The Recommendation on Research on Biological Materials of Human Origin: Another Brick in the Wall

Introduction

Given the goals, direction and growing capabilities of modern biomedical research, human biological material, in addition to being of great value, is of great significance to improving human health and healthcare. It is also a potential site for violations of our human rights. Recognising this early on, the Council of Europe adopted the Biomedicine Convention (1997), which was one of the first international instruments to recognise the scientific, therapeutic and commercial value of human tissue, and link research utilising it to human rights. It then adopted the Additional Protocol (2005), which addressed human subject research more specifically. On 15 March 2006, it took further action at the human tissue/human rights nexus by adopting a draft Recommendation on Research on Biological Materials of Human Origin, an instrument concerned not with traditional human subject research, but with the procurement, storage and utilisation of excised human tissue for research.

The Committee of Ministers of the Council of Europe justified its introduction of yet another (non-binding) international instrument in this field on the grounds that worries over data security and scandals concerning unauthorised use of tissue

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1 The human tissue market was calculated at over US$4 billion in 2001: M. Reymond et al., “Ethical, Legal and Economic Issues Raised by the Use of Human Tissue in Post-genomic Research” (2002) 20 Dig. Dis. 257-265.
2 Convention for the Protection of Human Rights and Dignity of Human Beings with regard to the Applications of Biology and Medicine, ETS No. 164, 1997.
4 Additional Protocol to the Biomedicine Convention, ETS No. 195, 2005.
persist, and there is no international regulation to cover this particular type of research. Unfortunately, even a cursory review of the Recommendation exposes the fact that it contains little in the way of original contribution to biomedical research regulation; it reiterates well worn general principles, albeit in the context of biobanks (and population biobanks). However, the excised human tissue storage/research context throws up unique regulatory issues and opportunities, making the Council’s status quo approach is somewhat disappointing. A few observations should serve to illustrate the narrowness of its approach. Thus, after first briefly review the Recommendation’s philosophical foundation and substantive content, I will address some key issues of particular relevance to biobanks, namely (1) consent, (2) commercialisation, (3) custodianship, and (4) collapse.

Analysis

I. Perspective and provisions of the recommendation

That the human rights perspective (founded on the values of autonomy and equality) informed the Council’s effort, and that the Recommendation is intended to be a human rights protecting instrument is obvious from the Explanatory Memorandum:

... If [human biological material] were not utilised and research had to be undertaken relying only on prospective collection of biological materials specifically for each project, it would mean ... comparable research results would not be available for ... years. ... The purpose of this recommendation is to set out and safeguard fundamental rights of individuals whose biological materials are used in biomedical research, while recognising the importance of freedom of research.8

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7 Indeed, as conceded in the Preamble and the Explanatory Memorandum, much of the content is already enunciated in other international instruments. In particular, see the European Convention on Human Rights (1950), the European Convention on Personal Data (1981), and the Biomedicine Convention (1997) and its Additional Protocol Concerning Biomedical Research (2005), the UNESCO International Declaration on Human Genetic Data (2003), as well as the more binding EU Personal Data Directive 95/46/EC, and the EU Good Clinical Practice Directive 05/28/EC. The proliferation of regulation, particularly that addressing use of genetic data, which is assumed to be special, is also noted by J. Bovenberg, Property Rights in Blood, Genes and Data: Naturally Yours? (Leiden: Martinus Nijhoff, 2006), at 8-28.
8 Steering Committee on Bioethics, supra, note 6, at 2-3.