

## Guidance on the use of clinical samples for a range of purposes that are not within the remit of Research Ethics Committees (RECs) (3<sup>rd</sup> edition)

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<b>Comments</b>	This document will supersede the 2007 version and all earlier versions. In accordance with the College's pre-publications policy, it was put on The Royal College of Pathologists' website for consultation from 8 August to 5 September 2012. Eighteen items of feedback were received and it was further reviewed by College Council. As a result of significant changes, a second consultation was also held from 8 to 15 November 2012. Seventy-three items of feedback were received and the authors considered them and amended the document as appropriate. Please email <a href="mailto:publications@rcpath.org">publications@rcpath.org</a> if you wish to see the responses and comments. <b>Dr Peter Cowling</b> <b>Director of Communications</b>

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## 1 Introduction

- 1.1 For the avoidance of doubt, this paper is concerned with tissues from living persons only.
- 1.2 The purpose of this paper is to provide guidance on the taking, storage and use of clinical samples for a range of **non-research** purposes, and has been produced in response to queries received by the College. (Guidance on tissue research can be found in the Human Tissue Authority (HTA)'s *Code of Practice on Research*).<sup>1</sup>
- 1.3 Tissue may be taken in a variety of circumstances, for example:
- in the course of diagnostic procedures, such as a blood or urine test, a tissue biopsy or cervical screening
  - in the course of treatment, such as removing tissue (organs, tumours, etc.) during surgery.
- 1.4 This document offers guidance in three main areas.
- What activities are lawful?
  - Is consent needed?
  - What steps need to be taken to maintain confidentiality?

In addition, the status of incidental findings and sources of further advice on the use of tissue samples are briefly considered.

## 2 Lawful activities

- 2.1 In England and Wales, the **taking** of clinical samples for diagnosis or within treatment is covered by the common law or, where appropriate, by the *Mental Capacity Act 2005*. The **storage** and **use** of human tissue ("material which has come from a human body and consists of, or includes, cells") is covered by the *Human Tissue Act 2004* ('2004 Act'). This Act is concerned with tissues from both the living and the deceased.

In Scotland, the legal position is different. The taking and use of tissue from deceased persons is covered by the provisions of the *Human Tissue (Scotland) Act 2006* ('2006 Act'), and the *Adults with Incapacity (Scotland) Act 2000*. It should be noted that, unlike the 2004 Act, the 2006 Act is concerned with cadaveric tissues only, and contains no provisions that relate to tissues from living persons. Nevertheless, ethical issues relating to the taking and use of tissues from the living, as outlined below, are common to all parts of the UK.

- 2.2 With regard to tissues taken from the living, the 2004 Act defines the following activities as "scheduled purposes", therefore lawful. In each case, valid prior consent must be obtained:
- obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
  - research in connection with disorders, or the functioning, of the human body
  - transplantation.
- 2.3 The following uses of tissue taken from the living are specifically excluded under the 2004 Act from the need for consent:
- clinical audit
  - education or training relating to human health
  - performance assessment (defined in HTA's glossary<sup>4</sup>)

- public health monitoring
- quality assurance.

(**Note:** consent **is** needed for these (and other) activities in relation to tissue taken from deceased persons.)

### 3 Consent

- 3.1 Consent for treatment and examination is dealt with under the common law (and the *Mental Capacity Act 2005* where appropriate). Consent for scheduled purposes (see paragraph 2.2 above) is dealt with under the 2004 Act. Consent for each of these separate activities may be obtained at the same time; but it is important to explain clearly the activity for which consent is being obtained, including the risks and wider implications. Consent for DNA analysis is a special case within the 2004 Act; the requirements are outlined below at paragraph 3.3.
- 3.2 Trusts and other health care bodies are required to have local policies in place for obtaining consent to treatment, with which all staff must comply. It is also important for all doctors to be familiar with the GMC's guidance on consent and decision making.<sup>2</sup> Members and Fellows of the College should in addition be familiar with the College's *Guidance on consent for the processing and analysis of clinical samples following an initial consultation*<sup>3</sup> and the Human Tissue Authority's *Code of Practice on Consent*.<sup>4</sup>
- 3.3 As noted above, consent for DNA analysis is a special case. Practical guidance on the consent requirements for DNA analysis can be found in the Human Tissue Authority's *Code of Practice on Consent*<sup>4</sup>, from which the following notes are derived:
  - 3.3.1 In all but exceptional cases (such as the prevention or detection of crime), the 2004 Act requires that consent is obtained from the person whose DNA is to be tested.
  - 3.3.2 If consent to use material has been obtained under the 2004 Act for a scheduled purpose, it is not necessary to obtain separate consent where that use also involves DNA analysis, but it should be made clear to the donor that their bodily material may be used for this purpose, if that is the intention. When discussing consent, the donor should be made aware if the intended DNA analysis may reveal significant results, e.g. a family genetic condition. Their decision on whether they wish such information to be made known to them should be respected in appropriate cases.
  - 3.3.3 However, within the 2004 Act, there are "excepted purposes" regarding DNA analysis, for which prior consent is **not** required. In most circumstances, it is an offence (throughout the whole of the UK) to hold material with the intent of analysing DNA without qualifying consent. However, the offence does not apply if the results of the analysis are intended to be used for excepted purposes. (A full list of excepted purposes can be found at paragraph 154 of Part 3 of the HTA's Code of Practice: Consent.<sup>4</sup>)
- 3.4 It is good practice to obtain prior consent to use surplus tissue in an external arrangement with a commercial company (unless the work is a REC approved research project using anonymised tissue).

### 4 Confidentiality/anonymisation

- 4.1 Confidentiality is central to trust between doctors and patients.
- 4.2 In addition, the *Data Protection Act 1998* requires that all personal data must be processed "fairly" and "lawfully".

- 4.3 The GMC has issued *Guidance for Doctors: Confidentiality*.<sup>5</sup> This guidance sets out the principles of confidentiality and respect for patients' privacy "that you are expected to understand and follow". A useful further guide to implementation of anonymisation has been produced by NHS Connecting for Health.<sup>6</sup>

The following paragraphs (4.4 to 4.6) are congruent with GMC guidance and are of particular relevance to the use of clinical samples for non-research purposes.

- 4.4 Most patients understand and accept that information must be shared within the healthcare team in order to provide their care. You should make sure information is readily available to patients (for example in leaflets, on posters, on websites, face to face), explaining that, unless they object, personal information about them will be shared within the healthcare team, including administrative and other staff who support the provision of their care.

- 4.5 When disclosing information about a patient, you must:

- use anonymised or coded information if practicable and if it will serve the purpose
- be satisfied that the patient:
  - (i) has ready access to information that explains that their personal information might be disclosed for the sake of their own care, or for local clinical audit
  - (ii) knows that they can object
  - (iii) has not objected
- get the patient's express consent if identifiable information is to be disclosed for purposes other than personal care or local clinical audit, unless the disclosure is required by law or can be justified in the public interest
- keep disclosures to the minimum necessary
- keep up to date with, and observe, all relevant legal requirements, including the common law and data protection legislation.

- 4.6 Additional guidance relating to education

- The use of information about patients is essential to the education and training of medical and other healthcare students and trainees. For most of these uses, anonymised information will be sufficient and should be used whenever practicable.
- It might be necessary to disclose personal information, or not be practicable to anonymise it, and also not be practicable to seek a patient's express consent to disclosure. However, if information has been made readily available to the patient about the disclosure and of their right to object, and they have not objected, you may disclose personal information necessary for the education of medical and other healthcare students.

## **5 Incidental findings**

- 5.1 It is a general principle that any important information, however obtained during an investigation, should not be ignored, but should be explained to the patient by an appropriate member of the investigating team.
- 5.2 Examination of anonymised samples (for example, in the course of teaching) may produce incidental (or unexpected) results. When anonymisation is reversible, patients may be informed, unless they have made in clear in advance that they do not wish to be informed.

## 6 A source of further advice about tissue samples

- 6.1 All establishments that are licensed to store and use tissues under the 2004 Act must have a Designated Individual (DI). The DI is the person under whose supervision the licensed activity is authorised to be carried out. DIs have the primary (legal) responsibility under Section 18 of the Human Tissue Act to secure, amongst other responsibilities, that suitable practices are used in undertaking the licensed activity.
- 6.2 To resolve any uncertainties, the advice of the local DI should be sought in the first instance.

## References

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