British Society for Human Genetics

Draft Guidelines on Human Biobanks and Genetic Research Databases

Response to the Consultation from the Organisation for Economic Co-operation and Development

The BSHG welcomes the draft OECD guidelines as a contribution to improving and harmonising the governance and standards of operation of Biobanks and research data bases.

We suggest that the guidelines are structured to concentrate less on specific and detailed measures but to emphasise recommendations for well structured and transparent governance arrangements. In our view these arrangements should ensure that the interests of the individual participant and relevant communities are strongly and independently represented. We would also recommend an international dimension to oversight arrangements where the scale and scope of a Biobank makes it appropriate. In addition the guidelines could usefully encourage national and international networks of Biobank governance bodies to share experience and good practice, bring to light and deter poor practice and encourage transparency. In part this emphasis might be achieved by bringing section 3 'Governance Management and Oversight' forward in the text and perhaps merging it with section 1.

We feel that the guidelines might usefully focus more closely on protections for populations who may not be able to easily represent their interests in these activities; for example small ethnic groups in developing countries. This is especially relevant to these international guidelines as the collection of materials and/or data may be organised across national frontiers in particular from OECD to developing countries.

At a more detailed level the difference between statements of principle and best practice is not necessarily clear and the text would benefit from editing to remove repetition and clarify the points made.

In this draft the guidelines risk appearing too detailed and over prescriptive. Their literal application may result in a mass of 'small print' consisting of warnings and caveats in the consent to participate. This could have the unintended consequence of obscuring the purpose of the Biobank and the protections for the individual participant and deterring participation.

Finally we have a concern about the lack of references in the consultation or via the web link to other organisations' work e.g. the Human Genome Organisation Ethics Committee statement on human genomic databases (2002) the Nuffield Council on Bioethics work on the ethics of research related to healthcare in developing countries (2002 and follow up in 2005), and the UK Biobank Ethics and Governance Framework and Council. We would have thought it helpful for the OECD to refer to these documents and highlight points of similarity and difference.

A more general point not specific to the OECD guidelines is that there is a plethora of similar guidance and it is difficult for interested parties and the public to know which guidance takes precedence over others, and how to deal with contradictions between different guidelines. An introductory statement on the specific role of OECD as an intergovernmental body and the place of its guidelines in international treaty obligations or law might therefore be helpful.

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