

OECD: Draft Guidelines for Biobanks and Human Genetic Research Databases**Response by the Wellcome Trust**

May 2008

1. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending around £650 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.
2. We are pleased to have the opportunity to comment on the OECD's draft Guidelines for Human Biobanks and Genetic Research Databases (HBGRD). The Wellcome Trust has been a major source of funding for the international cooperative endeavour to sequence the human genome and to use of genetic information to understand, prevent and treat human disease. We fund UK Biobank, a large-scale study designed to identify genetic, environmental and behavioural factors involved in a range of common illnesses, in partnership with the UK Medical Research Council (MRC), the Department of Health, the Scottish Executive and the Northwest Regional Development Agency. UK Biobank will gather tissue samples and personal information from 500,000 people, currently aged 40-69, from around the UK.
3. We commend the OECD for taking the initiative to bring together best practice recommendations into this useful set of guidelines. In the course of establishing UK Biobank, the Wellcome Trust and our partners have dedicated considerable effort working with stakeholders to develop good practices for managing a biobank resource. This includes the establishment of the independent UK Biobank Ethics and Governance Council, which acts as guardian of UK Biobank's Ethics & Governance Framework, advises the Board on UK Biobank's activities within this framework, and safeguards the interests of the participants and the public.
4. Based on our experience, we find the draft OECD guidelines to be a sensible way forward to address a complicated set of issues. We would suggest that the draft guidelines are appropriate and should be maintained in their current form. Three especially important features of the current draft guidelines that must be preserved are:
 - Rapid sharing of data and materials to advance research must be encouraged. This is necessary in order to make the best use of participants' donations of tissue samples and other contributions to the HBGRD.
 - In establishing an HBGRD, steps must be taken to facilitate data exchange with other HBGRD resources, such as adopting international standards for database compatibility and interfaces, as well as standard approaches to the collection, storage and analysis of materials and data. Enabling HBGRD resources to be used together enhances their value for research.
 - The current draft guidelines take the right approach to the issues of participants' consent, offering a strong level of protection for participants that encourages research and maintains public confidence.

5. We support the prompt adoption of the draft guidelines as they are. There is a need for international guidance on the management of human biobanks and genetic research databases and the sooner this is available the better.
6. This area of science is progressing quickly, constantly raising new issues. For example, as more research is carried out in developing countries, particular challenges arise around ensuring that the interests of developing country participants and researchers are protected. Several Wellcome Trust supported projects, such as the INDEPTH Network and MalariaGEN have had to deal with these issues. Large scale population studies and genome wide association studies linking genotype to phenotype, regardless of where they are carried out, are also presenting new challenges. The Wellcome Trust Case Control Consortium is one example. It will be important for the OECD to have in place a system for reviewing and updating these guidelines to take account of such developments in the future.