

**Presidenza del Consiglio dei Ministri
NATIONAL BIOETHICS COMMITTEE**

**BIOBANKS AND RESEARCH ON HUMAN
BIOLOGICAL MATERIAL.**

Opinion of the NBC on a Recommendation of the Council of Europe and on a document of the National Committee for Biosecurity and Biotechnology

Approved in the Plenary session of the 9th of June 2006

In the meeting of the 16th of December 2005, the NBC examined the work carried out by the Steering Committee for Bioethics of the European Council (SCB) on the topic: “Draft Recommendation on research utilising human biological material”, concluded in the plenary session of the Committee which took place in Strasburg from the 17th to the 21st of October 2005 and transmitted to the Delegations of the Ministers of the European Council.

This document was accepted by the Committee of the Ministers of the European Council on the 16th of March 2006, without modifications.

In the plenary Assembly of the 6th of June, the NBC has examined the document of the National Committee for Biosecurity and Biotechnologies (NCBB) “Guidelines for the creation and certification of biobanks”, developed on the 19th of December 2005 and received by the NBC, courtesy of Professor Leonardo SANTI.

Taking into account that the two documents come from independent sources but fully coincide in time, the NBC deems appropriate to express the following considerations:

1 – The “Project” developed by the EBC has become necessary for the recent passing of the “Additional protocol to the Convention for the protection of human rights and human dignity in the application of biology and medicine regarding biomedical research” (adopted by the Committee of Ministers on the 30th of June 2004 and published as STCE No. 195, 2005), as the aforementioned protocol does not take into consideration the treatment of biological material involved in biomedical research, but simply determines the principles and regulations the contracting States need to put in place for the protection of people and their rights in the diverse general conditions that could arise in exercising biomedical research.

This protection is now extended to the conservation and to the availability, given specific conditions for research even by third parties, of the biological samples and of the data deriving from the people participating in the research and donating biological material, taking inspiration from the principles of the Convention of human rights and biomedicine (STE No. 164, 1997) and of the Convention for the protection of people with regards to automated use of personal data (STE No. 108).

The NCBB Document was born out of the necessity to offer – to the Italian legislator – guidelines for the correct definition of “biobank”, to establish criteria for the founding and organisation of it, to determine the necessary conditions for the correct management and certification of this activity, and it finally dwells on the ethical and legal criteria effective in ensuring respect for the rights of the donors of biological samples, the activities of coordination between biobanks, between biobanks and researchers, and their exact function with regards to public opinion.

The NBC takes note primarily of the convergence in the inspiration underlining the two documents, which cover largely comparable ethical and legal areas.

In fact, although the two documents start from different points of view (taking as model and route, the first, the protection of personal rights; the second, the biobank’s capability and potential of service), the point of arrival for both is common under many aspects. Furthermore, both documents are interested in the same area of applications, which is well defined and excludes trespassing into fields which are differently regulated or are currently being regulated.

2 – With regards to the content, the NBC in particular has taken note that both documents have clearly identified the principles that should preside over the correct behaviour of the researchers in utilising biological material and the data deposited in the

different typologies in which the structure of conservation is classified, in the interest of each donor of the biological material and in the interest of society, but also of those very same researchers. It deals with principles that are well known in bioethics, regarding primarily the duty to evaluate risks/benefits, which must precede any participation to the research protocol and the privilege generally given to anonymity, in different forms, of the samples and data, towards a clear strengthening of the protection of privacy, provided that the non-anonymous (therefore identified and codified) use of the biological material or of the joined data, is in the interest of the subject and freely accepted by him/her.

Completely comparable are – in addition – the proposals contained in the two documents – regarding the specific information and the consequent agreement or disagreement by the donor of the biological material, with regards to the typology and extent of the use of the biological material itself, and/or the data deriving from it; the principle of the gratuitousness of the donation; the exclusion of remuneration to the donor; the prohibition of interference with his/her private life and of personal discrimination or of the group he/she belongs to, with regards to the participation to the research or to the knowledge of the data deriving from the preserved samples; the right of the interested party to access and control his/her own information, within a sensible but strictly regulated frame – when it comes to genetic data – even with regards to sharing with his/her family information absolutely indispensable to other people's health.

3 – On the basis of the aforementioned details, the NBC agrees with the recommendations, contained in both documents, regarding the correct procedures for the collection of the material, its preservation and use, in conformity with a criteria of information and agreement as much as possible “specific”, but that – where necessary and agreed upon by the donor – is not limited to immediate uses but extends also to future uses,

coherent with those for which the collection has been carried out.

Furthermore, the NBC deems appropriate the distinction made in the EBC Document, between “collections” of biological material and the respective storage of the data, and “tissue banks”; the first ones (collections) in accordance with criteria of particular specialization in the collection of material, the second ones (banks) with a wider aim of “service” offered to researchers, even external to the body that promotes and manages the bank.

Moreover, such distinction is also present in the NCBB document, which anticipates, within the tissue banks, different typologies in the collection as well as different aims and dimensions.

Both “models” for the collection and preservation of the material and/or of the data, should include explicit validation and procedures for the management of the different activities.

The NBC is in favour – consequently – of timely defining, in legal terms, the responsibility of the management, including the periodical publication of their activities, particularly with regards to the tissue banks and to the data open to researchers, according to principles of transparency and of monitoring of the effectiveness/efficiency of the administration.

The NBC, finally, deems appropriate the recommendation contained in both documents, so that every research project – even if conducted on biological material that does not involve the physicality of the person and has been made available for research by that same person (through a donation without lucrative purpose) according to well defined protocols, which guide the procedures of information/consensus – should be the object of an independent examination regarding both the scientific pertinence and the ethical acceptability.

4 – In concluding the analysis of the two documents; the NBC – agreeing with the appropriateness of elaborating norms directly applicable in the national legislation which would complete the outline of the protection of every human being, expected by the Convention on human rights and biomedicine (Oviedo 1997) and respective protocols – hopes that in a topic in rapid technical evolution, like the one regarding biobanks, we will proceed in establishing principles that will direct the behaviour of those who will manage them and of those who will use them, without however imposing regulations too rigid and detailed, which would be ignored or rapidly overcome by concrete needs. The NBC hopes for a preliminary census of the collections of biological material and of the tissue banks already existing today within state and private institutions in Italy and the possible founding of a National Register. The NBC stresses, furthermore, that the future outlook of biobanks – whether collections or tissue banks – is to grow in scale, from local to national, and from national to European, and these changes in scale might have an effect on ethical issues and on their elaboration, in the sense of directing them towards less individualism and a new sense of solidarity. More than in the rights of the individual, and within the respect of private life, biobanks could become tools in a new form of solidarity between groups and generations, based on a voluntary sharing of samples and information, for a common resource that must be available on a basis of rules of democratic participation.