

## **A Consultation on the Revised Codes of Practice to the Human Tissue Act: Response from the PHG Foundation**

### **Introduction**

The Foundation for Genomics and Population Health is the successor body to the Public Health Genetics Unit. Its overarching purpose is to foster and enable the application of biomedical science with a view to the improvement of human health. Among its specific objectives is the promotion of a social and regulatory environment that is receptive to innovation, without imposing an undue or inequitable public burden. The Foundation has a particular interest in genetic and genomic advances and their impact upon clinical and public health services.

Our comments are restricted to those codes which have the most direct applicability to our areas of expertise and activity.

### **General Comments**

The revised codes improve existing drafts: the language used in the codes is more accessible than previous versions and the citation of appropriate electronic references supplements existing guidance. The codes make sufficient reference to the Mental Capacity Act and supporting codes of practice but wider use of examples might be helpful. The revised codes more clearly differentiate between those actions which are legally required and statements of best practice.

We do have concerns about how the interface between the legal framework supporting coroners and the Human Tissue Act is dealt with in the codes. In particular there is insufficient account taken of the needs of family members where inherited conditions may be implicated in the death of a deceased person. For example, although we support the imposition of an obligation upon coroners and their officers to seek relevant consents under the HTA (in the Post-mortem and Disposal of Human Tissue Codes), this position seems anomalous in the context of inherited conditions. Coroner's officers may find themselves legally responsible for obtaining consents which ideally require additional specialist expertise and/or resources. In our view systemic and coherent reform is needed, and we are hopeful that the forthcoming Coroners and Death Certification Bill will provide an opportunity for wider evaluation and debate. Our view is that the amendments to these Codes provide a limited but pragmatic solution pending reform of the Coroners' legislation.

We welcome the publication of a code for researchers which draws together relevant guidance from the other codes of practice and will provide useful source of reference for the sector.

### **Specific comments (numbers refer to paragraph numbers in respective codes)**

#### **Introductory sections shared by all codes**

It would be helpful to amplify the statement that 'consent for diagnosis and treatment is not in the scope of the HT Act' to clarify that the retention and storage of material taken for the purpose of diagnosis and treatment (of the living person whose body created the material) also falls outside the Act. This seems particularly relevant to the code on research.

The Human Tissue (Scotland) Act 2005 regulates some types of tissue samples (such as blocks and slides) differently from the Human Tissue Act (2004) and regards them as part of the deceased medical record. This distinction needs to be made explicit (particularly in the Code on Post-mortems, paragraph 120 onwards).

## **Code 1: Code of Practice on Consent**

### **Qualifying relationships: should other people be added to the hierarchy?**

Uncle/aunt is omitted from the hierarchy and consideration should be given to adding this relationship to the list of qualifying relatives.

#### **Other comments:**

The use of narrowly framed consents has the potential to hamper research and restrict the effective use of samples. For that reason we endorse use of generic consent and the practice of seeking consent for multiple activities (para 47-49).

137. PIAG has statutory authority to authorise certain classes of research using identifiable patient data without consent (by regulation). PIAG is shortly to be replaced by the National Information Governance Board.

## **Code 3: Code of practice on post-mortem examination**

The PHG Foundation has recently led a multidisciplinary project assessing the need for a specialist service for inherited cardiac conditions. As part of this project it has carried out a review of ethical legal and social issues arising from such conditions including the interface between the coroners' legislation and the Human Tissue Act.

### **Coroner's post-mortem examination**

Consultation question 1. Will the code be helpful to coroners officers and help improve communication?

Our view is that the code is useful in that it clarifies the need for effective and robust communication between the various stakeholders. However the effectiveness of that communication is constrained by the existing legal framework which does not serve the interests of families well, particularly those who are at risk of inherited cardiac conditions.<sup>1</sup>

It would be helpful to include an example of a family in which there had been a sudden cardiac death, where the continued retention of samples from the deceased is needed to clarify ongoing risks to surviving family members. There is also a need for the clinical needs of those relatives to be recognised by coroner's officers, and routes to referrals to specialised medical experts clarified (clinical genetics or cardiology departments).

Our comments about the process for disposing of samples following coroners' post-mortem examinations apply equally to Code 5: Disposal of human tissue.

### **Disposal following coroners' post-mortem examinations**

(i) Although we are mindful of the sensitivities associated with the retention of tissue from the deceased, and relevant legal judgements, the interests of some families might be better served if continuing retention of samples were not regarded as a matter for the discretion of surviving family members (pursuant to the Human Tissue Act) but rather as part of the remit of the coroner to avoid future deaths. If this were the case, consent would not be at issue because samples could be retained pursuant to the coroner's authority. However, the current situation depends upon there being effective systems for taking consent;

(ii) Existing systems are not robust, in part because those taking consent (namely coroners officers) may not understand the vital significance of samples from the deceased in establishing risk to at-risk relatives, for example by mutation analysis. For this reason the codes should provide that those obtaining consent have sufficient understanding of medical genetics and access to additional specialist advice;

(iii) At the very least, coroners and their officers should be mindful of situations where an inherited condition may be implicated in causing death, and should exert particular care to

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<sup>1</sup> Over 50 conditions have been described including long QT syndrome, Brugada syndrome and hypertrophic cardiomyopathy.

ensure relatives are fully informed of the consequences of their choice whether or not to retain samples;

(iv) Where appropriate, a copy of a post-mortem report should be sent to the deceased person's GP who may in a position to identify other at-risk family members.

### **Storage of blocks and slides**

The code could helpfully distinguish how the Scottish law differs from that in England, Wales and Northern Ireland.

### **Other comments: (numbers refer to paragraph numbers)**

26. The reference to the definition of relatives is unclear.

51. Where appropriate, the discussion should include the importance of retaining samples for use by relatives for confirming a genetic diagnosis or susceptibility to future inherited disease.

71. We would like to see Coroners developing links with clinical genetics departments so that where appropriate, relatives can access specialist advice.

### **Code 5: Code of practice on Disposal of Human Tissue (62-66)**

1. The Coroners' role in obtaining consent under the Human Tissue Act

See comments above.

Disposal following coroners' post-mortem examinations (para 66)

2. (a) Is it appropriate for tissue to be retained in these circumstances?

The continued retention of samples may be in the clinical best interests of relatives in cases where a genetic condition is suspected. Our preference is for the authority of the Coroner to be extended to ensure that samples are retained in such cases so that in these exceptional cases the ongoing retention of samples should not be dependent upon obtaining consent. The default position for retention of samples in these cases should be retention rather than disposal of samples.

2. (b) Is 4-6 weeks an acceptable length of time for retention?

In complex genetically heterogeneous conditions of incomplete penetrance, such as some cardiac genetic conditions<sup>2</sup>, 4-6 weeks is likely to prove inadequate to make a conclusive diagnosis and assess the potential impact upon family members. Obtaining a definitive diagnosis may subsequently involve a range of skilled health care professionals including clinical genetics services and cardiologists and may take many months of investigation. At the very least, in cases of sudden adult death, the reasonable period of time for retention of samples pending obtaining consent from the family should be extended.

Other comments:

Before samples are disposed of, consideration should be given as to whether they can be used for other scheduled uses such as research, education or training. This is compatible with the statement in the research code that samples retained for research should only take place as a last resort. The flow chart in Appendix A should be amended accordingly in all codes.

### **Code 9: Code of practice on research**

46. This paragraph requires clarification;

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<sup>2</sup> Over 50 conditions have been described including long QT syndrome, Brugada syndrome and hypertrophic cardiomyopathy.

The code fails to mention 'bodily material' yet the requirement for 'qualified consent' applies explicitly to that class of material. This requires some explanation and clarification in the glossary to all the codes.

67. The statement that 'the disposal of relevant material should only take place as a last resort if it is no longer valuable for use in research' is an extremely important statement of principle and should be repeated in other relevant codes.

78. This seems incorrect. Our understanding is that the Act specifically provides for an exemption to the requirement to seek consent where the proposed use is research involving non-identifiable samples from the living,<sup>3</sup> and REC approval for the research has been granted or is pending. Paragraph 78 seems apply an additional requirement which is not apparent from the Act that 'there is no evidence that the patient has not given consent'. This appears to conflict with the requirement to keep the samples non-identifiable.

79. The relevance of the reference to 'diagnostic material' needs some clarification: it is not clear whether this term is intended to refer to relevant material taken to determine the cause of death (a scheduled purpose) or to material from the living to clarify diagnosis or treatment (for which an exemption exists).

PHG Foundation  
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<sup>3</sup> HTA 1(8), (9) and (10)