



The Royal College of Pathologists

*Pathology: the science behind the cure*

## Guidance on the use of clinical samples retained in the pathology laboratory

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<b>Comments</b>	<p>First draft produced January 2007. Revised February 2007 with comments from Ethics Committee. In accordance with the College's publications policy, this document was placed on the Fellows' and Members' area of the College website for consultation, from 30 March–27 April 2007. A total of 28 comments were submitted and the authors considered them and amended the document accordingly. Please email <a href="mailto:publications@rcpath.org">publications@rcpath.org</a> if you wish to see the responses to the feedback.</p> <p>This publication replaces <i>Interim guidance on the use of clinical samples retained in the pathology laboratory</i>, published in 2005</p> <p><b>Professor Carrock Sewell</b> <b>Director of Publications</b></p>

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## **1 INTRODUCTION**

- 1.1 The College has received requests for guidance on the use of clinical samples for a range of purposes that are not within the remit of Research Ethics Committees (RECs). The Human Tissue Act (2004) became effective from September 2006 and has established the Human Tissue Authority, which gives guidance on the Act's interpretation and administration.
- 1.2 It should be noted that more stringent requirements are laid down by the Act for samples taken after death, for which the following guidance does not apply.

## **2 CONSENT**

- 2.1 For most clinical identifiable samples, consent is obtained by clinicians (healthcare personnel with clinical contact) at the time of consultation. It is good practice for consent forms to include a section on consent for the use of surplus tissue to be stored and used for approved research, either within an NHS Trust or by external organisations. It should be noted that any conditions laid down by the patient at this point (e.g. the exclusion of the use of samples for teaching) should be respected.
- 2.2 The scope of patient consent for identifiable samples is the subject of a separate paper from the Ethics Committee (*Guidance on consent for the processing and analysis of clinical samples following an initial consultation*, January 2005), but it should be noted that it is not necessary to anonymise material for teaching within a clinical service where clinicians, pathologists or scientists share clinical responsibility for named patients and have a contractual obligation of confidentiality.

## **3 TEACHING AND TRAINING**

- 3.1 It is important to maintain confidentiality when teaching or training but no extra consent is required for this purpose.
- 3.2 It is possible that during an educational exercise a significant change may be made to a diagnosis. It is essential that, in these circumstances, anonymisation is reversible in the interests of patient care.

## **4 RESEARCH**

- 4.1 Research requires approval by RECs, which are also able to assess the feasibility of obtaining consent in any given situation and to define the circumstances in which samples may be used prospectively or retrospectively, without consent having been obtained. Decisions may be made as to whether anonymisation should be reversible or irreversible.
- 4.2 Where there is doubt concerning a project, the National Research Ethics Service and/or appropriate REC should be consulted so that a valid independent view can be obtained on the acceptability of a particular course of action.

## **5 OTHER USES**

- 5.1 It is not essential to obtain consent for a range of purposes associated with clinical care. These include:
  - clinical audit
  - public health monitoring

- quality assurance
- reference range evaluation
- method comparison
- assay development
- validation of new methodology.

It may be difficult to distinguish between work to develop a new assay (research) and work to validate new but developed methodology. When there is doubt, an REC should be consulted. In cases of uncertainty, this may need to include an application for REC approval.

- 5.2 In all these situations, samples are usually anonymised since the identity of the patients is not relevant in most cases.
- 5.3 Where new judgements concerning individual samples might be made following further analysis, such as clinical audit, quality assurance and validation of new methodology, anonymisation should be reversible.
- 5.4 It is also important to distinguish between residual clinical samples, which may be reversibly anonymised and used for internal or external quality assurance without further consent, and samples that are taken specifically for quality assurance purposes and not for clinical care, where specific explicit consent is required.
- 5.5 Particular care must be taken in the management of human genetic testing. There is a spectrum of sensitivity:
- tests that have no health implications, either for the patient or relatives
  - tests that may have implications for the patient, but not for offspring or other relatives
  - tests that may have a bearing on the health of offspring and/or other relatives, as well as the patient.

Researchers should consider where their project lies within this spectrum and RECs will advise.

Amongst other issues, researchers should also be aware that genetic testing can reveal unexpected results, for instance about parentage.

Attention is drawn to the detailed guidance on use of clinical samples for genetic analysis from the Joint Committee on Medical Genetics of the Royal College of Physicians, Royal College of Pathologists and British Society for Human Genetics in *Consent and Confidentiality in genetic practice: guidance on genetic testing and sharing genetic information*.

- 5.6 Children may consent to the storage and use of their tissue if they are competent to do so. A child is considered competent in relation to a particular decision if he or she has sufficient maturity fully to understand what is involved. It is also important to make sure that the child's consent has been given voluntarily, without undue pressure from others.

A person who has parental responsibility (usually the child's parent) can consent on the child's behalf, but only if the child is either not competent to make the decision for him or herself, or is competent and chooses not to make this decision.

It will usually be good practice to consult the person who has parental responsibility for the child, and involve them in the child's decision-making process, but if the child is competent, his or her decision must be respected. A competent child may also have the right to insist that his or her parents are not informed about the decision.

Further information on seeking consent from children can be found in the Department of Health's booklet *Seeking Consent: Working with Children*, and in the GMC's guidance *Children and Young People: Doctors' Roles and Responsibilities*.

In Scotland the age of legal capacity is 16 years.

## 6 CONCLUSION

- 6.1 The use of clinical samples for teaching, training, clinical audit, quality assurance and other aspects of laboratory management and development is an integral and critical part of the practice of pathology. This is not direct clinical care, nor is it research, but it is a vital extension of the everyday practice of pathology now and for the future. The Human Tissue Act accepts the argument that consent is not required for the use of residual material in ways that are essential to the running of the health service. The work benefits every patient who chooses to use the National Health Service and whose samples are sent to the laboratory for analysis and diagnosis, leading to effective treatment and care.

## 7 REFERENCES

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