

Presidenza del Consiglio dei Ministri



Abstract

PEDIATRIC BIOBANKS

11th of April 2014

In this Opinion, the Committee deals with pediatric biobanks, characterised by the collection of biological samples from minors and aimed at scientific research. The document, starting with the recognition of pediatric biobanks as a valuable resource for scientific research, addresses emergent bioethical issues. It upholds the general ethical principles involved in the donation of biological samples (accreditation of biobanks, free donation, protection of privacy), addresses some specific problems with regard to the vulnerability of minors (informed consent of the parents and the child on becoming an adult, the principle of subsidiarity, risk / benefit assessment, the right to know and not to know).

The Committee emphasises that the interests and welfare of the individuals whose biological material is used for research must always prevail over the sole interests of society or science - even more so if they are minors.

To this end, the Committee reiterates the need for normative regulation regarding this field that takes into account aspects of ethical importance: adequate and detailed information (scientific interest of research, protection of privacy, time and place of research) to the parents or the legal representative for purposes of consent which is appropriate whether it be restricted or partially restricted; listening to the will of the minor, in relation to progressive states of maturity, as well as informing the minor as regards the disposal of his biological material by parents and those in charge of biobanks; limitation of the parents' right not to know in cases where the information is trustworthy and useful for the health of the minor in preventive and therapeutic terms; the guarantee of the right to know or not to know, of the minor on becoming an adult and being capable of adequately expressing will.

The Committee also considers necessary the establishing of a supervisory body for the various phases of conservation and management of biological material and the presence of an ethics committee; it recommends appropriate training for the researchers and staff of the biobank; and calls for a census of pediatric biobanks and the possibility of establishing a National Registry.