

**HUGO Ethical, Legal, and Social Issues Committee
Report to HUGO Council**

Based on the Discussion Paper, "Ethical Issues in International Collaborative Research
on the Human Genome: The HGP and the HGDP,"
Bartha Maria Knoppers, LL.D., Member HUGO-ELSI Committee; Marie Hirtle, LL.M. and
Sébastien Lormeau, B.Sc., 1995.

Statement on the Principled Conduct of Genetics Research

The Human Genome Project (HGP), proposed in the 1980s and formally initiated in 1990, has as its specific goals identification of all human genes and sequencing of the entire genome. Completion of the HGP in the projected 15 years will provide a source book for biology and medicine. Yet, in this time frame, the function of all genes, singly and in concert, will not be known, nor will the worldwide variation in the genes have been defined.

The Human Genome Diversity Project (HGDP) is an international scientific endeavor that complements the HGP by examining the genomic variation of the human species, through analysis of DNA from populations, families, and individuals worldwide. The HGDP promises to help us understand the fundamental unity of humankind, human biological history, population movements, and susceptibility or resistance to various human diseases.

The HGP, the HGDP, and other genetic research have given rise to a number of concerns:

- Fear genome research could lead to discrimination against and stigmatization of individuals and groups and be misused to promote racism;
- Loss of access to discoveries for research purposes, especially through patenting and commercialization;
- Reduction of human beings to their DNA sequences and attribution of all social and other human problems to genetic causes;
- Lack of respect for the values, traditions, and integrity of populations, families, and individuals; and
- Inadequate engagement of the scientific community with the public in the planning and conduct of genetic research.

The Council of the Human Genome Organisation (HUGO) asked its Ethical, Legal and Social Issues Committee (HUGO-ELSI), comprising experts from a number of countries and disciplines, to provide guidance and procedures which would address these concerns and ensure that ethical standards are met as the HGP and the HGDP proceed.

Statement on the Principled Conduct of Genetics Research

21 December 1995

Page 2

The HUGO-ELSI Committee bases its recommendations on the following four principles:

- Recognition that the human genome is part of the common heritage of humanity;
- Adherence to 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 HUGO-ELSI Committee recommends:

- That scientific competence is the essential prerequisite for ethical research. It includes appropriate training, planning, pilot and field testing, and quality control through continual review.
- That communication not only be scientifically accurate, but understandable to the populations, families, and individuals concerned and sensitive to their social and cultural context. Communication is a reciprocal process; researchers must strive to understand as well as to be understood.
- That consultation should precede recruitment of possible participants and should continue throughout the research. Cultural norms vary, as do perceptions of health, disease, and disability; of family; and of the place and importance of the individual.
- That informed decisions to consent to participate can be individual, familial, or at the level of communities and populations. An understanding of the nature of the research, the risks and benefits, and any alternatives is crucial. Such consent should be free from coercion by scientific, medical, or other authorities. Under certain conditions and with proper authority, anonymous testing for epidemiological purposes and surveillance could be an exception to consent requirements.
- That any choices made by participants with regard to storage or other uses of materials or information taken or derived therefrom be respected. Choices to be informed or not with regard to results or incidental findings should also be respected. Such choices bind other researchers and laboratories. In this way, personal, cultural, and community values can be respected.
- That recognition of privacy and protection against unauthorized access be ensured by the confidentiality of genetic information. Coding of such information, procedures for controlled access, and policies for the transfer and conservation of samples and information should be developed and put into place before sampling. Special consideration should be given to the actual or potential interests of family members.

Statement on the Principled Conduct of Genetics Research

21 December 1995

Page 3

- That collaboration between individuals, populations, and researchers and between programs in the free flow, access, and exchange of information is essential not only to scientific progress but also for the present or future benefit of all participants. Co-operation and co-ordination between industrialized and developing countries should be facilitated. An integrated approach and standardization of conditions and consents is essential to ensure viable collaboration and comparison of results.

- That any actual or potential conflict of interest be revealed at the time information is communicated and before agreement is reached. Such actual or potential conflicts should also be reviewed by an ethical review committee before any research begins. Honesty and impartiality are the cornerstones of ethical research.

- That undue inducement through compensation for individual participants, families, and populations should be prohibited. This prohibition, however, does not include agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of health care or of information infrastructures, reimbursement of costs, or the possible use of a percentage of any royalties for humanitarian purposes.

- That continual review, oversight, and monitoring is essential for the implementation of these recommendations. Such review should include, where possible, representatives of participants in this research. Indeed, without continuing evaluation, the potential for exploitation, for duplicity, for abandonment, and for abuse by all cannot be ignored. Like competence, continual review is imperative to respecting human dignity in international collaborative genetic research.

HUGO-ELSI Committee Members

Professor Kåre Berg
Professor Alex Capron
Professor Ruth F. Chadwick
The Honorable Justice Michael Kirby
Professor Bartha Maria Knoppers
Dr. Darryl R.J. Macer
Dr. Victor A. McKusick

Professor Benno Müller-Hill
Dr. Thomas H. Murray
Professor M.F. Niermeijer
Professor Alain Pompidou, Cochairperson
Professor Stefano Rodotà
Dr. Hiraku Takebe
Dr. Nancy S. Wexler, Cochairperson