



Presidenza del Consiglio dei Ministri

NATIONAL BIOETHICS COMMITTEE

BIOBANKS AND RESEARCH ON HUMAN BIOLOGICAL MATERIAL

The NBC's opinion on a Council of Europe Recommendation and on a document of the National Committee for Biosafety and Biotechnologies

(9th of June 2006)

abstract

The opinion deals with the issue of the use of human biological material in research, the main subject of a draft recommendation (*Draft Recommendation on the research using human biological material*) at the Steering Committee on Bioethics of the Council of Europe (CDBI) – approved, with no modifications, by the Council of Ministers of the European Council on 16th March 2006 – and of a document of the National Committee for Biosafety and Biotechnologies (*Guidelines for the creation and certification of biobanks*). With regard to this, the NBC considers the *Draft* necessary insofar as the *Additional protocol to the Convention for the protection of human rights and the dignity of the human being with regard to the application of biology and medicine* (adopted by the Committee of Ministers on 30th June 2004 and published as STCE No. 195, 2005) establishes the principles and rules for the safeguard of persons and their rights, to be respected in the course of biomedical research, not taking the treatment of biological material into consideration.

In the two documents are clearly identified the principles which should control the correctness of the researchers' behaviour in the use of biological material and data that is recorded in the different typologies in which the conservation facility is classified, in the interest of the single donors of biological material and society, but also in the interest of the researchers themselves. Furthermore, the proposals presented in both documents can be compared: specific information and consent or dissent of the donor; gratuitousness of the donation; exclusion of direct remuneration to the donor; prohibition to interfere with the private life and to exert personal discrimination for the participation in research or the knowledge of data deriving from conserved samples; right to access and control their own personal details of the party concerned.

The NBC agrees with the recommendations, contained in both the documents, which concern the correct procedures for the removal of material, its conservation and utilisation, in accordance with a criterion of information and consensus which is as far as possible "specific", but which – where necessary and agreed upon by the donor – is not limited to immediate use but regards future uses that are coherent with those for which the sample was taken. The Committee, moreover, is in favour of defining the responsibilities of the running of tissue banks with legal regulations as soon as possible. NBC is in favour of the

distinction - made in the CDBI document (and also in that of the CNBB) – between “collections” of biological material and the relative storage of data and “tissue banks”. NBC agrees also to the recommendation (to be found in both the documents), so that every research project becomes the subject of an independent examination both from a point of view of its scientific pertinence and ethical acceptability.

Lastly, the NBC promotes the idea for a preliminary census to be taken of the collections of biological material and the tissue banks already existing in public and private healthcare facilities, and for a National Register to be set up, stressing that biobanks could open up new prospects for a common resource available on the basis of the rules of democratic participation.