

**HUGO ETHICS COMMITTEE:
STATEMENT ON HUMAN GENOMIC DATABASES
December 2002**

Recognizing:

- The potential global good arising from genetic research;
- The scientific and clinical uses of genomic databases;
- The potential for conflicts between the free flow of information that is crucial to research advances and the legitimate rights to return from research expenditure;
- The potential risk of misusing genetic data;
- The need to rapidly place primary genomic sequences in the public domain.

Recalling:

- The 1996 HUGO Ethics Committee Statement on the Principled Conduct of Genetic Research, and the principles upholding it:
 - Recognition that the human genome is part of the common heritage of humanity;
 - Adherence to the international norms of human rights;
 - Respect for the values, traditions, culture, and integrity of participants; and
 - Acceptance and upholding of human dignity and freedom.
- The 1998 HUGO Ethics Committee Statement on DNA Sampling: Control and Access,
- The 2000 HUGO Ethics Committee Statement on Benefit Sharing,
- The position of UNESCO's 1997 Universal Declaration on the Human Genome and Human Rights that research results be used only for peaceful purposes,
- The public accessibility of data generated by the SNP Consortium as a positive example of international collaboration.

Proposing that some of the principles and recommendations that follow may apply to both human and non-human genomic databases, The HUGO Ethics Committee adopts the following principles as a basis for its recommendations:

1. Human genomic databases are global public goods.
2. Individuals, families, communities, commercial entities, institutions and governments should foster the public good.
3. The free flow of data and the fair and equitable distribution of benefits from research using databases should be encouraged;
4. The choices and privacy of individuals, families and communities with respect to the use of their data should be respected;
5. Individuals, families and communities should be protected from discrimination and stigmatization;
6. Researchers, institutions and commercial entities have a right to a fair return for intellectual and financial contributions to databases;

For the purposes of this Statement on Human Genomic Databases, the HUGO Ethics Committee adopts the following definitions:

- A genomic database is a collection of data arranged in a systematic way so as to be searchable. Genomic data can include inter alia, nucleic acid and protein sequence variants (including neutral polymorphisms, susceptibility alleles to various phenotypes, pathogenic mutations), and polymorphic haplotypes. The work associated with a database includes collecting, annotating, curating, storing, validating and preparing specific sets for transmission.
- Global public goods are those whose scope extends worldwide, are enjoyable by all with no groups excluded, and, when consumed by one individual are not depleted for others.

RECOMMENDATIONS

1. Human genomic databases are global public goods.
 - a. Knowledge useful to human health belongs to humanity.
 - b. Human genomic databases are a public resource.
 - c. All humans should share in and have access to the benefits of databases.
2. Individuals, families, communities, commercial entities, institutions and governments should foster the public good.
 - a. Public engagement is a prerequisite of public responsibility
 - b. Access to social goods such as medical care, education and a decent standard of living will foster such responsibility.
3. The free flow of data and the fair and equitable distribution of benefits from research using databases should be encouraged.
 - a. Insofar as it benefits humanity, the free flow, access, and exchange of data are essential.

- Cooperation and coordination between industrialized and developing countries should be facilitated.
- b. Repositories should be established and funded to ensure the continuation of publicly available databases.
 - c. Compatibility should be fostered through the use of common nomenclature, and, where possible, the pooling of databases should be encouraged.
 - d. There is a scientific responsibility to ensure the professional competence of researchers working with data, as well as the quality and accuracy of the data.
4. The choices and privacy of individuals, families and communities should be respected.
- a. Choices may be with regard to: donation, storage and uses of samples and the information derived therefrom. (e.g. specific, related or other uses subject to authorization by an ethics committee, etc.). Informed consent may include notification of uses (actual or future), or opting out, or, in some cases, blanket consent.
 - b. Mechanisms should be established to ensure respect for such choices.
 - c. Participants should be informed of the degree of identifiability of their data (e.g. coded, anonymized, aggregate, etc.) and of the security mechanisms in place to ensure confidentiality.
 - d. Participants should be told that samples or the information derived therefrom may be shared with other researchers including those from other countries, with commercial entities and through publication and availability on the WEB.
5. Individuals, families and communities should be protected from discrimination and stigmatization.
- a. Prior consideration should be given to the possible negative socio-economic effects, if any, of the collection, sharing, and publishing of the data.
 - b. This consideration should include an assessment of both benefits and risks, as well as strategies for the management thereof.
6. Researchers, institutions, and commercial entities have a right to a fair return for intellectual and financial contributions to databases.
- a. There should be reciprocity and exchange of information with fair return.
 - b. There are various mechanisms available for fair returns, for example, non-exclusive licenses, copyright, monetary, non-monetary (e.g. publication or credits), database pools, and central repositories.
 - c. Any fees should not restrict the free flow of scientific information and equitable access.

HUGO Ethics Committee 2002

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