

4 October 2005

By email to: HTActconsultation@dh.gsi.gov.uk; enquiries@hta.gov.uk

Some comments by the Genetic Interest Group on: Regulations to be made under the Human Tissue Act 2004, and Human Tissue Authority Draft Codes of Practice

The Genetic Interest Group is a national alliance representing individuals and families affected by genetic disorders. We have around 130 groups in membership, ranging from small charities whose main focus is support for family members to large organisations which carry out a range of functions, including financial support for and / or active participation into research on a particular condition or set of conditions. Whether small or large, our members are concerned that research should be encouraged, and that unnecessary obstacles should not be put in the way of this.

Regulations and codes serve a number of proper purposes. But we are also aware that researchers in general feel burdened by the sheer number of requirements they are sometimes asked to meet, and the time taken up in meeting them: from research ethics committee approval to local governance rules to animal licenses (where relevant) to data protection rules to mention just the most obvious. This can be a particular problem in the case of rare genetic disorders (one of our primary concerns) where research funds are often limited.

In this response to the consultation we focus on three issues: licensing, consent, and the rules governing existing collections, with a particular focus on rare disorders where this is relevant.

Licensing

The issue that concerns us is covered in the Consultation on Regulations. It seems that licensing is being used to enforce consent provisions and / or to compensate for perceived deficiencies in the kinds of consents gained in practice (with tougher rules for researchers using material from the deceased compared with those using samples from living donors). Exceptions are made for researchers with ethical approval or ethical approval pending for specific research projects.

The concession to end user researchers is probably more apparent than real. It is our understanding based on discussions with officials that if a researcher sought a general consent as well as a specific consent when collecting the samples to provide for further uses in the future, s/he would trigger the need for a license immediately. Since researchers in general will not want to waste a precious commodity—the tissue—they will want to retain the possibility of using it for future projects by securing a broader consent. This implies that most if not nearly all researchers will therefore in fact be required to work under a licensing system.

We can see little clear logic in this. Put another way we are not clear what interest is being protected. As we understand it, it is not the fact that the researcher is holding the tissue beyond the end of the project that is important, since a researcher engaged on a specific project with no aims beyond that will be allowed to retain the tissue as a record of the research. Furthermore, compliance with ethical codes would be achieved by ethics committee oversight of future projects.

The only basis on which we can see that the distinction is proposed is a perceived deficiency in open-ended or general consent for future research. This issue came up a number of times during debate on the Bill as it was at the time, and the Government's stated position was that general or open consent could be perfectly valid. We share this view. Indeed, general or open consent can be as valid (informed) as specific consent. It is our experience that patients are often happy to give this kind of consent.

Consent

For the Government Lord Warner, in the first Lords debate, upheld the validity of generic and enduring consent in the following terms: 'The Bill does not set out the form consent should take in any particular situation. Let me state clearly that the Bill does not require consent to be specific to each research project for which tissue might be used. Consent can be broad. Consent to research can be generic and enduring.'¹ Many tried to get this viewpoint written into the Act itself. Earl Howe explained the keenness to see the statements written into law in the following terms:

'...many scientists in the research community are anxious to ensure that some kind of generic and enduring consent will be legal when the Bill becomes law.

¹ *Lords Hansard*, 22 July 2004, columns 369-70.

At Second Reading, the Minister gave reassurances on that point. However, worries persist. They persist principally because of the requirement for specificity of consent laid down by many research ethics committees. They also stem from the fact that the Bill is silent on the whole matter. If we are serious about the need to maintain the momentum of medical research in this country, and about imposing on it the least possible administrative burden, there is a case for ensuring on the face of the Bill that obtaining generic and enduring consent will be one option open to medical researchers when presenting their proposals to research ethics committees for approval. A signal of that kind would be important for the HTA.²

This illustrates the sometimes-perplexing character of the regulatory regime facing researchers at the moment. The Government argues that generic and enduring consent is valid. The Government also states that they cannot second-guess the decisions of Research Ethics Committees, to whom they are looking to make the decisions in practice. At the same time Research Ethics Committees often insist on specific and time-limited consent. They in turn look for guidance, but receive little from the Government beyond general statements. Researchers find themselves caught in the middle, and increasingly feel themselves to be knocked from pillar to post.

We are disappointed that the Code of Practice on Consent follows this same pattern of providing little clear guidance on how things might or ought to work in practice. We would hope that changes are made and that the Human Tissue Authority is able to give a lead to research ethics committees (something many people on such bodies would welcome) and endorse the validity of general consent. But in particular, if we are right and, implicitly, the draft regulations are assuming a distinction between specific and general consent in relation to licensing, then this is a disappointing step backwards that should be rectified by making provision to exempt end user researchers from licensing requirement whether or not they gain an additional open consent for future uses of tissue.

Rare disorders

The Regulations and Codes as they currently stand might pose particular difficulty for those working on rare disorders. Samples from people with rare diseases are by definition often unique or particularly useful. We would be appalled if any incentive was created for the destruction of these samples after initial use. We fear that the proposed Regulations might create such a pressure for the reasons set out above, or might simply discourage some researchers from studying such disorders if they were required to gain a license.

² *Lords Hansard*, 15 September 2004, column GC 517.

Consider a scenario raised with us by Ann Hunt of the Tuberous Sclerosis Association, a scenario that will occur with variations in research into many of the rare disorders. Tissue becomes available with appropriate consent for research. Up until now the normal practise would be to donate this to a researcher known to have an interest in the condition. Unfortunately the researcher might not currently be engaged on a specific research project for which it is relevant. Perhaps the material is a brain tumour and the only contemporary project is renal disease. The effect of the proposed licensing arrangements would appear to be that the researcher would not be able to accept the material if they did not have a license, even though appropriate consents had been given. In other words, this form of altruistic donation becomes illegal in the absence of such a license.

We assume that such problems will be less keenly felt in the case of common disorders where there will be a greater number of ongoing research projects and perhaps a number of associated tissue banks for which a licensing structure can be dealt with at a managerial level. We fear that once again researchers engaged in studying rare disorders will be burdened by extra work (or worse discouraged) as a result of a policy applied inflexibly across the board.

Existing Collections

The Code of Practice on Consent suggests that steps to gain appropriate consent (where this is or may be absent) for research using existing collections should be considered. This disturbs us for two reasons: (i) as a matter of principle, there is a real risk of undermining the value of such collections if this is done; and (ii) the Government gave a clear commitment during the passage of the Bill through Parliament that existing collections would not be affected by the change in the law. This commitment had a political significance in that it was presented and widely seen as a concession by Government to secure support for the Bill from many patient support groups and the research community.

We would be happy to meet to discuss the above points if this would be useful, or to comment in more detail on any particular issues the Department or Authority wishes to consult on further.