



Ethics Assessment in Different Countries

Spain

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Annex 4.i

Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries

Deliverable 1.1

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1 Introduction

The aim of this report is to analyse the existing structures and agents for the ethical assessment of research and innovation in Spain, both for the public and private sector. It will be analysed how national and regional governments have put into place organisational structures, laws, policies and procedures for ethical assessment, how both publicly funded and private research and innovation systems address ethical issues in research and innovation, and how ethical assessment plays a role in the activities of professional groups and associations for research and innovation and of civil society organisations (CSOs).

We will begin with providing some basic information about Spain and the historical development of ethics assessment institutions in the country. Spain, officially the Kingdom of Spain, is a sovereign state located on the Iberian Peninsula in South-western Europe. Spanish territory also includes two archipelagos; two cities in continental North Africa and small islands along the North African coast. With an area¹ of 505.991km² and a population of 46.815.916² people, Spain is one of the largest countries in Europe. The largest cities are Madrid, Barcelona, Seville, Valencia and Zaragoza.³ Madrid is the country's capital⁴ and holds the seat of government and Parliament. The official language is Spanish (also called Castilian)⁵. Catalan, Galician, Basque and Valencian are co-official languages in some autonomous communities. Other regional languages (Aranese, Bable and Aragonese) are also recognised and protected in their respective regions⁶. Spain is established as a social and democratic State, subject to the rule of law. The political form of the Spanish State is the Parliamentary Monarchy⁷. Spain is divided in 17 autonomous communities (*Comunidades Autónomas*, CCAA), with their own elected parliaments, governments, public administrations, budgets, and resources, and two autonomous cities (Ceuta and Melilla, in North Africa).

Spain has a developed economy; in 2011 it had a Gross Domestic Product (GDP) of 1.075.147⁸ million euros, being the thirteenth largest economy in the world and the 47th in terms of GDP per capita. Textiles and apparel (including footwear) are the largest industrial sector in Spain. Other major industries include food and beverages, metals and metal manufactures, chemicals, aeronautical, shipbuilding, automobiles, machine tools, tourism, clay and refractory products, pharmaceuticals and medical equipment.⁹

¹ National Statistics Institute (INE), *España en Cifras*, ed. 2014. INE. ISSN 2255-0410.
http://www.ine.es/prodyser/espa_cifras/2014/index.html#4/z

² National Statistics Institute. http://www.ine.es/censos2011_datos/cen11_datos_inicio.htm

³ National Statistics Institute. <http://www.ine.es/jaxiT3/Datos.htm?t=2911>

⁴ Cortes Generales, Constitución Española (CE), Art. 5. BOE 311, December 29th 1978, p.29313 - 29424.

<http://www.boe.es/buscar/doc.php?id=BOE-A-1978-31229> (in English:

http://www.congreso.es/portal/page/portal/Congreso/Congreso/Hist_Normas/Norm/const_espa_texto_ingles_0.pdf)

⁵ CE, art. 3.

⁶ <http://www.congreso.es/consti/constitucion/indice/sinopsis/sinopsis.jsp?art=3&tipo=2>

⁷ CE, art. 1.

⁸ OECD MSTI database, 2011 figures. https://stats.oecd.org/Index.aspx?DataSetCode=MSTI_PUB

⁹ <https://www.cia.gov/library/publications/the-world-factbook/geos/sp.html>

In 2011, the Gross Domestic Expenditure on Research and Development (GERD) was 14.184,29 million Euros, which amounted to 1,32 percent of GDP.¹⁰ Table 1 and table 2 show a breakdown of the GERD, in terms of percentages, by financing sector and performing sector.

Industry	Government	Other national sources	Sources abroad
44,31	44,48	4,53	6,68

Table 1: A breakdown of the GERD, in percentages, by financing sector in 2011

Business enterprise	Higher education	Government	Non-profit
52,14	28,21	19,47	0,17

Table 2: A breakdown of the GERD, in percentages, by performing sector in 2011

The practice of ethical assessment of research and innovation in Spain is decentralised and independent from the government. Since the Oviedo Convention's entry into force in 2000,¹¹ the ethical assessment of research has been regulated by law. These laws establish the creation of ethical committees to evaluate biomedical research involving humans, their samples or data, clinical trials and animal research. These committees can be local (located in hospitals, universities and research centres) or regional (either covering a whole Autonomous Community or a part of it). Private industry (pharmaceutical companies, hospitals, private universities) can also create their own committees or ascribe to any already established committee. The Law on Biomedical Research also created the Spanish Bioethics Committee for the consultation of all aspects with ethical and social implications in the field of Medicine and Biology. Other national committees are the National Commission on Assisted Human Reproduction and the Commission of Guarantees for the Donation and Use of Human Cells and Tissues. Some Autonomous Communities have launched their own bioethics committees.

In Spanish history, one of the earlier appearances of ethical debate was in the XVI century. The rise of humanism, the Counter-Reformation and new geographical discoveries and conquests raised issues that were addressed by the intellectual movement now known as the School of Salamanca, which developed the first modern theories of what are now known as international law and human rights.¹² In Spain the development of bioethics follows a different path than the rest of the world due to its particular political situation. During the 1970s the end of a 40-year dictatorship and a political transition to a democratic system occurs. The problematic aspects of health care and other issues related to health and disease or life and death occupy a secondary place in the scale of social priorities. In the 1980s issues of sexuality and reproduction were subjected to intense debates, but in the field of medicine there is no ethical debate and there is still no confidence in the law. In the 1990s there was a radical change in the situation of bioethics. With the economic improvement, research initiates the development of Research Ethics Committees in accordance with the development of the European Directive on clinical drug trials. Also healthcare ethics committees emerge, in

¹⁰ OECD MSTI database, 2011 figures.

¹¹ Convention on Human Rights and Biomedicine, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, 1999.
<http://www.boe.es/buscar/doc.php?id=BOE-A-1999-20638>

¹² Ludwig Hernandez, Bonar, "The Las Casas-Sepúlveda Controversy: 1550-1551", *Ex Post Facto*, San Francisco State University, 10, pp. 95–104. Nd.

which the ethical debate opens up to society. Today, bioethics is not limited to strictly medical issues, but also incorporating ethical conflicts and problems relating to life in its broadest sense, thus broadening this field to issues not only related to research on human subjects, but also to the use of animals in research, protection of workers, environmental protection and protection of personal data.

2 National and regional government institutions and policies

This chapter will provide a discussion of the Spanish national government institutions and policies relating to research and innovation. In the sections, the following will be examined: the general institutional structure of Spanish government and government-controlled institutions; governmental institutions with a role in ethics assessment; national laws and policies for ethics assessment; and regional policies and institutions.

2.1 Institutional structure of government

In this section, the general institutional structure of Spanish government and government-controlled institutions, as it relates to research and innovation, will be laid out. The following topics will be included in the discussion: the form of government; the nature of and relations between executive, the legislative and judicial branches; the major ministries and government organisations; and the role of government in research and innovation in the private sector

2.1.1 General structure of government

Spain is a social and democratic State, subject to the rule of law, which advocates freedom, justice, equality and political pluralism as the highest values of its legal system. The political form of the Spanish State is the Parliamentary Monarchy.¹³ The King is the Head of State, the symbol of its unity and permanence, assumes the highest representation of the Spanish State in international relations, especially with the nations of its historical community, and exercises the functions expressly conferred on him by the Constitution and the laws. His acts need to be countersigned by the President of the Government or the competent Ministers; otherwise they will not be valid.¹⁴

Executive power is held by the Government, which initiates law and policy and usually consists of 13 to 18 ministers. The Government consist of the President, Vice-Presidents, Ministers and other members, as may be created by law.¹⁵ The Government is jointly accountable before the Congress for its conduct of political business.¹⁶

The Parliament (*Cortes Generales*) represents the Spanish people and consists of the Congress and the Senate. The Parliament exercises the legislative power of the State and adopts its Budget, controls the action of the Government and have the other competences assigned by the Constitution.¹⁷ The Congress consists of 350 members elected in direct elections on the basis of party-list proportional representation. The Senate is the house of territorial representation. The number of members varies after each election, as it depends on the population of each CCAA. Currently it has 266 members, of which 208 are elected in direct elections (a fixed number for each provincial constituency) and 58 are appointed by the parliaments of the Autonomous Communities, proportionally to their population.

¹³ CE, art. 1.

¹⁴ CE, art. 56 and 64.

¹⁵ CE, art. 98.

¹⁶ CE, art. 108.

¹⁷ CE, art. 66.

Justice is administered on behalf of the King by judges and magistrates: members of the Judicial Power who shall be independent.¹⁸ The highest governing body of Justice is the General Council of the Judicial Power (*Consejo General del Poder Judicial*). The court system comprises different areas of law and a variety of bodies.

The State is organised territorially into municipalities, provinces and the 17 Autonomous Communities. All these bodies have self-government for the management of their respective interests.¹⁹ Relations between National laws and CCAA's laws are not based in hierarchy but on competences, determined by the Constitution and the Autonomy Statutes.²⁰

2.1.2 Government organisations relevant to research and innovation

Within government, responsibility for research and innovation policy is mainly dependent of the Ministry of Economy and Competitiveness (Mineco).

According to the National R+D+I Plan²¹, the Department of Science and Innovation under the Ministry of Economy has the responsibility of proposal development, management, monitoring and evaluation of national programs and strategic actions. However, there are several ministerial departments that hold competencies in R+D+I: Science and Innovation accounts for 84 percent of the total amount awarded; Industry, Tourism and Trade (15%); Education (0.5%) and the Environment and Rural and Marine Affairs (0.06%).

The main management units dedicated to Science and Innovation, within the Mineco, that open grant calls include the Centre for the Development of Industrial Technology (CDTI), the Directorate General for Technology Transfer and Business Development, and the Directorate General for Research and Management of the National R+D+I Plan. These units fund 80 percent of the total amount funded by the Ministry.

In addition to Mineco, other ministries, such as the Ministry Health, Social Services and Equality (MSSSI) or the Ministry of Education, Culture and Sports (MECD), the Ministry of Agriculture, Food and Environment (MAGRAMA) and the Ministry of Defence, develop and implement specific research policies for their respective sectors. Within the MSSSI, aside from the Institute of Health Carlos III (ISCIII),²² that depends jointly of this ministry and Mineco, there is the FIPSE (Foundation for the Research and Prevention of AIDS in Spain, *Fundación para la Investigación y la Prevención del Sida en España*),²³ funded in 1998. Research in the MECD is mainly centred in archaeology and Cultural Heritage through the Institute of Cultural Heritage of Spain (*Instituto del Patrimonio Cultural de España*, IPCE).²⁴ Research on environment is done through the National Parks Autonomous Agency (*Organismo Autónomo Parques Nacionales*, OAPN),²⁵ dependent of the MAGRAMA. Within

¹⁸ CE, art. 117.

¹⁹ CE, art. 137.

²⁰ CE, art. 148-149

²¹

http://www.idi.mineco.gob.es/stfls/MICINN/Investigacion/FICHEROS/Plan_Estatal_Inves_cientifica_tecnica_innovacion.pdf

²² <http://www.isciii.es>

²³ <http://www.msssi.gob.es/ciudadanos/enfLesiones/enfTransmisibles/sida/investigacion.htm#fipse>

²⁴ <http://ipce.mcu.es/>

²⁵ <http://www.magrama.gob.es/es/parques-nacionales-oapn/>

the Ministry of Defence, the main Research and Development is the 'La Marañosa' Institute of Technology (ITM),²⁶ an organ of technical support for managing and developing R&D in accordance with the directives under the Armament and Equipment Master Plan (PDAM).²⁷

2.2 Governmental institutions for ethics assessment

2.2.1 Spanish Bioethics Committee

The Spanish Bioethics Committee²⁸ was created through Law 14/2007 of July 3rd on Biomedical Research (BOE July 4th) as a "collegiate, independent and consultative professional body, which will develop its responsibilities, with full transparency, on materials related to the social and ethical implications of Biomedicine and Health Sciences".²⁹ The Committee was established on October 22nd 2008 and forms part of the Ministry of Health, Social Services and Equality.

Its mission is to issue reports, proposals and recommendations for public authorities at state and regional level on matters related to the ethical and social implications of Biomedicine and Health Sciences. Equally, it is responsible for establishing the general principles for the production of codes of good practice in scientific research and for representing Spain in supranational and international forums and bodies involved in bioethics. The Committee's ethical assessment reflects its members' individual moral and expertise, taking into consideration the values of the Spanish society and the law. Their recommendations and opinions are not binding.

The Committee is composed of twelve members, elected among scientific, medicine, legal and bioethical experts. Its members are nominated by several Ministries and Autonomous Communities through the Inter-regional Council of the National Health System and the Ministries of Health, Justice, Industry and Economy. The committee is funded by the Institute of Health Carlos III.

2.2.2 Other Commissions (National level)

- The National Commission on Assisted Human Reproduction³⁰ is a consultative body, under the Ministry of Health, Social Policy and Equality aimed at providing guidance on the use of these techniques and collaborating with public authorities regarding this matter and scientific derivations. Its decision is binding.
- The Commission for the Donation and Use of Human Cells and Tissues is a consultative body aimed at providing advice and guidance on research and experimentation utilising biological samples of human embryonic nature, and

²⁶ <http://www.defensa.gob.es/areasTematicas/investigacionDesarrollo/ITM/>

²⁷ <http://www.defensa.gob.es/Galerias/politica/armamento-material/ficheros/DGM-Plan-director-PDAM-2008.pdf>

²⁸ <http://www.comitedebioetica.es>

²⁹ <http://Jefatura del Estado, Law 14/2007 on Biomedical Research, art. 77. Boletín Oficial del Estado, Adopted on 05-07-2007. http://www.boe.es/buscar/act.php?id=BOE-A-2007-12945&tn=1&p=20110602&vd=#tviii>

³⁰ www.cnrha.msssi.gob.es/

contribute to updating and disseminate scientific and technical knowledge in this field. The commission's decisions are binding.³¹

- The Spanish Research Ethics Committee (*Comité Español de Ética de la Investigación, CEEI*). Created by the Law of Science,³² under the Council for Science, Technology and Innovation Policy, as a collegiate body of independent and consultative character, on matters related to professional ethics in scientific and technical research. Its functions are:
 - Issue reports, proposals and recommendations on matters related to professional ethics in scientific and technical research.
 - Establish the general principles for the development of codes of good practice of scientific and technical research, which include the resolution of conflicts of interest between public and private activities. These codes will be developed by the Spanish Bioethics Committee and the Research Ethics Committees.

2.3 National laws and policies for ethics assessment

2.3.1 Legal provisions for ethics assessment

Research in human subjects:

In Spain there are different laws that contemplate different aspects related to research in human subjects. The Law on Biomedical Research³³ (*Ley de Investigación Biomédica, LIB*), enacted in 2007, gives the principal framework on biomedical research. This law emerged to fill a legal vacuum in relation to the ethical evaluation of research projects in human subjects, as the only research in human subjects regulated until then were the clinical drug trials (Royal Decree 223/2004³⁴). Until the approval of this law, ethical assessment was regulated by Royal Decree 223/2004 on clinical drug trials. The Oviedo Convention was published in 1997 and came into force in Spain in 2000. The principles adopted in the Convention are enforced by the legislation that regulates medical and clinical research on human subjects.

The Law on Biomedical Research adopts the human rights indicated in the Spanish Constitution, the regulation on Data Protection and patient autonomy, as well as the principles of the Helsinki Declaration and other international regulations. This law adopts the principles of protection of human rights and dignity of the human being with regard to the application of biology and medicine, adopted by the Oviedo Convention. The law declares that the health, interest and wellbeing of humans participating in biomedical research shall prevail over the interest of society or science.

The law provides for free personal autonomy, the right to non-discrimination, the duty of confidentiality in respect of personal information, the principle of free donations of biological

³¹ Law 14/2007. <http://www.boe.es/buscar/doc.php?id=BOE-A-2011-9617>

³² Jefatura del Estado, Law 14/2011 on Science, Technology and Innovation, adopted 02-06-2011. <http://www.boe.es/buscar/doc.php?id=BOE-A-2011-9617>

³³ Law 14/2007 on Biomedical Research, articles 77-81.

³⁴ Ministerio de Sanidad y Consumo, Real Decreto 223/2004, adopted 01-05-2004 <http://www.boe.es/buscar/act.php?id=BOE-A-2004-2316>

materials, among others.³⁵ RECs are the oversight bodies of methodological and ethical adequacy and regulatory compliance regarding research on human subjects. Local RECs need to be accredited.³⁶ For the accreditation of a REC the following criteria must be weighted: independence and impartiality of its members with regard to promoters and researchers in biomedical research projects as well as its cross-disciplinary composition.³⁷

In clinical drug trials it is necessary to include the authorisation of the Spanish Agency for Medicines and Health Products, Ministry of Health, Social Services and Equality³⁸ and the report from the REC.

Research projects involving the use of human embryonic stem cells or cell lines derived from them, as well as research projects involving the use of tissues and cells of human origin in the field of regenerative medicine must comply with the provisions of Law on biomedical research and Royal Decree 2132/2004³⁹. Any research project involving these materials needs the approval of the Commission of Guarantees for the Donation and Use of Human Cells and Tissues⁴⁰ and the Research Ethics Committee. Any other research involving humans must abide by the Law on Data Protection. In research centres that use personal data, as the law requires informed consent,⁴¹ the research projects are assessed by Ethical Committees. Projects that use only aggregated data (in sociological research) do not need previous ethical assessment.

For other types of research, the Law on Science⁴² establishes the Spanish Research Ethics Committee (see above, Governmental institutions for ethics assessment).

Research on animals:

Legislation on Animal research is regulated by Royal Decree 53/2013,⁴³ establishing the basic rules applicable to the protection of animals used in experiments and other scientific purposes, including teaching. This Royal Decree develops Law 32/2007, for the care of the animals on

³⁵ Law 14/2007, art. 2

³⁶ Law 14/2007, art. 12: “The Research Ethics Committees of those centres that undertake biomedical research shall be duly accredited by the corresponding authority of the autonomous community to which they belong or, in the case of centres that belong to the General Administration of the State, by the corresponding authority of such, in order to assure its independence and impartiality.”

³⁷ Law 14/2007, art. 12

³⁸ Institute of Health Carlos III, Resolution of the Institute of Health Carlos III, approving the call of 2014 for grants from the Strategic Action for Health 2013-2016 from the State Program for Research Oriented Challenges of the Society under the State Plan of Scientific and Technical Research and Innovation 2013-2016, 2014 <http://www.boe.es/boe/dias/2014/06/10/pdfs/BOE-A-2014-6169.pdf>

³⁹ Royal Decree 2132/2004 that regulates the requirements and procedures for requesting the development of research projects involving stem cells obtained from surplus pre-embryos. BOE 262, adopted 30-10-2004. p.35905-35907

⁴⁰ Royal Decree 1527/2010 that regulates the Commission for the Donation and Use of Human Cells and Tissues and the Registry of research projects. BOE 294, December 4th 2010, p.101083-101091

⁴¹ Office of the head of state, Organic Law 15/1999, adopted 14-12-1999 art. 6

⁴² Jefatura del Estado, Law 14/2011 on Science, Technology and Innovation. BOE n.131, adopted 2-06-2011, p. 54387-54455. <http://www.boe.es/buscar/doc.php?id=BOE-A-2011-9617>

⁴³ Ministerio de la Presidencia, Real Decreto 53/2013, BOE 34, adopted 08-02-2013. <http://www.boe.es/buscar/act.php?id=BOE-A-2013-1337>

farming, transport, experimentation and sacrifice⁴⁴ and transposes Directive 2010/63/EU revising Directive 86/609/EEC on the protection of animals used for scientific purposes.⁴⁵ Hunting and fishing, wildlife, pets, bullfights and regulated sports competitions using animals are not included in this regulation, as they are regulated by their specific laws.⁴⁶

The main principle in animal research is the principle of the three R (Replacement, Reducing, Refinement).

- The replacement of animals for other options in which they are not used, such as audio-visual media or virtual reality techniques.
- Reducing their number, through the development and application of statistical studies that establish clearly what is the minimum number of individuals that enable scientists to obtain satisfactory results, or the choice of the most appropriate animal species for the study.
- Refinement of actions on the animals, and improving their living conditions. Associated with this idea are concepts such as environmental enrichment, use of anaesthesia and analgesia, the classification of severity of procedures or establishment of early endpoint criteria.

Animal research has to be subjected to the evaluation of an ethics committee.⁴⁷

2.3.2 Ethics Assessors

Research Ethics Committees:

According to the law, any biomedical research involving human beings or/and human materials or data, and animal research has to be subjected to the evaluation of an ethics committee⁴⁸ (a REC or an Animal Welfare Committee). The committee's opinion is binding; no research project can start without the previous favourable review from the REC⁴⁹. In clinical drug trials it is necessary to include the authorisation of the Spanish Agency for Medicines and Health Products, Ministry of Health, Social Services and Equality.⁵⁰ Research projects involving human embryonic samples, must obtain the approval of the Advisory Committee for Human Tissue and Cell Donation and Use (see above, Governmental institutions for ethics assessment).

⁴⁴ Jefatura del Estado, Law 32/2007, BOE 268, 8 November 2007. <http://www.boe.es/buscar/act.php?id=BOE-A-2007-19321>

⁴⁵ European Parliament and the Council, DIRECTIVE 2010/63/EU on the protection of animals used for scientific purposes, adopted 22 september 2010.

<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32010L0063&from=EN>

⁴⁶ Ministry of agriculture, food and environment, Law 31/2003, on conservation of wildlife in zoos, Law 10/1991, on administrative authority about bullfights, and regulated sports competitions including necessary actions for doping control in animals. Adopted 28-10-2003 & 17-01-1991

⁴⁷ Law 14/2007 on Biomedical Research, art. 2.e)

⁴⁸ Law 14/2007, art. 2.e)

⁴⁹ Law 14/2007, art. 12.e)

⁵⁰ Ministerio de Economía y Competitividad, Other provisions III, adopted 10-06-2014.

<http://www.boe.es/boe/dias/2014/06/10/pdfs/BOE-A-2014-6169.pdf>

In Spain, the Research Ethics Committees (*Comités de Ética en Investigación, CEI*) are the oversight bodies of methodological and ethical adequacy, as well as regulatory compliance regarding research on human subjects. They consist of an independent multidisciplinary group of people whose main role is to impartially assess, research projects involving humans in order to guarantee the protection of participants, ensuring that all projects meet the methodological requirements, respect basic ethical principles and human rights, and comply with the law. The Law of Biomedical Research designated the Research Ethics Committees for the review of all types of research projects involving humans, including drugs clinical trials and health products, studies using biological identified or identifiable samples, embryonic material, as well as when handling personal data. According to the LIB, the REC may also act as an external ethic committee of a biobank, ethically evaluating applications for the transfer of samples and data associated with them.⁵¹ In Spain, similarly to its neighbouring countries, there are institutional or local committees and others of regional level, without implying a hierarchy between them.

These Committees were first regulated in 1978 as "Clinical Trials Committees". In 1990 the name was changed to Clinical Research Ethics Committees (*Comités de Ética en Investigación Clínica, CEIC*) and while further the basic and common aspects in terms of composition, functions and working procedures was established. In May 2004, the Royal Decree 223/2004 transposing the European Directive (20/2001/CE) came into force.⁵²

Currently, in Spain there are over 140 accredited Clinical Research Ethics Committees (CRECs), with many different scopes, and also highly variable levels of activity. Since the last decade of the twentieth century many CREC also assessed other research projects involving the use of personal data or human biological samples. This situation led to the creation of Research Ethics Committees (RECs) in Universities and Public Research Organisations. Their mission is to evaluate research projects involving human subjects, personal data or human biological samples (not drug trials). Some of these committees also review research on animals, or other studies that use biological agents or genetically modified organisms. RECs base their ethical assessment mainly in the respect of human rights, the international and local law and the principlalist theory.

Other Committees for Human research:

- The Spanish Data Protection Agency⁵³ (*Agencia Española de Protección de Datos, AEPD*) is the state independent supervisory authority responsible for ensuring compliance with data protection legislation. It guarantees and protects the fundamental right of protection of personal data of citizens. The Agency is an entity of public law, which is fully independent of the government in the exercise of their functions. It relates to the Government through the Ministry of Justice.
- The Spanish Agency of Consumer Affairs, Food Security and Nutrition (*Agencia Española de Consumo, Seguridad Alimentaria y Nutrición*) is a merger between

⁵¹ Law 14/2007 on Biomedical Research, art. 12

⁵² Ministerio de Sanidad y Consumo, Royal Decree 223/2004 on clinical trials on medicaments, Boletín Oficial del Estado, adopted 7-02-2004. <http://www.boe.es/buscar/doc.php?id=BOE-A-2004-2316>

⁵³ <http://www.agpd.es/>

the Spanish Agency for Food Safety and Nutrition and the National Consumer Institute.⁵⁴ It is under the Ministry of Health, Social Services and Equality. The fundamental objectives of the Agency are:

- Promoting exercise and promoting the rights of consumers and users, both in terms of product safety and its economic interests.
- Promoting food security, providing objective guarantees and consumers and traders of Spanish food sector information.
- Plan, coordinate and develop strategies and actions to promote information, education and health promotion in the field of nutrition, particularly in the prevention of obesity.
- Health Technology Assessment Agencies. There are some regional agencies, and a national agency (*Agencia de Evaluación de Tecnologías Sanitarias*), located in the Institute of Health Carlos III.⁵⁵ The function of the latter is to meet the advisory needs of the National Health System in relation to the definition of its Health Benefits Policy in the prevailing line of socially advanced Healthcare Systems. The agency offers objective assessments of the health, social, ethical, organisational and economic impacts of the techniques and procedures of medical-sanitary, which help support science-based decisions of authorities and other health workers.

Animal research:

Animal research projects need to be authorised by the regional competent body prior to its realisation (in Madrid, it is the Department of Environment and Territorial Regulation, in Andalusia it's the Directorate General of Agricultural and Livestock Production). In order to request this authorisation, the researcher needs to obtain first the favourable report of the body responsible for animal welfare in the animal facility and the favourable report of the ethics committee (called authorised body).⁵⁶

The committees need to have the expertise and resources needed to carry out the functions and no conflict of interest for the performance of their duties.⁵⁷

The ethics committee must include researchers and other scientific members not directly related to the project and a person with experience and knowledge in animal welfare that has no direct relation with the animal facility centre or the project.⁵⁸

Royal Decree 53/2013 created the Spanish Committee for the protection of animals used for scientific purposes (*Comité español para la protección de animales utilizados con fines*

⁵⁴ Ministerio de hacienda y administraciones publicas, Royal Decree 19/2014, of the autonomous bodies National Consumer Institute and Spanish Agency for Food and Nutrition Security will be consolidated into a new autonomous body called the Spanish Agency of Consumer Affairs, Food Security and Nutrition and its Statutes are approved, adopted 3-02-2014. <http://www.boe.es/boe/dias/2014/02/03/pdfs/BOE-A-2014-1092.pdf>

⁵⁵ <http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-estructura-directiva/fd-subdireccion-general-investigacion-terapia-celular-medicina-regenerativa/fd-centros-unidades/agencia-evaluacion-tecnologias-sanitarias.shtml>

⁵⁶ Royal Decree 53/2013.

⁵⁷ Royal Decree 53/2013, art. 43.

⁵⁸ Royal Decree 53/2013, art. 39.

científicos, CEPAFIC),⁵⁹ dependent of the MAGRAMA. The CEPAFIC is an advisory body to the Central Government, the CCAAs, the cities of Ceuta and Melilla and the bodies responsible for the welfare of the Animals on issues pertaining to the acquisition, breeding, accommodation, care and use of animals used in procedures. Other functions are to allow sharing of best practices and act as an instrument of coordination between different entities.

2.4 Regional institutions and policies

The Spanish territorial organisation means that also the Autonomous Communities (CCAAs) may make rules (with force of law and below) on matters within their competence. The promotion and general coordination of scientific and technical research is included within the exclusive competences of the State.⁶⁰ Some CCAAs have created regional Research Ethics Committees, who perform the ethical assessment of research projects performed in the region.

Some Autonomous Communities (Basque Country, Catalonia, Aragon, Andalusia, Galicia, and Valencia) have launched their own bioethics committees. Their ethical assessment reflects their members' individual moral and expertise, taking into consideration the values of the Spanish society and the national and regional law. In this section we will examine more closely three of them.

2.4.1 Catalonia

The Bioethics Committee of Catalonia (CBC)⁶¹ is an advisory body in bioethics and a reference forum on bioethics debate of the Government and Administration of Catalonia, as well as the scientific community; it addresses issues that affect the society and, therefore, has a pluralistic, multidisciplinary, independent, transparent and non-dogmatic approach⁶².

It consists of 30 members representing the world of medicine, health management, research, law, economics, education, media and the humanities.

Its missions are:

- Develop recommendations for professionals who serve as a model for action in different situations ethically controversial in the field of clinical practice.
- Issue reports and positions relative to matters that raise ethical issues related to advances in biomedical research and health sciences.
- Organise outreach events to disseminate knowledge and advice in the field of bioethics. Analyse specific cases of conflict from the Government or ethics committees and express their opinion.
- Promote training and information on bioethics in the scientific and medical community, and between all citizens, in order to encourage critical and informed reflection.

⁵⁹ RD 53/2013, art. 44

⁶⁰ CE, art. 148-149

⁶¹ <http://comitedebioetica.cat/el-comite/que-hace-el-comite-de-bioetica/> (Spanish only)

⁶² Comité de Bioética de Cataluña. <http://comitedebioetica.cat/el-comite/que-hace-el-comite-de-bioetica/> (Spanish only)

2.4.2 Andalusia

The Bioethics Committee of Andalusia⁶³ is the highest body of participation, consultation and advice on care ethics and biomedical research in Andalusia⁶⁴.

Its objectives are:

- To promote the harmonisation of the use of biomedical sciences and technologies with the rights and freedoms of citizens.
- Promote the adoption of appropriate measures to ensure the dignity, autonomy, integrity and other rights and fundamental freedoms of women and men in the field of health care and biomedical research, ensuring the effective exercise of their rights according to their needs and encouraging measures to promote the responsibility of citizenship and the performance of their duties.
- Encourage the bioethical issues in clinical activity.
- To promote and stimulate public debate and specialised in relation to ethics, health care and research, to document the opinions, attitudes and responses.
- Promote and develop the ethical perspectives of biomedical research in Andalusia.
- Promote gender in biomedical research and bioethical aspects of primary care.

2.4.3 Galicia

The Galician Bioethics Commission,⁶⁵ created in 2001, is a consultative body that aims to ensure the protection of fundamental rights in the Galician healthcare⁶⁶.

The Galician Bioethics Commission has the following functions:

- Provide advice and guidance to the Ministry of Health and the Galician Health Service in bioethics.
- Issue reports and studies on bioethical issues that are suggested or considered relevant for the health community Galician Ministry of Health.
- Be a reference body in bioethics for Ethics Committees.
- Assist in the development and harmonisation of standards and protocols regarding bioethical issues.
- Promote bioethics training of health care professionals.

The Galician Bioethics Commission is composed of 19 members, of which the president will direct the Department of Health Care.

The members of the commission are appointed by the Ministry of Health, for a period of three years, renewable for a similar period.

⁶³ <http://si.easp.es/eticaysalud/content/comite-bioetica-andalucia> (Spanish only)

⁶⁴ Junta de Andalucía, Consejería de Igualdad, Salud y Políticas Sociales.

<http://si.easp.es/eticaysalud/content/comite-bioetica-andalucia> (Spanish only)

⁶⁵ http://www.sergas.es/MostrarContidos_N3_T01.aspx?IdPaxina=63105 (Spanish only)

⁶⁶ Xunta de Galicia, Consellería de Sanidade.

http://www.sergas.es/MostrarContidos_N3_T01.aspx?IdPaxina=63105 (Spanish only)

Its composition will be at least:

- Three graduates in medicine and surgery.
- A degree in pharmacy.
- A diploma in nursing.
- Two health professionals than the above qualifications.
- Two people outside the health professions; of which at least one must be a graduate in law.

2.4.4 Ethics in Social Intervention.

There is a growing interest in the ethical evaluation of social aspects. Some Autonomous Communities (Basque Country, Catalonia, and Asturias) have launched social ethics committees. It is especially important the objective of achieving an inclusive society and the obligation to challenge social conditions that contribute to exclusion, stigmatisation or social subjugation. Spain has ratified as a law the UN Convention on the Rights of Persons with Disabilities.⁶⁷

⁶⁷ Jefatura del Estado, Instrumento de ratificación de la Convención sobre los derechos de las personas con discapacidad, hecho en Nueva York el 13 de diciembre de 2006. Boletín Oficial del Estado, adopted 21-04-2008. <https://www.boe.es/boe/dias/2008/04/21/pdfs/A20648-20659.pdf>

3 Public research and innovation systems

This chapter provides a discussion of ethics assessment of R&I in public research and innovation systems. The sections below discuss, respectively: the general structure and the role of government; the role of industry national research associations and standard-setting bodies; the role of research funding organisations; and, finally, the role of research performing institutions.

3.1 General structure and the role of government

This section provides an overview of the general structure of the publicly funded and controlled R&I and higher education system and the role of the government within this structure. A description of the different organisations and their interrelations will be provided, as well as an outline of the executive and regulatory powers of the government.

Responsibility for research and innovation policy is mainly dependent of the Ministry of Economy and Competitiveness (Mineco).

3.1.1 Spanish University System

The Spanish University System (SUE) consists of a total of 82 universities in the 2013-2014 year. Of the 82 universities, 50 are publicly owned and 32 private; 6 universities provide distance education. The number of private universities has been increasing in recent years, especially since 2001 as 14 private universities have been created, i.e., practically a university per year.

In Spain there are 1,75 universities per million inhabitants. Taking into account only the theoretical college age population (aged 18 to 24) the number of universities per million citizens stood at 24,6. In short, Spain has a university for every 569.852 inhabitants, and taking into account only the population between 18 and 24, there are 40.584 young people per university; on average, there are 19.000 students per university.

Universities have registered 481 research institutes, 29 doctoral schools and 47 university hospitals.⁶⁸ In Spain, Universities can be created by the CCAAs or the Parliament,⁶⁹ with the report from the General Conference for University Policy. Universities are responsible for the organisation of their studies and may have university research institutes, focused mainly on technical and scientific research. These centres may be created as collaboration with other universities, public or private organisations or other public research bodies, as well as the National Health Service and public or private non-profit research centres.

⁶⁸ Ministerio de Educación, Cultura y Deporte. *Datos básicos del sistema universitario español. Curso 2013-2014*. http://www.mecd.gob.es/dms/mecd/educacion-mecd/areas-educacion/universidades/estadisticas-informes/datos-cifras/DATOS_CIFRAS_13_14.pdf

⁶⁹ Jefatura del Estado, Organic Law 6/2001. BOE n. 307, adopted 24-12-2001. <http://www.boe.es/buscar/act.php?id=BOE-A-2001-24515>

3.1.2 Public Research Organisations

The Public Research Organisations (*Organismos Públicos de Investigación, OPI*) are institutions of public research at national level which, together with universities, form the core of the Spanish public system of scientific research and technological development, and running most of the activities scheduled in the National Plan for Scientific Research, Development and Technological Innovation. OPIs were first homogeneously regulated in 1986. There are currently eight OPIs, seven of them attached to the Ministry of Economy and Competitiveness:

- Spanish National Research Council (*Consejo Superior de Investigaciones Científicas, CSIC*)⁷⁰
- Centre of Energetic, Environmental and Technological Research (*Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas, CIEMAT*)⁷¹
- Geological and Mining Institute of Spain (*Instituto Geológico y Minero de España, IGME*)⁷²
- Spanish Institute of Oceanography (*Instituto Español de Oceanografía, IEO*)⁷³
- National Agricultural Research Institute (*Instituto Nacional de Investigaciones Agrarias, INIA*)⁷⁴
- Institute of Health Carlos III (*Instituto de Salud Carlos III, ISCIII*)⁷⁵
- Canary Islands Astrophysics Institute (*Instituto de Astrofísica de Canarias, IAC*)⁷⁶
- National Institute for Aerospace Technology (*Instituto Nacional de Tecnología Aeroespacial, INTA*,⁷⁷ attached to the Ministry of Defence

The scientific and technological capacities of these agencies, as well as their size and structure are very diverse. Their financing depends heavily on the public transfers they receive through the State Budget, plus their own resources, captured through competitive public calls from the National Plan, calls from the CCAA, services offered to government and contracts obtained from the private system.

The functions that the Law on Science established for these organisations are:

- Manage and implement national and sectorial programs allocated to them in the National Plan and, where appropriate, derivatives agreements signed with regional governments, as well as develop programs for training researchers that the Plan assigns to them.
- Contribute to the definition of the objectives of the National Plan and assist in their assessment tasks and monitoring.
- Advise on scientific research and technological innovation to Organisms dependent of the State Administration or the CCAAs.

⁷⁰ <http://www.csic.es/>

⁷¹ <http://www.ciemat.es/>

⁷² <http://www.igme.es/>

⁷³ <http://www.ieo.es/>

⁷⁴ <http://www.inia.es/>

⁷⁵ <http://www.isciii.es/>

⁷⁶ <http://www.iac.es>

⁷⁷ <http://www.inta.es/>

- Any other issue that is entrusted to them by the competent authority.

3.1.3 Foundations

Foundations are non-profitable entities created by the public or private sector which represent a key component as an intermediary between supply and demand for R&D and innovation and science, technology and business worlds. Foundations have not ceased to grow in number in recent years.⁷⁸

The Mineco has three main foundations focused on promoting the Spanish science, technology and innovation system:

- The Spanish Science and Technology Foundation (*Fundación Española para la Ciencia y Tecnología*, FECYT)⁷⁹
- Spanish National Cancer Research Centre (*Centro Nacional de Investigaciones Oncológicas*, CNIO)⁸⁰
- Spanish National Cardiovascular Research Centre (*Centro Nacional de Investigaciones Cardiovasculares*, CNIC)⁸¹

3.1.4 Bodies and Agencies Promoting Innovation

The bodies and agencies whose aim is to promote innovation are organisations inside the public, regional and local administrations, which operate as tools for facilitating the implementation of actions. These bodies and agencies are public entities with different legal forms: Spanish Patents and Trademarks Office (*Oficina Española de Patentes y Marcas*, OEPM)⁸²; Regional and Local Development Agencies.

The most important is the Centre for the Development of Industrial Technology (CDTI).⁸³ The Centre is a Public Business Entity, answering to the Ministry of Economy and Competitiveness, which fosters the technological development and innovation of Spanish companies. It is the entity that channels the funding and support applications for national and international R+D+I projects of Spanish companies. The CDTI thus seeks to contribute to improving the technological level of the Spanish companies by means of implementing the following activities:

- Financial and economic-technical assessment of R&D projects implemented by companies.
- Managing and fostering Spanish participation in international technological cooperation programmes.
- Fostering international business technology transfer and support services for technological innovation.
- Supporting the setting up and consolidating technological companies.

⁷⁸ http://cordis.europa.eu/spain/agents_en.html

⁷⁹ <http://www.fecyt.es/>

⁸⁰ <https://www.cnio.es/>

⁸¹ <https://www.cnic.es>

⁸² <https://www.oepm.e>

⁸³ <https://www.cdti.es/>

3.1.5 Not-for-profit institutions

These institutions constitute another focal point of the Science and Technology system.

- Scientific and Technological Parks are infrastructures which act as industrial development incubators where technologically advanced small and medium-sized enterprises arise, and spin-offs from Universities emerge (see below, Initiatives for public-private partnership)
- Technological Centres and Technological Innovation Support Centres provide companies with R&D and innovation services and act as a support platform by generating technological know-how and facilitating its exploitation.
- Finally, the European Business and Innovation Centres offer promoters and entrepreneurs cover and integrated advice comprising a comprehensive range of supports, monetary aids and services necessary for the preparation and success of new activities.

3.2 National research associations and standard-setting bodies

This section aims at providing an overview of the research associations and standard-setting bodies in Spain as well as at analysing their role in ethics assessment.

3.2.1 Research associations

The main university association in Spain is the Conference of Rectors of Spanish Universities (*Conferencia de Rectores de las Universidades Españolas, CRUE*)⁸⁴. The CRUE, founded in 1994, is a non-profit association formed by a total of 76 Spanish universities, 50 public and 26 private. The CRUE is the main interlocutor for universities with the central government and plays a key role in all regulatory developments affecting higher education in Spain. It also promotes initiatives of various kinds in order to foster relations with the productive and social fabric, institutional relations both nationally and internationally. It aims to contribute to the development and progress of current and future society, through the improvement of higher education, scientific research and knowledge transfer.

The CRUE counts among its main tasks to serve as a forum for dialogue for those who are responsible for research and development (R+D+I) in universities and provide adequate coordination between universities' scientific policies.⁸⁵ This task is performed by the Sectorial Commission for R+D+I (*Comisión Sectorial I+D+i*), formed by the heads of research of Spanish universities. It is intended as a forum for dialogue for the positioning of the Spanish Universities in everything that affects the field of R&D and knowledge transfer by providing adequate coordination between scientific policies of different universities. In summary, CRUE facilitates and encourages the development of joint activities, exchanging experiences and promoting university research.

From the Sectorial Commission for R+D+I depend two working groups: the RedOTRI, created in 1997 to promote the development and professionalisation of the OTRI (Research

⁸⁴ <http://www.crue.org>

⁸⁵ <http://www.crue.org/InvestigacionInnovacion/Paginas/default.aspx?Mobile=0>

Results Transfer Offices), and RedUGI (Unit Management Research Network), created in 2006 to help improve the management of R&D in Spanish universities.

3.2.2 Standard-setting bodies

National Accreditation Entity:

The National Accreditation Entity⁸⁶ (*Entidad Nacional de Acreditación, ENAC*) is the body designated by the Government to assess technical competence in accordance with international standards.

In Spain, ENAC has been appointed as the Spanish National Accreditation Body by virtue of the Royal Decree 1715/2010⁸⁷, endowed with public authority to award accreditations, in accordance with what is established in Regulation (CE) n°765/2008 of the European Parliament and the Council, of 9 July 2008.

ENAC is an independent non-profit organisation declared to be of public interest with over 25 years' experience. It develops its mission with a clear vocation of public service, geared both towards the government and the market in general, ensuring that all its activities are based on the principles of impartiality, independence and transparency, with a marked technical nature, bringing value to stakeholders in the different aspects of accreditation.

ENAC provides enterprises and the Spanish market with an infrastructure of competent conformity assessment bodies having by way of ENAC accreditation, full international recognition.

The purpose of ENAC is to build trust in the market and in the wider community in relation to the technical competence of accredited conformity assessors, thus contributing to people's safety and welfare, the quality of products and services, and environmental protection, and thereby to the increased competitiveness of Spanish products and services and to a reduction in the costs for society due to these activities.

To perform its function, ENAC carries out the following activities:

- Declaring technical competence of conformity assessors through an independent, impartial and transparent assessment system based on international criteria.
- Promoting international acceptance of activities of accredited conformity assessors by arranging recognition agreements, thus facilitating business exchanges in a global marketplace.
- Cooperating with government and other accreditation user organisations, assuring that the accreditation service that they are going to make use of meets their needs.
- Offering conformity assessors a high value-added service that represents a differential feature in the market by being a guarantee of integrity and competence and thus increasing business opportunities and inspiring public confidence in their activities.

⁸⁶ <https://www.enac.es/web/english/home>

⁸⁷ BOE n. 7 & 8th January 2011, p.1670-1673. <http://www.boe.es/buscar/doc.php?id=BOE-A-2011-398>

- Managing the accreditation system with efficacy criteria and in keeping with client needs.
- Furthering and disseminating accreditation criteria and procedures to assist conformity assessors in their access to accreditation and publicise the concept of accreditation and ENAC activities and its accredited bodies to all stakeholders.
- Cooperating with national and international institutions and organisations on aspects relating to its aims and objectives.

National Evaluation and Foresight Agency:

The National Evaluation and Foresight Agency (ANEP)⁸⁸ belongs to the Directorate General for Research and Management of the National R&D + Innovation Plan, within the State Department of Research of the Ministry of Science and Innovation. The Agency performs the scientific evaluation and must rely upon the certification from the centre management to which the researcher belongs to certify that the project has all the documentation.

The Agency's objectives are: ⁸⁹

- To evaluate the scientific and technical quality of proposals seeking government funding sent to the Directorate and other public and private entities.
- To improve the capacity of the public system of Science and Technology.
- To contribute so the decisions to allocate resources to R&D are made based on criteria of excellence and scientific-technical.

The Agency's functions are:

- Scientific-technical, objective and independent evaluation of units, teams and research proposals to participate in the programs and projects of the National Plan and monitor the results. Also the evaluation of any scientific and technical proposals assigned to de Agency by the Directorate General of Research and Management of the National R+D+I.
- Studies and prospective analyses in scientific research and technological development.

3.3 Research funding organisations

The Ministry of Economy and Competitiveness (MINECO) finances research via the Secretariat of State for Research, Development and Innovation (SEIDI) and the National Plan for Scientific and Technical Research and Innovation. The Plan consists of four state programmes that correspond to the general objectives set out in the Spanish Strategy for Science, Technology and Innovation, in accordance with the Horizon 2020 programme of the

⁸⁸ <http://www.anep.idi.mineco.gob.es/>

⁸⁹

<http://www.idi.mineco.gob.es/portal/site/MICINN/menuitem.26172fcf4eb029fa6ec7da6901432ea0/?vgnextoid=3d5167b99490f310VgnVCM1000001d04140aRCRD>

European Union. State programmes are deployed in a total of 18 multiannual sub programmes, to be mainly held on a competitive basis of calls.⁹⁰

Prior to receiving financing, the scientific-technical quality of proposals seeking public financing from both public and private organisations is evaluated by the ANEP. For biomedical research projects involving human beings or/and human materials or data, and animal research, the needed documents include the positive ethical evaluation by an authorised ethics committee, as required by law.

Public funding is managed by:

- The Sub-Directorate General for Research Assessment and Promotion⁹¹ evaluates the scientific merits of the projects applying for funding and sees that they meet the prioritisation criteria established in the calls. It is centred in Biomedical and Health Research of the National Plan for Scientific Research. The scientific evaluation is performed by peers, by the ANEP as well as by groups of experts convened by the institution. Therefore, an ethical evaluation per se is not performed, but it is a prerequisite for project funding that the projects have a favourable report from an authorised Research Ethics Committee (REC).
- The Directorate of Scientific and Technical Research⁹² evaluates, from a scientific and technical point of view, research proposals, programs (long-term projects, call for centres of excellence) related to all areas of scientific and technical research.
- The Directorate of Innovation and Competitiveness⁹³ develops the national strategies for innovation.

Private foundations are responsible of only 0,6% of the total expenditure on R&D⁹⁴ Any research projects funded must have the positive ethical evaluation by an authorised ethics committee, when required by law.⁹⁵ Some of the private foundations funding research and innovation are:

- The Alicia Koplowitz Foundation (*Fundación Alicia Koplowitz*)⁹⁶ is a non-profit organisation that focuses its efforts on Child and Adolescent Mental Health,

⁹⁰ http://www.idi.mineco.gob.es/stfls/MICINN/Investigacion/FICHEROS/Spanish_RDTI_Plan_2013-2016.pdf (Spanish only)

⁹¹ <http://www.eng.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-estructura-directiva/fd-subdireccion-general-evaluacion-fomento-investigacion/presentacion-sgefi.shtml>

⁹² <http://www.idi.mineco.gob.es/portal/site/MICINN/menuitem.7eeac5cd345b4f34f09dfd1001432ea0/?vgnnextoid=5e858a9d84518210VgnVCM1000001d04140aRCRD>

⁹³ <http://www.idi.mineco.gob.es/portal/site/MICINN/menuitem.7eeac5cd345b4f34f09dfd1001432ea0/?vgnnextoid=42348a9d84518210VgnVCM1000001d04140aRCRD>

⁹⁴ <http://www.ine.es/jaxi/tabla.do?path=/t14/p057/a2011/10/&file=01003.px&type=pcaxis&L=0>

⁹⁵ Fundación Alicia Koplowitz, Convocatoria de Ayudas a Proyectos de Investigación 2015, Bases Convocatoria 2015. Fundación BBVA, Convocatoria Fundación BBVA de Ayudas a Proyectos de Investigación, 2015.

http://www.fbbva.es/TLFU/dat/Bases_convocatoria_ayudas_proyectos_investigacion_.pdf

<http://www.fundacionaliaciakoplowitz.org/en/component/jdownloads/finish/2/221>

⁹⁶ <http://www.fundacionaliaciakoplowitz.org/en/>

developing a programme aimed at promoting and improving the training of medical professionals dedicated to psychiatric care for children, as well as encouraging advances in scientific and clinical research in this discipline.⁹⁷

- The ONCE Foundation for the Cooperation and Social Inclusion of People with Disabilities (*Fundación ONCE para la Cooperación e Inclusión Social de Personas con Discapacidad, Fundación ONCE*)⁹⁸ funds awards and research projects aimed at improving the quality of life of people with disabilities or improving accessibility, as well as grants for researchers with disabilities.⁹⁹
- BBVA Foundation (see below, Private research and innovation system, industry)
- Víctor Grifols i Lucas Foundation (see below, Private research and innovation system, industry)

3.4 Research performing organisations

In this section, it will be examined what general ethical standards, procedures and organisational units Spanish research performing institutions contain for ethics assessment, including their Codes of Good Scientific Practice.

Public sector research in Spain is performed by a number of organisations, which includes 47 public universities, about 300 Hospitals and 7 Public Research Organisations.

Spain ratified the Oviedo Convention in 1999 and Spanish legislation includes international guidelines and recommendations (Declaration of Helsinki, the UNESCO Universal Declaration on the Human Genome and Human Rights, etc.). In addition to the universally accepted ethical principles there are different regulations relating to ethics concerned with evaluating the elements or principles related to best practices in research.

Research centres must comply with legislation concerning ethical issues in relation to four areas:

- Human Research, human samples and / or data from human population.
- Animal research and/or research with animal samples.
- Research with Genetically Modified Organisms (GMOs).
- Research in Biological Agents (AB) that pose a risk to humans, plants and/or environment.

According to law, biomedical research projects involving human beings or/and human materials or data, and animal research, require the positive ethical evaluation by an authorised ethics committee (a REC or an Animal Welfare Committee).

Law 14/2011 establishes that the technical staff of the public research institutions of the State General Administration should adhere to the recognised ethical practices and disciplines

⁹⁷ <http://www.fundacionaliciakoplowitz.org/en/medical-scientific-activity/training-fellowships-and-research-grants-2015>

⁹⁸ <http://www.fundaciononce.es/>

⁹⁹ <http://www.once.es/new/sala-de-prensa/publicaciones-y-documentos/Documprensa/memoria-2013-de-la-once-y-su-fundacion/documentos/memoriaONCE2013capitulo5.pdf>

relevant to their ethical principles and ethical rules in the various ethical codes.¹⁰⁰ In general, the research centres, either national or regional, have developed their own codes of good scientific practices, based mainly in the laws 14/2011, 14/2007 and 15/1999, as well as other relevant legislation and international recommendations and declarations (as the Declaration of Helsinki, Committee on Publications Ethics (COPE)). The main principles included are, aside from principles as dignity, autonomy and others indicated in the laws in the matter, the quality of research, security, confidentiality, distributive justice, the evaluation of consequences, veracity. The good practices codes include also the obligation for the researcher of declaring any possible conflict of interests.

The law also creates the Spanish Committee for Research Ethics, which has not yet been appointed, with the functions, among others, to:

- Issue reports, proposals and recommendations on matters related to professional ethics in scientific and technical research.
- Establish the general principles for the development of codes of practice for scientific and technical research, which include the resolution of conflicts of interest between public and private activities. The Committees will develop these codes for Research Ethics and Bioethics Committee of Spain.

In Spain there are not any specific agencies addressing the issues related with ethics in scientific publication.

The instruments include the following:

- Recommendations of the Spanish Bioethics Committee for the impulse and implementation of Good Scientific Practice in Spain¹⁰¹
- Code of good scientific practices and Committee for research integrity (*Código de Buenas Prácticas Científicas y Comité de Integridad de la Investigación*). Instituto de Salud Carlos III.¹⁰²
- Spanish National Research Council (CSIC):
 - Code of Good Scientific Practices¹⁰³
 - Accountability of authors in multidisciplinary publications¹⁰⁴

The codes of good scientific practices provide recommendations; however, the centres may have arbitration procedures for conflict resolution, as well as standards for the protection of both persons who may make a complaint and the accused persons. RECs and ad hoc commissions are in charge of settling scientific integrity problems. These committees are independent and their decisions can be binding, although there is a right of appeal.

¹⁰⁰ Law 14/2011, art 28

¹⁰¹ http://www.comitedebioetica.es/documentacion/docs/buenas_practicas_cientificas_cbe_2011.pdf

¹⁰² <http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-comites/CodigoPracticasCientificas.pdf>

¹⁰³ <https://apps.caib.es/sacmicrofront/archivopub.do?ctrl=MCRST4827ZI145180&id=145180>

¹⁰⁴

http://www.csic.es/web/guest/buscar?p_p_state=maximised&p_p_lifecycle=1&_contentviewerservice_WAR_alfresco_packportlet_struts_action=%2Fcontentviewer%2Fview&p_p_id=contentviewerservice_WAR_alfresco_packportlet&_contentviewerservice_WAR_alfresco_packportlet_nodeRef=workspace%3A%2F%2FspacesStore%2Ff9a030e2-4a0b-4f40-91a4-eae21f58436a&p_p_mode=view&contentType=article

4 Private research and innovation systems

This chapter will provide a discussion of ethics assessment of R&I and *corporate social responsibility* (CSR) in private research and innovation systems. First, the general structure and the role of government will be examined. Then, the role of industry associations and accreditation, certification and standard-setting organisations will be reviewed. Finally, the role of industry itself will be discussed.

4.1 General structure and the role of government

In this section, the following topics will be discussed: the Spanish industry landscape; major Spanish organisations that represent industry; Spanish government policies and initiatives supporting ethics assessment and CSR in private industry; and Spanish initiatives for public-private partnerships with regard to ethics assessment and CSR.

4.1.1 Spanish industry landscape

Spanish industry is of great economic and social value to the country. In 2014, Spain had an employed population of 17.344.200 people, of which roughly 12 percent, or 2.141.400 people, were employed in industry (excluding construction and tourism industry).¹⁰⁵ Furthermore, the industrial sector generated roughly 16 percent of Spain gross domestic product in 2013.¹⁰⁶ Textiles and apparel (including footwear) are the largest industrial sector in Spain. Other major industries include food and beverages, metals and metal manufactures, chemicals, aeronautical, shipbuilding, automobiles, machine tools, tourism, clay and refractory products, pharmaceuticals and medical equipment.¹⁰⁷ Leading Spanish international industrial corporations include Inditex, Camper, Desigual, Repsol, Telefónica, Ferrovial, NH, Meliá. In January 2015, SME (companies with less than 250 employees) represent 99,86% of the total of Spanish companies, with 61,67% of employees.¹⁰⁸

4.1.2 Organisations that represent industry

Important Spanish industry-representing organisations include:

- The Confederation of Employers and Industries of Spain (*Confederación Española de Organizaciones Empresariales, CEOE*)¹⁰⁹ groups together almost 2 million companies and self-employed entrepreneurs of all sizes and from all sectors of activity, through base associations networked within 240 sectorial and territorial organisations. The organisation act as economic and social partner to the Government, the Public Administrations, the trade unions, the political parties and the international institutions.
- The Spanish Confederation of Small and Medium Enterprises (*Confederación Española de la Pequeña y Mediana Empresa, CEPYME*)¹¹⁰ is a professional, national organisation of confederal and intersectorial nature representing and promoting the

¹⁰⁵ <http://www.ine.es/jaxiT3/Datos.htm?t=4875>

¹⁰⁶ <http://www.ine.es/jaxi/menu.do?type=pcaxis&path=%2Ft35/p008&file=inebase&L=0>

¹⁰⁷ <https://www.cia.gov/library/publications/the-world-factbook/geos/sp.html>

¹⁰⁸ Cifras PYME. Enero 2015. http://www.ipyme.org/es-ES/publicaciones/EstadisticasPYME/Documents/CifrasPYME_enero2015.pdf

¹⁰⁹ http://www.ceoe.es/ceoccat-164-que_es_ceoe.html

¹¹⁰ <http://www.cepyme.es/es/que-es-cepyme/>

interests of SMEs and self-employed entrepreneurs. CEPYME is recognised as the most representative business organisation at the state level.

- The Spanish Business Confederation of Social Economy - CEPES (*Confederación Empresarial Española de Economía Social*) is a confederation with a national scope and cross-sector nature. It is an institution on the highest level of Spain's social economy and a platform for institutional dialogues with public authorities. As an organisation that pools existing economic actions under the social economy model, CEPES is made up of 28 organisations. All of them are national or regional confederations and specific business groups representing the interests of Cooperatives, Worker-Owned Societies, Mutual Benefit Societies, Insertion Companies, Special Employment Centres, Fishermen' Guilds or Disability Associations with more than 200 support structures at a regional level.¹¹¹

4.1.3 Government policies and initiatives to support ethics assessment in private industry

Spanish policies and initiatives to support ethics practices in private industry mostly concern *corporate social responsibility (CSR)*. The first public initiative was the creation, in the Ministry of Labour and Social Affairs, of a Technical Expert Commission in 2002, with the aim to write a report on CSR. Later, Royal Decree 221/2008¹¹² created the National Council for Corporate Social Responsibility¹¹³. The Council's objectives are:

- Provide a forum for discussion on CSR among the most representative Business and Trade Unions, Public Administrations and other organisations and institutions in the field of CSR serve as a framework for developing Social Responsibility of Enterprises in Spain.
- Encourage CSR initiatives, proposing the Government as part of its advisory and consultative functions, measures going in this direction and paying special attention to the uniqueness of SMEs.
- Report on initiatives and government regulations affecting, if any, the performances of enterprises, organisations and public and private institutions, which are an added value to fulfil their legal obligations, contributing to both the social and economic progress in the context of sustainable development.
- Promote standards and/or characteristics of the reports and/or reports on CSR and sustainability, as well as most suitable tools for processing and monitoring.
- To analyse the development of CSR in Spain, the European Union and third countries, and report on actions related to Social Responsibility of Companies.

In compliance with the established objectives, the National Council for Corporate Social Responsibility has the following functions:

- To issue reports and conduct studies to government request or on its own initiative.

¹¹¹ http://www.cepes.es/cepes_page=1

¹¹² BOE n. 52, 29th February, 2008. <http://www.boe.es/buscar/act.php?id=BOE-A-2008-3868>

¹¹³ http://www.empleo.gob.es/es/sec_trabajo/autonomos/economia-soc/RespoSocEmpresas/consejo_rse/

- To prepare and submit an annual report to the Government
- To establish itself as the Observatory of Corporate Social Responsibility in Spain.
- To promote and encourage corporate social responsibility initiatives.
- To collaborate and cooperate with other similar councils, including internationally.
- To participate in the way it is determined, in national and international fora set up to address issues of CSR.

In June 2014 a draft for a National Plan on Business and Human Rights (coordinated by the Human Rights Office within the Ministry of Foreign Affairs and Cooperation) was published. It establishes that businesses must avoid activities cause or contribute to causing adverse effects on human rights. Businesses must tackle such consequences should they occur and prevent or mitigate the negative impact on human rights directly related to operations, products or services by their business relationships - even if they have not contributed to generate these negative impacts.¹¹⁴

The 2014-2020 Spanish Strategy of CSR¹¹⁵ establishes tools to promote the integration of CSR in the education and training in responsible behaviour. The Strategy also includes measures to stimulate socially responsible investment in R+D+I. CSR can be established as an element in attracting long-term investment and as an incentive for a responsible and sustainable growth.

4.1.4 Initiatives for public-private partnerships

In Spain there has traditionally been little interaction between industry and the public sector, which has discouraged patenting and has created imbalances between academic supply and work demand.¹¹⁶ To improve this situation, the following mechanisms were created:

- The Research Results Transfer Offices (*Oficina de Transferencia de los Resultados de la Investigación, OTRI*) are structures to promote and facilitate cooperation in R&D activities between researchers and companies, both in national and European frameworks. Currently there is an OTRI in almost all public universities and national research centres, as well as in university-industry foundations and in many technology centres.¹¹⁷
- Science and Technology Parks (*Parques Científicos y Tecnológicos, PCT*) promotes coexistence between public research organisations, universities, the business network and the city.¹¹⁸
- The Centre for the Development of Industrial Technology (see above, Bodies and Agencies Promoting Innovation).

¹¹⁴ Government of Spain. National Plan on Business and Human Rights, draft for processing in the Council of Ministers, June 26th, 2014.

¹¹⁵ Estrategia Española de Responsabilidad Social de las Empresas.
http://www.empleo.gob.es/es/sec_trabajo/EERSE_WEB.pdf

¹¹⁶ DG Research, Monitoring Policy and Research Activities on Science in Society in Europe (MASIS) National Report, SPAIN. October 2011. Available at <http://www.morri.res-agera.eu/masis>

¹¹⁷ http://www.redotriuniversidades.net/index.php?option=com_content&task=view&id=113&Itemid=167

¹¹⁸ <http://www.apte.org/es/>

- University-Enterprise Foundations (*Fundación Universidad Empresa, FUE*)¹¹⁹ are private non-profit organisations created jointly by the Universities and Chambers of Commerce with the aim to promote and develop mechanisms of knowledge, dialogue and collaboration between Universities and Businesses, tackle the challenges, grasp the opportunities and build a healthy relation between institutions, as well as bring the collectives to work together. There are at present 33 FUEs, operating in 17 Spanish Autonomous Communities. The Foundations support initiatives specifically directed to innovation and comprehensive service of talent orientation.
- Industrial Liaison Offices (ILOs) are intermediaries in the science-technology-business system. Their fundamental mission is to strengthen relations among the stakeholders and work to identify technological needs of the socioeconomic sectors and to nurture technology transfer between public and private sectors.¹²⁰

4.2 Industry associations and accreditation, certification and standard setting organisations

4.2.1 Industry associations

Within industrial associations, Forética¹²¹ is the leader association of companies and professionals working with corporate social responsibility and sustainability in Spain and Latin America. The mission of Forética is to promote the integration of social and environmental aspects as well as good governance in the strategy and management of companies and organisations. It currently consists of over 200 partners. In Spain, Forética is a member of the National Council for Corporate Social Responsibility. Its mission is to promote a culture of ethical management and social responsibility providing the organisations with knowledge and tools to successfully develop a competitive and sustainable business model.

Other industrial associations include:

- The Spanish Global Compact Network (*Asociación Española del Pacto Mundial, ASEPAM*)¹²² was created in 2004 as a national affiliate of the Global Compact.
- The Sustainability Excellence Club (*Club de Excelencia en Sostenibilidad*)¹²³ is a business association whose work focuses on the training, dissemination and creation of events related to Corporate Social Responsibility.
- The Observatory of Corporate Social Responsibility (*Observatorio de RSC*)¹²⁴ was founded in 2004 as a network for cooperation and research, to enhance CSR in the core of society. It is composed of representatives of civil society, including trade unions, NGOs and consumer associations.

¹¹⁹ <http://www.fue.es/>

¹²⁰ http://cordis.europa.eu/spain/agents_en.html

¹²¹ <http://foretica.org/>

¹²² <http://www.pactomundial.org/>

¹²³ <http://www.club sostenibilidad.org>

¹²⁴ <http://www.observatoriorsc.org/>

4.2.2 Standard setting organisations

The first standardisation organisation in Spain was the Institute of Rationalisation and Normalisation (*Instituto de Racionalización y Normalización, IRANOR*), created in 1945 within the Superior Council for Scientific Research.

This organisation was replaced by the Spanish Association for Standardisation and Certification (*Asociación Española de Normalización y Certificación, AENOR*) in 1986.¹²⁵ AENOR is a private, non-profit organisation which is recognised nationally, in the European Union and internationally. It is the organisation that is legally responsible for developing and disseminating technical standards in Spain. AENOR offers one of the most extensive catalogues available, with more than 28.900 standard-related documents containing effective solutions. AENOR is one of the 10 most important certification organisations in the world, issuing certificates in more than 60 countries.¹²⁶ AENOR has issued various standards regarding CSR, including social responsibility towards childhood.

4.2.3 External Ethics Committees

The rules established in the Law on Biomedical Research for biomedical research conducted on human subjects, their samples or data, apply also to any biomedical research done by the industry. Any industry can create and request the accreditation of an independent REC or ascribe to any existent REC. Similarly, regarding animal experimentation, any research must be assessed, from an ethical point of view by an authorised ethics committee. Any industry can create and request the qualification of an animal welfare committee.

4.3 Industry

Many Spanish companies have been proactive in the adoption of CSR; eleven Spanish businesses are among the 187 leaders in the fight against climate change, according to the Carbon Disclosure Project¹²⁷, which places Spain as the 5th country with biggest representation as of 2014.

Spain is the country with the highest number of participants in the Global Compact¹²⁸ with 1693 participants.¹²⁹ The Spanish Network has elaborated a specific Communication on Progress (COP) for large companies as well as a COP for SME and others organisations to promote transparency and communication.

It is important to signal the divergence in the level of CSR implantation in businesses depending on their size. The grade of penetration in SME is low in comparison with large corporations: in 2011 only a 4% of the small enterprises (those with up to 49 employees) had

¹²⁵ Presidencia del Gobierno, Royal Decree 1614/1985 regulating normalisation and certification activities. BOE n. 219, adopted 12-09-1985, p. 28799-28802. <http://www.boe.es/buscar/doc.php?id=BOE-A-1985-19377>

¹²⁶ <http://www.aenor.es>

¹²⁷ CDP, “Driving sustainable economies”. *The A List. The CDP Climate Performance Leadership Index 2014*. <https://www.cdp.net/CDPResults/CDP-climate-performance-leadership-index-2014.pdf>

¹²⁸ The Global Compact is a strategic policy initiative for businesses that are committed to aligning their operations and strategies with ten universally accepted principles in the areas of human rights, labour, environment and anti-corruption

¹²⁹ [https://www.unglobalcompact.org/participants/search?commit=t&country\[\]=56](https://www.unglobalcompact.org/participants/search?commit=t&country[]=56)

advanced policies and tools of CSR, versus a 54% in medium (50-249 employees) and large companies (with 250 or more employees). However, more than half the businesses certified in the Norm of Social Responsibility SGE 21 in Spain are SME, which indicates an improvement.¹³⁰

Large companies may have their own good practices codes, especially in the pharmaceutical sector. These codes can establish standards for accepting gifts and invitations (Lilly, personal interview; 17-12-2014);¹³¹ giving or receiving gifts with the purpose or the appearance of influence on decisions related to the company should be avoided. One of the most important values for the company is the principle of transparency. This includes the EFPIA Disclosure Code for the transfer of value from pharmaceutical companies to healthcare professionals and healthcare organisations¹³². Lilly was one of the first pharmaceutical companies to publish their clinical drug trials protocols before having the trials results, to ensure publication of negative results too.

CSR in Lilly includes awards and activities for the promotion of excellence and quality research, as well as a Chair of Innovation and Value of medicine organised jointly with the University of Alcalá. Further they place great importance on complying with environmental legislation.

Large companies of all sectors, including banks, have created foundations to develop their CSR. Here we will look at some of them, focused on promoting research:

- The Lilly Foundation (*Fundación Lilly*)¹³³ was created by the Lilly Group in Spain to contribute to the improved development and promotion of health care in Spain through the support for biomedical research, dissemination of knowledge, the creation of forums to express opinions and exchange ideas, health training and education, the prevention of diseases and other activities.
- The BBVA Foundation (*Fundación BBVA*)¹³⁴ expresses the Corporate Social Responsibility of the BBVA Group, in particular, its engagement with projects to advance the societies where it conducts its business activity. This commitment has given rise to an extensive body of work in diverse knowledge areas. The Foundation engages in the promotion of research, advanced training and the transmission of scientific knowledge to society at large, focusing especially on the analysis of emerging issues in five strategic areas: Environment, Biomedicine and Health, Economy and Society, Basic Sciences and Technology, and Arts and Humanities. The BBVA Foundation designs, develops and finances research projects in these areas; facilitates advanced, specialist training through grants, courses, seminars and workshops; organises award schemes for researchers and professionals whose work has contributed significantly to the advancement of knowledge; and communicates and disseminates such new knowledge through publications, debates and lectures.

¹³⁰ Informe Forética 2015 sobre el estado de la RSE en España. Ciudadano consciente, empresas sostenibles

¹³¹ <http://www.lilly.com/SiteCollectionDocuments/pdf/RedBook.pdf>

¹³² <http://transparency.efpia.eu/the-efpia-code-2>

¹³³ <http://www.fundacionlilly.com>

¹³⁴ <http://www.fbbva.es>

- The Víctor Grífols i Lucas Foundation (*Fundación Víctor Grífols i Lucas*)¹³⁵ was created with the mission of promoting bioethics through dialogue between specialists in a range of areas. Grifols is a Spanish holding company specialised in the health-pharmaceutical sector and parent company of Grifols Group of companies. Grifols is active in the research, development, manufacture and marketing of plasma derivatives, I.V. therapy products (serums), enteral nutrition, reagents, instruments for clinical diagnostics and medical materials. The Foundation seeks to foster ethical attitudes in organisations, companies and individuals active in the field of human health. The Foundation awards six grants for research in bioethics every year to research projects to be undertaken on any issue related to bioethics and its practical application; an annual journalism prize, open to pieces of journalism tackling bioethical issues which have been published throughout the year in any medium; prizes for research in bioethics conducted by senior high school students and to educational institutions in Catalonia with projects that encourage ethical awareness and sensitivity among students in relation to scientific issues.

¹³⁵ <http://www.fundaciongrifols.org>

5 Professional groups and associations in the R&I field

This chapter will provide a discussion of the role in ethics assessment of R&I by professional associations in R&I or the ethics assessment thereof.

5.1 National associations for R&D professions

The Spanish Constitution guarantees the creation of professional associations (*Colegios Profesionales*) that are defined by the Law on Professional Associations as "corporations of public law, with legal personality and full capacity to fulfil its purposes."¹³⁶ The essential purposes of these associations are "the organisation of professional practice, the exclusive representation of them and the defence of the professional interests of its members."

As for their functions, it is especially noteworthy that corresponds to these professional associations to order the professional activity of their members, ensuring professional ethics and dignity, guarantee respect for individual rights and exercise disciplinary power in their field¹³⁷.

Therefore, the professional associations play a triple role:

- They set a number of criteria governing the exercise of the profession, thus ensuring greater effectiveness and efficiency.
- They elaborate codes of professional conduct that are imposed on the members, based in the law and the respect of human rights.
- They have the ability to punish members who violate the ethical codes.

The associations of technical professions (mainly engineering and architecture) revise their member's professional work¹³⁸. This revision is an act of technical control of certain work which is usually delegated by the Administration through legislation. The purpose of the revision is to check, at least, the identity and professional qualifications of the author of the work and formal correctness and completeness of documentation of professional work according to the rules applicable to the work concerned.

5.2 National organisations for (ethics) assessors

There are a number of Spanish national associations for ethics assessment of research, centred mainly in bioethics and biomedical research. They include the *National Association of Research Ethics Committees (Asociación Nacional de Comités de Ética de la Investigación, ANCEI)*, the *Network of Ethics Committees in Universities and Public Research Centres in Spain (Red de Comités de Ética de Universidades y Organismos Públicos de Investigación de España, RCE)*, and the *Spanish Association of Bioethics and Medical Ethics (Asociación Española de Bioética y Ética Médica, AEBI)*. These organisations generally contribute to ethics assessment practices by promoting, in a variety of ways, reflection and discussion on important contemporary ethics topics among members of the profession and society at large.

¹³⁶ Jefatura del Estado, Law 2/1974 on Professional Associations. Boletín Oficial del Estado, adopted 15-02-1974 <http://www.boe.es/buscar/act.php?id=BOE-A-1974-289>

¹³⁷ Law 2/1974, article 5.i.

¹³⁸ Law 2/1974, article 13.1.

- The *National Association of Research Ethics Committees*¹³⁹ is a voluntary, nationwide and non-profit association, which brings together persons who are or have been part of any Research Ethics Committee and other persons with a common interest. The Association aims to promote basic and further training of those who are or will form part of the RECs, and be the meeting place for ANCEI's members and other associations formed for similar purposes, both nationally and internationally.
- The *Network of Ethics Committees in Universities and Public Research Centres in Spain*¹⁴⁰ was created due to the need for the RECs to share information and experience to define, unify or at least standardise procedures affecting Committees, research and society, to achieve "common guidelines of agreed procedures" and also "promote setting up a Network among these Committees to share resources and exchange information and experiences". To that end, the Network organises annual meetings and maintains a website to allow the RECs to have a showcase - a means of an open rapid contact and tool for a wider debate. This website aims to easily provide the Committee members and the scientific community with all the relevant information: protocols, regulations and other items, documents, news and exams, links of interest and a Forum for discussion in this field.
- The *Spanish Association of Bioethics and Medical Ethics*¹⁴¹ aims to promote the ethical dimension in medicine and scientific research related to life and mankind. The purposes of the Association are: (1) promote studies on ethical values in the research and practice of the professionals involved in the life sciences; (2) inform and educate the public about the importance of Bioethics for society; (3) organise meetings, courses and conferences of multidisciplinary character on Bioethics, Biolaw and national and international related matters; (4) promote publications and books on Bioethics; (5) deliver to the association's members the Journal of Bioethics magazine and make available a comprehensive information service, which includes a rich documentary collection of the most important magazines and publications in this field.

¹³⁹ <http://www.ancei.es/> (Spanish only)

¹⁴⁰ <http://www.ub.edu/rceue/index2.htm>

¹⁴¹ <http://www.aebioetica.org/> (Spanish only)

6 CSOs

6.1 The CSO landscape

This section will provide a review of the CSO landscape in Spain. An overview will be given of national legislation and regulation for CSOs and major CSOs and their societal roles.

6.1.1 National legislation and regulation for CSOs

CSOs in Spain are regulated by the Law on Associations (Law 1/2002).¹⁴² This law does not include the regulation of consumers associations nor religious communities and associations, which are regulated by their specific laws.¹⁴³ There is no specific regulation the funding of CSO. According to a study elaborated by Eroski Consumer, 25% of the main NGOs in Spain receive more than 70% of their funding from public subsidies, while 32% depend mainly on private funding (donations, organising events, merchandising, lottery...).¹⁴⁴

6.1.2 Major CSOs and their societal roles

The following are the most important Spanish CSOs with regard to ethics assessment of research and innovation. Organisations with a thoroughly international character, such as *Intermón Oxfam* and the *World Wildlife Fund*, are not included in the list.

Religious organisations:

- The Spanish Episcopal Conference (*Conferencia Episcopal Española*)¹⁴⁵
- The Spanish Islamic Commission (*Comisión Islámica de España*)¹⁴⁶
- The Spanish Federation of Jewish Communities (*Federación de Comunidades Judías de España*)¹⁴⁷

Environmental and animal rights organisations:

- Ecologists in Action (*Ecologistas en Acción*)¹⁴⁸
- SEO/BirdLife (*Sociedad Española de Ornitología*)¹⁴⁹
- Animal Equality (*Igualdad Animal*)¹⁵⁰

Civil liberties/human rights organisations:

- Spanish Association of Science Communication (*Asociación Española de Comunicación Científica, AECC*)¹⁵¹

¹⁴² Jefatura del Estado, Law 1/2002, BOE n. 73, adopted 26-03-2002, p. 11981-11991.

<http://www.boe.es/buscar/doc.php?id=BOE-A-2002-5852>

¹⁴³ Ministerio de la Presidencia, Royal Legislative Decree 1/2007, approving the revised text of the General Law for the Protection of Consumers and Users and other complementary laws. BOE n. 287, adopted 30-09-2007, p. 49181-49215. <http://www.boe.es/buscar/doc.php?id=BOE-A-2007-20555>.

¹⁴⁴ <http://ong.consumer.es/>

¹⁴⁵ <http://www.conferenciaepiscopal.es/index.php> (Spanish only)

¹⁴⁶ <http://ucide.org/>; <http://feeri.es/> (Spanish only)

¹⁴⁷ <http://www.fcje.org/> (Spanish only)

¹⁴⁸ <http://www.ecologistasenaccion.org/> (Spanish only)

¹⁴⁹ <http://www.seo.org/> (Spanish only)

¹⁵⁰ <http://www.igualdadanimal.org/> (Spanish only)

- Spanish Romani Union (*Unión Romani Española*), an organisation that helps the integration of the Gipsy community in Spain.¹⁵²
- Karibu Association (*Asociación Karibu*), an organisation that helps the integration of sub-Saharan immigrants.¹⁵³

Consumer organisations:

- Consumers in Action (*FACUA-Consumidores en Acción*)¹⁵⁴
- Consumers and Users Organisation (*Organización de Consumidores y Usuarios, OCU*)¹⁵⁵

Development (aid) organisations:

- Action against hunger (*Acción contra el hambre*)¹⁵⁶
- Doctors of the world (*Médicos del mundo*)¹⁵⁷
- Help in Action (*Ayuda en Acción*),¹⁵⁸ development NGO whose main objective is to improve the living conditions of children, their families and communities.
- Vicente Ferrer Foundation (*Fundación Vicente Ferrer*),¹⁵⁹ development NGO committed to improving the living conditions of the most disadvantaged communities in Andhra Pradesh (India).
- Equimercado,¹⁶⁰ NGO that imports and distributes fair trade products.

Disease charity and patient/disabled rights organisations:

- National Organisation for the Blind (*Organización Nacional de Ciegos Españoles, ONCE*)¹⁶¹
- Spanish Association Against Cancer (*Asociación Española Contra el Cáncer, AECC*)¹⁶²
- Spanish Federation of Blood Donors (*Federación Española de Donantes de Sangre*)¹⁶³
- Diabetes Foundation (*Fundación para la Diabetes*)¹⁶⁴
- Federation of Organisations for Persons with Intellectual Disability (*Federación de Organizaciones en favor de Personas con Discapacidad Intelectual, FEAPS*)¹⁶⁵
- Spanish Federation of Cystic Fibrosis (*Federación Española de Fibrosis Quística*)¹⁶⁶

¹⁵¹ <http://www.aecomunicacioncientifica.org/> (Spanish only)

¹⁵² <http://www.unionromani.org/> (Spanish only)

¹⁵³ <http://www.asociacionkaribu.org/> (Spanish only)

¹⁵⁴ <http://www.facua.org/> (Spanish only)

¹⁵⁵ <http://www.ocu.org/> (Spanish only)

¹⁵⁶ <http://www.accioncontraelhambre.org/> (Spanish only)

¹⁵⁷ www.medicosdelmundo.org

¹⁵⁸ <http://www.ayudaenaccion.org/> (Spanish only)

¹⁵⁹ <http://www.fundacionvicenteferrer.org>

¹⁶⁰ <http://www.equimercado.org/> (Spanish only)

¹⁶¹ <http://www.once.es>

¹⁶² <https://www.aecc.es/> (Spanish only)

¹⁶³ <http://www.donantesdesangre.net> (Spanish only)

¹⁶⁴ <http://www.fundaciondiabetes.org> (Spanish only)

¹⁶⁵ <http://www.feaps.org> (Spanish only)

- Spanish Association of Patients with Hepatitis C (*Asociación Española de Enfermos de Hepatitis C*)¹⁶⁷
- Spanish Confederation of People with Physical and Organic Disabilities (*Confederación Española de Personas con Discapacidad Física y Orgánica, COCEMFE*)¹⁶⁸
- Spanish Federation for Rare Diseases (*Federación Española de Enfermedades Raras, FEDER*),¹⁶⁹ whose main objective is to promote and raise funds for research of rare diseases.
- Spanish Society of Rheumatology (*Sociedad Española de Reumatología, SER*)¹⁷⁰

Labour unions:

- General Workers' Union (*Unión General de Trabajadores, UGT*)¹⁷¹
- Worker's Commissions (*Comisiones Obreras, CCOO*)¹⁷²

6.1.3 Role of CSOs in research and innovation

Several CSOs, especially disease charities, spend a (substantial) part of their funds on scientific research. The following are some examples:

- AECC Foundation has awarded 144 grants and projects developed in 46 research centres, for a total of 24,8 million euros since 2009, such being the social and private entity that allocates more funds to cancer research. Since 2009, the foundation has received over 1.800 applications for projects through public calls, with an annual increase of about 30%.¹⁷³
- The SER, through its Foundation (FER) develops a Plan for the Promotion of Research with an allocation of € 144,000 for scholarships for the 2015 call.¹⁷⁴

6.2 The role of CSO's in ethics assessment

This section will provide a discussion of the roles of CSOs as stakeholders in public discussions, and as participants in ethics assessment panels and procedures.

6.2.1 CSOs as stakeholders in public discussions

Spanish CSOs play an important role in societal debates on the use of (new) technologies and products such nanotechnology, GMOs; the rights of patients in clinical trials. They inform the public through information campaigns, public demonstrations and appearances in the media; and convey their concerns to other stakeholders.

¹⁶⁶ <http://www.fibrosisquistica.org> (Spanish only)

¹⁶⁷ <http://www.aehc.es> (Spanish only)

¹⁶⁸ <http://www.cocemfe.es>

¹⁶⁹ <http://www.enfermedades-raras.org/>

¹⁷⁰ <http://www.ser.es>

¹⁷¹ <http://www.ugt.es> (Spanish only)

¹⁷² <http://www.ccoo.es/> (Spanish only)

¹⁷³ AECC Annual Report. <https://www.aecc.es/Investigacion/Paginas/InformeAnualFC2013.aspx>

¹⁷⁴ <http://www.ser.es/investigacion/Investigacion.php>

6.2.2 CSOs as participants in ethics assessment panels and procedures

In general, Spanish CSOs do not participate in the ethical assessment of research and innovation, nor do they engage in ethics assessment themselves. Neither the RECs nor the assessor Committees (such as the Spanish Bioethics Committee) have any policy or regulation for the participation of civil society organisations in their meetings. The Draft Royal Decree regulating clinical trials with medication¹⁷⁵ anticipates that a patient representative will be a part of the RECs that evaluate clinical trials. This provision will ensure the participation of patient associations in the ethical assessment of clinical trials.

¹⁷⁵ Ministerio de Sanidad, Servicios Sociales e Igualdad, Royal Decree regulating clinical trials with medication, the Ethics Committees of the Drug Research and Clinical Trials Register, adopted 17-05-2013.
<http://www.msssi.gob.es/normativa/docs/Rdensayosclnicosm.pdf>

7 Discussion

In recent years, Spain has shown great interest in the ethical review of research and innovation. This has been linked to the development of research and the incorporation of new technologies in the field of health, engineering and the environment.¹⁷⁶ Ethical assessment has focused in the area of biomedicine. However, in recent years systems development on Ethical Management and Social Responsibility are being introduced in the business sector.

In Spain, ethical assessment in biomedicine research has been well established since the 1990s. In those years, in hospitals were developed Research Ethics Committees in line with the development of the European Directive on clinical drug trials and healthcare ethics committees were created. The policies implemented to support organ transplants and stem cell research created the need to strengthen the ethical guarantees with the creation of ethics committees to advise and evaluate these actions.

Nowadays, Spain has a network of Research Ethics Committees in health centres, universities and public research bodies conducting the ethical review of research projects and their favourable report is mandatory for the project's implementation. Ethical assessment of research in Universities has been in constant development. At the start, the main issues were those present in engineering and Law; in the 1990s started the ethical issues of biomedical research (medicine, nursing, physiotherapy...). Currently, universities' ethical committees are receiving more issues in humanities and social sciences research, like sociology and psychology (J. de la Torre, personal interview, 15-01-2015).

Further, there are assessor committees (for advisory and guidance) at national level (Spanish Bioethics Committee, Spanish Research Ethics Committee) and regional level. There are also a high number of foundations concerned with education in ethical aspects as well as the development of guidelines and recommendations on ethical issues related to research and other topics that generate social concern.

Biomedical research (both basic research and clinic research) in Spain is highly regulated, mainly by the Law on Biomedical Research, adopted in 2007. The Law adopts the human rights indicated in the Spanish Constitution, the regulation on Data Protection and patient autonomy, as well as internationally accepted ethical principles. The law declares that the health, interest and wellbeing of humans participating in biomedical research shall prevail over the interest of society or science. The law provides for free personal autonomy, the right to non-discrimination, the duty of confidentiality in respect of personal information, the principle of free donations of biological materials, among others.

Animal research is also highly regulated, both by national and regional legislation as well as European Directives. Any research project involving animals needs the favourable report of an Animal Welfare Committee and the ethics committee (called authorised body), as well as the authorisation of the regional competent body.

¹⁷⁶ European Commission, Research and Innovation performance in the EU, Innovation Union progress at country level, Brussels, 2014, p. 269: http://ec.europa.eu/research/innovation-union/pdf/state-of-the-union/2014/iuc_progress_report_2014.pdf

In other fields, especially environment protection, there is no formal ethical assessment. Research projects are evaluated taking into account the criteria established in applicable national legislation, and European guidelines.

Industries are incorporating ethical evaluation through the development of CSR. One of the biggest challenges in this sector is to increase the incorporation of SMEs, especially today, as the economic crisis is making it complicated to increase investment in CSR. Another difficulty is posed by the fact that the draft of the National Plan on Business and Human Rights, published in June 2014, has not yet been adopted.

One of the challenges in ethical assessment in Spain is the limited participation of civil society. It would be necessary to find ways to increase participation of the public and CSOs in ethics committees and increase the public debate in ethical issues.

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