



*Presidenza del Consiglio dei Ministri*

## **ITALIAN NATIONAL BIOETHICS COMMITTEE**

### **COLLECTION OF BIOLOGICAL SAMPLES FOR RESEARCH: INFORMED CONSENT**

(16th February 2009)

#### *abstract*

One of the most important problems for those working in the sector of scientific research with biological material, is to establish the limits and with which methods it is licit to preserve samples beyond the time necessary to achieve the aim for which the sample was collected, and if it is legitimate to also use samples for purposes that are different from those initially identified. In fact it often happens that, in scientific research institutes, collections of biological samples are preserved for future new studies. It is important to consider the diversity of the situations that occur, according to whether the samples are collected (or obtained) anonymously, or whether they are deposited anonymously (irreversibly breaking the link between the sample and the subject's data), or whether they are still identifiable (but always through protection codes).

The National Bioethics Committee and the National Committee for Biosafety, Biotechnologies and Life Sciences (hereinafter "the Committees") decided to predispose a specific guideline in order to contribute to the harmonisation process of the informed consent used by Italian biobanks instituted for research purposes, The Committees propose a model which allows people to express an attitude of solidarity towards other people, including future generations, by donating their biological samples.

Many studies on informed consent highlight the fact that people generally want to control whether their samples are used for research purposes, but also that the majority of them is happy to donate samples. The model of informed consent elaborated by the NBC and the NCBBLS respects this request, by informing donors about the future use of the biological material and the information derived from it, as well as by guaranteeing that the correct procedures are adopted in order to protect personal data. The proposed model for informed consent allows us to obtain the right balance between social interest and the protection of personal information. The proposed model for the consent to "donation" is not in contrast with the respect for the guidelines found in the Italian recommendations and in the Oviedo Convention, article 2 of which states: "The interest and benefit of man must prevail on the mere interest of society and science".

In particular, the Committees:

- 1) agree with the general statements of "Recommendation number 4- 2006" of the European Council;
- 2) stress that the donation of biological samples for research purposes, and for their preservation in biobanks or collections, cannot have any lucrative purposes;
- 3) believe that it is important to highlight what has already been expressed in the NBC's Opinion (2006) regarding the need for a census of biological material collections and of tissue banks, existing today within public and private structures, in order to create a National Register;
- 4) take into account the need to create also in Italy a number of biological biobanks suitable to regional programming, disciplined by clear regulations, which also include their coordination by a local Ethics Committee, to ensure respect for the ethical regulations in force for the protection of the interested party; the Committees confirm the need to diffuse the

knowledge on the scientific value of the collection of samples, in order to educate the general population towards civil solidarity;

5) the Committees recommend that donors are in any case given, in writing, information that is clear, true, precise and communicates in a way that does not lead to false hopes, aimed at allowing the exercise of free will with regards to the use of biological samples;

6) propose the adoption, in the necessary discipline of information and informed consent to the concession and use of biological samples and associated personal data (so-called "donation"), of different modules, proportionate to the foreseen use of samples and/or of data, agreed with the donor (so-called "wide consent, partially restricted, multi-optional, specific");

7) believe that a geneticist's presence is necessary in the local Ethics Committees, in case the research submitted to the local Ethics Committees must be carried out on preserved samples and is of genetic interest;

8) the Committees, with regards to the samples' legal discipline, suggest that the samples belong to the donor with the general formula of "concession for use", or are considered as "explicit and irreversible donation", with regards to the choice made in writing by the donor, confirming in any case the principle of gratuity and the prohibition of personal discrimination; in the cited hypothesis of the option called "concession for use", the possibility of the interested party checking on his/her own samples and information and the right to repeal the consent initially granted;

9) the Committees propose the drawing up of rules on the basis of which the local Ethics Committee can allow – on the researchers' motivated request – the use of preserved collections when such a use does not affect any of the interests of untraceable living donors, with regards to the protection of personal data, and when anonymity is ensured, in line with what has been recommended in the European Council;

10) finally, the Committees stress that, highlighting the social value of the research with biological samples, personal rights are not overlooked. In contrast, proposing a suitable system for the protection of individual rights through the informed consent, they promote at the same time personal interest and social interest.

The proposed model for informed consent is only applied to the collection of biological samples created for research purposes.