



ANNUAL REPORT OF ACTIVITIES

2013

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COMPOSITION OF THE SPANISH BIOETHICS COMMITTEE (SBC)

Title VII of the Biomedical Research Act 14/2007 of 3 July (*Ley de Investigación Biomédica*) sets up the Spanish Bioethics Committee as *an independent, collegiate, consultative body, concerned with matters relating to the ethical and social implications of Biomedicine and Health Sciences* (Article 77).

MEMBERS



Mª Teresa López López

Doctor of Economic Sciences, she directs the Extraordinary Chair of Family Policy at the University Complutense-AFA. She is also a professor of Applied Economics (Public Finance) at the Faculty of Economics and Business Administration of the UCM, of which she was Dean from 1998 to 2003. She has taught in the Master of Bioethics at the University Rey Juan Carlos and she is an expert in social policy and family economy and social security. As a result of her research she has published numerous books and articles. She has been Vice President of the Family Action Foundation. In 2004 she was awarded the Medal of Honor from the Complutense University of Madrid.

President



Federico De Montalvo Jääskeläinen

Doctor in Law and Associate Professor of Constitutional Law at the Faculty of Law (iCade) of the Universidad Pontificia Comillas. He also has taught at the Universidad Complutense, Carlos III and Rey Juan Carlos of whose Faculty of Health Sciences he is honorary Professor of Professional Ethics and health legislation. He is a member of the Ethics Committee of the Hospital Doce de Octubre CEIC-R from the Community of Madrid. He is a member of the Law Association of Health and the Board of Directors of the Iberoamerican Society of Medical Law. He is a member of the Santander Chair in Law and Minors of the Universidad Pontificia Comillas. He has published several books and articles on Constitutional Law and Medical Law and Biolaw. He participates as a teacher in several Masters courses and lectures on medical law and Biolaw.

Vice-president



Carlos Alonso Bedate

He holds degrees in Philosophy from the University of Alcalá de Henares, and in Theology and Biology from the University of Granada, as well as a Master's Degree in Genetics from the University of California (USA). He is a doctor of Sciences from the University of Nijmegen and Granada. Professor of Research at the Molecular Biology Centre of the Spanish Council for Scientific Research (Consejo Superior de Investigaciones Científicas - CSIC) at the Autonomous University of Madrid. He has participated in 14 national call projects in three EU projects, in 21 anthologies, directed 22 doctoral theses and 200 scientific papers indexed. Monitor in the International malaria vaccine trial (Tanzania). Ethical Adviser for EU projects. Vocal CDBI (European Council).



Vicente Bellver Capella

Doctor in Law and Professor of Law Philosophy and Political Philosophy at the University of Valencia. He was Deputy Judge of the Provincial Court of Valencia, Director of the International University Menéndez Pelayo (UIMP) Centre in Valencia, Director General of Scientific Policy of the Generalitat Valenciana and member of the Steering Committee on Bioethics of the Council of Europe. He is currently a member of the Advisory Council on Bioethics Valencia.



Fidel Cadena Serrano

Prosecutor of the Criminal Division II of the Supreme Court. Member of the Committee on Reform of the Law on Criminal Procedure of the State prosecution service in 2010. Member for two years of the examining board for the joining in the judiciary career of renowned lawyers. Deputy vocal of the National Commission on Regulation of DNA in forensic investigation. Distinguished Cross to the legal merit of St. Raymond of Peñafort, first and second class. He has been Professor of Civil Law and Criminal Law in the National University of Distance Education (UNED) and Associate Professor of Criminal Law at the Department of Criminal Law at Zaragoza. Author of numerous publications on Criminal Law.



Manuel de los Reyes López

He is Doctor of Medicine and Master of Bioethics at the Complutense University of Madrid. Specialist in Cardiology. Founding member and first president of the Basic and Clinical Bioethics Association (1994-2005) and Honorary Member thereof. Member of the Advisory Council of the Department of Bioethics at the University Pontificia Comillas and professor of the Master in Health Bioethics. He coordinates the Bioethics Commission of the San Jose Institute, Madrid (Hospitaller Order of SJD) Foundation. Coordinator of the document 'Ethical Framework of the Spanish Society of Cardiology' (2006). Co-editor of several publications, highlighting the treaty 'Bioethics and Paediatrics. Projects fulfilling lives' (2010).



Pablo Ignacio Fernández Muñiz

He is a physician, specializing in General and Digestive Surgery, exercising today as Area Medical Specialist in San Agustín Hospital (Avilés). Master of Breast Pathology at the Autonomous University of Madrid. Member of the Spanish Association of Surgeons. Teaching at the University of Oviedo. Masters in Bioethics from the University of the Basque Country, Zaragoza, La Laguna, Las Palmas de Gran Canaria and Rovira i Virgili. He was president of the Ethics Committee for Health Care Area Health Service of the Principality of Asturias. Member of the Advisory Committee on Bioethics of the Principality of Asturias.



Nicolás Jouve de la Barreda

Ph.D. in Biological Sciences from the Complutense University of Madrid. Professor of Genetics at the University of Alcalá. He was President of the Spanish Society of Genetics (1990-1994). He has over 200 scientific publications, most of them in international journals in his specialty. He has directed 20 doctoral theses. He is the author of several books on genetics and bioethics. He was responsible for the science module in the Bioethics course from the UNESCO Chair directed by Dr. Dolores M. Vila-Coro until 2010.



Natalia López Moratalla

Dr. in Biology. Professor of Biochemistry and Molecular Biology. President of the Spanish Association of Bioethics and Medical Ethics. Author of nearly a hundred international scientific publications in areas of biomedicine. Author of a hundred publications and 10 books on Bioethics, Theoretical Biology and Scientific Communication. Director of the projects "Scientific Advances of Ethics and Social Relevance" (ACRE) and "The secrets of your brain."



César Nombela Cano

He graduated in Pharmacy and Chemistry and a PhD from the University of Salamanca. Professor of Microbiology, Faculty of Pharmacy, Complutense University of Madrid and director of the Special Chair in Genomics and Proteomics, he is currently president of the International University Menéndez Pelayo. He has been president of the Superior Council for Scientific Research (1996-2000) and the Ethics Advisory Committee for Scientific and Technological Research for the FECYT of the Ministry of Science and Technology (2002-2005). From 1998 to 2004 he was a member of the International Bioethics Committee of UNESCO.



Carlos Romeo Casabona

Professor of Criminal Law (UPV / EHU), Director of the Department of Law and Human Genome, University of Deusto and UPV-EHU. Doctor in Law, Diploma in Criminology, Doctor of Medicine, and six honorary doctorates. Director of the Journal of Law and Human Genome and the Encyclopaedia of Biolaw and Bioethics. He has given lectures and courses in 38 countries. He is or has been a member of the Bioethics Committee of the Council of Europe, the Ethics Committee of HUGO, the Advisory Board of the European Research Area in the EC and CNRHA, chairman of the Research Ethics Committee of the Basque Country. Six six-year of research in the CNEAI.



Jose Miguel Serrano Ruiz-Calderón

Doctor in Law. Professor of Philosophy of Law at the Complutense University of Madrid. Researcher at the Institute of Human Rights at the UCM. Member of the Board of the Association of Bioethics of the Community of Madrid. He has published numerous books and journal articles on Bioethics, Human Rights, Professional Ethics and Business Ethics. He has especially worked on issues related to care at the end of life, euthanasia and status of the embryo.

ACTIVITIES UNDERTAKEN

PRINCIPAL RESOLUTIONS PASSED BY THE SBC

- Approval of the Annual Report of Activities for the year 2012.
- Start of the activities concerning the preparation of a report on prenatal genetic counselling.
- Assistance of Mr. Carlos Alonso Bedate and Mr. José Miguel Serrano Ruiz-Calderon to the XIX NEC Forum Dublin in June on behalf of the Bioethics Committee of Spain.
- Approval and publication of the Report of the Bioethics Committee of Spain on the Draft Royal Decree on Clinical Trials.
- Approval and publication of a statement on care at the end of life.
- Approval and sending of a letter of support to the implementation of a Regional Documentation Centre on Bioethics in Spanish in the CIBIR facilities in Logroño.
- Approval and sending a letter in support of Circular 1/2012 of the Public Prosecutor's Office.

PLENARY MEETINGS

During 2013 the following plenary meetings of the Spanish Bioethics Committee were held:

- 29th January 2013
- 12th February 2013
- 13th March 2013
- 11th June 2013
- 23rd July 2013
- 10th September 2013
- 12th November 2013

MEETINGS OF THE STEERING COMMITTEE

During 2013 the Steering Committee held the following scheduled meetings:

- 18th April 2013
- 16th July 2013

ATTENDANCE AT NATIONAL AND INTERNATIONAL EVENTS

19th NEC Forum and European Group on Ethics (EGE), held in Dublin, Ireland, in June. The topics addressed were as follows:

- Joint Meeting of the EGE and NEC Forum on Ethics of Security and Surveillance
- Ethical Questions Regarding Neurosciences
- Bioethics and Public Policy
- BioData: Ethical Considerations of Large-scale Biological Databases

It was agreed that Mr. Carlos Alonso Bedate and Mr. José Miguel Serrano Ruiz-Calderon attend as representatives of the SBC.

II Congress of Bioethics: Ethical issues in the management of information, organized by the ISCIII Animal Research Ethics and Welfare Committee.

In this Congress the topic areas addressed were not confined to research but extended to health care and bioethics in general.

Insofar as the round tables were concerned, issues of maximum interest were chosen, whether in research, including the limits of anonymization and confidentiality, the new regulation in data protection, returns of information in the context of genetic testing and biobanks, good practices in information management, new regulatory rules of Research Ethics Committees, and ethical aspects of research with iPS.

Attended the conference, as speakers, Mr. Federico de Montalvo Jääskeläinen and Mr. Carlos Alonso Bedate as members of SBC.

DOCUMENTS APPROVED IN 2013



Opinion of the Spanish Bioethics Committee on the Draft Royal Decree on Clinical Trials

The paper develops the various ethical and legal issues raised by the Draft Royal Decree on clinical drug trials, Research Ethics Committees for clinical trials of medicinal products and clinical trials registry. The report addresses the guarantees for trial subjects and, in particular, the new regime of assurance of clinical trials; new organizational aspects that are included in the project, especially with regard to the Research Ethics Committees for clinical trials of medicinal products (CEIm); and some formal aspects overall raised by the project.



Declaration on care at the end of life

The paper concerns the recognition of care at the end of life as one of the fundamental challenges of contemporary medicine and the consideration that it is a requirement of justice in social provision. In this regard, several studies at national level of the European countries and in the framework of the European Union and the countries belonging to the Council of Europe, have insisted on a set of minimum requirements for the quality of the provision. The Bioethics Committee of Spain considers necessary to advance the Specific Training in Palliative Care, in order to guarantee the rights of patients and families in this sensitive field of Medicine.

WORK IN PROGRESS

In 2013 the following topics were discussed:

- 1) Prenatal Genetic Counseling

DOCUMENTS PUBLISHED

FIRST TERM (2008-2012)



Opinion of the Spanish Bioethics Committee as to the Organic Bill on Voluntary Interruption of Pregnancy

7 October 2009



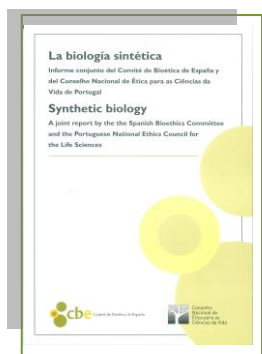
Recommendations for implementation of Good Scientific Practices in Spain

12 April 2010



Opinion of the Spanish Bioethics Committee on Conscientious Objection in Medical Care

13 October 2011



Synthetic biology

Joint Report of the Spanish Bioethics Committee and the Portuguese National Ethics Committee for Life Sciences

24 October 2011



**Opinion on Blood and Tissue Banks of the Umbilical Cord
and Placenta**
**Joint Report of the Spanish Bioethics Committee and the
Portuguese National Ethics Committee for Life Sciences**

1 October 2012

SECOND TERM (2013-)



**Opinion of the Spanish Bioethics Committee on the Draft
Royal Decree on Clinical Trials**

23th July 2013



Declaration on care at the end of life
23th July 2013

ANNUAL REPORT



2009 Annual Report of Activities



2010 Annual Report of Activities



2011 Annual Report of Activities



2012 Annual Report of Activities