

HUGO Ethics Committee,

STATEMENT ON BENEFIT-SHARING

April 9 2000

A. Introduction

The HUGO Ethics Committee subscribes to the following four principles presented in the HUGO *Statement on the Principled Conduct of Genetic Research* (1996):

- 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 above *Statement* further provided:

"That undue inducement through compensation for individual participants, families and populations should be prohibited. This prohibition 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".

The Committee believes that the issue of benefit-sharing merits further discussion because expenditures by private industry for genetic research now exceed the contributions of governments.

Many new products, including vaccines and drugs for common diseases, are now based on genetic research. Much government or nonprofit research will eventually be commercialized. Companies involved in human health may have special moral obligations.

The HUGO Ethics Committee considers it important to further outline the underlying principles and issues related to benefit-sharing, with a view to making recommendations.

In order to do so, it has examined the historical background, possible definitions of community, beliefs about the common heritage of humankind, and the principles of justice and solidarity before applying these principles to the concept of benefit-sharing.

B. Historical Background

HUGO has addressed controversies surrounding research in its previous statements. The issue at hand for the Ethics Committee is whether and how to distribute profits that may accrue to commercial enterprises, governments, or academic institutions on the basis of the participation of particular communities.

This issue predates genetics by many years. In the past, many researchers sought no specific reward for biomedical research. More recently, due to increasing private investment, researchers and institutions often demand a share of monetary benefits deriving from their research.

Moreover, in the interest of justice, the last decade has witnessed an emerging international consensus that groups participating in research should, at a minimum, receive some benefit. In this consensus, the concept of benefit was often limited to the possible therapeutic benefit of participating in clinical trials or of payment to research participants.

Certain objections regarding research involving indigenous populations raised awareness of the need to develop further the concept of benefit-sharing, these concerns apply not only in the developing world, but also among research participants in developed nations.

C. Defining Community.

Community is a term that can never be dissociated from the social perceptions of those both inside and outside the community. The type of community most easily visualized has some combination of shared geography, history, race, culture, and religion, such as a tribe living in a given territory.

There are many different types of communities. Communities of origin are founded on family relationships, geographical areas, cultural, ethnic, or religious groups in which one is born or raised. For example, the extended family constitutes a community based on inheritance. Communities of circumstance are groups in which one finds oneself, by choice or chance, later in life. These include groups based on shared interests, workplaces, labor unions, and voluntary associations.

Both types of communities can be defined across several dimensions, including geography, race/ethnicity, religion or disease state. For example, a small town may be a community of origin if most inhabitants were born there, or a community of circumstance if most are newcomers. Persons with the same disease could form a community of origin if there is a family history, as may be the case for monogenic disorders (single gene), or a community of circumstance, which is usually the case for common multifactorial diseases. People with common multifactorial diseases, such as heart disease, hypertension, cancer, or diabetes may not regard themselves as communities.

D. Common Heritage.

As a species, we all share in essence the same genome. This common genome allows for reproduction between all groups of mankind. At this collective level, the genome is the common heritage of humanity. In contrast, apart from identical twins, individuals exhibit significant variation. Rare variant genes at different gene loci are the causes of the vast number of monogenic conditions. Most diseases are partly based on normal genetic variation (i.e. polymorphisms). Diseases where genetic polymorphisms are of importance are much more frequent than monogenic conditions. Many persons with such polymorphisms will escape disease if lifestyle, dietary and environmental factors are favorable, since the diseases in question are caused by interaction between genes and environment. Furthermore, most common diseases know no national or political boundaries.

The chance of discovering a gene that could lead to a product may vary among populations. The search for genes may therefore focus on specific populations or families. Sometimes, findings in families with extremely rare diseases may have implications for larger groups with more common disorders.

While not respected by all nations, the concept of common heritage also resonates under international law (e.g. the sea, the air, space, ...). Applied to human genetics, it maintains that beyond the individual, the family, or the population, there is a common shared interest in the genetic heritage of mankind. Therefore, the Human Genome Project should benefit all humanity.

E. Justice.

Justice is a central issue. There are at least three different meanings of the concept of justice, all of which are relevant in our context of benefit-sharing: 1) Compensatory justice: meaning that the individual, group, or community, should receive recompense in return for contribution; 2) Procedural justice: meaning that the procedure by which decisions about compensation and distribution are made is impartial and inclusive; and, 3) Distributive justice: meaning an equitable allocation and access to resources and goods. At present there is a great inequality between the rich and poor nations in the direction and priorities of research and in the distribution and access to the benefits thereof. When there is a vast difference in power between those carrying out the research and the participants, and when there is a possibility of substantial profit, considerations of justice support the desirability of distributing some profits to respond to health care needs.

F. Solidarity.

The sharing of genes may call for strong solidarity within certain groups of people. Members of a small group with rare genes who have helped research would be particularly deserving recipients of benefits. Moreover, research efforts should promote health universally and so include developing countries. In the future, much prevention and treatment will be based on genetic knowledge. It is in everyone's best interest that wealthy and powerful nations as well as commercial entities foster health for all humanity.

G. Benefit-Sharing.

A benefit is a good that contributes to the well-being of an individual and/or a given community (e.g. by region, tribe, disease-group...). Benefits transcend avoidance of harm (non-maleficence) in so far as they promote the welfare of an individual and/or of a community. Thus, a benefit is not identical with profit in the monetary or economic sense. Determining a benefit depends on needs, values, priorities and cultural expectations.

In genetic research in general, benefit-sharing has also been established as a principle of international law in the area of biodiversity and genetic resources in food and agriculture.

People with common multifactorial diseases, may have few shared beliefs about benefit. Indeed, benefit will often be that of eventual prevention or treatment and affordable medical services.

Prior consultation with individuals and communities and their involvement and participation in the research design is a preliminary basis for the future distribution of benefit and may be considered a benefit in itself. Such prior discussion should include consideration of affordability and accessibility of eventual therapy, and preventive and diagnostic products of research.

The actual or future benefits discussed should not serve as an inducement to participation. Nor should there be any financial gain from participation in genetic research. This does not exclude, however, the possibility of reimbursement for an individual's time, inconvenience and expenses (if any), even if there is a general distribution of benefits to the community. Participants should be told of such general distribution at the outset.

In the very rare case where the extended family or a small group/tribe harbours an unusual gene, yet the research eventually benefits those with another disorder, justice may require that the original group deserve recognition. In this situation, benefits could be provided to all members of the group regardless of their participation in the research. Limiting the returns to only those who participated could create divisiveness within a group and is inconsistent with solidarity.

Even if there are no results or profits, at a minimum, individuals, families and groups participating in research should be thanked (e.g. letter, or a small token or gift where the culture expects this). They should also receive information about the general outcome(s) of research in understandable language. The ethical advisability of provision of information to individuals about their results should be determined separately for each specific project. Moreover, immediate benefits such as medical care, technology transfer, or contribution to the local community infrastructure (e.g., schools, libraries, sports, clean water, ...) could be provided.

<>In the case of profit-making endeavours, the general distribution of benefits should be the donation of a percentage of the net profits (after taxes) to the health care infrastructure or for vaccines, tests, drugs, and treatments, or, to local, national and international humanitarian efforts.

Recommendations

Whereas:

- we all share a common genetic heritage, and
- there are different definitions of community, and
- communities may have different beliefs about what constitutes a benefit, and
- genetic research should foster health for all human beings,

The HUGO Ethics Committee recommends:

- 1) that all humanity share in, and have access to, the benefits of genetic research.
- 2) that benefits not be limited to those individuals who participated in such research.
- 3) that there be prior discussion with groups or communities on the issue of benefit-sharing.
- 4) that even in the absence of profits, immediate health benefits as determined by community needs could be provided.

- 5) that at a minimum, all research participants should receive information about general research outcomes and an indication of appreciation.
- 6) that profit-making entities dedicate a percentage (e.g. 1% - 3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts.

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