

Frequently Asked Questions (FAQ):

Public Consultation of the Draft Guidelines for Human Biobanks and Genetic Research Databases

Why Guidelines for human biobanks and genetic research databases?

The completion of the mapping of the human genome under the Human Genome Project has opened up huge potential for research into the ways in which genes relate to human conditions, diseases, capacities, impairments and susceptibilities. Research involving the human genome and resulting applications open up new prospects in improving the health of individuals and of humankind as a whole.

The success of such research is dependent on the sharing of vast amounts of knowledge comprised of data, biological samples and information derived from the analysis of those samples and the ability to bring together these different strands of information and data within resources such as human biobanks and genetic research databases (HBGRDs). Current uses of HBGRDs are already contributing significantly to our understanding of genetic and environmental factors that influence disease risk and treatment. However, establishing HBGRDs raises numerous challenges.

The OECD has begun to develop Guidelines for addressing issues arising in the establishment, governance, management and use of Human Biobanks and Genetic Research Databases. The Guidelines are intended to assist both OECD member countries and non-OECD economies in the development of policies applicable to such HBGRDs. Within these Guidelines, the principles and best practices aim to balance the interests, amongst others, of researchers and participants.

How is the OECD developing these Guidelines?

The OECD held a workshop in Tokyo to investigate the issues and concerns that arise in the establishment, governance, management and use of human genetic research databases. The intention to develop guidelines was proposed by the Tokyo Workshop expert participants and endorsed by the OECD's Committee on Scientific and Technological Policy meeting at ministerial level as well as by OECD health ministers. The Workshop report [www.oecd.org/sti/biotechnology/hbgrd] sets out areas where the development of guidelines would be useful.

OECD member countries agreed the development of Guidelines for human biobanks and genetic research databases. They determined that the development of the guidelines would be best developed through a series of experts meetings. Experts meetings were held in 2007 and 2008 to develop the draft Guidelines. Over the course of these meetings, the revision of the draft Guidelines benefitted extensively from the experience, knowledge and contributions of national experts who manage and are involved with national or international biobanks, human genetic research databases, or collections. Experts were drawn from the public and private sector.

Why is the OECD conducting a public consultation on the draft Guidelines?

The OECD is inviting public comment on the draft Guidelines in order to ensure that the final text is useful for the needs of all those involved with biobanking, human genetic research databases and collections. These include but are not limited to entities involved in the establishment, governance, management and use of human biobanks, genetic research databases, and collections; directors and managers of biobanks, genetic research databases, and collections; governments and legislators; patients and patient groups; researchers; and from experts involved in the ethical, social, legal and financial fields.

Who should participate and what type of input would be useful?

The invitation to comment is open to all interested parties. We would welcome input from public and private sector entities involved in the establishment, governance, management and use of human biobanks, genetic research databases, and collections; directors and managers of biobanks, genetic research databases, and collections; governments and legislators; patients and patient groups; researchers; and from experts involved in the ethical, social, legal and financial fields.

Public comments are invited on all aspects of the draft Guidelines. In order to ensure that comments are available for consideration in the further development of the draft Guidelines, please ensure that comments are provided before **16th May 2008**.

What will happen next?

The consultation period will end 16th May 2008. Once the consultation period is closed, the comments received will be collated and analysed. These comments will be taken into account in the further development of the draft Guidelines.

The Guidelines will continue to be revised through experts meetings at which the comments received via the public consultation will be considered in addition to experts' and OECD member countries representatives' comments. The Guidelines are expected to be made public in their final form in Spring 2009.

Contact

Comments may be submitted via email to: hbgrd.guidelines@oecd.org

Additional information is available on our website at: www.oecd.org/sti/biotechnology/hbgrd