



# **ANNUAL REPORT OF ACTIVITIES**

# **2015**

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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<sup>a</sup> 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 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.



### **Javier Arias-Diaz**

Dr. Arias-Diaz is Professor of Surgery at Madrid's Complutense University, Specialist (Consultant) in surgery at the San Carlos Clinical University Teaching Hospital, Co-ordinator of the Surgical Infection Committee of the Spanish Association of Surgeons, Subdirector-General of Cellular Therapy and Regenerative Medicine at the Carlos III Institute of Health (ISCIII), Director of the National Bank of Stem Cell Lines (Banco Nacional de Líneas Celulares/BNLC), Chairman of the ISCIII Research Ethics and Animal Welfare Committee, and Member of the Board and representative of the Ministry of Science & Innovation on the Council of Europe's Steering Committee of Bioethics (CDBI). He is the author or co-author of more than 150 papers in scientific journals, with a total impact factor of over 180 and a Hirsh index of 15.

**Secretary until  
June 2015  
(vested with the  
right to speak  
but  
not to vote)**



### **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 since  
June 2015  
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## ACTIVITIES UNDERTAKEN

### PRINCIPAL RESOLUTIONS PASSED BY THE SBC IN 2015:

- Approval of the 2014 Annual Report of Activities.
- Approval of the Report of the Bioethics Committee of Spain on Prenatal Genetic Counseling.
- Attendance of Carlos Alonso Bedate and Federico de Montalvo Jääskeläinen at the Global Summit of National Ethics Committees' in Berlin, 17<sup>th</sup> and 18<sup>th</sup> March 2016, on behalf of the Spanish Bioethics Committee.
- Continuation of the renewal process of the Committee and communication to the authorities.
- Discussion about the capacity of minors in the field of medical treatment.
- Initial discussion for the Report on Ethical and Legal Issues about Vaccine Rejection and Proposals for a Debate.
- Start up of the work group about mechanical and pharmacological restraint.

### PLENARY MEETINGS:

During 2015 the following plenary meetings of the Spanish Bioethics Committee were held:

13<sup>th</sup> January 2015

24<sup>th</sup> February 2015

14<sup>th</sup> April 2015

16<sup>th</sup> June 2015

6<sup>nd</sup> October 2015

### MEETINGS OF THE STEERING COMMITTEE

During 2015 the Steering Committee held the following scheduled meetings:

1<sup>st</sup> December 2015



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## ATTENDANCE AT NATIONAL AND INTERNATIONAL EVENTS

**3rd Bioethics Conference: Ethical Issues on Access to Health Data, organized by the Research Ethics and Animal Welfare Committee of the Institute of Health Carlos III, held in Madrid, 19th and 20th November.**

The Conference treated the difficulties around Big Data. The massive data analysis sets out important problems from the point of view of the ethical evaluation. A round table was dedicated to the challenges in the use of the health history in research and another one to the problems obtaining informed consent in specific situations such as in minors, in the absent of the capacity to consent, or when this is diminished or in medical urgencies.

On behalf of the Spanish Bioethics Committee Pablo Ignacio Fernández Muñoz attended the Conference as speaker, and Mr. Carlos Alonso Bedate as moderator.

## PRIZE AWARDED TO THE SPANISH BIOETHICS COMMITTEE

The Spanish Bioethics Committee has been awarded with the prize “Best Ideas 2015” in the field of legal, ethical and deontological field by *Diario Médico*, in recognition of the report on Prenatal Genetic Counseling.

## DOCUMENTS APPROVED IN 2015



### **Report of the Spanish Bioethics Committee on the prenatal genetic counseling.**

This report stresses the value of the prenatal genetic counseling as an informative procedure and not a directive one. Keeping in mind that both, the specialist and the affected patients have to deal with a complex situation, it is maintained that the counseling should aim to protect human beings in contexts of vulnerability and possible lack of protection to safeguard the dignity of the person.

## WORK IN PROGRESS

Works related to following subjects were set out:

- Ethical and Legal Issues about Vaccine Rejection and Proposals for a Debate.
- Mechanical and pharmacological restraint.

## 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



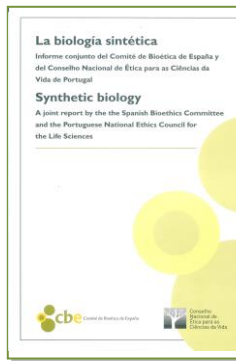
#### **Recommendations for implementation of Good Scientific Practices in Spain**

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

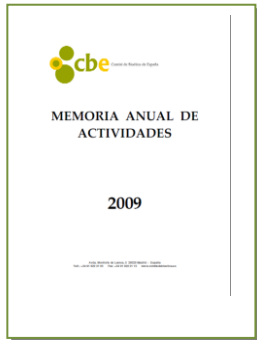


## Report of the Spanish Bioethics Committee on the prenatal genetic counseling

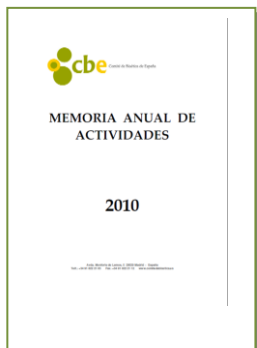
13<sup>th</sup> January 2015

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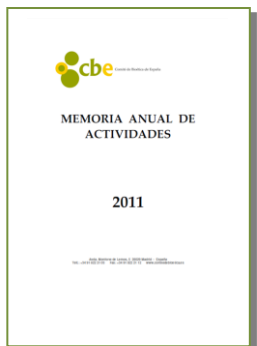
ANNUAL REPORTS



**2009 Annual Report of Activities**



**2010 Annual Report of Activities**



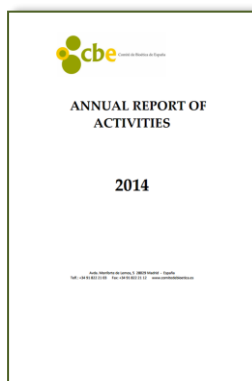
**2011 Annual Report of Activities**



**2012 Annual Report of Activities**



### **2013 Annual Report of Activities**



### **2014 Annual Report of Activities**