NATIONAL BIOETHICS COMMISSION

R E C O M M E N D A T I O N

ON BANKS OF BIOLOGICAL MATERIAL OF HUMAN ORIGIN (BIOBANKS) IN BIOMEDICAL RESEARCH

The National Bioethics Commission met upon invitation by the President thereof on the 17th of March, the 14th of April, the 19th of May and the 30th of June 2006 in order to consider the ethical, legal and social issues within its jurisdiction which arise from biological material banks and their role in biomedical research.

The Commission underlines that the completion of the human genome mapping project in 2001 marked the beginning of a better understanding of how genes function and interact with each other and the environment in the manifestation of disease or protection from it. At the same time, the Commission notes that, parallel to scientific developments, technological progress in IT has made possible the collection, management and processing of huge amounts of information paving the way to large-scale research projects.

In its recommendation on the collection and management of genetic data (2002) the Commission already signalled the particular case of population genetic research and recognized the need to adopt specific rules and procedures to ensure freedom of research and avoid social discrimination.

There is a trend, both nationally as well as internationally, towards the development of human biobanks, on the one hand, and the incorporation of existing biobanks into biomedical research projects, on the other hand. These developments raise a number of ethical, legal and social issues associated with the scale and operation of biobanks as these types of research combine processing of biological information extracted from specimens and personal, often "sensitive", data of donors.

By the present recommendation, the Commission focuses its attention specifically on genetic research involving biological specimens of human origin that are collected and processed in biobanks.

1. Definition

The term biobank includes any collection of human biological material. The critical ethical, legal and social issues emerge when the biological specimens are linked to records of personal data of donors.

The biological specimens may include tissues, cells, blood or DNA isolated from them and may have been collected for medical or educational or research purposes by public or private agencies.
Personal data records include sensitive personal information, especially genetic data, and information from the medical records of donors, genealogical data or social information on lifestyle.

2. The importance of biobanks for biomedical research

a) Generally

The immediate results of genetic research conducted in biobanks are expected to demonstrate which groups of persons with a given genetic makeup are more likely to manifest this or other medically interesting phenotype compared to the general population. This is valuable information in terms of public health as it may lead to adoption of specific preventive measures.
The Commission stresses that these results do not necessarily prove a cause-and-effect relationship between the genetic makeup of the persons concerned and the onset of disease. It recognizes, though, that they lay the foundations for a potential identification of the genes involved in the future. Therefore, in the long run, research in biobanks may lead to development of new diagnostic methods and/or treatments. These long-term results attract considerable private investment in the research conducted in biobanks.
It is worth noting that when information on the pharmaceutical treatment of donors of biological specimens is collected as part of their medical records, genetic research may reveal to what extent a person's genetic makeup affects their response to a particular drug (pharmacogenetics). This type of results is believed to make possible the so-called "tailor-made" individualised medicine since a genetic diagnostic test will be able to establish if a particular drug is safe and/or effective for a particular patient. A significant part of investment in this area of research comes from the pharmaceutical industry.

b) Research in Greece

For the time being, research in Greece focuses on diseases with a known, at least in part, genetic basis. Public and private organizations are taking active part in these research activities. As in these cases the relationship between the genetic makeup of the persons involved and the onset of disease is more or less well-

established, the main purpose of genetic research is to identify new mutations in the genes under investigation which occur in the Greek population or/and the wider geographical region of the Balkans.

3. Bioethical concerns

a) Striking a balance between autonomy and solidarity

The major bioethical issue raised by biobanks is the relationship between personal autonomy and social solidarity. On the one hand, research in biobanks, if linked to named personal data, goes to the core of individual autonomy and fundamental rights. Indeed, the handling of sensitive data is so broad here as to objectively entail high risk for the data and, in extension, for the autonomy of donors. On the other hand, however, this kind of research can yield significant benefits to the protection of public health leading to more rational planning – and, thus, greater efficiency – of national health systems based on the associations between varying sets of information from large population samples. Therefore, voluntary participation is ultimately an act of social solidarity in that it contributes to serving the public interest.

The Commission believes that the prospects of significant benefits for public health justify the operation of biobanks. It also believes that any state-promulgated rules should encourage the dimension of social solidarity albeit safeguarding personal autonomy.

b) The question of commercial exploitation of research

Serving the public interest or not, the operation of biobanks carries an unmistakable whiff of private profit-making. The commercial exploitation of the findings of research – especially through patents – is an essential driver of private investment. This is a legitimate pursuit provided appropriate measures are put in place to protect the personal autonomy of participants.

The Commission endorses the social demand for partaking in the benefits arising from research and its applications according to the UNESCO's Declarations on Genetic Data (art. 19) and Bioethics (art. 15). Aside from responding to an obvious demand for justice, this approach ensures further incentives to encourage research and promote the public interest through the operation of biobanks.

4. Comments on the development and operation of biobanks

The above bioethical concerns have specific practical implications for the development and operation of biobanks in our country in the context of implementation of relevant legislation. The Commission finds it appropriate to point out these implications.

a) Consent

Respect for personal autonomy requires informed consent prior to collection and processing of biological specimens or/and personal data (genetic, medical or on lifestyle).

The information to be given prior to consent must clearly state the purpose or purposes served by the processing of data in the biobank. Therefore, the donor's consent must be written and specific, i.e. it must be given for a particular use/s of the harvested material especially in regard to named data. To all intents and purposes, the Commission recognizes that this information may include elements of a more general interest such as the importance of research for public health. Therefore, it would not be unthinkable to present donors with an option between a specific or a "blanket consent" provided, in the latter case, that their data will be anonymized or encrypted. The term "blanket consent" covers research activities that are impossible to predict at the time the consent is given or not directly linked to the purpose of the particular handling of data. Needless to say, the extent of consent, in this case, is to be determined by the donor.

Furthermore, it must be stressed that in order to have direct access to named data collected by other agencies (hospitals, social security funds, etc.) biobanks must ensure that this is also covered by the donor's initial consent.

b) Ownership of biological specimens and control of personal data

i) The Commission holds that the ownership of biological specimens may be transferred to the biobank with the donor's consent according to the general rules of civil law. To all intents and purposes, this should feature in the information to be given prior to consent in order to avoid any defects of will (in particular, misrepresentation). If donors do not consent to the transfer of ownership, they maintain all the powers emanating therefrom, particularly the power to withdraw the specimen. At any rate, it is not impossible for the biobank to acquire ownership without the donor's consent if the processing underwent by the

specimen qualifies for acquisition of property according to the rules of *specificatio* (art. 1061 of the Civil Code).
ii) In principle, the control of processed data vests in the donor (Act 2472/1997). This data may become the object of transaction (except in case of legal prohibition); therefore, it may be considered as part of a person's property which can be transferred to a biobank according to the general rules of law on transfer of property.

c) Commercial exploitation

The ownership of specimens and the property-aspect of personal data are directly linked to the potential of commercial exploitation of the findings of biomedical research. Considering the obvious world-wide interest of private investors in biobanks, the Commission holds that the potential of commercial exploitation and any such respective profits as donors or third parties may be expecting to gain in view of the above discussion (see 3b) must be covered specifically in the information to be provided prior to consent, particularly if exploitation is one of the immediate goals of the research activity.

d) Third party access

The Commission purports that third party access to specimens of biological material and/or the personal data linked to them can be free only if the data is anonymized or encrypted. If the data is named, third party access is allowed only with the donor's consent according to the general rules of consent (Act 2472/1997).

e) State licenses

i) A biobank is legally set up by a license issued by the responsible authority, which may be a university.
ii) In case the biobank will collect and process named personal data it must also obtain a license from the Authority for the Protection of Personal Data (art. 7(2) and 8(3), Act 2472/1997 respectively).

These legal provisions are undoubtedly preventive clauses to protect the personal autonomy of donors and to serve the public interest. The Commission, however, believes that this situation of double licensing is excessive. It is preferable to confer responsibility in one authority only.

f) Criteria of proper operation

When a state license is applied for, the Commission holds that certain elements should be submitted to the responsible authorities to ensure the protection of persons and the quality of research conducted in biobanks.

1. Specifications of Operation. Biobanks must operate according to specifications that meet internationally recognized quality standards. These standards mainly regard the safe storage and processing of biological specimens and guarantee the quality of analyses, especially when the results are to be used for diagnostic purposes, in addition to research.
2. Consent and Information Forms. Another requirement for obtaining a license should be the inclusion of consent and information forms when the biological specimens or personal data will be collected by the biobank itself. The consent form must contain specific mention of the ownership of data, the commercial exploitation of the results of research and the terms of third party access to the biological specimens or data.
3. Confidentiality. If records of named data will be kept and processed (irrespective of whether they will be collected by the biobank itself or acquired by another source) the Authority for the Protection of Personal Data must be informed of the method of safe encryption of the donor's identity and of the persons who will have right of access to it.
4. Duration of storage of specimens or/and personal data. The Authority for the Protection of Personal Data should be notified of the planned duration of storage of specimens and/or personal data and of the destiny of specimens and/or records in case the biobank ceases its operations.

g) A Single Registry

The Commission recommends the creation of a single registry for storage or/and processing banks of biological material and personal data. The registry should be open to the public and provide information, especially on the kind of biological specimens and personal data that are kept and handled, the purpose of each biobank and its sources of financing.

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