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Human Bodies, Human Choices

The Law on Human Organs and Tissue in England and Wales, A Consultation Report

A response from the Genetic Interest Group

The Genetic Interest Group is a national alliance representing individuals and families affected by genetic disorders. We have around 130 groups in membership, and a smaller number of individual members. Some of our member groups and members are involved in research that uses human material and body parts. Some of our members, as individuals, have consented to the use of human material taken from deceased relatives. This response has been approved by the Trustee Board of GIG and circulated for comment to the full membership. The limited time available led to a brief consultation. If it would help, we would be more than happy to select a number of GIG's groups and arrange a detailed discussion on the issues raised.

The question of amending and updating the law arises from the interim report of the Bristol inquiry and the report of the Alder Hey inquiry. As was quickly discovered, many organs and other human material had been obtained without explicit consent and were being held in hospitals and universities across the UK. It was easy to see in this something untoward, and the rapid disposal of some of this material can have only added to that sentiment. However, it is important that we do not rely on such knee-jerk judgements in framing future law and regulations.

In this brief response we focus on some of the issues raised in the consultation that bear upon the interests of individuals and families with genetic disorders. However, there are a number of questions that are not considered in the consultation, but which are equally important to us. These centre on what can be done to ensure that human organs and material are *effectively* used in research. Part of the problem with the large amount of material being stored in some centres was that it wasn't being used effectively; in some cases it wasn't being used at all. In considering future regulation, ensuring the widest possible access and use consistent with maximising the potential of the collection should be a priority. Proper documentation should be looked upon as a means to help in this process. Similarly, reducing unnecessary barriers to the collection and use of new material is equally important.

1. It is said that the Human Tissue Act needs to be updated since it is out of date and insufficiently clear on the issue of consent. However, it is also stated, more than once, that the HTA does require professionals to ask for consent from relatives, and that the Department of Health's present view is that 'only by operating a policy of properly informed consent by relatives can the requirements of the Human Tissue Act 1961 be met effectively.' (p. 36). Pulling things together, it is said later on that: '*For the future*, provided that valid consent is obtained for the retention, storage or legitimate use of organs or tissue, there should not, in general, be difficulties of principle. As the interim statement asserts, this should, in practice, be so even under the present law.' (p. 54). It is important that any process of updating the law focuses on useful and practical clarifications. Among these we would include:

- a. that a family can give general consent for a body to be used for research purposes without having to go into the details of this with professionals;
- b. that the process of consent should not and cannot become too complex or detailed if it is to be truly informed;
- c. recognition that investigation, for example into the cause of death in childhood or the cause of miscarriage, may encompass a number of steps that cannot all be predicted in advance. The law should allow and facilitate consent to an investigative process;
- d. that where research might benefit a blood relative a process should facilitate the considerations of this if a spouse objects.

2. In relation to the use of tissue obtained from people who have subsequently died, our view is that proper consent should of course be secured from the person or their legal guardian while they are alive. However, any changes should not be applied retrospectively. In other words, researchers should not be under an obligation to seek consent from relatives to continue research using material taken while a person was alive if the material was taken and stored in good faith. It must also be recognised that in the case of rare conditions that are lethal in early childhood, ante-mortem samples from children who have subsequently died, or post-mortem samples may be the only way to undertake research into this category of disorders. Care must be taken when framing the law to ensure that research that might benefit patients with these conditions is not frustrated.

3. The proposal to consider legal penalties for someone guilty of nothing more perhaps than using a slide in research or teaching passed on from a colleague is excessive. There is already a stigma attached to pathology; this would only make that worse.

4. As already indicated above, we would wish to echo a concern raised by clinical geneticists concerning the interests of blood relatives in post-mortem research: the law accords the primary role to the spouse of the deceased. However, from a genetic research point of view it is the blood relatives who might have the greatest interest and stake.

5. In discussing oversight and compliance comparisons are made with, among other things, the Human Fertilisation and Embryology Act and the Authority it established. This does not persuade us. As is indicated by the quote above (p. 54 of the report), the key issue is a much simpler one of

ensuring that valid consent has been gained. An updated law does not necessarily require an accompanying Authority.

6. This consultation covers a very wide range of issues, arguably too wide given the specific issues that gave rise to it and other parallel consultations. There is the very real danger that, if implemented, some of the proposals—such as the need for some projects to receive specific licenses—will create an excessive regulatory burden where a simple clarification of the existing legal and regulatory position is all that is required.