterate our call for the current regulatory framework to be streamlined'.

'The NHS is an unparalleled potential source of data that could fuel essential research that will benefit the public's health'.

1.3 Equally, the NHS is an unparalleled source of human biological material that historically has been used for a variety of purposes including research, teaching and audit. Facilitating the future use of this material, particularly for research, education and training, is therefore of prime consideration for the Academy.

1.4 Although some issues were ultimately resolved as the Bill progressed through Parliament, the draft Regulations and Codes leave other important matters unresolved.

2: General Comments

Terminology

2.1 The terminology in the draft Regulations is not used consistently throughout the document, nor is it consistent with that in the draft Codes of Practice or the Human Tissue Act. For example, draft Regulations C and paragraphs 60-62 of the transplantation Codes provide different definitions of the term 'paired donations', while the term 'pooled donations' in section 4 of Regulations C is not found in the transplantation Codes at all.

2.2 As noted by the Royal College of Pathologists, the summary of the Regulations states that:

'The Act allows research using residual tissue without consent provided the research project has ethical approval (and the tissue is anonymised).'

The Academy seeks clarification that this is true only in respect of tissue samples from the living. If unresolved, this lack of clarity will not only make the Regulations difficult to enforce, it will also make researchers afraid to pursue valid research interests that would otherwise be lawful.

- 2.3 The summary of the Regulations goes some way to making them more accessible and intelligible. Cross-reference to the Codes of Practice would further improve clarity.

Regulations for health research in the overwhelming public interest

(pursuant to section 7(4) HTA 2004, Consent Code paragraph: 96)

- 2.4 The Secretary of State is empowered to make regulations to provide consent for health related research where it would be in the overwhelming public interest. To avoid these regulations being prepared and implemented in haste during a time of crisis, the Academy would like to see them prepared and sent out for consultation before the Human Tissue Act comes into force.

3: Regulations A

Licensing

- 3.1 Draft Regulations A allow material to be stored for specified research projects without a license, providing it has received, or is awaiting, Research Ethics Committee approval. Conversely, material stored for unspecified research needs to be licensed. The Academy is concerned about the administrative and financial burden licensing will place on the storage of material for unspecified research purposes.
- 3.2 The details and magnitude of these costs and burdens are currently unclear. Nevertheless, even if only a fraction of the three million solid tissue samples and 30 million blood samples from living patients processed by the NHS every year are stored for unspecified research purposes it is likely that an excessive number of tissue bank licenses will be required (DH *et al*, 2001).
- 3.3 Parliamentary debate during the passage of the Human Tissue Bill indicated that licensing systems are likely to be person/site and purpose specific, with end users being exempt from license requirements. However, adopting a person/site and purpose specific model is unlikely to have this effect. Rather, the systems would not exempt the end-user from licensing requirements, since many end-users acquire material prospectively for unspecified research use.
- 3.4 The Academy seeks clarification as to whether a storage license is required if the storage of material from the living can be justified for purposes that do not require a licence (such as clinical audit, education or training, or public health monitoring) and appropriate or qualifying consent for ultimate use in research has been obtained. Samples from living patients are frequently stored in the form of paraffin blocks primarily for the benefit of the donor. These blocks are often of value for other purposes such as research. Another example are the blood samples from neonates used in the Guthrie test. These are of great importance in identifying the contribution of metabolic disorders to unexplained death in infancy and childhood. They are also potentially useful for research. Guthrie spots therefore combine the 'determining cause of death', 'public health monitoring' and 'research' Scheduled purposes under the Human Tissue Act. The regulations fail to clarify how the consent and licensing systems will operate in such cases where samples are held for multiple Scheduled purposes.
- 3.5 The Academy seeks clarification from the Human Tissue Authority as to the practical steps that will be required to demonstrate the purposes for which samples are taken. In addition, it wishes to lend

support to the Royal College of Pathologists' suggestion that the decision to license should be based on the principal function of the collection.

- 3.6 The Academy would like to raise the following outstanding issues for consideration:
- To what extent must the terms of the consent be purpose specific? Parliamentary debate suggested that consent should be purpose specific rather than a broader consent for all 'Scheduled purposes'. The degree of specificity with which the purposes must be defined is unresolved by the draft Regulations or Codes of Practice.
 - The Academy presumes that where material is analysed as part of a specific project, licence fees will be part of the grant application or otherwise be deducted from operating costs. However, the Academy seeks further clarification on the resource implications of the Regulations and how the licence fees might be funded.
 - What is the time frame within which researchers must dispose of tissue samples when Research Ethics Committee approval that is pending is ultimately rejected? The Academy supports the Royal College of Pathologist's suggestion that reasonable time must be given for disposal.
- 3.7 The need for storage licenses for unspecified research will make it less likely that individual researchers will retain material for use in future research. This will reduce the pool of material that is available for research, making it more expensive and time consuming to complete new research projects.
- 3.8 These administrative and financial burdens could disadvantage patients, who will not receive the benefits of the new medicines resulting from research as quickly or in as greater numbers. In addition, wealth creation may be hindered as research into economically valuable new medicines is stifled. The Academy therefore urges that a 'light touch' approach should be taken to licensing tissue banks.
- 3.9 The Academy proposes an extension to the Regulations to waive the requirement for a storage license if the terms of associated consent provides.

Powers of entry and search

- 3.10 Section four of Regulations A describes the powers of entry and search where offences under the Act are suspected. Material seized under these powers should be stored in a manner that prevents its degradation thus rendering it unusable even if the seizure be judged unwarranted. In the interests of clarity, and to avoid misunderstanding, section four of Regulations A should stipulate that an explanation of why the search is taking place is required. These points are also raised by the Royal College of Pathologists.

4: Regulations B

Mentally incapacitated adults

- 4.1 Inconsistencies remain between the terms of the draft Regulations B, relating to persons who lack capacity to consent, and the Mental Capacity Act. The draft Regulations provide for the lawful storage and use of

relevant and bodily material from persons who lack capacity to consent in three circumstances – namely where it is in the incapacitated person's best interests, as part of a clinical trial, and to provide transitional relief pending the introduction of the Mental Capacity Act 2005.

- 4.2 The draft Regulations differ from the Mental Capacity Act in that they only provide for research to be approved if the research:

'is in connection with disorders, or the functioning, of the human body'.

- 4.3 The wording of the equivalent section in the Mental Capacity Act, 31(2), allows research to be done if it is connected with an impairing condition affecting P, or **its treatment**.

- 4.4 'Impairing condition' means a condition which is (or may be) attributable to, or which causes or contributes to (or may cause or contribute to) the impairment of, or disturbance in the functioning of the mind or brain. The Regulations should be amended so that they unambiguously allow research into treatments, in similar terms to the Mental Capacity Act.

- 4.5 It is vital that the interpretation of 'P's best interests' as set out in paragraph 3(2)(a) of the draft Regulations allows the analysis of DNA for the benefit of relatives of P who may require P's bodily material to be analysed to confirm their own diagnosis. This is discussed in the Consent code at paragraph 38 which gives the example:

'where there is, or is believed to be, a genetic disorder in the patient's family and it would be in the patient's own best interests for information to be derived by DNA testing from the sample of his/her tissue that would be relevant to other family members'¹.

- 4.6 The extent to which potential benefit to other family members should be taken into account if two relatives of equal ranking disagree, should be made explicit in the Consent code and the draft Regulations relating to storage and use of material from incompetent persons (as in Post mortem Code, paragraph 31)

Anonymisation and DNA analysis

- 4.7 The Regulations and Codes fail to take account of the fact that the concept of 'anonymisation' may have limited application in the context of DNA analysis, given that rare mutations may allow individuals to be identified regardless of whether they have been de-identified or not. The effect of the draft Regulations B will be that researchers will have to justify their use of identifiable material to the Research Ethics Committee. This will require Research Ethics Committee to be sufficiently informed and educated about genetics.

Further queries

- 4.9 The draft Regulations relating to persons who lack capacity to consent require the terms of any approval from a Research Ethics Committee to give express permission for the storage and use of relevant material, and the use of the results of analysing DNA from persons lacking capacity to consent.

- 4.10 The Academy is concerned that the Department of Health and other authorities ensure that Research Ethics Committees receive appropriate guidance and training. The membership of the Research Ethics Committees should also have sufficient expertise so that they are able to implement the approval process relating to the analysis of DNA from persons lacking capacity to consent consistently and appropriately, without prejudicing legitimate research.

5: REGULATIONS C and D

- 5.1 Broadly the Academy supports draft Regulations C and D. However, Regulation C imposes an additional level of bureaucracy on certain types of transplantable material. Here, the Academy has three concerns. In order for the Human Tissue Authority to fulfil its role effectively it needs to be funded appropriately. Sufficient funds also need to be provided for the training and education of 'qualified persons' to ensure that appropriate consents have been given and no rewards have been offered or paid in accordance with sections 32-34 of the Human Tissue Act.
- 5.2 The Academy's second concern is that the additional procedures imposed by these Regulations will cause delay that may prejudice successful transplants. Finally, the Academy is concerned that the definition of 'transplantable material' set out in Regulations C excludes some types of material that should properly be regulated. One example is 'bone', which is excluded from the Regulations because it is not vascularised. The Academy understands that the transplantation of femoral heads is becoming increasingly common.
- 5.3 As discussed previously, there are also some inconsistencies between the terminology used in draft Regulations C and the draft transplantation Codes.

The independent Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are translated as quickly as possible into benefits for patients. The Academy's 800 Fellows are the United Kingdom's leading medical scientists from hospitals, academia, industry and the public service.

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European Commission Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

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