



*Presidenza del Consiglio dei Ministri*

**NATIONAL BIOETHICS COMMITTEE**

**NBC OPINION ON THE EUROPEAN PROTOCOL  
ON BIOMEDICAL RESEARCH**

(19th November 1999)

*abstract*

The NBC examines the document “An alternative framework for the preliminary plan of the draft protocol on biomedical research” proposed by the secretariat of the steering committee on Bioethics (CDBI of the Council of Europe), as a contribution to the work of drafting the “Protocol on biomedical research” (in accordance with the Convention of Oviedo). The Committee makes the following observations:

- a) the need to apply to research carried out on human beings of third countries the safety guarantees stated in the protocol in their entirety (and not only the fundamental guarantees);
- b) the opposition to the continued use of placebo in comparative demonstrations of the superior efficacy of new drugs carried out on persons who require treatment with traditional drugs;
- c) the replacing of the term “minimal risk” with “integrity”, regarding the protection of the patient, and also for the purpose of requesting consent, this comprises both psychological as well as physical integrity;
- d) the need for the obligation to provide clear information, regarding research projects, the possible use of collected data and documentary material, for industrial purposes or any other purposes;
- e) the ambiguity of the wording regarding experimentation during pregnancy;
- f) the need to ensure that the objective of possible research conducted on dependent persons and those deprived of their liberty is strictly for their direct benefit.

The NBC appreciates the improvements made to the text, and generally, for any clarification in wording regarding the relationship between the researcher and the person subjected to research; however, it is critical of the conclusions, as there is no clear reference to the need to make explicit the aims of research from the two standpoints of scientific analysis and ethical evaluation. This confirms the fundamental role of Ethics Committees which should be entrusted with such tasks as the examination and approval of research projects, expressing binding decisions regarding their implementation.