



*Presidenza del Consiglio dei Ministri*

## **ITALIAN NATIONAL BIOETHICS COMMITTEE**

### **GUIDELINES FOR ETHICS COMMITTEES IN ITALY**

(13th July 2001)

#### *abstract*

The opinion suggests a theoretical and systematic reflection on the nature and significance of the local and regional ethics committees, which in general organise and supply healthcare, or carry out research activities or clinical or pharmacological trials on human beings. The document highlights some problematic issues about the existence of ethics committees, like the risk of bureaucratisation; the difficulties in punctually carrying out their broad range of duties; the uncertainties about the relationship with the institutions of reference and the legal ambiguity in the nature of such relationships; the value and efficacy of the opinion expressed by the ethics committees and the associated issue of their members' responsibility. We analyse also the distinction between the role of Institutional Review Board for clinical trials and the other roles that an ethics committee can have in healthcare structures and in research centres. Finally, in the perspective of an eventual reorganisation of the matter, the opinion invites to take into account the European Directive 2001/20, concerning bringing together the legislations of the European States in relation to the application of the regulations for clinical good practice when carrying out pharmacological studies.

The NBC hopes that the legislator, when dealing with the by now considerable amount of national and international regulations regarding this issue, could offer an organic and coherent legal foundation for the activity of ethics committees. We recommend also to define the distinction between the different areas of work of the ethics committee which anticipate, on the one hand, the evaluation and monitoring of pharmacological and biomedical research, to be carried out by approving compulsory and binding opinions; on the other hand, the issues concerning clinical practice, the supply of healthcare and formative intervention, to be carried out through a non-compulsory and non-binding ethical consultancy. The ethics commissions for clinical trials also have the task of carrying out a permanent assessment of the studies practiced in research centres, guaranteeing that the subjects are informed of the changes made to the protocols, of the new facts that affect their safety and of every significant increase in the level of risk. The legal intervention should also define the role of ethics committees in approving the protocols relative to clinical studies on animals, to guarantee that the regulations in force and the norms for the protection of animal welfare are followed.

It is necessary to clearly define the responsibilities of the members of ethics committees for clinical trials, with the activation, by the structures of reference, of a suitable insurance cover for their roles. Ethics committees must also be provided with an appropriate scientific secretariat and a technical-administrative secretariat, with functional autonomy and made up of qualified personnel. The independence of the members of the ethics committee from the institution they belong to is considered a value to protect. Finally, we hope, in the respect of the privacy of the people involved, a transparent management of the activities of the committees and the protection of their autonomy from external pressures. Regional and national committees have no hierarchically higher power and cannot limit or bind the activity of local ethics committees.