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European Society of Human Genetics

EUROPEAN SOCIETY OF HUMAN GENETICS

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On behalf of the European Society of Human Genetics (ESHG) please receive the following considerations regarding the draft Declaration of the World Medical Association on Health Databases and Biobanks.

The ESHG is a non-profit organization. Its aims are to promote research in basic and applied human and medical genetics, to ensure high standards in clinical practice and to facilitate contacts between all persons who share these aims, particularly those working in Europe. The Society encourages and seeks to integrate research and its translation into clinical benefits and professional and public education in all areas of human genetics. The European Society of Human Genetics fully supports the aims and objectives of the Council of Europe's Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes.

The ESHG appreciates the renewed discussion generated by the draft Declaration of the World Medical Association on Health Databases and Biobanks, even though non-binding, as guidance for health professionals in the context of development of new technologies, in particular in Genetics. The Declaration dated from 2002 needed to be revised in this context.

The ESHG reasserts that genetic information, covered by this draft Declaration (preamble point 7), is considered as sensitive personal information such as all other kinds of health information. In this context, geneticists must adhere to their professional duties of protecting confidentiality of genetic information in respect of professional secrecy and in accordance with broader ethical values such as respect for privacy.
Nevertheless, these principles are not considered as absolute and can be limited by facts or other values. A first limit consists in the development of new technologies in Genetics and their impact on the capability of researchers and medical doctors to protect genetic information against breaches of confidentiality. Whole Exome/Genome Sequencing techniques permit to obtain and identify detailed sequences of unique individuals that may by their very nature enable re-identification even if used in anonymized or pseudonymized state. As a result, anonymity in principle cannot be guaranteed.[1] However, it has been realized that occurrence of this risk is quite low and therefore should not have to lead to tightening or increasing regulation.

1. Homer N, Szelinger S, Redman M, Duggan D, Tembe W, Muehling J, et al. (2008) Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays. PLoS Genet 4(8): e1000167. doi:10.1371/journal.pgen.1000167

There is a difference between biomedical research projects for which specific consent may be obtained and biobanking activities that may involve future, currently unspecified, uses, which impacts on the acceptable level of regulation and informed consent.
In case of a health database the main goal is the creation of a resource where – apart from providing information when solicited (16) - return to individuals is relevant which influences facilities to withdraw and recontact (17). In both biobanks and health databases removing one's information or biological material may not always be possible when shared with third parties.

The optimal way to ensure the balance between data-sharing and respect of privacy consists in coupling ethical principles with governance mechanisms (23-26) as is supported in this draft. Nevertheless, it should be clearly stated that classical tools for respect of human dignity (consent and information) must be adapted to biobank activities in pushing for innovative consent procedures together with strong internal governance mechanisms rooted in transparency, solidarity and active participation as core principles. In some countries protocols for biobanks and health databases have a long-standing tradition and other oversight mechanisms besides an independent medical ethical committee may have juridical backing. In addition, recent literature suggests that active participation of research subjects or patients in oversight structures may be a welcome alternative or complement to ethical committees.

The ESHG therefore is concerned about the lack of support for data-sharing in the proposed draft declaration and the absence of recognition of such a need in the era of genomics and personalized medicine. In this respect, data-sharing is only referred to in the document in art. 22 and only in the scope of intellectual property which is leading to confusion and a false perception. ESHG calls for responsible data-sharing as a crucial issue to advance knowledge in science and in Genetics in particular as a basis for improving health care. From rare diseases to chronic diseases, sharing data is essential to obtain the necessary statistical power to answer scientific questions. Even though increasing health data circulation can increase the risks of breach of confidentiality, ESHG (in line with various funders) is encouraging and supporting data-sharing where necessary guarantees are in place to protect participants' autonomy.

On behalf of the European Society of Human Genetics,

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Chair ESHG Public and Professional Policy Committee