

Presidenza del Consiglio dei Ministri



Abstract

**THE ROLE OF “BIOETHICS EXPERTS” IN ETHICS
COMMITTEES**

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The opinion examines the problem of how to define the essential competencies of those who work as experts in the field of bioethics. The problem had already been highlighted by the Italian Committee for Bioethics (ICB) both in the field of training (*Bioethics and training in the healthcare system*, 7 September 1991) and in that of Ethics Committees (*Guidelines for Ethics Committees in Italy*, 13 November 2001; *Clinical Ethics Committees*, 31 March 2017).

The current Opinion focuses attention on the definition of essential competencies for the "bioethics expert", who is among the members of the Committees according to the Decree of the Ministry of Health "*Criteria for the composition and functioning of ethics committees*" of 8 February 2013.

From a reconstruction of the Italian debate on the subject, from the two editions of the American Report *Core Competencies for Health Care Ethics Consultation* (1998 and 2011) and the English document *Core competencies for clinical ethics committees* (2010), two basic problems emerge: the focus of attention on the bioethicist who works as a consultant in clinical ethics; the tension between the need to define competencies, to give reliability to this figure, and the other, its opposite, not to define them too rigidly, undermining the complexity of bioethics, inherent in its interdisciplinary status.

The Opinion revolves around these two cruxes of the problem. First of all, it highlights how identifying the bioethicist as clinical ethics consultant overshadows the other roles that the bioethicist covers (in the Ethics committees for experimentation on human subjects and in other areas of bioethics). The ICB, on the other hand, believes it no longer possible to postpone the proposal for a broad and in-depth debate on the competencies of those who work in the various fields of bioethics, also hoping for the involvement of the competent Ministries, Universities, Research Bodies, Scientific Societies and Associations involved in bioethics.

On the other hand, bearing in mind the complexity of the problem, the ICB believes that the time is not yet ripe just now to indicate a formalization of the various training courses to acquire the essential competencies of the "bioethics expert".

In the current situation, given the proximity of regulatory adaptation on Ethics Committees compliant with the European Regulation of 2014, the ICB recognises the need to focus attention on the current figure of the "bioethics expert" who works in these Committees.

Undertaking to return to the issue in a more extensive Opinion, the result of broad consultation, the ICB proposes Recommendations that can be of support to the Institutions that appoint "bioethics experts" to Ethics Committees. These experts must have an interdisciplinary education, i.e., possess, in addition to expertise in their own subject and/or professional field, basic skills both in life sciences and in health care as well as in the ethical and legal fields, attested by at least two of the following experiences:

- post-graduate education in the field of bioethics at institutions accredited by the Ministry (doctorates, masters, specialization courses);
- teaching and/or research activity in the field of bioethics, carried out for at least three years at university and/or in the field of healthcare;
- publications, in the last ten years, in the field of bioethics, in refereed scientific journals or volumes with ISBN and *peer review*;
- have already taken part, at least for three years, in Ethics Committees set up at national, regional, territorial level or at Research organizations/Institutes.

- Lastly, it is recommended that bioethics experts appointed to Ethics Committees for experimentation have an adequate knowledge of the methodology related to clinical and preclinical trials, and that the experts appointed to Clinical Ethics Committees have knowledge and skills in the field of clinical ethics consultation.