

A comment appeared in a recent issue of *The Lancet* entitled 'Consent for biobank tissue in somatic-cell nuclear transfer'¹ which referred to the role of the UK Biobank Ethics and Governance Council. A response from the Council appears below.

Response from the UK Biobank Ethics and Governance Council

I refer to the commentary in last week's issue by Drs Jones and McKellar entitled 'Consent for biobank tissue in somatic-cell nuclear transfer'. This related in part to correspondence between the authors and the UK Biobank Ethics and Governance Council (EGC) concerning potential future uses of the UK Biobank resource and the role of the EGC². There are several matters which require correction and others which might usefully be added to the debate.

The UK Biobank Ethics and Governance Council is an independent body set up by the Wellcome Trust and the Medical Research Council to advise and monitor UK Biobank; it is not a creation of UK Biobank itself. The Council exists to speak *about* UK Biobank and not *for* UK Biobank. It is not for the EGC to decide on uses of the UK Biobank resource, as suggested by Drs Jones and McKellar, but rather to advise on and recommend courses of action as the project develops. All of this was explained in the correspondence with the authors.

The overarching responsibility of the Council is to safeguard participants' and public interests now and in the future because it is the long-term nature of the project which brings most challenges. No one can predict which applications might be made once the resource is established and participants agree to take part on this understanding by giving broad consent "to participate in UK Biobank". The project has as its primary objective the creation of a research resource for health-related research in the long-term. UK Biobank has been explicit about its hope to attract applications across a broad spectrum of scientific fields, but it does not follow that all of these will be granted. The EGC exists to monitor and advise on the obligations of UK Biobank to keep participants informed about developments in the project, and most particularly to advise on applications to use the resource as and when they arise.

The proposition put by Drs Jones and McKellar relating to somatic cell nuclear transfers was a hypothetical example and the Council took the view after a full discussion at its June 2009 meeting that it is not its role to second guess science or social attitudes at an as-yet-undetermined time. It is its role to be part of the robust scrutiny mechanisms to consider controversial applications if and when these should ever be made. It should be noted that no access to the UK Biobank resource is contemplated before 2011.

The commitments of UK Biobank to its participants are laid out in its Ethics and Governance Framework (available on UK Biobank's website). This explicitly states that: 'Further consent will be sought for any proposed activities that do not fall within the existing consent.' Whether this is the case is not a trivial matter. It depends on

¹ Jones, D. and MacKellar, C. (2009) 'Consent for biobank tissue in somatic-cell nuclear transfer', *The Lancet*, vol 374 No. 9693 pp 861 – 863 available at www.thelancet.com

² See the Council's nineteenth meeting report available at www.egcukbiobank.org.uk/meetingsandreports

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what is proposed scientifically, the expectations of participants, social mores at the time that the application is made, and a host of other factors. It is the responsibility of the EGC to advise on such circumstances. The point to note is that a role for specific consent is not ruled out; indeed it is expressly provided for. If a particular future application were controversial then an obvious recommendation from the EGC would be for UK Biobank to seek specific consent from participants and/or to consult and dialogue with its participants before any decision on access was made.

It is undeniable that consent is an important mechanism to protect research participants but its value is tested to its limits with longitudinal projects such as UK Biobank. The UK Biobank Ethics and Governance Council was set up precisely in recognition of this fact and as a means to provide additional protection for the interests of research participants.

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Chair

For and on behalf of the UK Biobank Ethics and Governance Council