

## **Law 14/2007, of 3 July, on Biomedical Research**

**Juan Carlos I**

**King of Spain**

To all who view and understand this,

Be it known:

That the Spanish Parliament has passed and I ratify the following Law.

### **Preamble**

#### **I**

Biomedical research and the health sciences, which are key elements in improving the quality and life expectancy of citizens and their well-being, have substantially changed, both methodologically as well as conceptually in the last few years.

The development of new analytic tools has led to great discoveries which allow us to foster reasonable hopes for treatments and even cures in the not too distant future of pathologies which are not capable of being dealt with at present.

In the past few years, the collection, use, storage and transfer of biological samples for diagnostic or research purposes has acquired enormous relevance. Research involving invasive procedures on human beings is becoming more frequent, and research with gametes, embryos or embryonic cells has become indispensable for cell therapy and regenerative medicine.

However, these scientific advances and the procedures and tools used to achieve them generate serious ethical and legal uncertainties that must be adequately regulated, with the balance and prudence that is demanded of such complex matters that affect the identity

of the human being in such a direct manner.

Furthermore, these new scientific advances challenge the organisational basis of biomedical research. This new context requires a multidisciplinary approach, a close connection between basic and clinical research and coordination and work in networks, as necessary guarantees for quality research.

Spain, which already actively participates in the generation of biomedical knowledge, is not unaware of the interest raised by this research and the debate it generates. In this sense, the public administration is decisively supporting biomedical research and is providing important economic and human resources and the necessary infrastructures to foster such ends.

Both the General Administration of the State, when exercising its jurisdiction with regard to the fostering and general coordination of scientific and technical research, as established in Article 149.1.15 of the Constitution, as well as the administrations of the autonomous communities, which in their statutes have unanimously stated their jurisdiction to foster research, are establishing structures for biomedical research in networks that facilitates participation and collaboration between private enterprises, other research entities, universities and their own centres within the National Health System. This is being done in order to take advantage of the available resources in an efficient manner and to obtain results from the contributions of various research groups, which can be applied to improving the health of all citizens.

In this vein, there is compliance in the field of biomedical research with the mandate established in Article 44.2 of the Spanish Constitution, which entrusts public powers to promote science and

scientific and technical research for the general welfare.

This Law is set within this context. On the one hand, it responds to the challenges that are posed by biomedical research and attempts to take advantage of its results for the collective health and well-being of all citizens. On the other hand, the Law also promotes and stimulates coordinated action by public powers, together with public and private entities and institutions dedicated to research, which are better equipped to comply with this task.

Furthermore, in order to achieve these objectives, this Law establishes regulations in areas that were either previously unregulated, or only partially regulated, so that provision is made for more recent scientific advances, such as genetic analysis, research with human biological samples, particularly those of an embryonic nature, and biobanks.

## II

Bearing these considerations in mind, it is necessary to ensure that an adequate normative framework is in place that provides answers to new scientific challenges while at the same time guarantees the protection of the rights of persons who could be affected by such research.

In fact, both at the international and Spanish societal level, some of the most sensitive aspects of biomedical research have been the subject of open and thorough debate, which has allowed the formulation of principles and criteria that have become more widely accepted with time. From this, behavioural norms and regulations are being created to provide the necessary equilibrium between the needs of researchers and the trust of society in scientific research.

In accordance with this spirit, a core priority of this Law is to ensure respect for and protection of fundamental human rights and public liberties, which

have been established in our legal regulation – notably within the Spanish Constitution and the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of the Council of Europe, signed in Oviedo on April 4 1997, and which came into effect in Spain on January 1 2000. Consequently, the Law proclaims that the health, interest and well-being of human beings who participate in biomedical research shall prevail over the interests of society or science.

In particular, this Law is founded on the principles, of integrity of the person and protection of the dignity and identity of those persons involved in any biomedical research that involves intervention on human beings, as well as in the undertaking of genetic analysis, the processing of genetic data of a personal nature and the use of human biological samples in research.

Along these lines, the Law establishes the free will of the person as the foundation from which the specific right to consent and to obtain previous information derive.

Likewise, it establishes the right not to be discriminated against, as well as the duty of confidentiality upon any person who, in the exercise of their duties, has access to personal information. The Law also provides for the principle that there shall be no profit in relation to donation of biological material and sets standards for quality and safety, which include the traceability of human cells and tissues and strict compliance with the precautionary principle in the different activities that it regulates.

In regulating all of these matters, Basic Law 41/2002, of 14 November, on the Autonomy of the Patient and the Rights and Obligations in Matters of Clinical Information and Documentation and Basic Law 15/1999, of 13 December, on the Protection of

Data of a Personal Nature have been taken into account, both of which are established as subsidiary in those matters that are not regulated by this Law.

From the research perspective, the Law guarantees the freedom of research and of scientific production in the terms provided in Article 20 of our Constitution. But such an ambitious legal framework on advanced research in the field of biomedicine must also take into account the human, scientific, structural and social context in which it must develop in its daily practice. This Law regulates the mechanisms for fostering and promoting, planning, evaluating and coordinating biomedical research based on the principles of quality, efficacy and equal opportunity, in order to ensure that the results of this research are transformed into efficient therapies to combat different pathologies.

Notably, it is becoming easier for research in health centres to be considered as routine practice. Collaboration among basic biomedical research centres and hospitals and other centres of the National Health System is also being encouraged, and ties between the public and private sector are being fostered through research in networks and the mobility of researchers and practitioners.

From an organisational perspective, the Law creates a number of professional entities, each of which has specific responsibilities for oversight of its members, based on impartiality, independence, technical capacity and professional competency.

Research Ethics Committees are required to ensure that every research centre which undertakes research on human beings or biological samples of human origin does so in accordance with methodological, ethical and legal standards.

The Commission for the Guarantees on the Donation and Use of Human Cells and Tissues is responsible for the compulsory evaluation of all research projects that require the collection or use of tissues, embryonic stem cells or other similar matter of human origin, which are obtained through diverse techniques of cell reprogramming that either already exist or that could be discovered in the future. The Commission is also responsible for provision of information as well as the development of other functions on scientific, ethical or legal bases.

Finally, the Spanish Bioethics Committee is created as the authority for consultation in relation to all practices with ethical and social implications in the field of medicine and biology and is called upon to set guidelines and general principles for the drafting of codes of good practice in scientific research that are developed by the Research Ethics Committees.

### III

In accordance with the gradualist perspective on the protection of human life set out by our Constitutional Court in rulings such as 53/1985, 212/1996 and 116/1999, this Law expressly prohibits the creation of human pre-embryos and embryos exclusively for the purpose of experimentation. However, the use of any technique for collecting embryonic stem cells for therapeutic or research purposes that does not entail the creation of a pre-embryo or of an embryo exclusively for this purpose, and in the terms provided by this Law, is allowable.

In relation to the use of supernumerary embryos from assisted human reproduction techniques, the starting point is to be found in Law 14/2006, of May 26, on Assisted Human Reproduction Techniques, which expressly forbids so-called reproductive human cloning.

#### IV

This Law regulates a broad and complex set of matters, compiled in 90 Articles, 15 Chapters, eight Titles, three additional dispositions, one repealing and five final dispositions.

The general dispositions of Title I are the regulating and integrating axis of the Law.

The object and scope of application of this Law are set out in Title 1, establishing a set of principles and guarantees for the protection of the rights of persons and legal goods involved in biomedical research.

This object and scope confirm that the biomedical research to which reference is made covers basic and clinical research and excludes clinical trials with medication and the implantation of organs, tissues and cells, which shall be regulated in a specific regulation.

A specific list of guarantees is provided that sets the limits on the principle of freedom of research in favour of the dignity and identity of human beings and the protection of their health. The following are also specifically regulated: informed consent and the right to information; protection of personal data and the duty of confidentiality; non-discrimination due to genetic reasons or due to the refusal to undergo a genetic analysis or to participate in research; no profit from the donation and use of biological samples; guarantee of traceability and safety in the use of cells, tissues and any biological material of human origin; and lastly, the limits that must be adhered to in genetic analysis.

Additionally, this Title specifies the criteria that biomedical research must follow regarding quality, efficacy and equality. Biomedical Research Committees are created as fundamental tools for the evaluation and monitoring of research projects.

Lastly, Article 3 establishes a broad list of definitions, which are based on scientific, technical and legal knowledge, and which aim to delimit some relevant concepts of the Law.

The first specific matter of the Law, compiled in Title II, is dedicated to biomedical research that involves invasive procedures on human beings, excluding those that are merely observational. These provisions complete the normative framework of our legal regulation on research in which human beings are direct participants, for which specific regulation already exists relating to clinical trials with medications and health products.

This Title's five Chapters include the following topics. The first Chapter provides the general principles of research, with express reference to consent and the precise information that must be provided to participants in such research. The second Chapter establishes systems of evaluation and authorisation and assurance of potential damages, aimed at reducing to the utmost any damage that may result from research that entails invasive procedures in human beings. Chapter III regulates the specificities of research during pregnancy and lactation and research involving minors, the disabled and other persons unable to provide their consent due to clinical reasons.

The fourth Chapter of this Title regulates the safety and supervision systems in the research process, with specific reference to the evaluation of the state of health of participants in research, non-interference in clinical intervention and the system of verification that, under the supervision of the Research Ethics Committee, must be performed throughout the research. Finally, the last Chapter of the Title sets out the obligation to inform participants about relevant data regarding their health that could be obtained throughout

the research process, as well as the obligation to publicise their results.

Title III, containing two Chapters, compiles the set of regulations dealing with the donation and use of human embryos and fetuses, their cells, tissues or organs, with two main objectives. The first of these is to revise and update the legal regime that was in effect before the entry of this Law; specifically, Law 42/1988, of 28 December, on the donation and use of human embryos or fetuses or their cells, tissues or organs. The second objective is to incorporate these provisions into the global approach that is taken in this new Law, in order to eliminate unnecessary normative digressions related to biomedical research. Law 42/1988, of 28 December, which in its time was a noteworthy and novel legislative development and was recognised as a reference in comparative law, is repealed as a consequence.

The first Chapter in Title III sets out the conditions for the donation of human embryos and fetuses. It includes prohibitions on the termination of a pregnancy for the purpose of donation and on the use of the aborted embryos or fetuses by the professional members of the medical team that perform the termination. It establishes that for the donation to be valid there must be a concurrence between informed consent by the donor and termination based on the lack of viability of the embryos and fetuses.

The second Chapter provides that research with live embryos and fetuses in the uterus shall only be undertaken for diagnostic or therapeutic purposes for their own benefit, and establishes the requirements for the authorisation of such research projects with embryos, fetuses and their biological structures.

In Title IV, donation, use and research involving human embryonic cells and tissues and other similar cells is

regulated, in full accordance with the provisions in Law 14/2006 on Assisted Human Reproduction Techniques, which already regulates the donation of surplus oocytes and pre-embryos in vitro, the application of assisted reproduction techniques, as well as the requirements for the use of these pre-embryos or their biological structures for research or experimentation. This Law imposes further obligations. The Guarantees Commission for the Donation and Use of Human Cells and Tissues must issue a favourable report and the first two Chapters of Title IV impose further conditions, guarantees and requirements.

The first Chapter of this Title expressly prohibits the creation of human pre-embryos or embryos for experimentation. It authorises the use of any technique for collecting human stem cells for therapeutic or research purposes, including the activation of oocytes through nuclear transfer, provided that this does not entail the creation of a pre-embryo or embryo in the terms defined in this Law. Chapter II specifies the conditions that must be satisfied in research involving biological samples of an embryonic nature. The third Chapter establishes the composition and function of the aforementioned Guarantees Commission. The Commission also has responsibility for providing information on research that is listed in the Law on stem tissues and cells or other functionally similar materials and on procedures or techniques for collecting them, including collecting embryonic stem cell lines from third countries. Lastly, Chapter four establishes a system for promotion and coordination of research with human embryonic cells and tissues, while also highlighting the role of the National Bank of Cell Lines, which is afforded a central node network structure and appointment to the Institute of Health Carlos III.

Title V regulates other emerging matters related to the expanding field of biomedical research, such as the undertaking of genetic analysis, access and use of its results, and collection and use of human biological samples. Despite the enormous difficulties associated with establishing the limits between research and diagnosis in the ambit of genetic analysis, due to substantive and systematic coherence and in view of the important rights of persons who might be involved in such analysis, this Law cannot neglect the need to establish a legal framework in which we must take a stance in the performance of genetic analysis for any purpose, including diagnostic purposes.

In this regard, the Law, while prescribing a set of guarantees in relation to genetic analysis and biological samples within the ambit of the protection of personal data, creates a set of norms aimed at providing trust and safety to researchers, as well as public and private institutions, thus eliminating any current legal uncertainties. Aside from other normative principles mentioned above, the guiding principles include accessibility, equity and quality in the processing of data, prior consent and anonymisation of biological samples. Lastly, specific rules are established pertaining to the deceased and to pre-embryos, embryos and fetuses, guaranteeing the protection of data and the duty of confidentiality. It is also noteworthy that the Law sets out the need to accredit the centres and persons capable of undertaking genetic analysis.

Collection, conservation, use and transfer of biological samples are likewise the objects of detailed regulation in Chapter III of this Title. Logically, the legal framework again depends upon the consent of the source of the samples and on the previous information that must be provided in this regard. Recognising that there is a

divergence between the grant of completely generic or specific consent on the use or latter uses of the sample, the Law has chosen an intermediate and flexible option. The initial consent may be sufficient if in the information provided to the subject source prior to obtaining this consent includes a provision about later research related to the initial research, including research that may be undertaken by third parties and transfer of the data or of identified or identifiable samples to them. In any event, a transitory arrangement has been established in respect of biological samples obtained for any purpose before the entering into effect of this Law, so that their use for research is not hindered, while at the same time the interests of the subject source are monitored.

In close relation with the use of samples of human origin, this Law defines and clears up the legal status of biobanks and differentiates them from other collections of biological samples that could exist for biomedical research purposes, notwithstanding that in both cases these must be registered in the National Biobank Registry. A single system of registration is set up, irrespective of the purpose of the bank. This includes banks used for clinical purposes in patients, whether or not they are used exclusively for that purpose or also for research. It applies notwithstanding that specific measures must be developed by regulation for the functioning of each bank in accordance with its particular nature and purposes.

The Law also establishes that authorisation for the creation of biobanks shall be obtained from appropriate entities within relevant autonomous communities, except for the initiatives that the Institute of Health Carlos III could take relating to the creation of national banks of biological samples for research in accordance with the general welfare, in which case the

authorisation shall be obtained from the Ministry of Health and Consumption.

Title VI establishes a regime of administrative breaches and sanctions that are based on the principles of legality, minimum intervention, proportionality, and subsidiarity regarding criminal offences. The specific breaches included in this Law are complementary to like provisions in Law 14/2006 of 26 May on Assisted Human Reproduction Techniques, notwithstanding those which might likewise be applicable by the General Health Law and others provided in the regulation of the autonomous communities and on the regulation on the protection of data of a personal nature.

Furthermore, this Law aims to respond to the need for a State entity to take on a consultative role on matters related to the ethical, legal and social implications of medicine and biology through the creation of the Spanish Bioethics Committee. This Committee will also represent Spain in supranational and international forums and bodies that are involved in bioethics and collaborate with other State and autonomous committees with counselling functions on these matters. Title VII of this Law includes provisions on its composition and functioning, aiming to guarantee its independence through the designation of its members from accredited qualified persons of the scientific, legal and bioethical world.

Lastly, Title VIII of this Law, which is particularly relevant, is aimed at the promotion and coordination of biomedical research within the National Health System, elaborating on a sector initiative within the National Plan for Scientific Research and Technological Development and Innovation. Together with this and due to the continuous demands of certain research groups, the aim is better regulation of the promotion

and coordination of biomedical research in Spain. In order to achieve both objectives, an instrumental normative framework is created for the promotion of scientific research excellence, aimed at resolving the health needs of the population. The framework particularly focuses on clinical practice based on scientific knowledge within the structures of the National Health System, allowing the capacity to hire personnel dedicated to research activities to those centres that are part of it and opening up the possibility that research activity will become an integrating part of the professional career of statutory personnel. Furthermore, measures are established for mobility of research personnel within the general administration of the state and out to private research entities through temporary leaves of absence.

Additionally, cooperation between the public and private sectors is strengthened. Relevant measures include collaboration and participation of private entities in research activities within the National Health System and the possibility that personnel from these private entities could participate in research projects in the National Health System.

Among those provisions that conclude the Articles of this Law, special mention must be made of the provision which revises and updates the regulation of the Institute of Health Carlos III as a basic instrument of the General Administration of the State for fostering biomedical research.

The diverse provisions and regulations established in this Law offer an innovative normative set, which is complete and, to a great extent, capable of adapting to circumstances and situations that biomedical research is foreseeably headed towards in the coming years. It is a normative instrument that, while complying with its aim of guaranteeing the legal rights

and goods involved in biomedical research, also provides firm support for the development of public policies and private initiatives that provide impetus to biomedical research that is progressive and competitive within our scientific environment and that operates in a clear legal framework that allows efficiency and quality of research.

## **TITLE I** **General Provisions**

### **Article 1. *Object and Scope.***

1. The object of this Law, with full respect afforded to human dignity, identity and the inherent rights of a person, is the regulation of biomedical research, particularly:

- a. Research related to human health that uses invasive procedures.
- b. The donation and use of human oocytes, sperm, pre-embryos, embryos and fetuses or their cells, tissues or organs for biomedical research purposes and its possible clinical applications.
- c. The handling of biological samples.
- d. The storage and movement of biological samples.
- e. Biobanks.
- f. The Spanish Committee on Bioethics and other entities with competence on biomedical research matters.
- g. The mechanisms for fostering and promoting, planning, evaluating and coordinating biomedical research.

2. Similarly, and exclusively with regard to health, this Law regulates the undertaking of genetic analysis and the processing of genetic data of a personal nature.

3. The biomedical research to which this Law makes reference includes basic and clinical research, with the exception of clinical trials with medication and sanitary products, which shall be regulated by its own specific regulation.

a. The implantation of organs, tissues or cells of any origin shall be

regulated by 30/1979 of October 27, on the Extraction and Transplantation of Organs and other applicable legislation, and is excluded from the scope of application of this Law.

### **Article 2. *Principles and guarantees of biomedical research.***

The undertaking of any biomedical research activity within this Law shall be subject to compliance with the following guarantees:

a. The dignity and identity of the human being shall be protected in relation to any research that involves intervention on human beings in the field of biomedicine, thus guaranteeing to every person, without any discrimination, respect for their integrity and other fundamental rights and freedoms.

b. The health, interest and well-being of the human being who participates in biomedical research shall prevail over the interests of society or science.

c. Research on human biological samples shall be undertaken in a framework of respect towards fundamental rights and freedoms, guaranteeing confidentiality in the handling of data of a personal nature and in biological samples, especially in the undertaking of genetic analysis.

d. Freedom of research and of scientific production in the area of biomedical sciences shall be guaranteed.

e. The authorisation and development of any research project on human beings or their biological material shall require mandatory prior approval by a Research Ethics Committee.

f. The research shall be undertaken in accordance with the precautionary principle in order to prevent and avoid risks for life and health.

g. The research shall be the object of evaluation.

### **Article 3. Definitions.**

The following shall be used when interpreting this Law:

a. “Genetic Analysis”: a procedure aimed at detecting the presence, absence or variations of one or several segments of genetic material, which includes indirect tests to detect a gene product or a specific metabolite that is especially indicative of a specific genetic change.

b. “Genetic-population analysis”: research aimed at understanding the nature and magnitude of genetic variations within a population or among individuals of the same group or different groups.

c. “Anonymisation”: a process whereby it is no longer possible to establish through reasonable means the nexus between the subject and his or her data. It is also applicable to biological samples.

d. “Biobank”: a public or private non-profit establishment which has a collection of biological samples conceived for biomedical diagnostic or research purposes, and organised as a technical unit with criteria relating to quality, order and destination.

e. “Genetic counsel”: a procedure aimed at informing a person about the possible consequences for him or her, or his or her descendants, and about the results of a genetic analysis or screening, its advantages and risks and, where appropriate, counselling on the possible alternatives derived from an analysis. It shall take place before, as well as after, a genetic test or screening, and even in the absence of both.

f. “Consent”: the manifestation of a free and conscious volition that is validly expressed by a capable person or through an authorised representative, after adequate information has been provided.

g. “Genetic Screening”: a public health programme aimed at identifying

certain genetic determinants in individuals, for which an early medical intervention could lead to the elimination or reduction of mortality, morbidity or disabilities associated with such determinants.

h. “Anonymous data”: registered data without a nexus to an identified or identifiable person.

i. “Anonymised or irreversibly disassociated data”: data that cannot be associated to an identified or identifiable person, as the nexus with all information that identified the subject has been destroyed or because such association demands an unreasonable effort, understood as the use of disproportionate amounts of time, expense and work.

j. “Genetic data of a personal nature”: information on the hereditary characteristics of a person, identified or identifiable that is obtained through nucleic acid analysis or through other scientific analysis.

k. “Codified or reversibly disassociated data”: data that is not associated to an identified or identifiable person as the information that identified that person has been substituted or detached using a code that permits the reverse operation.

l. “Embryo”: a phase of embryonic development from the moment in which the fertilised ovocyte is found in the uterus of a woman until the beginning of organogenesis and which ends 56 days from the moment of fertilisation, with the exception of the computation of those days in which the development could have been stopped.

m. “Observation study”: a study undertaken on individuals in reference to whom there is neither the modification of the treatment or intervention to which they could be subject nor a prescription of any other guideline that could affect their personal integrity.

n. “Foetus”: an embryo with human appearance and with its organs formed, which matures from the 57th day after the moment of fertilisation until the moment of birth, taking out of the computation those days in which the development could have been stopped.

o. “Biological sample”: any biological material of human origin capable of conservation and that can hold information on the genetic endowment that is characteristic of a person.

p. “Anonymised or irreversible disassociated biological sample”: a sample which cannot be associated with an identified or identifiable person as the nexus which had contained the information that identifies the subject has been destroyed or because such association requires an unreasonable effort.

q. “Non-identifiable or anonymous biological sample”: a sample collected without a nexus with an identified or identifiable person which, as a result, has an unknown origin and is impossible to trace.

r. “Codified or reversibly disassociated biological sample”: a sample not associated to an identified or identifiable person as the information that identifies that person has been substituted or disassociated using a code that allows the reverse operation.

s. “Pre-embryo”: an embryo constituted in vitro that is formed by the group of cells that are the result of the progressive division of the oocyte from the time it is fertilised until 14 days after.

t. “Invasive procedure”: any intervention undertaken for research purposes that involves a physical or psychic risk for the affected subject.

u. “Minimum risk and burden”: health impacts and discomforts that could be borne by the participating subject in research and whose effects

can only be of a minor and temporary nature.

v. “Source subject”: a living being, no matter his or her state of health, or a deceased from whom the biological sample is obtained.

w. “Processing of genetic data of a personal nature or of biological samples”: operations and procedures that allow the collection, storage, use and conveyance of genetic data of a personal nature or biological samples.

x. “Traceability”: the capacity to associate a specific biological material with registered information to any step in the chain of its collection, as well as through all the processes of research.

#### **Article 4. *Informed consent and the right to information.***

1. The free will of persons who may participate in biomedical research or who could provide their biological samples shall be respected. Their prior express and written consent must be given once adequate information has been provided.

The information provided shall be written and shall encompass the nature, importance, implications and risks of the research in the terms provided for in this Law.

People with disabilities shall be provided this information in accessible manners and formats that are appropriate to their needs.

If the subject of research is unable to write, the consent may be granted through any means admitted by law that allows the stating of a record of a person’s will.

2. When a person is legally disabled or is a minor, consent shall be sought from the person with legal authority to give consent on their behalf, provided that there are no other alternatives to the research.

The granting of the consent by the person with legal authority to do so

shall be proportionate to the research to be undertaken and shall be done in accordance with the respect of the dignity of the person and for the benefit of their health.

The disabled and minors shall participate, so far as is possible and in accordance with their age and capacities, in the decision-making process throughout the research.

3. Those persons who participate in biomedical research shall be able to revoke their consent at any time, notwithstanding the limitations provided in this Law. Those persons or entities that have received this consent shall have available those measures that are necessary for the effective exercise of this right.

4. Refusal to consent, or revocation of consent that has been previously granted, shall not entail any detrimental consequences in terms of the health care assistance provided to the subject.

5. Every person has the right to be informed of his or her genetic data and other data of a personal nature which may be obtained in the course of biomedical research, in accordance with the terms to which he or she assented. The same right is recognised in relation to the person who has provided, for the aforementioned purpose, biological samples or when other biological materials are obtained from these samples.

The right of the person not to know that data referred to in the former paragraph, including unexpected findings that could arise, shall be observed. Nonetheless, when disclosure of this information, according to the criteria of the doctor in charge, is necessary in order to avoid serious damage to the person's health or the health of their biological family members, a close family member or a representative shall be informed, after consulting with the clinical ethics committee, if it exists. In any case, the

communication shall be limited exclusively to the data necessary to satisfy these ends.

#### **Article 5. *Protection of personal data and guarantees of confidentiality.***

1. The protection of personal privacy and the confidential treatment of personal data that are the result of biomedical research shall be guaranteed, in accordance with the provisions in the Basic Law 15/1999, of 13 December on the Protection of Data of a Personal Nature. The same guarantees shall apply to biological samples that are the source of information of a personal nature.

2. The transfer of data of a personal nature to third parties outside the medical-assistance act or to biomedical research shall require the express and written consent of the interested party.

In the event that the data obtained from the subject source could reveal information of a personal nature about his or her family members, the transfer to third parties shall require the express and written consent of all those concerned.

3. The use of data related to the health of persons with purposes different to those for which the consent was given shall be forbidden.

4. Any person who, in the duty of their functions relating to the provision of medical health care services or biomedical research, has access to data of a personal nature shall be subject to the duty of secrecy.

5. If the publication of results of particular research is not possible without identifying the person who participated or who provided biological samples, then these results shall only be published when there has been previous and express consent given by this person.

#### **Article 6. *Non-discrimination.***

No one shall be the object of any type of discrimination on account of their genetic characteristics. Also, a person shall not be discriminated against on the basis of their refusal to undergo a genetic analysis, to provide their consent to participate in a biomedical research, or to donate biological material, particularly in relation to the conveyance of medical health care assistance that corresponds to the person.

**Article 7. *Non profit.***

The donation and use of human biological samples shall be gratuitous, whatever its specific origin, and the compensation that is provided for in this Law can in no way be of a lucrative or commercial nature.

Likewise, donation implies the waiver of any right of the donor, whether economic in nature or otherwise, to the results that could be directly or indirectly obtained through the research that takes place using these biological samples

**Article 8. *Traceability and safety.***

The traceability of cells, tissues and any biological material of human origin must be guaranteed in order to assure compliance with regulations on quality and safety, the duty of confidentiality and the provisions in Basic Law 15/19999, of 13 December on the Protection of Data of a Personal Nature. When undertaking research using cells or tissues aimed at human application, the data guaranteeing their traceability must be kept for at least 30 years.

The activities related to biomedical research shall be undertaken with strict compliance with the precautionary principle in order to prevent serious risks for human life and health.

**Article 9. *Limits on genetic analysis.***

1. The protection of the rights of persons shall be assured in the undertaking of genetic analysis and in the treatment of genetic data of a personal nature in the health field.
2. Genetic analysis shall take place based on the criteria of pertinence, quality, equity and accessibility.
3. Predictive tests of genetic diseases, or tests that permit identification of the subject as the carrier of a gene responsible for a disease, or tests that detect a predisposition to genetic susceptibility of a disease, shall only be carried out for medical purposes or for medical research purposes and with genetic counselling, when indicated, or for the study of inter-individual differences in the response to medicaments or genetic-environmental interactions, or for the study of the molecular basis of diseases.

**Article 10. *Promotion and quality of biomedical research.***

1. The promotion of biomedical research shall be based on the criteria of quality, efficacy and equal opportunities.
2. Any biomedical research must be scientifically justified, must comply with generally accepted scientific criteria and must be undertaken in accordance with adequate professional obligations and standards, under the supervision of a scientifically qualified researcher. Furthermore, such research shall be evaluated again at its conclusion.

**Article 11. *Transborder flows of biological samples.***

Transborder flows of biological samples of human origin, both within EU countries and those outside the EU, for the research purposes mentioned in this

Law, shall be governed by the regulations that are established by law.

When the biological samples come from biobanks, there shall be additional observance of the conditions relating to conveyance and safety which are provided in Title V of this Law.

## **Article 12. *Research Ethics Committees.***

1. 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.

As a minimum, the following criteria shall be considered when accrediting a Research Ethics Committee: independence and impartiality of its members with regard to promoters or researchers of biomedical research projects, as well as its cross-disciplinary structure.

The corresponding authorities may create Research Ethics Committees that carry out their functions in two or more centres that undertake biomedical research.

2. The Research Ethics Committee of a centre shall exercise the following functions:

a) To evaluate the qualification of the main researcher and that of the research team as well as the feasibility of the project.

b) To consider the methodological, ethical and legal aspects of the research project.

c) To balance the anticipated risks with the benefits arising from the study.

d) To oversee compliance with the procedures that provide assurance of the traceability of samples of human origin, notwithstanding the provisions in the

legislation on the protection of data of a personal nature.

e) To inform, after an evaluation of the research project, of all biomedical research that implies interventions on human beings or that use human biological samples, notwithstanding other reports that must be created. No research project may be authorised or developed without prior approval by the Research Ethics Committee.

f) To develop codes of good practice in accordance with the principles established by the Spanish Bioethics Committee and to manage conflicts and proceedings generated by its non-compliance.

g) To coordinate its activities with that of similar committees of other institutions.

h) To oversee confidentiality and to exercise other functions that may be assigned by the regulation in the development of this Law.

3. Research Ethics Committees, in the exercise of their functions, may obtain all information that is needed, and particularly information relating to the financial sources and financial quantity of the studies and the distribution of expenses.

4. The members of Research Ethics Committee shall declare their activities and interests and shall abstain from taking part in the deliberations and votes in which they have a direct or indirect interest in a matter being examined.

## **TITLE II**

### **Research that involves invasive procedures on human beings**

#### **CHAPTER I**

### **General principles and information requirements and consent**

**Article 13. *Consent.***

The carrying out of research on a person shall require the express, specific and written consent of that person, or their legal representative, in accordance with the general principles set out in Article 4 of this Law.

#### **Article 14. *General Principles.***

1. Research on human beings shall only take place in the absence of another alternative with comparable efficacy.
2. Research shall not involve disproportionate risks or discomforts for the human being in relation to the potential benefits that may be obtained.
3. Notwithstanding what has been established in the earlier paragraph, when research does not have the possibility of producing results that directly benefit the health of the participating subject, then the research can only begin in cases that involve a minimum risk and burden for the subject, in accordance with the decision of the Research Ethics Committee that must evaluate this research.

#### **Article 15. *Information to the subjects participating in the research.***

1. Prior to the commencement of any procedure, those persons who have been asked to participate in a research project shall receive all necessary information, duly documented and in a comprehensible manner, and, when dealing with disabled people, in a manner suited to their circumstances.
2. The information shall include the purpose, detailed plan, burdens and possible risks and benefits of the research. This information shall specify the following matters:
  - a) The nature, extent and duration of the proposed procedures, particularly those that may affect the participation of the subject.

b) Any available preventive, diagnostic and therapeutic procedures.

c) Measures to guard against adverse occurrences that bear upon the subjects who participate in research.

d) Measures to assure respect for participants' private lives and the confidentiality of personal data in accordance with the demands established in the legislation on the protection of data of a personal nature.

e) Measures to allow the subject access to information that is relevant to them and that may arise during the research, or in the final results, in accordance with the terms provided for in Article 4.5.

f) Measures to assure adequate compensation in the event of the subject suffering damage.

g) The identity of the professional who is responsible for the research.

h) Any potential future use of the results of the research, including those of a commercial nature.

i) The financial source of the research project.

In the event that any of the foregoing is unknown, there shall exist an explicit undertaking to give this information to the subject if, and when, it becomes available.

3. In the event of future or simultaneous use of genetic data or biological samples being foreseen, the provisions of Chapters II and III of Title V of this Law shall be applicable.

4. Furthermore, persons who are asked to participate in research shall be informed of the rights and safeguards that are provided in this Law for the purpose of their protection. Specifically, such persons shall be informed of their right to refuse consent or to revoke it at any moment without this affecting their right to health assistance.

## **CHAPTER II**

### **Evaluation, authorisation and assurance of the damage**

**Article 16. *Evaluation and authorisation.***

All biomedical research that involves an invasive procedure on a human being shall be previously evaluated by the Research Ethics Committee with reference to the submitted research project, and authorised by the corresponding autonomous authority. The evaluation must predate the authorisation, must be favourable, duly motivated and shall take into account the scientific suitability of the project, its relevance, feasibility and the suitability of the main researcher and the research team.

In the event that the partial results obtained require that the project be modified, such modification shall require approval by the Research Ethics Committee and the competent autonomic authority shall be notified, for all pertinent purposes.

In the case of research projects that are undertaken in several centres, the unity of criteria and the existence of a sole report shall be guaranteed.

**Article 17. *Control and Follow up Guarantees.***

1. Without exception, the carrying out of research shall abide by the content of the project that has been granted authorisation.

2. The health authorities shall have at all times the ability to inspect the research, being able to have access to the individual clinical histories of the subjects of the study, and, in every case, must adhere to the confidential nature of such information.

3. The autonomous authority shall temporarily suspend, either on its own instance or on behalf of the Research Ethics Committee, any authorised research in cases where the requirements provided by this Law are

not met, and whenever else necessary to protect the rights of citizens.

**Article 18. *Compensation for damages and its assurance.***

1. Those persons who have suffered damage as a consequence of their participation in a research project shall receive corresponding compensation, in accordance with in the provisions in the following sections.

2. The undertaking of research that entails an invasive procedure on a person shall require the previous assurance of general and special damages that could be awarded to the person.

3. When, for whatever reason, an insurance policy does not fully cover the damage caused, the promoter of the research, the researcher in charge and the hospital or centre in which it was carried out, shall be jointly and severally liable for such damage, even if there is no fault, and thereby being responsible to bear the burden of proof. Neither the administrative authority, nor the approval of the Research Ethics Committee, shall release the abovementioned parties from liability.

4. Unless proven otherwise, there exists the presumption that damage that affects the health of a person subject to research, during its undertaking and in the year following its conclusion, has arisen as a consequence of such research. However, once the year has passed, the subject of the research shall be obliged to prove the damage and the nexus between the research and the damage caused.

5. In reference to other aspects related to liability for damage and its assurance, for the provisions in the legislation on guarantees and the rational use of medicines and health products shall be applicable.

**CHAPTER III**

## **Specific Situations**

### **Article 19. *Research during pregnancy and lactation.***

1. Any research in which a pregnant woman participates, which does not produce a direct benefit to her, or the embryo, the foetus or the child after birth shall only be authorised if the following conditions are met:

a) That the aim of the research is to contribute to the production of results that are for the benefit of other women, embryos, fetuses or children.

b) That research of similar efficacy is not possible to be undertaken in non-pregnant women.

c) That the research entails minimum risk and damage for the woman and, in its case, for the embryo, foetus or child.

d) That the pregnant woman, or the legal representatives of the child, in its case, provide their consent in the terms provided in this Law.

2. When research is carried out during a woman's lactation period, special care must be taken in order to avoid an adverse impact on the health of the child.

### **Article 20. *Protection of persons without the capacity to provide their consent.***

1. Research on a minor or a disabled person, except when a judicial ruling on disability establishes that the person can provide his or her consent to research in accordance with a degree of discernment, can only be undertaken if the following conditions are met:

a) That the results of the research can produce real or direct benefits for his or her health.

b) That research of comparable efficacy cannot be carried out on persons capable of providing their consent.

c) That the person who is going to participate in the research has been provided written information about his or her rights and the limits provided in this Law and in the regulation that further develops it for his or her protection, unless that person is not in a state to receive that information.

d) That the legal representatives of the person who is going to participate in the research have provided their written consent, after having received the information established in Article 15. The legal representative shall take into account the desires and objections that have been previously expressed by the affected person. Additionally, in these cases, action must be in accordance with the provisions in Section 1 of Article 4 of this Law.

2. When it is foreseeable that the research is not going to produce results for the direct health benefit of the subjects referred to in Section 1 of this Article, the research may be authorised in exceptional circumstances if, in addition to the requirements established in subsections b), c) and d) of the earlier Section, the following conditions are met:

a) That the object of the research is to contribute, through meaningful improvements of the understanding of the disease or the condition of the individual, to a beneficial result for other persons of the same age or with the same disease or conditions, within a reasonable time frame.

b) That the research entails a minimum risk and burden to the participating individual.

c) That the authorisation of the research is made known to the Ministry of the Public Prosecutor.

### **Article 21. *Research on persons unable to consent due to their clinical situation.***

1. When undertaking research in situations of clinical emergency, in which the person involved may not provide their consent, the following specific conditions must be met:

a) That research of comparable efficacy is not capable of being undertaken on persons who are not in that emergency situation.

b) That in the event that it is not foreseeable that the research will produce beneficial results for the health of the patient, it has the purpose of contributing in a meaningful manner to the understanding of the disease or the condition of the patient, with the purpose of benefiting other persons with the same disease or condition, and that that it entails minimum risk and discomfort to the patient.

c) That the authorisation of the research is made known to the Ministry of the Public Prosecutor.

2. Any previously expressed objection by the patient that is known by the doctor in charge of providing assistance, by the researcher or by the Research Ethics Committee of the centre shall be observed.

3. In reference to Section One of this Article, research in emergency situations is considered to occur when the person is not in a condition to provide his or her consent and that, due to their state and the emergency of the situation, the authorisation of the legal representatives of the patient or, if there are none, of the persons with whom he or she lives, is impossible to obtain within the required time.

4. Persons who participate in research in an emergency situation, or where appropriate, their legal representatives, shall be informed in the shortest time possible of the terms provided in Article 4 of this Law. Likewise, consent to continue participating in the research must be obtained when the patient is in a condition to provide it.

## CHAPTER IV Safety and Supervision

### **Article 22. *Risk prevention.***

1. Aside from the provisions in Article 18, necessary measures shall be taken in order to guarantee the safety of research and to reduce the risks and discomforts for participating individuals.

Medical decisions relating to the health of the participating subjects in research belong to the doctor in charge of their assistance.

2. The researcher in charge of the project must provide assurance that the members who are part of the research team have the adequate qualification and experience in the ambit of the proposed research.

### **Article 23. *Evaluation of the state of health.***

1. Those persons who intend to participate in research have a duty to provide real data about their physical well-being or their health. In any case, the researcher shall take the necessary measures, which shall include, where appropriate, consultation with the doctors responsible for the provision of medical assistance to the participants, in order to verify such matters affecting their physical well-being and health before the beginning of the research in order to ensure that persons for whom the research entails a special risk are excluded from such research.

2. When research involves women of a fertile age, the possible adverse impact on an unknown existing pregnancy or a later one, as well as on the health of embryos, foetuses or a child shall be taken into account.

### **Article 24. *Non-interference with necessary clinical interventions.***

1. Research must not delay or deprive the participants of any preventive, diagnostic or therapeutic medical procedures that are necessary for their state of health.

2. In research associated with the prevention, diagnosis or treatment of diseases, there must be an assurance that the participants who are assigned to the control groups receive proven procedures of prevention, diagnosis or treatment.

The researcher must place on record the procedures of prevention, diagnosis or treatment to which reference is made in the previous Section in the protocol of the trial that he or she is going to submit for evaluation and authorisation.

3. A placebo may be used only if there are no methods of proven efficacy or when the withdrawal of these methods does not entail unacceptable risk or damage to the patient.

#### **Article 25. *Verification of the progress of research.***

1. The Research Ethics Committee shall take adequate measures in order to verify that the continuity of the project is justified in light of new knowledge that is gained throughout its execution.

The main researchers must send to the Committee, without delay, any relevant information for the safety of the participating subjects.

2. The purpose of the aforementioned verification in the earlier Section is to determine, with finality:

a) Whether it is necessary to interrupt the research or to make changes to the project in order for it to continue.

b) Whether the participants in the research or, where appropriate, their representatives, must be informed of events that may happen.

c) Whether it is necessary to obtain the additional consent of the participants.

3. Any relevant modification in the authorised conditions for a research project shall not take place without the prior approval of the Research Ethics Committee and the approval of the corresponding authority.

4. Any relevant information on participation in research shall be made known via written communication to the participants or, where appropriate, to their representatives as soon as possible.

5. The Research Ethics Committee shall proceed to follow up on compliance as established in the previous Section, having a duty to report the incidents that are observed to the corresponding authority that provided the authorisation for that research, so that corresponding measures may be adopted, in accordance with Article 17 of this Law and with full respect to the provisions in existing regulations on matters of the protection of data of a personal nature.

6. The researcher in charge shall report the reasons for the early termination of any research project to the Research Ethics Committee and to the corresponding authority which agreed to the research being undertaken.

## **CHAPTER V Management of Information**

#### **Article 26. *Duty to inform.***

According to the provisions in Article 4.5, if research provides relevant information on the health of the participants, then this must be made available to them. This shall be done within the framework of assistance that is underway, or where no such framework exists, by providing specific counselling.

#### **Article 27. *Information on the results.***

1. Once research has concluded, the researcher in charge shall forward a summary of it to the corresponding authority that provided the authorisation and to the corresponding Research Ethics Committee.
2. The research results shall be communicated to the participants, whenever such a request is made.
3. The researchers shall make public the general results of their research once such research has concluded, taking into account the requirements relating to data of a personal nature that are mentioned in Article 5.5 of this Law and without detriment to the corresponding rights of intellectual and industrial property that may be derived from this research.

### **TITLE III**

#### **On the donation and use of human embryos and foetuses, their cells, tissues or organs.**

### **CHAPTER I**

#### **Donation of human embryos and foetuses**

#### **Article 28. *Donation of human embryos and foetuses.***

1. Human embryos that have lost their capacity for biological development, as well as dead human embryos or foetuses, may be donated for biomedical research or other diagnostic, therapeutic, pharmacological, clinical or surgical purposes
2. The termination of a pregnancy can never be for the purpose of the donation and later use of embryos, foetuses or their biological structures. The procedure and manner of the practice of terminating the pregnancy shall be subject only to the legal demands and limitations and the surrounding characteristics and circumstances.

The professionals, who are part of the medical team that undertakes the termination of the pregnancy, shall not intervene in the use of the aborted embryos, foetuses or their biological structures. To this effect, the members of the research team shall leave written record of this matter, as well as the absence of any conflict of interest with the medical team.

3. Foetuses that are prematurely and spontaneously expelled shall be clinically treated while they remain biologically viable, with the sole purpose of favouring their development and vital autonomy.

4. Before proceeding to any intervention on human embryos, which have lost their capacity to biologically develop, or on dead embryos or foetuses, a record shall be made by the corresponding medical personnel that such circumstances have taken place.

#### **Article 29. *Requirements on donation.***

1. Aside from the provisions in the previous Article, the donation of human embryos or foetuses or their biological structures for the purposes provided in this Law shall meet the following requirements:

a) That the donor or donors of the embryos or foetuses have previously granted their express and written consent. If any of such donors is a non-emancipated minor or is disabled, then the consent of their legal representatives shall also be necessary.

b) That the donor or donors or, where appropriate, their legal representatives, have been provided written information before the granting of their consent in relation to the purposes that might be achieved with the donation, its consequences, as well as the interventions that may be undertaken to extract embryologic or foetal cells or structures, from the

placenta or casings, and of the risks that may follow from these interventions.

c) That the expulsion, spontaneous or induced, of these embryos or foetuses has been made in the gestating woman and that it has not been possible to maintain their vital autonomy as provided in Article 28.3

2. In the event that the person from whom the embryos or foetuses derives is deceased, it is necessary that there is no record of their express opposition. If the deceased is a minor or disabled person, then the donation shall take place unless there is a record of express opposition by those that exercised, in the life of the person, legal representation.

## CHAPTER II

### Conditions for biomedical research with human embryos and foetuses

**Article 30. *Limitations on research with live embryos and foetuses in the uterus.***

Intervention on the live embryo or foetus in the uterus shall be authorised solely when the purpose of such intervention is diagnostic or therapeutic in its own right, notwithstanding what is legally established on the voluntary interruption of a pregnancy.

**Article 31. *Requirements on the use.***

1. Research on human embryos or foetuses or their biological structures must comply with the following requirements:

a) That the embryos or foetuses fit within one of the situations specified in Section 1 of Article 28 of this Law.

b) That the conditions established in Article 29, on the donation of the embryos and foetuses that are going to be used, are taken into account.

c) That an application has been drafted on the expected use and that it

has been approved by the Guarantees Commission for the Donation and use of Human Cells and Tissues.

d) That the corresponding autonomous or State authority has provided authorisation to its expected use.

2. The team responsible for the authorised project must communicate its result both to the entity that authorised the submitted project, as well as to the Guarantees Commission for the Donation and use of Human Cells and Tissues.

## TITLE IV

### On the collection and use of cells and tissues of human embryonic origin and other similar cells

## CHAPTER I

### On the use of ovocytes and pre-embryos

**Article 32. *Donation of ovocytes and pre-embryos.***

1. Research involving ovocytes and pre-embryos must have the consent of the persons from whom they come. Such persons can revoke this consent at any time without affecting the research undertaken.

2. The donation of ovocytes and pre-embryos shall be governed according to the provisions in Law 14/2006, of 26 May, on Assisted Human Reproduction Techniques.

In the case of ovocytes, the consent of the donors shall make express reference to the authorisation for the use of a specific technique or techniques that are to be applied to the donated ovocytes. For that purpose, the health professionals who are responsible for collecting these ovocytes shall provide the donors with the appropriate information before consent is granted, leaving clear written records of all of the above.

**Article 33. *Obtaining of embryonic cells.***

1. The creation of human pre-embryos and embryos exclusively for experimentation purposes is prohibited.
2. The use of any technique for obtaining human stem cells for therapeutic or research purposes is allowed, but only when it does not entail the creation of a pre-embryo or an embryo exclusively for this purpose, in accordance with the terms provided in this Law, including the activation of oocytes through nuclear transfer.

**CHAPTER II**

**On research with embryonic biological samples**

**Article 34. *Guarantees and requirements for research.***

1. Research or experimentation involving surplus oocytes or pre-embryos from assisted reproduction techniques, or their biological structures, for purposes related to the obtaining, development and use of embryonic stem cell lines or for other purposes not associated with the development and application of assisted reproduction techniques, shall be undertaken in accordance with the provisions in Law 14/2006, of 26 May, and shall comply with the following requirements:

a) That the research abides by ethical principles and the applicable legal regime, especially the provisions in this Law and the regulation that develops it, and that it follows the principles of relevance, feasibility and suitability, with particular obligations on the main researcher, the research team and the installations of the centre in which the research takes place.

b) That it is based on a research project that is authorised by the State or

an autonomous authority, after having received approval by the corresponding Guarantees Commission for the Donation and Use of Human Cells and Tissues, in projects dealing with matters established in Article 35.

2. The authorisation of research projects shall be conditioned to the project including, as a minimum, the following elements:

a) The authorisation of the management of the centre in which the research is conducted, as well as the approval of the corresponding Research Ethics Committee.

b) The disclosure of any common relations and interests that exist, of whatever nature, or the absence of such, between the team and the centre that has been involved in the processes of assisted reproduction that generated the pre-embryos or in obtaining the oocytes.

c) The written agreement to provide the relevant public authority the data that enables it to identify and to know the conservation of the cell lines that could be obtained as a consequence of the development of the research.

d) The agreement to gratuitously convey cell lines that could be obtained in the development of research for use by other researchers.

e) Where oocytes or pre-embryos are used, the indication and justification of their number and origin and the document of the informed consent, signed by the donor, or progenitors, respectively.

**Article 35. *Report of the Guarantees Commission for the Donation and Use of Human Cells and Tissues.***

1. The approval of the Guarantees Commission for the Donation and Use of Human Cells and Tissues shall be required for those research projects that deal, in whole or in part, with the following matters:

a) Research with human pre-embryos for the derivation of cell lines, for embryologic research and for other research purposes, except for those related to the development and application of assisted reproduction techniques.

b) Research with human embryonic stem cells

c) The activation of oocytes through nuclear transfer for therapeutic or research purposes.

d) Any other technique that, using human biological samples in whole or in part, can lead to the obtaining of stem cells.

e) Research with embryonic cells or tissues obtained through any of the procedures mentioned in Article 33.2.

f) Any other line of research that includes cell material of human embryonic origin or other functionally similar material.

g) Research involving embryonic stem cell lines that come from another country, whether within or outside the EU. The origin shall be specified in the project submitted for authorisation.

2. The authority that granted authorisation of the research project mentioned in the earlier Section, shall annually forward its results to the Guarantees Commission for the Donation and Use of Human Cells and Tissues.

**Article 36. *Access to cryopreserved oocytes and pre-embryos.***

The Institute of Health Carlos III shall guarantee access to surplus cryopreserved pre-embryos from assisted reproduction techniques that have been donated for research purposes. The same criteria shall be followed with oocytes donated for research.

**CHAPTER III**

**On the Guarantees Commission for the Donation and Use of Human Cells and Tissues**

**Article 37. *Creation of the Commission.***

1. A Guarantees Commission for the Donation and Use of Human Cells and Tissues is created as an association composed of several persons, assigned to the Institute of Health Carlos III, of a permanent and consultative nature, aimed at providing counsel and guidance on research and experimentation with human embryonic biological samples and to contribute to the updating and dissemination of scientific and technical knowledge in this matter.

2. The counterpart commissions that are created in the autonomous communities shall be considered as commissions to provide support and reference to the Guarantees Commission for the Donation and Use of Human Cells and Tissues and shall collaborate with it in the exercise of its functions.

**Article 38. *Functions of the Commission.***

1. The Commission shall have the following assigned functions:

a) To assure the scientific, ethical and legal guarantees that may be demanded in relation to the research mentioned in Article 35 and to annually evaluate the results.

b) To provide, upon request of the State health authorities and the autonomous communities, reports on biomedical research with human embryonic cells and tissues and their clinical applications in the field of regenerative medicine.

c) To provide a compulsory report on research projects that require transborder flows of embryonic

material. In the case of a research project with embryonic stem cell lines from non-EU member countries, the Commission shall only issue its report when the project incorporates the documentation that accredits the origin, procedures and guarantees in the obtaining and treatment of stem cell lines and the regulation of the country of origin on this matter.

2. The Commission shall issue its compulsory report on research projects that have been submitted within a maximum time period of three months.

**Article 39. *Composition of the Commission.***

1. The Commission shall be made up of twelve members. All shall be notable specialists of repute in research on cell therapy or regenerative medicine, in bioethics and law related to bioethical matters.

2. The members of the Commission shall act at all times with independence and impartiality.

3. The members shall be named by the Minister of Health and Consumption for three year terms, with the following distribution:

a) Six representatives designated by the Inter-territory Council of the National Health System, as proposed by the autonomous communities.

b) Six representatives of the General Administration of the State, two by the Ministry of Health and Consumption, two by the Ministry of Justice and two by the Ministry of Education and Science.

4. The President of the Commission shall be named from among its members by the Minister of Health and Consumption.

5. The Secretary of the Commission shall be a civil servant with the rank of Vice-Director General who belongs to the Institute of Health Carlos III, and who will have a voice, but no vote.

6. The members of the Commission shall have access to detailed information on research projects on cells and tissues that are referred to in this Title, on the National Registry of Activity and Results of the Assisted Reproduction Centres and Services which are referred to in Law 14/2006, of 26 May, on Assisted Human Reproduction Techniques and on the National Registry of Cell Lines.

**CHAPTER IV**

**On the promotion and coordination of research with human embryonic cells and tissues**

**Article 40. *Promotion and coordination.***

1. The promotion and coordination of research involving embryonic biological samples shall be the responsibility of the Ministry of Health and Consumption, through the Institute of Health Carlos III, notwithstanding that the autonomous communities may have corresponding competences.

2. The corresponding authority, via the Institute of Health Carlos III, shall forward those research projects that must have a report issued by the Guarantees Commission for the Donation and Use of Human Cells and Tissues in line with the procedure that may be established by regulations.

**Article 41. *Registry of projects.***

The Institute of Health Carlos III shall be responsible for the maintenance of the registry of research projects, in which data shall be based on that provided by the corresponding authorities with power to authorise the projects, and shall have the updated information on the registry of pre-embryos, oocytes and cell lines available in the centres for in vitro fertilisation, in the National Registry of

Donors and the National Bank of Cell Lines.

This registry shall include, at the least:

a) The identifying data of the centre that is carrying out the project and the research team responsible for its execution.

b) The documentation provided by the main researcher that states the objectives and protocols that proposed and the expected results of the project.

c) The report of the Guarantees Commission for the Donation and Use of Human Cells and Tissues.

d) The certification of authorisation to undertake research granted by the corresponding authority with the power to do so.

e) At the conclusion of the authorised research, an evaluation report by the Guarantees Commission for the Donation and Use of Human Cells and Tissues.

#### **Article 42. *National Bank of Cell Lines.***

1. The National Bank of Cell Lines shall be structured as a network, with a central node responsible for its coordination and shall be assigned to the Institute of Health Carlos III.

2. The National Bank of Cell Lines shall promote the quality and safety of the procedures over which it exercises competence, shall keep the confidentiality of the data and other demands in reference to those acts that it carries out, in accordance with the provisions in Law 14/2006, of 26 May, on Assisted Human Reproduction Techniques, and Basic Law 15/1999, of 13 December, on the Protection of Data of a Personal Nature, and shall act in accordance with the principles of precaution, proportionality and non-profit.

3. The Technical Commission of the National Bank of Cell Lines, whose composition and functions shall be

determined by order of the Minister of Health and Consumption, shall ensure that the access to cell lines for the execution of research projects is undertaken within those scientific, ethical and legal principles in force and must have available updated information on the registry of embryos and cell lines that are available in centres for in vitro fertilisation and in banks of cell lines.

#### **Article 43. *Use of cell lines.***

The use of cell lines or of biological samples that are derived from research that is referred to in this Title shall comply with the provisions in this Law and, where appropriate, in the regulation on clinical trials and on the clinical use of cells and tissues.

### **TITLE V**

#### **Genetic analysis, biological samples and biobanks**

### **CHAPTER I**

#### **General Dispositions**

#### **Article 44. *Object.***

The object of this Title is:

1. To establish the requirements that must be met by institutions and persons that carry out genetic analysis and that process or store genetic data of a personal nature and biological samples.

2. To ensure the correct use of biological samples for biomedical research.

3. To establish the requirements that must be met by biobanks for their creation and functioning.

4. To assure that there is no profit from the donation, transfer, storage and use of biological samples, throughout the process, both for source subjects as well as for those who deposit such samples, notwithstanding compensation for the costs involved.

**Article 45. *Specific guiding principles.***

Aside from those guarantees established in Title I of this Law, the following principles shall be applicable:

a) Accessibility and equity: equal access to genetic analysis must be guaranteed without economic considerations and without previous requirements relating to possible personal options.

b) Protection of data: the right to privacy and to the respect of the subject's will shall be guaranteed in relation to information, as well as the confidentiality of genetic data of a personal nature.

c) No profit: the processes of donation, transfer, storage and use of biological samples shall be devoid of financial gain or profit, in relation to both the source subjects as well as those who deposit such samples. Personal genetic data shall not be used for commercial purposes.

d) Consent: the written consent of the subject source, or where appropriate, of his or her legal representatives must be obtained prior to the treatment of samples for research purposes of personal genetic data.

e) Quality of the data: the data obtained from the genetic analysis shall neither be handled nor assigned for purposes other than those provided for in this Law.

**CHAPTER II**

**Genetic analysis and the treatment of personal genetic data**

**Article 46. *Indication of genetic analysis.***

In the terms provided in Article 1.2, genetic analysis shall be undertaken for the identification of an individual's condition as affected, non-affected or as carrier of a genetic variable that could predispose to the development of

a specific disease, or to condition his or her response to a specific treatment.

**Article 47. *Information prior to the undertaking of a genetic analysis for research purposes in the health sector.***

Notwithstanding what is provided in the legislation on the protection of data of a personal nature, before the subject provides his or her consent in the terms provided in Article 48, he or she must receive the following written information:

1. The purpose of the genetic analysis to which he or she consents.

2. The place at which the analysis shall take place and the way in which the biological sample will be treated at the end of the analysis, whether it is the disassociation of the identifying data from the sample, its destruction or other treatments, for which the consent of the subject source must be requested in the terms provided in this Law.

3. The persons who will have access to the results of the analysis when samples will not undergo a process of disassociation or anonymisation.

4. A warning about the possibility of unexpected findings and the possible implications for him or her, as well as his or her right to choose whether or not to receive this communication.

5. A warning about the possibility that information that might be obtained could have implications for his or her family members, and their interest, where appropriate, in having that information conveyed to them.

6. An agreement to provide genetic counselling, once the results of the analysis are obtained and evaluated.

**Article 48. *Consent.***

1. Express and specific written consent shall be necessary for the undertaking of genetic analysis.

2. In the area of health care, samples from deceased persons may be obtained and analysed when it may be relevant to the protection of health, except when the deceased has expressly prohibited it during his or her life, and this prohibition can be proven. To this end, documents of previous instructions shall be consulted and, where these are lacking, the closest family members of the deceased shall be consulted.

Access by the biological family members to information derived from the genetic analysis of the deceased shall be limited to the genetic data relevant for the protection of their health.

3. In order to have access to genetic screening, there must be explicit and written consent of the interested person. The Research Ethics Committee shall determine the situations in which such consent may be expressed verbally. In any case, when the screening relates to non-curable diseases or when the benefits are scarce or uncertain, consent must always be in writing.

4. The undertaking of genetic analysis on in vivo pre-embryos or on embryos and fetuses in the uterus shall require the written consent of the gestating woman.

Genetic analysis of an in vitro pre-embryo that has not been transferred shall be subject to the provisions in the Law on Assisted Human Reproduction.

**Article 49. *Right to information and right not to know.***

1. The subject source shall be informed of genetic data of a personal nature that is obtained in the genetic analysis according to the terms in which he or she has expressed his or her wishes, notwithstanding the right to access that is established in the legislation on the protection of data of a personal nature, which could result in

the revocation of the previously granted expression of free choice.

2. When the subject source has exercised his or her right not to know the results of a genetic analysis, then only that information that is necessary for the follow up of a prescribed treatment by the doctor and that has been accepted by the patient shall be provided. When this information is necessary to avoid serious damage to the health of his or her biological family, then the affected persons or their legally authorised representative may be informed. In every case, the communication shall be exclusively limited to the data necessary for these ends.

**Article 50. *Access to genetic data by health personnel.***

1. Health professionals of the centre or establishment that stores the clinical history of a patient shall have access to the data recorded in it, insofar as it is relevant to the assistance that is being provided to the patient, notwithstanding the duties of secrecy and confidentiality to which they are subject.

2. Genetic data of a personal nature can only be used for epidemiological, public health, research or educational purposes when the interested subject has expressly provided his or her consent, or when this data has been previously anonymised.

3. In exceptional cases in the interests of general health, the relevant authority, after receiving a favourable report from the authority on data protection, may authorise the use of codified genetic data, but only when an assurance is made that third parties may not be able to identify the source subject.

**Article 51. *Duty of confidentiality and the right to the protection of genetic data.***

1. The personnel who have access to genetic data in the exercise of their functions shall be permanently subject to the duty of secrecy. The disclosure of personal genetic data to third parties is only permitted with the express written consent of the person to whom such duty relates.

If the publishing of the results of research is not possible without identifying the source subjects, then such results may only be published with their consent.

2. In cases of genetic analysis involving several members of a family, the results shall be filed and communicated to each of them in an individual manner. In cases involving the disabled or minors, the information shall be provided to their guardians or legal representatives.

#### **Article 52. *Conservation of data.***

1. Personal genetic data shall be kept for a period of no less than five years from the date on which such data were obtained, after which time the interested party may request that the data be destroyed.

2. If there is no such request by the interested party, the data shall be kept for the time that may be necessary in order to preserve the health of the person from which it was obtained or of third parties related to him or her.

3. Outside of the above, data shall only be kept for research purposes in an anonymised manner, without the possibility of identifying the subject source.

#### **Article 53. *Genetic analysis on pre-embryos, embryos or fetuses.***

The results of genetic analysis undertaken on embryonic or foetal material shall be subject to the principles of protection of data and confidentiality provided in this Law.

The same criteria shall be applicable in relation to any other biological samples that may contain genetic information of the person who provided his or her biological material for that purpose.

#### **Article 54. *Genetic screening.***

1. Genetic screening is aimed at detecting a serious disease or health risk in the participating individual or in his or her descendants, for the purpose of early treatment of a disease or to offer access to preventive measures.

2. Based on objective criteria, health authorities shall determine the relevance of genetic screening in relation to the diseases to be prevented or treated. Likewise, authorities shall ensure that screening is able to be universally and equitably accessed by the population for which it is indicated, for the organisation and planning of the program, as well as the quality of the screening tests, diagnostic tests of a second level and the preventive and therapeutic services that are offered.

3. The psycho-social aspects of screening and its integration into the health system shall be taken into account whenever it is undertaken. Likewise, the specific program of screening shall be evaluated by the ethics committee of the centre that performs it.

4. Appropriate procedures shall be established for the continuous monitoring and evaluation of the program.

5. Participation in genetic screening shall be offered to all members of the population to which it is aimed, for which the previous written consent of each subject affected in the terms provided in Articles 4 and 48.3 shall be necessary.

6. The information made available prior to consent being given shall be in writing and shall make reference to:

- a) The characteristics sought and objectives of the screening.
- b) The voluntary nature of participation.
- c) The validity and reliability of the screening tests and of the diagnostic tests of a second level.
- d) The possibility of obtaining false positives and, in turn, the need to confirm or disregard the diagnosis.
- e) The time that will elapse between the different stages of the screening process.
- f) The existing possibilities of treatment and prevention of the disease once it has been diagnosed.
- g) The discomforts, risks and adverse events that may result from the diagnostic process, including those associated with the taking of samples and with the therapeutic or preventive measures that are offered by the program.

7. The regulations established by this Law for genetic analysis shall be applicable to tests used in genetic screenings.

#### **Article 55. *Genetic Counselling.***

1. When a genetic analysis is undertaken for health reasons, the interested person must be guaranteed appropriate genetic counselling, in a manner that is to be established by regulation, and always following the wishes of the interested person.
2. The professional who carries out or coordinates the genetic counselling must provide adequate information and counselling, in relation to both the consequences of the resulting genetic diagnosis, as well as the possible alternatives from which the subject may choose.

#### **Article 56. *Quality Requirements.***

The entire genetic counselling process and the practice of genetic analysis for

health purposes must be undertaken by qualified personnel and must be carried out in accredited centres that meet quality requirements established for this purpose by regulation.

#### **Article 57. *Accreditation of the centres for genetic analysis.***

The corresponding autonomous or state authority shall accredit the centres, whether they be public or private, that may perform genetic analyses and, in every case, such centres must comply with the provisions in Articles 46 to 57 of this Law.

### **CHAPTER III**

#### **Use of human biological samples for biomedical research**

#### **Article 58. *Collection of samples.***

1. The collection of biological samples for biomedical research shall be undertaken only when prior written consent has been obtained from the subject source, and only after the source has been informed of the consequences and risks that such procedures might entail for his or her health. The consent shall be revocable.
2. The consent of the subject source shall always be required when the aim is to use biological samples for biological research in circumstances where such samples have already been obtained for a different purpose, irrespective of whether there is anonymisation.

Notwithstanding this, in exceptional circumstances, codified or identified samples for biomedical research may be used without the consent of the subject source when obtaining this consent is not possible or when it entails an unreasonable effort as specified in Article 3.i) of this Law. In these cases, approval of the corresponding Research Ethics Committee shall be necessary,

which must take into account, as a minimum, the following requirements:

a) That the research is of general interest.

b) That the research is undertaken by the same institution that requested the consent for the collection of samples.

c) That the research is less effective or not possible without the identifying data of the subject source.

d) That there is no record of an express objection from the subject source.

e) That personal data is guaranteed confidentiality.

**3.** Notwithstanding in the provisions in Article 7 of this Law, economic compensation may be payable for any physical discomforts, expenses and other inconveniences that may be arise from the taking of the sample.

**4.** The subject source or his or her family may use the samples for health reasons, when required, provided that these are available and have not been anonymised.

**5.** The collection of biological samples from minors or the disabled for biomedical research shall be subject to the following conditions:

a) That the necessary measures are adopted in order to guarantee that the risks associated with intervention are minimal for the subject source.

b) That the research will provide relevant knowledge about a disease or about the situation that is the object of research, and that this knowledge is of vital importance to understand, palliate or treat it.

c) That this knowledge may not be obtained by other means.

d) That authorisation is obtained from the legal representatives of the minor or the disabled person or that, where appropriate, there are guarantees about the valid consent of the subject source.

**6.** Studies of genetic diversity shall always respect local and ethnic

traditions, and shall always avoid stigmatisation and discrimination.

### **Article 59. Information prior to the use of a biological sample.**

**1.** Notwithstanding the provisions in legislation on the protection of data of a personal nature, and particularly, in Article 45 of this Law, before providing consent for the use of a biological sample for biomedical research that is not going to be subject to an anonymisation process, the subject source shall receive the following written information:

a) The purpose of the research or the line of research for which he or she is providing consent.

b) The expected benefits.

c) Any possible inconveniences linked to the donation and collection of the sample, including the possibility of being contacted at a later time in order to collect new data or obtain other samples.

d) The identity of the person responsible for the research.

e) The right to revoke consent and the consequences of this, including the possibility of the destruction or anonymisation of the sample and the fact that, to this end, such revocation shall not be applicable to other research data that has already been obtained.

f) The location where the analysis shall take place and the way in which the sample at the end of the research: disassociation, destruction or other research, and where appropriate, this shall in turn comply with the requirements provided in this Law. Even if such information is not known at the time, the subject shall be informed of the above particulars when they become known.

g) The right to know genetic data that is obtained from the analysis of donated samples.

h) A guarantee of confidentiality in relation to the information obtained, indicating the identity of the persons who shall have access to the personal data of the subject source.

i) A warning about the possibility that information relating to their health may be obtained from the genetic analysis undertaken on their biological sample, as well as their right to choose whether or not to receive this communication.

j) A warning about the possibility that the information obtained could have implications for the person's family members and their **right**, where appropriate, to convey that information to them.

k) An indication on the possibility of contacting the person again, for which information will be sought on the best way so to do.

**2.** In the event of the use of samples that are going to be anonymised, the subject source shall receive the information contained in Sections a), b), c) and d) of this Article.

#### **Article 60. Consent on the use of a biological sample.**

**1.** Consent on the use of a biological sample shall be obtained either during the act of collection the sample, or later in a specific manner for specific research.

**2.** The initial consent may provide for the use of a sample for other lines of research related to those initially proposed, including those undertaken by third parties. If this is not the case, the subject source shall be asked to provide further consent, if deemed appropriate.

**3.** Consent may be revoked, either in whole or in part, at any time. When such revocation makes reference to any use of the sample, then it shall be immediately destroyed, notwithstanding that data resulting from research that

may have been previously undertaken may be kept.

#### **Article 61. Conservation and destruction of samples.**

**1.** Where a sample is kept, the subject source shall be informed in writing of the conditions of its conservation, objectives, future uses, or **transfer** to third parties so that he or she may ask that the sample be returned or destroyed. Nonetheless, biological samples used in biomedical research shall be kept solely as long as is necessary for the purposes that justified their collection, except if the subject source has granted his or her explicit consent for other later uses.

**2.** The previous Section is to be applicable insofar as the identification data of the sample has not been subject to anonymisation in accordance with the provisions in this Law.

#### **Article 62. Report of the Research Ethics Committee.**

In every case, approval by the Research Ethics Committee of the centre shall be necessary in order to obtain and use biological samples for biomedical research and for biodiversity studies, particularly where the use of biological samples that come from deceased persons has been foreseen, or where the aim is to incorporate a biological sample to a line of research that is not related to that for which the consent was initially granted.

### **CHAPTER IV Biobanks**

#### **Article 63. Scientific Interest.**

The authorisation for the creation of a biobank shall require that its organisation, objectives and available means justify its biomedical interest.

**Article 64. Authorisation.**

1. The Minister of Health and Consumption shall have the authority to create national banks of biological samples that are deemed necessary for the general welfare.
2. The authorisation of the corresponding authority of the autonomous community shall be necessary for the creation of other biobanks.

**Article 65. Ownership.**

1. The physical person or legal entity, whether public or private, that holds ownership of a biobank shall be responsible for it.
2. If there is a change in ownership of a biobank, or a modification or broadening of the objectives of a biobank, then this shall be communicated to the corresponding authority, which shall, where appropriate, grant new authorisation.

**Article 66. Organisation of the biobank.**

1. The biobank shall have a scientific director, who is responsible for the files and shall be assigned to two external committees, one scientific and the other ethical, that will assist the director of the biobank in his or her functions.
2. The director of the biobank shall have the following obligations:
  - a) To enforce the existing legislation.
  - b) To keep a registry of activities of the biobank.
  - c) To guarantee the quality, safety and traceability of stored biological data and samples and of the procedures associated with the functioning of the biobank.

d) To draft an annual report of activities, which shall be made available to the authority that granted the authorisation for the creation of the biobank.

e) To attend consultations or attend to complaints that may be addressed to the biobank.

f) To draft a document of good practices of the biobank.

g) To draft a descriptive memorandum that compiles the characteristics of collection, the criteria for the inclusion and the purposes for which the collection is created, the manner in which the historic collection has been compiled and the information that can be associated with the samples.

3. The person responsible for the files shall attend to all requests in the exercise of the subject source's right to access, rectification, cancellation or opposition, in accordance with the provisions in the existing legislation on the protection of data of a personal nature.

**Article 67. National Registry of Biobanks.**

1. Once a biobank is constituted in accordance with the previous procedure, the corresponding authority shall proceed to register it in the National Registry of Biobanks for Biomedical Research, which shall be dependent on the Institute of Health Carlos III. Before this, registration in the Spanish Agency for the Protection of Data must occur, in accordance with existing legislation. The data in this Registry shall be based on that specified by the authorities that are competent to authorise biobanks.

2. Any person or entity, public or private, that has one or more ordered collections of human samples or biological material that come from identified or identifiable persons, must likewise be registered in the National Registry of Biobanks. This requirement

shall be independent of its registration in the registries of other institutions, due to their special nature or purpose.

3. Once registered, The Ministry of Health and Consumption shall certify the nature and scope of the collection.

4. The following shall not be subject to the aforementioned registration: those collections kept by physical persons for their exclusive personal use; or those samples, though ordered as a collection, that have been obtained for the undertaking of pertinent analysis for diagnostic purposes and, where appropriate, for the treatment of the subject source and that are not kept stored for a period longer than the fulfilment of these objectives.

**Article 68. *Inspections and control measures.***

The corresponding authority shall make periodic inspections to guarantee that biobanks abide by the conditions of installation, organisation and functioning for which they were authorised.

**Article 69. *Collection and transfer of samples.***

1. The collection of samples shall be done in accordance with the provisions in Chapter III of this Title.

2. Any stored samples in a biobank shall be made freely available to third parties who require them for use in biomedical research. Samples shall only be made available where the request relates to a research project that has been scientifically approved. The request shall contain information on the project to be developed and the explicit commitment of the requesting centre and/or of the researchers who participate in the project to not use the requested material for a use different to that stated in the request. The request

must have the approval of the scientific and ethical committees of the bank.

3. The costs of collection, maintaining, handling and shipping of the samples as well as any other costs of a similar nature related to the samples may be passed on with the transfer of each sample. In every case, the quantity of the assigned samples shall be the minimum necessary for the undertaking of the project.

4. The collection, transportation, storage, handling and shipping of samples shall be done in conditions of biosafety in accordance with applicable legislation.

5. The total or partial refusal of the biobank to deliver samples which are solicited for biomedical research shall require a reasoned decision by the person in charge, who shall take into account the previous respective reports of the scientific director and the scientific and ethical committees that are mentioned in Article 66.1.

6. The transfer of samples may be accompanied by any associated clinical information, in which case the data shall be protected in accordance with the provisions in the Law of the Autonomy of the Patient and the Law for the Protection of Personal Data.

**Article 70. *Rights of the source subjects.***

1. The provisions in the Articles of Chapter III of this Title in relation to collection, previous information, consent, confidentiality, transfer, conservation of data and samples, access to data and the right not to be informed shall be applicable to biological samples deposited in biobanks.

2. Notwithstanding the provisions in the previous Section, those biological samples that are added to biobanks may be used for any biomedical research, in the terms provided in this Law, but only

when the source subject or, where appropriate, his or her legal representatives have provided their consent.

**Article 71. *Closure or closing of a biobank.***

1. The competent authority may decide to close a biobank, on its own motion or as requested and through a motivated resolution, in cases in which there is non-compliance with the requirements established in this Law for its creation, organisation and function, or when its owner manifests his or her will not to continue with its activity.
2. This resolution shall likewise provide for the destination of the stored samples of the biobank that is to be closed.

**TITLE VI**

**Breaches, sanctions and compensation for damages**

**Article 72. *General Dispositions.***

1. The breaches provided in this Law relating to the collection and use of human cells and tissues, the use of invasive procedures in biomedical research and personal genetic data, shall be the object of corresponding administrative sanctions, following charges being compiled in a case, notwithstanding any civil, criminal or other form of liability that may also arise.
2. The sanctioning authority provided in this Law shall be exercised, in those cases not provided in this Law, in accordance with the provisions in Law 30/1992 on the Legal Regulation of Public Administrations and the Common Administrative Procedure, in Law 14/1986, of 25 April, General Law on Health, and Basic Law 15/1999, of 13 December, on the Protection of Data of a Personal Nature.

3. When, in the opinion of the Administration, the breach could be an offence or misdemeanour, the administrative entity shall forward it to the Prosecutor's Office, abstaining from continuing with the sanctioning procedure until the judicial authority has made a pronouncement.

The criminal sanction shall exclude the imposition of an administrative sanction whenever it is imposed for the same acts and in relation to the same protected public interests, though all other responsibilities that arise from other acts or breaches that concur must be enforced.

If it is decided that there has not been a criminal offence or misdemeanour, then the administration shall continue with its sanctioning procedure, taking as its basis, where appropriate, those facts that the courts have considered as proven.

4. The administrative measures that would have been adopted in order to guard the right to the protection of health and safety of the people shall be maintained as long as the judicial authority does not make a pronouncement on such.

5. The limitation period for prosecution shall be: three years for 'very serious' breaches; two years for 'serious' breaches; and six months for 'minor' breaches. In case that, for any reason, the sentence has not been served, it must not be served at all after three years in case of sanctions imposed for 'very serious' breaches; two years in case of sanctions imposed for 'serious' breaches; and one year in case of sanctions imposed for 'minor' breaches.

**Article 73. *Responsibilities.***

1. The perpetrator shall carry sole responsibility for all breaches.
2. When, in accordance with the provisions in this Law, compliance with particular obligations is the

responsibility several persons jointly, then they shall be held joint and severally liable for non-compliance in accordance with that provide in Article 130.3 of Law 30/1992, of 26 November, of the Legal Regulation of the Public Administrations and the Common Administrative Procedure. The same shall be applicable to the directors of the centres or services relating to non-compliance with the aforementioned obligations by the biomedical professionals who are under their responsibility.

#### **Article 74. Breaches.**

1. Breaches shall be classified as 'minor', 'serious' or 'very serious', and shall be classified as such in accordance with the harmfulness of the act, the eventual benefit obtained, the health and social alteration produced and the degree of intent.

2. Aside from the provisions in the General Health Law, the Law on the Protection of Personal Data, the Law on Assisted Human Reproduction Techniques, Basic Law on the Autonomy of the Patient and of the Rights and Obligations in Matters of Clinical Documentation and on other regulations passed by the autonomous communities in accordance with this Law, the following breaches shall be considered as 'minor', 'serious' and 'very serious':

A) 'Minor' breaches are:

Those that entail the non-compliance with any obligation or the violation of any prohibition that is provided in this Law, when, in accordance with the criteria provided in this Section, such breaches cannot be classified as 'serious' or 'very serious' breaches.

B) 'Serious' breaches are:

a) Non-observance of the prescriptions, conditions, requirements or previous authorisations that are

provided in this Law for the functioning of the registries provided in this Law.

b) The omission of data, consent and references required by this Law.

c) The non-providing of data to the appropriate health authority responsible for the functioning of registries provided in this Law.

d) The breach of the conditions of confidentiality of donors' data established in this Law.

e) The non-fulfilment of the requirement not to profit from the donation of pre-embryos, embryos and foetuses in the terms provided in this Law.

f) The non-fulfilment of the norms and guarantees established for the transfer between countries of cells and tissues of human embryonic origin.

C) 'Very serious' breaches are:

a) The carrying on of any intervention aimed at the introduction of modification in the genome of descendants.

b) Continuing with the development in vitro of pre-embryos beyond the limit of 14 days after the fertilisation of the oocyte, leaving aside that time during which they may have been cryopreserved.

c) The keeping of living embryos and foetuses outside the uterus for any purpose other than procreation.

d) The extraction of cells or tissues from embryos or foetuses in development of the placenta or casings for purposes other than those that are diagnostic or therapeutic in nature, except in circumstances provided in Law 14/2006, of 26 May, on Assisted Human Reproduction Techniques.

e) Non-fulfilment of the provisions in Article 33.

f) The production of interspecific hybrids that use human genetic material, except the provisions in the Law on Assisted Human Reproduction Techniques.

g) Non-observance of the previous prescriptions, conditions, requirements or authorisations that are established in this Law for the collection and use of cells and tissues of human embryonic origin or other similar functions.

#### **Article 75. *Sanctions.***

1. 'Minor' infractions, as provided in this Law, shall be sanctioned with a fine of up to 600 Euros; 'serious' infractions, with a fine from 601 Euros to 10,000 Euros; and 'very serious' breaches with a fine from 10,001 to 1,000,000 Euros.

2. The amount of the imposed sanction, within the limits provided, shall be established taking into account the risk created, the social repercussion of the infraction, the benefit that has been provided to the offender of the sanctioned behaviour and the previous commission of one or more breaches of this Law.

3. In instances where the amount of the fine is less than the benefit obtained from the commission of the infraction, the sanction shall be increased to double the amount that the offender has obtained from the infraction.

4. If one act can be grounds for two or more classified breaches in this or other Laws, then only that which has the greatest sanction shall be taken into account.

5. The amount of the fines shall be periodically revised and updated by the Government, taking into account the variation of consumer price indexes.

6. Notwithstanding the sanctions provided in this Article, 'serious' or 'very serious' breaches shall entail revocation of the authorisation granted for that research or activity.

Likewise, in especially serious cases, the exclusion of the authorisation of any of the activities regulated in this Law may be accorded for a period of one to five years. Where this measure may be

imposed, the following shall be taken into account: the generated risk, the social repercussion of the infraction, the benefit obtained by the offender of the sanctioned behaviour and the previous commission of one or more breaches of this Law.

#### **Article 76.**

The competent authorities shall exercise the functions of control and inspection, ex officio or as requested by a party, as well as the bringing of charges and resolution of sanctioning cases.

### **TITLE VII**

#### **The Spanish Committee on Bioethics**

#### **Article 77. *Nature of the Committee.***

The Spanish Committee on Bioethics is created as an entity composed of several members, which is independent and of a consulting nature on matters related to the ethical and social implication of biomedicine and the health sciences.

It shall be assigned to the Ministry of Health and Consumption, which in turn shall designate its seat.

#### **Article 78. *Functions.***

1. The functions of the Spanish Committee on Bioethics are:

a) To issue reports, proposals and recommendations for the State and autonomous public powers in matters with relevant ethical implications.

b) To issue reports, proposals and recommendations on matters that the Committee considers relevant, relating to the ethical and social implications of biomedicine and the health sciences.

c) To establish general principles for the drafting of good practices codes for scientific research that shall be developed by the Research Ethics Committees.

d) To represent Spain in the supranational and international forums and organisations that deal with bioethics.

e) To draft an annual memorandum of activities.

f) Any other functions that are attributed to it, through regulations develop under this Law.

2. The reports, proposals, recommendations and other documents drafted by the Spanish Committee on Bioethics may be published for general knowledge and diffusion, in full compliance with constitutionally recognised fundamental rights.

3. The Spanish Committee on Bioethics shall collaborate with other State and autonomous committees that have counselling functions on the ethical and social implications of biomedicine and the health sciences and shall promote communication amongst these bodies, notwithstanding their respective functions.

#### **Article 79. *Composition and designation of its members.***

1. The Committee shall be made up of a maximum of 12 members, chosen from persons who are accredited and qualified in the areas of science, the law and bioethics. The Committee's composition shall exhibit a balance of members involved in the abovementioned varying disciplines.

2. The members of the Committee shall be named by the Minister of Health and Consumption, in the following manner:

a) Six members, as proposed by the autonomous communities, in accordance with that agreed within the Interterritorial Council of the National Health System.

b) Six members proposed by the General Administration of the State in the following proportion:

1) One by the Ministry of Justice.

2) One by the Ministry of Education and Science.

3) One by the Ministry of Industry, Tourism and Commerce.

4) Three by the Ministry of Health and Consumption.

3. The Minister of Health and Consumption shall name the President of the Committee from among its members.

4. The Secretary of the Committee shall be a civil servant with the rank of Vice-Director General belonging to the Institute of Health Carlos III, who shall have a voice but no vote.

#### **Article 80. *Duration of the mandate and the exercise of the post.***

1. Committee members shall have a mandate of four years, renewable only once, except if they substitute, before the expiration of the term of another previously designated member, in which case their mandate shall be for the time remaining until the completion of the four years from the time of the naming of the original member, without prejudice to the possibility of re-appointment.

2. Half of the members' terms shall be renewed every two years, save for the first time, which shall be decided by draw.

3. The Committee members shall cease to hold office for the following reasons:

a) Expiration of their mandate.

b) Resignation, which shall take effect by mere notification to the Minister of Health and Consumption.

c) Accorded separation by the Minister of Health and Consumption, after meeting with the interested party, due to permanent incapacity in the exercise of their function, serious non-fulfilment of their obligations, unexpected incompatibility or due to the commission of a wilful offence. To these effects, the opening of the stage of

trial during which testimony is given shall be similar to the bill of indictment.

4. The members of the Committee shall act independently from the authorities that proposed or named them as members and shall not be able to belong to governing entities of the Administration of the State, of autonomous communities or of local governments, as well as to the Spanish Parliament or the Legislative Assemblies of the Autonomous Communities.

#### **Article 81. *Functioning.***

1. The Committee shall act in banc and in Standing Committees. The composition and functions of both entities shall be determined by regulation.

2. The functioning in banc and in the Standing Committees shall be developed by an internal regulation that shall be approved by the Committee in banc.

3. This regulation shall include, as a minimum, the following matters:

- a) Frequency of meetings, which shall be, at least, every three months.
- b) Procedures of deliberation and making of decisions.
- c) Extension and limits of the duty of confidentiality upon its members.
- d) Independence of its members and any conflicts of interest.
- e) Election procedure of its President.

### **TITLE VIII**

#### **Promotion and coordination of biomedical research in the National Health System**

#### **Article 82. *Sectorial initiative on Health Research.***

1. In the drafting of the Sectorial Initiative on Health Research, integrated in the Plan for Scientific Research,

Development and Technological Innovation, the Ministry of Health and Consumption shall take into account the proposals submitted by the autonomous communities for the establishment of priority areas, in accordance with the health needs of the population and the various objectives in health services and public health.

In the exercise of their competencies, the autonomous communities may establish their own plans for biomedical research and shall have available, through the Sectorial Initiative on Health Research, a national reference framework for the better use of existing resources and the strategic adaptation of research to the national plans on health services.

2. In the elaboration of the Sectorial Initiative on Health Research, the human, material and budget resources necessary to assure the regular financing of the promotion and development of quality scientific and technical research in biomedicine shall be taken into account.

#### **Article 83. *Promotion of research activity in the National Health System.***

1. Research activities must be promoted throughout the health system as a basic element for its progress.

2. The Institute of Health Carlos III shall contribute to providing the structure of research within the National Health System in the terms provided in Article 48 of Law 16/2003, of 28 May, on the Cohesion and Quality of the National Health System, and shall promote and coordinate research in biomedicine through the undertaking of basic and applied research, promoting epidemiological research, and in public health, scientific and technical accreditation and future health control, scientific-technical counselling and health training and education in biomedicine.

3. In relation to the provisions for regulating research in Chapter IV of Law 16/2003, of 28 May, on the Cohesion and Quality of the National Health System, the Ministry of Health and Consumption and the autonomous communities shall promote the intervention of hospitals as structuring nuclei of research through cooperation and as a network. The centres of primary care may participate in these research networks.

4. Research-based public entities, which are dependent on the General Administration of the State and on the autonomous communities, whether they belong to the National Health System or not, as well as universities and enterprises and non-profit public or private organisations that undertake activities of research and technological development, may participate in the undertaking of biomedical and health sciences research of the National Health System.

The programs included in biomedical research may be likewise executed in collaboration with foreign institutions.

5. The entities, enterprises and institutions that are mentioned in the previous section may contract scientific personnel, experts in technological development and other specialists related with research and development activities, in order to collaborate in the execution of those technical research and development activities that correspond to the Sectorial Initiative on Research, in the conditions provided in Article 17 of Law 13/1986, of 14 April, on the General Promotion and Coordination of Scientific and Technical Research.

**Article 84. *Promotion and coordination of research training of National Health System personnel.***

1. The Public Administrations shall provide support for biomedical research

training through the development of those measures provided in this Law, scholarships and financial aid programs and the improvement of working conditions.

2. The National Council of Specialties in the Health Sciences shall promote technological and methodological research and innovation in specialised health education.

**Article 85. *Research career in the centres of the National Health System.***

1. The public administrations shall promote, within the planning framework of its human resources, the incorporation of research personnel into the statutory regime for health services.

In the case of centres associated with the new methods for managing the National Health System prescribed in Law 15/1997, of 25 April, the incorporation of research personnel shall be done according to the applicable legal regime.

In both cases, the incorporation shall be done through legally established procedures.

2. National Health System centres shall be able to hire temporary work personnel who are dedicated to research activities in accordance with the following conditions:

a) Researchers in training, who must be licentiates or engineers having obtained a Diploma of Advanced Studies or a substitute administrative document in accordance with the new structure of education adapted to the European Space for Higher Learning, for a maximum period of two years after having obtained the diploma, in accordance with Royal Decree 63/2006, of 27 January, which passed the statute on research personnel in training.

b) Researchers in a period of specialisation, who shall be doctors or specialists, have acquired specialised health training and who shall be hired

for research tasks under the conditions provided in Article 17.1.b of the Law on the General Coordination for Scientific and Technical Research.

3. The selection and hiring of these personnel must be subject to the principles of public concurrence, achievements, capacity and independent scientific evaluation that are expected of the scientific community.

4. The activities undertaken in accordance with the provisions in Section 2 of this Article, shall be included in an evaluation of the merits for the obtaining of a post as medical personnel in the health institutions of the National Health System. Likewise, the assistance activities that are carried out by these professionals shall also be taken into account in professional promotion within the National Health System.

5. The Public Administrations, within their ambit of competences, shall be able to include research activities as part of the merit system of the professional development of statutory personnel, in accordance with the provisions in Article 37 of Law 44/2003, of 21 November, on the Regulation of Health Professions.

6. In relation to health services, the necessary measures to facilitate compatibility between assistance activity and scientific activity in the health professions shall be arbitrated in accordance with Law 53/1984, of 26 December, of Incompatibilities of the personnel at the service of the Public Administrations.

#### **Article 86. *Mobility of research personnel.***

1. The mobility and exchange of health researchers between different centres within the national framework, the European Research Area, as well as reciprocal cooperation agreements with other States, shall be promoted.

Civil servants who belong to research entities or registries may be authorised to undertake work related to scientific and technical research outside the ambit of their appointments, through mobility mechanisms established in the regulation of public functions.

2. Whenever a technologically-based enterprise is created through patents or results generated by research projects, which are fully or partially financed by public funds and undertaken in research centres, the civil servants or statutory personnel who justify their participation in the abovementioned project shall be able to solicit authorisation to join that enterprise, through a temporary leave of absence.

The Government shall regulate the conditions and the procedures for the granting of this leave which, in each case, shall be for a maximum time limit of five years. During this period, the person on leave shall have the right to have their job post reserved and to their computation for seniority purposes. If prior to the last month of the end of the period for which the leave has been granted to the civil servant or statutory personnel, he or she decides not to return immediately to active service, then he or she shall be officially declared on his or her own motion in voluntary leave for private purposes.

#### **Article 87. *Temporary appointment of specialists.***

The Ministry of Health and Consumption, following authorisation by the corresponding entity, shall be able to temporarily appoint, whether full or part time, scientific personnel, experts in clinical research and technological development, who provide services in ministry departments, autonomous communities, universities, public centres of research and public entities. This appointment shall be drafted in accordance with the

regulations of the legal system of civil servants or labour personnel, whichever is applicable in each case.

The part time appointment of the abovementioned personnel shall be on the same terms as the part time job post that they hold. They shall also be able to contract, for a time that is not greater to the duration of the Sectorial Initiative on Health Research, any type of personnel not appointed to the public sector, in accordance with the provisions in Article 15.1, subsection a), of the Worker's Statute and in conformance with the corresponding Offers for Public Job Posts.

#### **Article 88. *Research Institutes and Networks.***

The National Health System shall collaborate with other institutions and organisations involved in research for the joint use of scientific infrastructures and the development of research projects. To this effect, the creation of institutes of biomedical research within the centres of the National Health System shall be promoted through the association of research groups.

In relation to participation in the convocations of the Ministry of Health and Consumption, the research capacity of these institutes may be certified by the Ministry of Health and Consumption, as proposed by the Institute of Health Carlos III or by the autonomous communities through the procedure that is established by regulation.

In accordance with the provisions in Article 42.2 of Law 30/1992, of 26 November, on the Legal Regime of Public Administrations and the Common Administrative Procedure, the term for the resolution and notification in the process of certification to which this Article makes reference shall be 12 months.

#### **Article 89. *Cooperation among the public and private sectors.***

1. In order to increase involvement of the private sector in the Biomedical and Health Sciences Sector, procedures for the participation of private entities that develop research activities or technological development in the execution of research actions of the National Health System shall be established.

2. In order to comply with the above objective, National Health System centres, public institutions, universities, as well as other entities involved in biomedical research and health sciences, may reach agreements with private entities that undertake scientific research activities and technological development. These agreements may establish the possibility that personnel employed by these private entities participate in the execution of research programs or projects of the National Health System. In no case shall this participation generate the right to access the public function or the service in the Public Administration through work ties or through any other means.

3. The Public Administrations shall promote a favourable environment for the development of private initiatives and shall foster the creation of new business opportunities that arise in the National Health System, including the creation of risk-capital entities aimed at investment in biomedical research.

4. Likewise, measures shall be taken that promote adequate returns to the National Health System in relation to the investments undertaken in the area of biomedical research.

#### **Article 90. *Financing.***

1. The Ministry of Health and Consumption, in its management of the activities mentioned in the previous Articles, shall finance such activities

through the instruments of finance provided in the National Plan of Scientific Research and Technological Development and Innovation. This financing shall be provided by the budget of this Ministry, notwithstanding the co-financing agreements that exist or that are established in the future with public or private entities.

2. The financing of the activities mentioned in the previous Article, which are managed by the Ministry of Health and Consumption, shall be done in accordance with the provisions in the National Plan of Research & Development & Innovation, even where the funds come from legally set tariffs, and shall be charged to the budget of this ministerial department, notwithstanding the existence of co-financing agreements with public or private entities.

***Additional First Disposition. Use of human cells and tissues for therapeutic ends.***

The use of any biological material of human origin referred to in this Law, for therapeutic purposes shall be regulated in accordance with Law 30/1979, of 27 October on the Extraction and Transplantation of Organs and Law 14/2006 of 26 May, on Assisted Human Reproduction Techniques and other dispositions that develop such laws, notwithstanding the provisions in Title II of this Law, in appropriate circumstances.

***Additional Second Disposition. Promotion of biomedical research by the Institute of Health Carlos III.***

One. Instrumental Means.

1. The Institute of Health Carlos III shall be considered as its own instrumental means and of technical assistance to the General Administration of the State and its organisms and

entities of public law in those matters that constitute its purposes and shall perform the tasks, services, studies, projects, technical assistance, works and any activities that are entrusted by these organisms in the form provided in the present disposition.

2. The payable amount for the works, services, studies, projects and other activities undertaken through the Institute of Health Carlos III shall be established by applying to the executed units those tariffs that have been fixed in relation to the cost of the service as ordered by the Minister of Health and Consumption and proposed by the Management of the Institute of Health Carlos III.

The compensation that must be paid in those cases in which a tariff does not exist shall be likewise established by order of the Minister of Health and Consumption.

3. In the events provided in Article 17.1 of the Law on Promotion and General Coordination of Scientific and Technical Research, classification as a contractor of the Institute of Health Carlos III shall not be a requirement in order to be adjudicated contracts by the Public Administrations.

Two. Own Research Centres.

The Institute of Health Carlos III shall promote research in thematic areas of priority through the creation of research units with the legal nature of a foundation or any other suited to the nature of the functions that it shall undertake. These units shall be considered as units of this Institute.

The finance contributions granted globally to these centres for their functioning shall not be understood as included within the ambit of application of Law 38/2003 of 17 November, on General Subsidies.

Three. Virtual Research Centres as a network.

The Institute of Health Carlos III shall establish the mechanisms so that the networks to which article 51 of Law 16/2003 of 28 May makes reference, after being duly evaluated and surpassing the criteria of quality and suitability, may become virtual centres of research in a network with their own legal personality.

***Additional Third Disposition. Post-graduate training in Health within the European Space for Higher Learning.***

The National Health School shall be able to teach post-graduate courses in health within the Framework of the European Space for Higher Learning.

***First Transitory Disposition. Commission of Follow-Up and Control on the Donation and Use of Human Cells and Tissues.***

The Commission on the Follow-Up and Control on the Donation and Use of Human Cells and Tissues, to which reference is made in Royal Decree 2132/2004 of 29 October, establishing the requirements and procedures to solicit the undertaking of research projects with stem cells obtained from surplus embryos, shall assume the functions of the Commission for the Guarantees in the Donation and Use of Human Cells and Tissues provided in Article 38 while the latter is being created and in accordance with Article 37. The former shall oversee the compliance of the guarantees and requirements established in Article 34 and 35 of this legal regulation.

***Second Transitory Disposition. Previously stored samples.***

Those biological samples obtained previous to the entry into effect of this Law may be used for biomedical research purposes when the subject

source has provided his consent or when the samples have been previously anonymised. Nonetheless, codified samples or those identified for biomedical research purposes may be used without the consent of the subject source when the obtaining of this consent entails a unreasonable effort as provided in section i) of Article 3 of this Law or when it is not possible due to the death of the subject source or when they can not be found. These cases shall require approval by the appropriate Research Ethics Committee, which must take into account, at least, the following requirements:

- a) That it is a research of general interest.
- b) That the research is less effective or not possible without the identifying data of the subject source.
- c) That there is no express objection by the subject source.
- d) That the confidentiality of the data of a personal nature is guaranteed.

***Third Transitory Disposition. Clinical Research Ethics Committees.***

Clinical Research Ethics Committees shall cease to exist as soon as Research Ethics Committees are established. Until these Committees are established, the Clinical Research Ethics Committees that are working in the centres which undertake biomedical research shall be able to assume their competences.

***Sole Derogatory Disposition. Regulatory Derogation.***

Law 42/1988 of 28 December on the Donation and Use of Human Embryos and Foetuses or their Cells, Tissues or Organs and whichever dispositions, whatever their rank, which are contrary to the dispositions established in this Law are derogated. Likewise, the following are derogated: Sections 5 and

6 of article 45, and articles 46, 47 and 50 of Law 16/2003 of 28 May on the Cohesion and Quality of the National Health System; Title VII and Chapters II and III of title VI of Law 14/1986 of 25 April of the National Health Law; Additional Second Disposition of Law 14/2006 of 26 May, on Assisted Human Reproduction Techniques; and articles 10 and 11 of the Statute of the National Centre for Transplantation and Regenerative Medicine, approved by Royal Decree 176/2004 of 30 January.

**First Final Disposition. Competency Title.**

This Law is based on Article 149.1.15 and 16 of the Spanish Constitution, which attributes to the State exclusive competency in matters of promotion and general coordination of scientific and technical research and in matters of basis and general coordination of health matters.

The State and the autonomous communities shall adopt, within the ambit of their respective competencies, those measures necessary to guarantee the effectiveness of this Law.

**Second Final Disposition. Suppletory Application.**

Law 41/2002 of 14 November, on the Basic Law of the Autonomy of the Patient and the Rights and Obligations in matters of Clinical Information and Documentation and Basic Law 15/1999 of 13 December, on the Protection of data of a Personal Nature, shall be applicable always when it is not incompatible with the principles provided in this Law.

**Third Final Disposition. Regulatory Development.**

The Government is granted power to dictate as many dispositions as

necessary to develop and execute this Law and in particular to establish:

a) The internal, intercommunity and extra community regulations on exchange and circulation of biological material of human origin for research purposes.

b) The basic requirements of accreditation and authorisation of the centres, services and biomedical teams related to the collection and use of any biological material of human origin for biomedical research purposes.

c) The functioning and development of the Commission on Guarantees for the Donation and Use of Human Cells and Tissues, which shall substitute the now in effect Commission for the Follow – Up and Control on the Donation and Use of Human Cells and Tissues.

d) The functioning and organisation of a National Registry of Biobanks for Biomedical Research that shall be appointed to the Ministry of Health and Consumption.

**Fourth Additional Disposition.**

Subsection 2 of section A of the Annex to Law 14/2006 of 26 May, on Assisted Human Reproduction Techniques shall be drafted in the following manner:

“2. Fertilisation in Vitro and intracytoplasmic injection of sperm with their own gametes or of a donor and with transfer of pre-embryos.”

**Fifth Additional Disposition. Entry into power.**

This Law shall enter into effect on the day following its publication in the “Official Gazette of the Spanish State”.

Therefore,  
I order all Spaniards, individuals and authorities, to obey and enforce this Law.

Madrid, 3 July, 2007.

The King JUAN CARLOS

The President of the Government,

JOSÉ        LUIS        RODRÍGUEZ  
ZAPATERO