The Nuffield Council on Bioethics consults on the use of human bodily material in research

The Nuffield Council on Bioethics on April 20th launched a public consultation on the ethical issues raised by the provision of bodily material, such as organs, eggs and sperm, for medical treatment and research. This includes blood samples for research. The closing date for responses is July 31st. Questions asked include what control individuals should have over donated samples, and the extent to which individuals should be encouraged to provide biological material for research. Further details can be found at the Nuffield Council website:

https://consultation.nuffieldbioethics.org/go/Default

Settlement in Native American DNA case: commentary

The Havasupai tribe has reached a settlement with the Arizona State University over alleged failings of adequate informed consent to the use of their DNA in research. This case has produced immediate comment about implications for other genomics research.

This is a US case, and moreover, since it settled it is unlikely that full details will ever be released. However, there are several troubling aspects of the case. Allegedly, more than 200 members of the tribe signed a consent form stating that their blood could be used to ‘study the causes of behavioural/medical disorders’ but many said they believed they were donating it only for research into diabetes. Commentators have discussed the exact terms of consent that should be obtained for research, which for some projects is rather specific and for others much broader. There are of course implications for notions of community consent in research with discrete populations. In response to the issue that a broad consent was included in the forms that the participants signed, it has been commented that it was the responsibility of the researcher overseeing the project to make sure that participants had actually understood the meaning of what they were signing.

Such a claim sounds plausible but hides major problems. In research I assisted with at Cardiff University, examining testing of adolescent girls for carrier status for haemophilia, informed consent to such testing had been obtained at the time. Subsequently, however, many look back and say that they had no real understanding of what it was all about until later in life. This would appear to be because there is no straightforward notion of having ‘understood’ something completely. In this case, the significance of a test that shows a risk at a much later date of giving birth to a son with haemophilia might not sink in, until the reality of possible motherhood hits home at an older age. Often we may say we do not ‘fully’ understand until we see things in a certain light. A great deal of work in medical sociology in general, and in relations to genetics in particular, shows that understanding may present challenges. What would count as having understood ‘fully’ the implications of research? If some psychological criterion of understanding were to be added to a written explanation, this could cause potential headaches for researchers.
Because the case settled, it may not act as a precedent even in the US. Whilst mindful of the poor current social and economic situation of many Native American tribes, and the history behind this, one hopes that inappropriate reactions do not occur that may hamper research without really furthering the interests of participants, and it will be interesting to watch for any developments from this or any other similar cases. As they say, ‘hard cases make bad law’.

**Procardis Ethics podcasts**

Oxbionet (a network of Oxford University Centres of Bioethics) have recently produced a number of podcasts on topics on ethics. Paula Boddington has contributed three podcasts on ethical issues arising from genomics research such as that conducted by the Procardis consortium. The podcasts will be freely available worldwide to any with access to the internet and are designed to introduce ethical issues to interested members of the public and should be online in May.

Indeed, one ethical issue of concern in medical research in general and in the complex world of genomics research in particular, is the level of understanding of participants and potential participants of the complex issues involved – as the Havasupai cases amply illustrates. These podcasts therefore hope to provide a resource for public education as a contribution to help fill this need. Further podcasts are planned and suggestions for topics are welcome.

One podcast provides a general introduction to ethics in genetics research. The second looks in more detail at what is involved in a genomics research project and what social and ethical issues might arise. The third podcast looks at a particular issue, the implications of genomics research for related individuals and how this causes difficulties for traditional ethical frameworks within research and medical ethics which focus on the individual. This podcast is partly based upon a paper forthcoming in Public Health Genomics, which will be discussed in the next newsletter.

**Publications on ethics**

The last newsletter mentioned current debates on privacy protection in genomics research.

A further publication on this topic has now appeared.


**Abstract:** “The protection of identity of participants in medical research has traditionally been guaranteed by the maintenance of the confidentiality of health information through mechanisms such as only releasing data in an aggregated form or after identifying variables have been removed. This protection of privacy is regarded as a fundamental principle of research ethics, through which the support of research participants and the public is maintained. Whilst this traditional model was adopted for genetics and genomics research, and was generally considered broadly fit for purpose, we argue that this approach is increasingly untenable in genomics. Privacy risk assessments need to have regard to the whole data environment, not merely the quality of the dataset to be released in isolation. As sources of
data proliferate, issues of privacy protection are increasingly problematic in relation to the release of genomic data. However, we conclude that, by paying careful attention to potential pitfalls, scientific funders and researchers can take an important part in attempts to safeguard the public and ensure the continuation of potentially important scientific research."

There is a commentary on this paper on the PHG foundation website suggesting that issues of privacy may be further highlighted in the future by financial pressures on insurance:

http://www.phgfoundation.org/news/5345/

Data Sharing in Genomics Conference, September 20 – 22,, Oxford

A reminder that abstracts can still be submitted for this conference.

See: http://helex.medsci.ox.ac.uk/data-sharing-international-conference-1/data-sharing-international-conference