



ANNUAL REPORT OF ACTIVITIES

2016

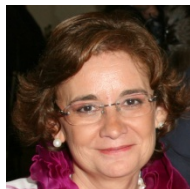
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COMPOSITION OF THE SPANISH BIOETHICS COMMITTEE (SBC)

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



M^a Teresa López López

President

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.



Federico De Montalvo Jääskeläinen

Vice-president

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.



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 in the La Fe Department of Health of Valencia and the Public Health Ethics Committee of the Generalitat.



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 (Hospital 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 Director of Hospital Universitario Central de Asturias (Oviedo). 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.

**Victoria Ureña Vilardell**

Graduated in Medicine and Surgery. Physician in the Immunology Service at the Ramón y Cajal Clinical University Teaching Hospital. She was Medical Assistant Director for Teaching, Research and Quality, and director of the Foundation for Biomedical Research at the Ramón y Cajal Clinical University Teaching Hospital. Master of Evaluation and Quality Improvement by the Autonomous University of Barcelona and the Avedis Donabedian Foundation. Master of Health Administration by the National School of Health, Carlos III Health Institute. Member of the Spanish Society for Immunology and of the Spanish Society of Health-Care Quality, and Founding Partner of the Madrid Association of Health-Care Quality.

Secretary

ACTIVITIES UNDERTAKEN

PRINCIPAL RESOLUTIONS PASSED BY THE SBC IN 2016:

- Approval of the 2015 Annual Report of Activities.
- Approval of the Report of the Bioethics Committee of Spain on Legal and ethical issues concerning the rejection of vaccines, and proposals for a necessary debate.
- Approval of the Report of the Bioethics Committee of Spain on Ethical and Legal issues about the use of mechanical and pharmacological restraints.
- Adhesion to the Statement on ethics and responsibility in the sustainability of the National health System, edited by Regional Ethics Committees and the Spanish Bioethics Committee.
- Start up of the work group about Surrogate Motherhood.
- Continuation of the renewal process of the Committee and communication to the authorities.

PLENARY MEETINGS:

During 2016 the following plenary meetings of the Spanish Bioethics Committee were held:

19th January 2016

7th June 2016

6th September 2016

15th November 2016

MEETINGS OF THE STEERING COMMITTEE

During 2016 the Steering Committee held the following scheduled meetings:

15th March 2016

DESIGNATION OF NEW MEMBERS

On 13 April 2016, Manuel de los Reyes López and Vicente Bellver Capella were designated chairs of the board at the Spanish Bioethics Committee by the National Health Service's Interterritorial Council.

DOCUMENTS APPROVED IN 2016



Legal and ethical issues concerning the rejection of vaccines, and proposals for a necessary debate

This report deals with the concern some social groups, still not very large, have risen among members of the Spanish Bioethics Committee, regarding the utility of vaccines and promoting its rejection. The report lays down that this position is not understandable because vaccines are the most successful tool for the Public Health System in its interest to fight against infectious illnesses, that not long before have seriously and fatally affected human health.



Ethical and Legal issues about the use of mechanical and pharmacological restraints

This document reviews the normative aspects regarding the use of restraints; propose some considerations about the necessity of its use as well as about the security problems and risks for the restrained patients. It entails a chapter on ethical considerations and lists 16 recommendations.

ADHESION TO STATEMENTS IN 2016



Statement on ethics and responsibility in the sustainability of the National health System

This Statement emerges by the initiative of the Regional Bioethics Committee in Aragón to which the Spanish Bioethics Committee and other Regional Committees were invited. It intends to contribute to the public reflection about sustainability of the National Health system based on the ethical values that should inspire responsibility of all agents implied in its development.

WORK IN PROGRESS

Works related to following subjects were set out:

- Repost on Surrogate Motherhood.

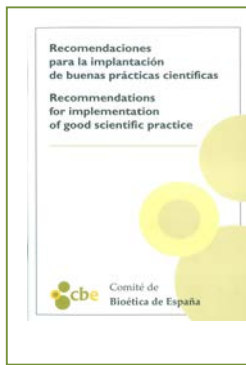
DOCUMENTS PUBLISHED

FIRST TERM (2008-2012)



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

7th October 2009



Recommendations for implementation of Good Scientific Practices in Spain

12th April 2010



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

13th October 2011



Synthetic biology

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

24th 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

1st 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



Report of the Bioethics Committee of Spain on the Draft to the Organic Law on Protection of the Rights of the Pregnant Woman and on the Rights of the Conceived.

13th May 2014



Approval of the report of the Bioethics Committee of Spain on the Draft Decree for the Regulation of Authorization for the Constitution, Operation, Organization and Register of Biobanks in the Region of Murcia.

2nd September 2014



Report of the Spanish Bioethics Committee on the prenatal genetic counseling

13th January 2015



Legal and ethical issues concerning the rejection of vaccines, and proposals for a necessary debate

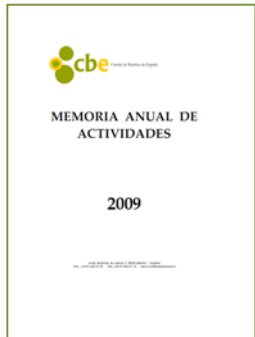
19th January 2016



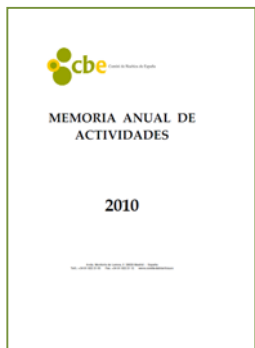
Ethical and Legal issues about the use of mechanical and pharmacological restraints

7th June 2016

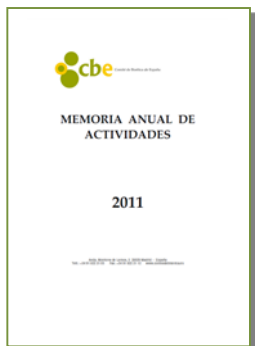
ANNUAL REPORTS



2009 Annual Report of Activities



2010 Annual Report of Activities



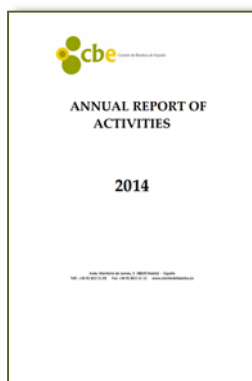
2011 Annual Report of Activities



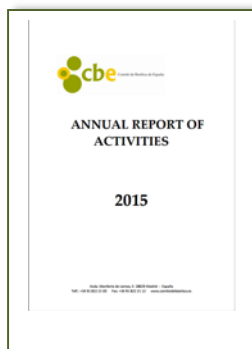
2012 Annual Report of Activities



2013 Annual Report of Activities



2014 Annual Report of Activities



2015 Annual Report of Activities