

Consent for biobank tissue in somatic-cell nuclear transfer?

The Human Fertilisation and Embryology Act 2008, which comes into force this October, has given a headache to biobanks in the UK. For the Act allows, on certain conditions, human tissue to be used for somatic cell nuclear transfers (hSCNT) with both human and non-human ova even though the tissue donor has not specifically consented to this procedure.¹ Thus each biobank in the UK now has to decide how to respond to questions from donors and the general public about whether they can use their stored tissue in this way.

Biobanks face a difficult problem in areas of research that are controversial. On the one hand, biobanks do not want to have to seek further consent for every particular use of tissue, which would be impractical. Instead they are keen to emphasise the validity of broad consent.² On the other hand, if a biobank does not inform a donor of the possibility of a controversial use, the consent cannot be considered as informed consent.³ Furthermore, on a pragmatic level, if donors subsequently hear that tissue was used in a manner which would offend them, without having sought their explicit consent, this use could undermine the important trust the public has for biobanks.

This kind of loss of trust was witnessed in the 1990s after the scandals in Bristol Royal Infirmary and Alder Hey Children's Hospital in Liverpool. In these hospitals, body parts of children were retained after postmortem examination on the assumption that this would be acceptable to parents. The subsequent public outcry led to an inquiry, governmental intervention, and restrictive regulation.⁴

In relation to hSCNT, the question for biobanks is: if a scientist requests the use of biobank tissue for hSCNT, must the biobank contact donors for consent before the tissue is released? One possible response is exemplified by UK Biobank, the largest bank of human tissue in the UK.^{5,6} The Ethics and Governance Council of UK Biobank discussed the issue at a meeting in June, 2009. Their decision was to keep open the possible future use of biobank tissue for hSCNT without requiring further specific consent: "While there were varying opinions on the Council as to whether or not participants might expect the creation of human and human admixed embryos to fall outside UK Biobank's general consent, this research use was not considered by the Council to be clearly ruled out in the broad consent model."⁷

UK Biobank is to be commended in setting up a transparent Ethics and Governance Council.⁸ Nevertheless, it is difficult to accept its claim that hSCNT could be covered by a broad consent to use of human tissue in research. There is good evidence that public opinion on hSCNT, and in particular hSCNT into non-human ova, is significantly divided.⁹ Moreover, neither US federal funding nor European Union funding can be used for hSCNT.^{10,11} Thus hSCNT is subject to funding or regulatory differences which mark it out from other less controversial uses of human tissue. Accordingly, if the controversial character of hSCNT is not recognised by biobanks and tissue is used for hSCNT without explicit consent from the donor, there is a risk of another outcry similar to Alder Hey.

A contrasting approach has been taken by Generation Scotland, one of the largest biobanks north of the border. In May, 2009, this biobank made a public commitment to seek explicit consent before this kind of use. "The Access Policy includes legally binding agreement that Generation Scotland undertakes never to use, or allow use of, any cells or tissue in its possession to create human embryos or human admixed embryos without

obtaining the prior explicit consent from donors to do this.”¹² The decision of Generation Scotland does not rule out the use of its stored tissues for hSCNT, but does reassure present and future donors that their tissue will not be used for this purpose without their express consent. In this way the biobank ensures that the public continues to support the important research it facilitates.

The approach exemplified by Generation Scotland is not only a safer option for biobanks. Their approach also represents best ethical practice. Indeed, the importance of informed consent has recently been reiterated in US President Barak Obama’s new National Institute of Health Guidelines for Human Stem Cell Research.¹⁰ The principle of explicit and informed consent is the very foundation for any research involving human participants and requiring public support.

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1 Human Fertilisation and Embryology Act 2008 Schedule 3: Paragraph 20 and following. http://www.opsi.gov.uk/acts/acts2008/ukpga_20080022_en_1

2 Hanson MG, Dillner J, Bartram CR, Carson JA, Helgesson G. Should donors be allowed to give broad consent to future biobank research? *Lancet Oncol* 2006; **7**: 266–69.

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4 Redfern M, Keeling JW, Powell E. The Royal Liverpool Children's inquiry report. London: HMSO, 2001. <http://www.rlcinquiry.org.uk/>

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6 Barbour V. UK Biobank: a project in search of a protocol? *Lancet* 2003; **361**: 1734–38.

7 Statement by UK Biobank Ethics and Governance Council, June 18, 2009 (available from DMc).

8 Anon. UK Biobank Ethics and Governance Council. <http://www.egcukbiobank.org.uk> (accessed July 10, 2009).

- 9 Jones DA. What does the British public think about human-animal hybrid embryos? *J Med Ethics* 2009; 35: 168-70.
- 10 National Institutes of Health. National Institutes of Health guidelines for human stem cell research. July 7, 2009. <http://stemcells.nih.gov/policy/2009guidelines.htm> (accessed July 10, 2009).
- 11 European Commission. Ethical issues in EU research proposals—checklist. July 30, 2007. <http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=370> (accessed July 10, 2009).
- 12 Generation Scotland. Samples, Information and Confidentiality FAQs. <http://129.215.140.49/gs/gfaqsic.htm> (accessed July 10, 2009).