

*Presidenza del Consiglio dei Ministri*



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

**28 May 2021**

## Presentation

The opinion examines the problem of how to define the essential competencies of those who work in the field of bioethics as experts. 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 July 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 healthcare 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 health care;
- 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 the bioethics expert appointed to the Ethics Committees for experimentation has an adequate knowledge of the methodology related to clinical and preclinical trials, and that the expert appointed to Clinical Ethics Committees has knowledge and skills in the field of clinical ethics consultation.

The Opinion is the result of the working group coordinated by Profs. Marianna Gensabella and Lucio Romano and formed by Profs. Salvatore Amato; Luisella Battaglia; Francesco D'Agostino; Maria Pia Garavaglia; Laura Palazzani; Carlo Petrini; Maurizio Mori; Assuntina Morresi.

With auditions by Profs. Silvia Camporesi, Associate Professor at King's College in London (25/03/2021); Paolo Cattorini, Full Professor of Bioethics at the Department of Biotechnology and Life Sciences of the University of Insubria in Varese (25/03/2021); Mario Picozzi, Associate Professor of Forensic Medicine at the University of Insubria in Varese (10/12/2020); Antonio Spagnolo, Full Professor of Bioethics and Director of the Institute of Bioethics and Medical Humanities of the Faculty of Medicine and Surgery of the "Catholic University of the Sacred Heart" in Rome (24/01/2019).

The text was written by Profs. Marianna Gensabella and Lucio Romano, with written contributions by Profs. Luisella Battaglia, Cinzia Caporale, Laura Palazzani and Carlo Petrini, drawing on the observations made by the members of the working group and the broad and active participation in debate of the entire ICB.

The opinion was unanimously approved by those present, Profs: Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Lorenzo d'Avack, Mario De Curtis, Riccardo Di Segni, Gianpaolo Donzelli, Silvio Garattini, Mariapia Garavaglia, Marianna Gensabella, Assunta Morresi, Laura Palazzani, Tamar Pitch, Lucio Romano, Monica Toraldo di Francia.

Prof. Francesco D'Agostino, absent from the session, subsequently abstained.

Profs: Bruno Dallapiccola, Massimo Sargiacomo, absent from the session, subsequently assented.

Profs: Carlo Caltagirone, Antonio Da Re, Maurizio Mori, Luca Savarino, Lucetta Scaraffia, Grazia Zuffa, absent at the time of voting, subsequently assented.

Despite their not having the right to vote assent was given by: Dr. Maurizio Benato, the delegate for the President of the National Federation of MDs and Dentists Colleges; Dr. Amedeo Cesta, the delegate for the President of the National Research Council; Prof. Carlo Petrini, the delegate for the President of the National Institute of Health. Prof. Paola Di Giulio, the delegate for the President of the Superior Health Council.

Dr. Carla Bernasconi, the delegate for the President of the National Federation of the Orders of Italian Veterinarians, absent from the session, subsequently assented.

Prof. Lorenzo d'Avack  
President of the ICB

## Introduction

The problem of defining the competencies of scholars that are "bioethics experts" does not pertain only to the present day and does not concern only our country. It is closely connected to the interdisciplinary nature of bioethics: for those who study, teach, work in various ways within this context, do the skills acquired within their profession and dialogue with other experts suffice? Or is there also the need for them, in addition to their own expertise, to acquire other competencies, that are transversal to the various disciplines involved, and, precisely for this reason, remain peculiar to bioethics?

The ICB posed the problem already in its first year of activity, in the Opinion on *Bioethics and training in the healthcare system* of 7 September 1991, comprehending the evident connection with bioethics training for healthcare professionals.

Before the conclusion of the document, there is a statement that represents a shared presentation of the question: "In the various training activities, the educational contents can be appropriately treated by a teaching team with different skills, precisely due to the interdisciplinary nature of the subject".<sup>1</sup>

So, the question was: who should teach bioethics? Some proposed individual people, for others a working group was preferable, in analogy with the advice of the Bioethics Committee. For example, an ethicist, a pharmacologist, a clinician, a pedagogist, a statistician, etc. could be required for teaching ethics in pharmacology.

However, the text also identified a third path, indicating its advantages: "But if coherent didactic continuity is considered necessary in the treatment of bioethical issues, there is a need for the specific figure of a bioethics educator, for whom a corresponding formative itinerary must be planned and structured (...). These educators will obviously also be able to act as coordinators of the aforementioned mixed didactic teams. To this end it is believed that the aim is to prepare a type of educator with dual medical-scientific and philosophical competences. This means that he/she must have on the one hand qualified theoretical preparation in the ethical field and on the other theoretical-practical knowledge in the bio-medical field, as also documented by study and research activities".<sup>2</sup>

The opinion also mentions the skills required: it is necessary to substantiate knowledge of how to work in a pharmacology laboratory, the stages of experimentation of a drug, but also knowledge of different ethical positions, otherwise the person will be a good pharmacologist or philosopher, but will not be able to teach bioethics.

The definition of competencies does not only concern those involved in bioethics training but also those working within Ethics Committees (EC).<sup>3</sup>

In its opinion *Guidelines for ethics committees in Italy*, of 13 July 2001, the ICB tackles the question in a decidedly critical way. Faced with a historical moment in which the presence of local and regional ECs is already now

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<sup>1</sup> Italian Committee for Bioethics (ICB), *Bioethics and training in the healthcare system*, 7 September 1991, p. 24.

<sup>2</sup> *Ibidem*.

<sup>3</sup> The Italian Committee for Bioethics (ICB) deems the definition "Committees of Ethics" more appropriate than "Ethics Committees". However, the Opinion makes use of "Ethics Committees" to encourage more immediate reference to the provisions of the Decree of the Ministry of Health of 8 February 2013 ("Criteria for the composition and functioning of ethics committees").

"branched and consolidated", and in which there is already a vast literature on the subject, the question of the competencies of the components still leaves many margins of doubt: "Even in the international debate, the poor level of preparation of the members of ECs is often noted, especially the non-medical ones, which is often the result of self-training processes entrusted to the good will of the subjects, and is in any case difficult to ascertain (...). In Italy the problem is even more serious, since training in bioethics has been, certainly up to a few years ago, but perhaps still is now, very underpowered, both at university level (...) and at non-university level. Moreover, the regulations in force do not provide, tools to ascertain the competence of the members called on to be part of the ECs".<sup>4</sup>

According to the ICB, these critical issues of no small importance are partly justifiable, given the situation of the Ethics Committees, still in transition from a phase of spontaneous birth, characterized by commitment on a voluntary basis, to an institutional phase. And yet it already appears necessary to bring order to the matter and reduce, as far as possible, undesirable spontaneous aspects. All because of a fundamental reason of an ethical nature: "The interlocutors of the EC have the right to expect their requests to be examined and evaluated competently and efficiently by experts".<sup>5</sup> It is therefore necessary to "ensure" the rights of recipients, "independently of variables such as social context or the good will of EC members in acquiring appropriate skills".<sup>6</sup>

But how can we obtain this assurance, this "public guarantee"? The Opinion poses the problem but does not solve it.

The problem of the bioethicist's expertise is cited again in the Opinion *Clinical Ethics Committees*, of 31 March 2017. In which it is proposed that the figure of a single ethics consultant should be replaced by "members" of the Committee delegated to carry out consultancy activities at the patient's bedside. These delegates should have the same competencies as those required of "single *ethics consultants*, bioethicists experts in clinical ethics"<sup>7</sup>, who in some countries have designated training courses and their own codes of ethics. Not so in Italy.

In a side note, the ICB notes that "The figure of the bioethics expert leaves room for considerable ambiguity, it having never been defined professionally or with regard to the training path. This *standard setting* process is extremely urgent also in relation to the profound revision of the sector".<sup>8</sup>

The problem is by no means a minor one and extends from Clinical Ethics Committees, at the centre of the aforementioned opinion, to the Committees for Experimentation. In both Committees, whose role the ICB has repeatedly drawn attention to in its Opinions<sup>9</sup>, the bioethicist is a professional figure that is envisaged by legislation, but, despite this, it has not been well defined.

### **Essential Competencies for the "bioethics expert"**

The Decree of the Ministry of Health of 8 February 2013, "*Criteria for the composition and functioning of Ethics Committees*", lays down that among the

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<sup>4</sup> ICB, *Guidelines for ethics committees in Italy*, 13 July 2001, pp. 31-32.

<sup>5</sup> *Ibidem*.

<sup>6</sup> *Ivi*, pp. 32-33.

<sup>7</sup> See ICB, *Clinical Ethics Committees*, 31 March 2017, p. 15.

<sup>8</sup> *Ivi*, p.8, note 9.

<sup>9</sup> In addition to the two opinions cited, see: ICB, *Ethics Committees in Italy: recent issues*, 18 April 1997 and ICB *Ethics Committees*, 27 February 1992. There are also several observations in the opinions of the ICB on the role of the ethics committees on delicate issues of bioethics.

members there must be the professional figure of the "bioethics expert".<sup>10</sup> This composition is not currently under discussion, despite the changes envisaged for the adaptation of the Ethics Committees to the European Regulation, as reflected in the still unsolved question of who can be recognized and therefore appointed within them as an "expert in bioethics."

This is a particularly complex problem that is encompassed in bioethics: its very epistemological status, with a clear interdisciplinary and pluralist vocation, poses many difficulties in defining skills, knowledge and therefore competencies. And yet, fifty years after its spread, years spent not only in theoretical studies, but also engaged in concrete work/deliberation, can we still wait for the time to be ripe for a definition of the "bioethics expert"?<sup>11</sup>

The problem becomes particularly evident when the bioethicist performs his/her functions within Ethics Committees, participating in Opinions that have a practical impact on trials and/or clinical cases.

The debate on the definition of the figure of the bioethicist, has, in fact, been around since the end of the 90's in the field of clinical bioethics, focusing in particular on the bioethicist who works as a consultant for clinical ethics.

In Italy the issue was already raised in 2001, with the conference "Towards professionalization of the bioethicist. Theoretical analysis and practical implications", aimed at those who worked in Ethics Committees and the health sector in general.<sup>12</sup> These reflections started out from American experiences, in particular from the Report *Core Competencies for Health Care Ethics Consultation* (May 5, 1998)<sup>13</sup>, to test the possibility of carrying out clinical ethics consultancy in Italy and what essential skills were required. We note how this need, still present, requires the definition of a process of recognition.

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<sup>10</sup> Ministry of Health, Decree of 8 February 2013, *Criteria for the composition and functioning of ethics committees* (13A03474) (GU General Series No. 96 of 24-04-2013). The Decree in art. 1, after framing the Committees as Ethics Committees for clinical trials, specifies that the Ethics Committees can also carry out consultative functions for ethical issues connected with scientific and welfare activities and training initiatives. A decree of the Ministry of Health on the 40 territorial ethics committees that have jurisdiction over clinical trials, as defined by Regulation no. 536 of 2018.

<sup>11</sup> It has been recognised in literature that the first use of the word and outline of the concept of bioethics goes back to 1927, with the text of the German Protestant philosopher and pastor Fritz Jahr (*Bio-Ethik. Eine Umschau über die ethischen Beziehungen des Menschen zu Tier und Pflanze*, in "Kosmos. Handweiser für Naturfreunde", 24 (1), 1927). His ideas, however, failed to take hold in the cultural and academic context of that period of time in Germany. We have to wait until the 1970s for bioethics to establish itself in the United States of America, through what has been defined by W.T. Reich a "bilocated genesis": the introduction of the term into the scientific world by the biochemist V.R. Potter (*Bioethics. The Science of Survival*, in "Perspectives in Biology and Medicine", vol.14, n.1, Autumn 1970, 127 -153; *Bioethics. Bridge to the Future* (1971), tr. It. By R. Ricciardi: *Bioetica: un ponte verso il futuro*, Sicania, Messina 2000); the academic structuring of the discipline by the gynecologist André Hellegers at Georgetown University of Washington (see W.T. REICH, *Il termine 'Bioetica'. Nascita, provenienza, forza*, in G. RUSSO (ed.), *Storia della bioetica*, Armando, Roma 1995, pp. 157-206). On the rediscovery of Fritz Jahr see: I. RINČIĆ, T. BUTERIN, R. DORIČIĆ et Al, *The right to Exit the Footnote: a Story of Rediscovery and Revival of Fritz Jahr's Bioethics (with Special Regard to Italy)*, in "Medicina e Morale", 1/2021, January/March, 11-24.

<sup>12</sup> The proceedings of the conference are published in the aforementioned volume M. PICOZZI, M. TAVANI, P. CATTORINI, *Verso una professionalizzazione del bioeticista*.

<sup>13</sup> The Report was prepared by a Task Force on Standards for Bioethics Consultation, promoted by the Society for Health and Human Values (SHHV) and by the Society for Bioethics Consultation (SBC). The Italian translation by M. PICOZZI is appended to the text referenced above (pp. 300-342).

The aforementioned Report, starting from the conviction that clinical ethics consultants should possess specific competencies, undertook to define them, distinguishing between essential skills (ethical assessment skills and the ability to conduct the consultancy process and manage interpersonal relationships) and essential knowledge, distinguishing internally between: ethical knowledge (moral reasoning and ethical theories; common issues and concepts in bioethics) medical knowledge (the healthcare system; the clinical context; local health organisations, the fundamental strategies of local health organisations) anthropological-cultural knowledge (the cultures and faiths of patients and health personnel); deontological knowledge (ethical codes, deontological codes and guidelines for accreditations) and legal knowledge (the main laws concerning health matters).

The Report also recommended that the health care institution in which the consultant carries out his work should define training paths and work experience before appointment, as well as continuous education.

In conclusion, the writers of the Report, however, considered it premature to define, according to specific criteria, accredited training courses or ways to certify the acquisition of skills. This could jeopardize the interdisciplinarity and pluralism of bioethics, opening up to bureaucratic drift. In addition, it was believed that the time had not yet come to open to a certain degree of professionalism. The Report was therefore proposed as a "voluntary guideline" and as a stimulus for further debate on the matter.<sup>14</sup>

The same basic orientation, albeit with several steps forward, was found, after years of intense debate on the subject in the United States,<sup>15</sup> in the second edition of the *Core Competencies for Healthcare Ethics Consultation*, published in 2011 by the American Society for Bioethics and Humanities (ASBH).<sup>16</sup> Here clinical ethics counselling was considered an "emerging professional practice", and the first edition of the Report was regarded as a milestone in the path towards professionalization.

While considering the latter as a goal still to be achieved, a further step was taken, both by deepening the indications relating to essential skills and knowledge, and by referring the training courses to the ASBH *Education Guide* and dedicating a space to ethical obligations and the indications for a code of ethics.

However, despite acknowledging the growing demand for guarantees, even this second edition, failed to establish standard training criteria. Given the difficulty both in finding valid tools to demonstrate skills and in objectively determining required knowledge, the same clinical ethics consultants were encouraged to adopt the criteria described in the document. Even the second version also remained, therefore, at the level of guidelines, to be followed on a voluntary basis.<sup>17</sup>

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<sup>14</sup> In fact, it is believed that "the certification of individuals or groups for ethical counselling is, at least for now, premature" and that the Report cannot be used "to establish national legal standards with regard to the necessary skills for ethical counselling" (see: *ivi*, p. 340).

<sup>15</sup> In 2004 A. R. Derse raises the question of whether bioethics is a profession, considering it important for the future of bioethics (A. R. DERSE, *ASBH Presidential Forum: The Seven-Year Itch*, "Journal of Bioethics", 2005, 5 (5), 1- 5). On the subject see also the articles dedicated by "The American Journal of Bioethics" to the pros and cons of a professionalization of the bioethicist.

<sup>16</sup> See the Italian translation of the Report found in the text by R. PEGORARO, M. PICOZZI, A. G. SPAGNOLO, *La consulenza di etica clinica in Italia*, Piccin, Padova 2016, pp. 41-126.

<sup>17</sup> "Having a mechanism by which these individuals can voluntarily demonstrate their qualifications to perform a CEAS would benefit both experienced clinical ethics consultants, and the patients

Moving along these same lines of providing recommendations and not norms for professionalization and engaged in the same context, that of Committees for clinical ethics, is the *Clinical Ethics Network* (UKCEN) in the United Kingdom. Sensing the need to outline training prerequisites and the definition of key competencies of its members, UKCEN launched a broad internal consultation, which led in 2010 to the drafting of the document *Core competencies for clinical ethics committees*.<sup>18</sup> The document, takes up the indications present in the first edition of the American Report, and adapts them to the British context, it delineates key competencies for those working in the field of clinical ethics and provides a series of recommendations as regards training.

Coming back to the situation in Italy, we see that in our country the problem of the competencies of "bioethics experts" has been predominantly identified with that of the qualifications necessary for clinical ethics consultants.<sup>19</sup>

However, this identification appears reductive since it leaves out the other roles that the bioethicist can take on. To remain within the scope of clinical bioethics, just think of those who carry out their activities within the Ethics committees for experimentation. But also, other areas, such as animal, environmental and social bioethics - the current pandemic emergency has drawn attention to this intertwining – and further emphasises the need to define the competencies of the "bioethics expert".

The debate on the professional figure of the bioethicist/clinical ethics consultant can therefore act as a "driver", highlighting needs and difficulties, but it must be rethought in a broader sense, adapting, on a case-by-case basis, the demand for competencies to the specific areas in which the bioethics expert is operating. And yet, there already emerges from that debate, the tension between a definition of this figure that gives guarantees and the fear that this definition will negatively affect interdisciplinarity and pluralism, both fundamental characteristics of bioethics. It is feared that defining these competencies, establishing criteria for the training in order to acquire them and other criteria by which to ascertain this, will reduce the richness, movement, the very life of bioethics, thought of not as being "a knowledge", but as a "dialogue between knowledge", not as "a specific ethical vision", but as a "dialogue between different ethical visions".

What bioethics will the "bioethics expert" trained according to defined criteria and working with proven competencies practice?

It is the same question which has created the debate on "education in bioethics". Even the answer cannot but be the same one: bioethics that is not only interdisciplinary, but also pluralist, which, in line with the main international documents, is open to dialogue between different ethical visions and, at the same time, animated by the tension towards shared ethical principles - such as dignity,

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and healthcare professionals they are called upon to help" (*ivi*, p. 119). A third edition of the Report is already planned, as can be seen from the American Society for Bioethics and Humanities website.

<sup>18</sup> See V. LARCHER, A. M. SLOWTHER, A. R. WATSON, *Core Competencies for Clinical Ethics Committees*, "Clin Med" (Lond), 2010 Feb., 10 (1): 30–33.

<sup>19</sup> In addition to the two collective texts cited, the 2015/16 issue of "Medicina e Morale" dedicated to the topic *Verso una professionalizzazione del bioeticista clinico* and the debate on the *Trento Document* and on how the clinical ethics consultant can be considered "a new professional figure" (see M. ZONZA, P. REFOLO, *Documento di Trento. La consulenza etica in ambito sanitario in Italia*, in "Medicina e Morale" 2014, 1, 121-127). The Trento document has been the object of no lack of decisively critical voices (See M. MORI, *La consulenza clinica "all'italiana". Una nota critica sul Documento di Trento*, in "Bioetica", XXII, 2014, 3/4, 463-470).

integrity, autonomy, responsibility, equality, justice, equity, solidarity, respect for diversity, vulnerability – and is, therefore, neither dogmatic in imposing values nor neutral in describing them.<sup>20</sup>

The same competencies that the bioethicist must acquire move in the direction of interdisciplinarity and pluralism, requiring, in addition to in-depth expertise in one's own discipline and/or professional field, a basic understanding of the various fields of knowledge involved and the ability to combine them, as well as the knowledge of different ethical theories and the ability to bring them into dialogue.

So many years after its inception, bioethics is still grappling today with the underlying problem of its epistemological status and the definition of the "bioethics expert" poses a challenging test. An undertaking that can not be escaped given the intertwining of theory and practice that characterizes it and which constitutes not only its complexity, but also its authentic richness.<sup>21</sup>

We are therefore faced with the difficulty of reconciling two opposing needs: on the one hand, the need to define competencies, to give reliability to those who work in the field of bioethics, and on the other the need not to define them too rigidly within defined criteria so as not to reduce the complexity of knowledge.

The two American Reports, which inspired both the English Report and the debate in Italy, identify essential expertise for ethical consultants, which are presented in the form of "recommendations". In this perspective, it is possible to envisage documentation produced by the bioethicists themselves (*curriculum or portfolio*) as certification of training and/or work experiences in the field of bioethics<sup>22</sup>. This can be the first step.

The ICB, after an extensive internal debate, having acknowledged the complexity of the problem, believes that, at the present stage, the time is not yet ripe to think about a formalization, however desirable it may be, of the various training courses existing today.

The current emergence of an ever-wider demand for bioethics, whose scope ranges from the medical to the animal and environmental fields, from computer science to robotic engineering and from artificial intelligence to social and human sciences, however, brings to no longer being able to defer the search for a clearer definition of the competencies of the "bioethics expert": competencies with a common basis but which are also differentiated according to the field in which one operates.

The Committee believes that the time has come to propose a broad and in-depth dialogue on the issue, involving the competent Ministries (MIUR, Ministry of Health, Ministry of Ecological Transition)<sup>23</sup>, Universities, Research Bodies,

Scientific Societies and Associations involved with bioethics.<sup>24</sup>

The ICB therefore proposes to work, subsequently, on a more extensive Opinion which is also the result of a broad round of consultation and which

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<sup>20</sup> See ICB, *Bioethics and education in schools*, 16 July 2010, p. 31.

<sup>21</sup> See S. CAMPORESI, G. CAVALIERE, *Can Bioethics be an Honest Way of Making a Living? A Reflection on Normativity, Governance and Expertise*, "J. Med. Ethics", 2020, 0, 1-5.

<sup>22</sup> M. PICOZZI, A. GASPARETTO, F. NICOLI, R. PEGORARO *Certification and evaluation of the clinical ethics consultant. A proposal for Italy*, in "Ann Ist. Super Sanità", 2018, vol.54. No.1, 61-66.

<sup>23</sup> To this end, it is desirable, where there is the possibility of joint actions, the signing of Protocols of Agreement with the Ministries.

<sup>24</sup> This is the methodology used to elaborate the first and second editions of the aforementioned American Report, as well as the English Report. A methodology that the ICB has already followed in drawing up the 2001 Opinion on Ethics Committees, already cited.

indicates: the essential competencies, the training criteria to acquire them and the methods by which to ascertain this.

To this end, it is necessary to take both a retrospective look, which puts order into the existing one, and a prospective look, which looks at what is to be done in the context of the training of the "bioethics expert".

In the current situation, given the proximity of compliant regulatory adaptation on Ethics Committees,<sup>25</sup> the ICB recognizes the need to focus attention on the figure of the "bioethics expert" working in these Committees. In this context, the ICB - after extensive debate and undertaking to return to the issue in an Opinion which identifies in a more precise manner essential skills, knowledge and competencies - proposes Recommendations that can provide support to Institutions in defining the minimum requirements necessary for appointing a "bioethics expert" to Ethics Committees.

## Recommendations

Bioethics experts must have an interdisciplinary education, as indicated by the very term "bioethics". In addition to expertise in their own discipline and/or profession, they must possess basic skills both in life sciences and healthcare, 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 3 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 in 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 concerning clinical and preclinical trials and that experts appointed to Clinical Ethics Committees have knowledge and skills in the field of clinical ethics consultation.

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<sup>25</sup> Adjustment made necessary for the implementation of Regulation (EU) no. 536/2014 of the European Parliament and of the Council, of 16 April 2014, "On clinical trials of medicinal products for human use" (Official Gazette and 27 May 2014, no. L158); see also Law no. 3 of 11 January 2018 (Official Gazette of 31 January 2018, no. 25).