HUGO ETHICS COMMITTEE:

STATEMENT ON DNA SAMPLING: CONTROL AND ACCESS
February 1998

INTRODUCTION

In this Statement on DNA Sampling: Control and Access, the Ethics Committee of HUGO addresses several ethical issues pertinent to sample collection and sharing in genetic research. Of primary importance is the source of the sample, that is, whether it was collected during routine medical care or during a specific research protocol since this affects the ambit and the choices available in the consent process. By its very nature, genetic information is both personal and familial. While in most situations, informed consent should be sought at every stage and for every test, genetic research is a continuum that requires improved procedures for long term storage, access and use so as to provide actual, real, living relatives with necessary risk estimation, choice and information. Eventually, these advances will be of benefit to the general population for disease prevention and treatment. In short, in the handling of the information provided and the choices offered, one cannot ignore the immediate or potential interests of family members.

Respect for the person and for the family can be facilitated and ensured by avoiding the use or transmission of identifiable samples wherever possible. Data protection is of the utmost importance. The coding of samples is a technique that protects confidentiality provided that stringent mechanisms are put in place. Another avenue is the anonymization of samples which would make tracing back impossible. While necessary demographic and clinical data may accompany the anonymized sample, careful consideration should be given before proceeding to strip samples of identifiers since other unknown, future uses may thereby be precluded as well as may the validation of results.

The family is the nexus of a variety of relationships (legal, moral, social and biological). Irrespective of legal definitions of the family and of its different social and cultural configurations, genetic research may yield genetic information that is important to immediate relatives. The very fact of participation in research or not, or, the decision to refuse to warn at-risk relatives or to withdraw, or, the failure to provide for access after death, all affect the interests of present and future relatives. These shared biological risks create special interests and moral obligations with
(Based on the discussion by the HUGO Ethics Committee of the paper: Knoppers B.M., Hirtle M, Lormeau S., Laberge C.M., Laflamme M. "Control of DNA Samples and Information", accepted by Genomics.)
respect to access, storage and destruction that may occasionally outweigh individual wishes. A different response is necessary however, in relation to institutional third parties, such as employers, insurers, schools, and government agencies because of possible discrimination. Counselling prior to participation is also necessary to avoid stigmatization. Standardization of procedures and the security of the samples are essential.

The HUGO Ethics Committee wishes to reaffirm its commitment to its position given previously in its Statement on the Principled Conduct of Genetic Research. In particular, it maintains that respect for free and informed consent and choice as well as for privacy and confidentiality in the collection, storage and use of human DNA are the cornerstones of ethical conduct in research. It reiterates the importance of recognizing that the pursuit of scientific knowledge is essential to human progress and to the relief of human suffering. This pursuit must adhere to international norms of human rights. In the context of research involving human beings, the acceptance and upholding of human dignity and freedom require prior ethical review. Respect for individual values, familial needs and cultural differences as well as the possibility of withdrawal of consent to participate without prejudice are ethical prerequisites.

Thus, provided there is ethical review, the HUGO Ethics Committee makes the following
RECOMMENDATIONS:

The choices offered in the consent process should reflect the potential uses of the DNA sample and its information. It is important to indicate whether the sample and its information will: identify the person, code the identity, or anonymize the identity so that the person cannot be traced although some demographic and clinical data may be provided. Even if anonymization is appropriate in certain circumstances in research, caution should be exercised in any irreversible stripping of identifiers from the samples since it may preclude valuable uses of the samples and validation of results.

Routine samples, obtained during medical care and stored, may be used for research if: there is general notification of such a policy, the patient has not objected, and the sample to be used by the researcher has been coded or anonymized. Routine samples obtained during medical care and stored before such notification of such a policy may be used for research if the sample has been anonymized prior to use.

Research samples obtained with consent and stored may be used for other research if; there is general notification of such a policy, the participant has not yet objected, and the sample to be used by the researcher has been coded or anonymized. For the use of research samples obtained before notification of a policy, these samples may be used for other research if the sample has been coded or anonymized prior to use.

Security mechanisms must be put into place to ensure the respect of the choices made and of the desired level of confidentiality.

Special considerations should be made for access by immediate relatives. Where there is a high risk of having or transmitting a serious disorder and prevention or treatment is available, immediate relatives should have access to stored DNA for the purpose of learning their own status. These exceptional circumstances should be made generally known at both the institutional level and in the research relationship.

In the absence of need for access by immediate relatives, stored samples may be destroyed at the specific request of the person. Such destruction is not possible for samples already provided to other researchers or if already entered into a research protocol or used for diagnostic purposes. By their very nature, anonymized samples cannot be withdrawn or destroyed.

Unless authorized by law, there should be no disclosure to institutional third parties of participation in research, nor of research results identifying individuals or families. Like other medical information, there should be no disclosure of genetic information without appropriate consent.

International standardization of the ethical requirements for the control and access of DNA samples and information is essential.

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