

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 are a key element to improve the quality and life expectancy of the citizens and to improve their well-being, which has substantially changed, both methodologically as well as conceptually in the last years. The appearance of new analytic tools has led to great discoveries which allow us to foster reasonable hopes on the treatment and even the cure in a not very distant future of pathologies which are not capable of being dealt with at present.

In a few years, the obtaining, use, storage and conveyance of biological samples for diagnostic or research purposes have acquired enormous relevance, the research that involves invasive procedures on human beings are each time more frequent, and the research with gametes, embryos or embryonic cells has become indispensable in the ambit of 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 by such a complex matter that affects the identity of the human being in such a direct manner.

Furthermore, these new scientific advances question the organisation that biomedical research had been based until now, that this new context requires a multidisciplinary approach, an approximation of the basic researcher to the clinical and coordination and work in networks, as necessary guarantees for the obtaining of a quality research.

Spain, which already participates in a decided manner in the generation of biomedical knowledge, is not foreign to the interest raised by these researches and the debate it arises. In this sense, the public administrations are decisively supporting biomedical research and are providing important economic and human resources and the necessary infrastructures to foster such end. Both the General Administration of the State, when exercising its jurisdiction of 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 open to the participation and collaboration with private enterprises, with different entities of research, universities and their own centres of the National Health System, in order to take advantage in an efficient manner of the available resources and to obtain results from the contributions of the different research groups, that can be applied to the improvement of the

health of their citizens. In this manner, there is compliance in the field of biomedical research with the mandate established in article 44.2 of the Spanish Constitution that entrust the public powers to promote science and scientific and technical research for the general welfare.

This law is set within this context and, on the one hand, responds to the challenges that are posed by biomedical research and tries to take advantage of its results for the collective health and well-being, while on the other, promotes and stimulates the coordinated action of the public powers and of the public and private entities and institutions dedicated to research, which are provided with better instruments to comply with their task. Furthermore and in order to achieve these objectives, the Law establishes regulations in areas that were not regulated up to the present, that have been so in a fragmented manner or that were foreign to the changes that have happened in the last years, such as genetic analysis, research with human biological samples, in particular of an embryonic nature, or biobanks.

II

Facing this outlook, it is necessary to have available an adequate normative framework that provides answers to the new scientific challenges while at the same time guarantees the protection of the rights of the persons who could be affected by the acts of research.

In fact, both at the international level as well as within Spanish society, some of the most sensitive aspects related with biomedical research have been the object of open and thorough debate, which has allowed to deduce principles

and criteria, each time of greater acceptance, from which to create norms and regulations of behaviour that achieve the necessary equilibrium between the needs of researchers and the trust of society in scientific research. In accordance with this spirit, this Law has as one of its priority axis the assurance of the respect and the protection of fundamental rights and public liberties of the human being and other legal goods related with them 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, April 4, 1997 and which entered into effect in Spain on 1, January 2000. Consequently, the Law proclaims that the health, interest and well-being of the human being that participates in biomedical research shall prevail over the interest of society or science.

In particular, the Law is built on the principles of the integrity of the persons and the protection of the dignity and identity of the human being in any biomedical research that involves the intervention on human beings as well as in the undertaking of genetic analysis, the processing of genetic data of a personal nature and of human biological samples used in research. Along these lines, the Law establishes the free will of a person as the foundation from which the specific rights to consent and to obtain previous information is derived. Likewise, it establishes the right to not be discriminated, the duty of confidentiality by any person that in the exercise of their duties has access to personal information,

the principle of gratuity of the donations of biological material and it sets the standards of quality and safety, which include the traceability of human cells and tissues and the strict compliance of the precautionary principle in the different activities that it regulates. In regulating all 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 a research point of view, the Law guarantees the freedom of research and of scientific production in the terms provided in article 20 of our Constitution. Furthermore, such an ambitious legal framework on advanced research in the field of biomedicine could not stop from bearing in mind the human, scientific, structural and social context in which it must develop in its daily practice, whereby this Law regulates the mechanisms to foster and promote, plan, evaluate and coordinate biomedical research from the principles of quality, efficacy and equal opportunity and in order to favour that the results of research are transformed into efficient therapies to combat different pathologies. Notably, the implantation of research in health centres as a routine practice is made easier, the collaboration among basic biomedical research centres and hospitals and other centres of the National Health System are encouraged and there is a fostering of the ties between the

public and private sector through research in networks and the mobility of researchers and practitioners.

From an organizational perspective, the Law creates different professional entities that are recognised with a specially qualified function based on its impartiality, independence, technical capacity and professional competency that are required to its members. On the one hand, Research Ethics Committees shall guarantee that each research centre that intervenes on human beings or biological samples of human origin does so in accordance with methodological, ethical and legal aspects. The Commission for the Guarantees on the Donation and Use of Human Cells and Tissues shall be responsible for the compulsory evaluation and providing of information of those with a favourable report of those research projects that require the obtaining or use of tissues, embryonic stem cells or other similar of human origin that are obtained through diverse techniques of cell reprogramming that already exist or that could be discovered in the future, as well as the development of other functions on scientific, ethical or legal aspects. Finally, the Spanish Bioethics Committee is created as the authority for the consultation of all aspects 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 practices in scientific research that are developed by the Research Ethics Committees.

The Law expressly prohibits the creation of human pre-embryos and embryos exclusively for the purpose of experimentation, 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, but allows the use of any technique for the obtaining of 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 in this Law.

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

IV

This Law regulates such a broad and complex set of matters, compiled in ninety articles, fifteen 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 and it establishes a set of principles and guarantees for the protection of the rights of persons and of the legal goods involved in biomedical research.

Regarding the object and scope of the regulation, there is clarification that the biomedical research that is made reference to by the regulation 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.

Regarding the system of guarantees, there is a specific list that sets the limits to the principle of freedom of research in favour of the dignity and identity of the human being and for the protection of the health and there is a specific regulation of the following: informed consent and the right to information, the protection of personal data and the duty of confidentiality, the non-discrimination due to genetic reasons or due to the refusal to undergo a genetic analysis or to participate in research, the gratuity of the donation and use of biological samples, the guarantee of the traceability and the safety in the use of cells, tissues and any biological material of human origin and lastly, it establishes the limits that must be abided in genetic analysis.

Additionally, this title regulates the criteria which biomedical research must follow regarding quality, efficacy and equality and the Biomedical Research Committees are created as fundamental tools for the evaluation and follow-up of research projects. Lastly, article 3 establishes a broad list of definitions, which based on scientific, technical and legal knowledge, 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. This regulation completes the normative framework of our legal regulation on research in which human beings are direct participating subjects, which already has specific regulations on

clinical trials with medications and health products.

Its five chapters regulate, firstly, the general principles of these research, with express references to the consent and to the precise information that must be provided to the participating subjects of the research; next, the systems of evaluation and authorisation and of assurance of potential damages are established, which aim to reduce to the outmost the damages that could be derived from the research that entails invasive procedures in human beings; thirdly, there is a regulation of the specificities of research during a pregnancy and lactation, in the event of minors or disabled and the scenario of research with persons unable to provide their consent due to clinical reasons.

The fourth chapter of this title regulates the safety and supervision systems in the process of research, with specific references to the evaluation of the state of health of the participants in research, the non-interference in the clinical intervention of these and the system of verifications that, under the supervision of the Research Ethics Committee, must be performed throughout the research. The last chapter of the title, finally, sets out the obligation to inform the participants in research about the relevant data for their health that could be obtained throughout it as well as the obligation to publicise their results.

Title III, with its two chapters, compiles the regulation on the donation and use of human embryos and fetuses, of 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; and secondly, to incorporate this matter to the global approach of this new Law, in order to eliminate unnecessary normative dispersions related with biomedical research. The repeal of Law 42/1988, of 28 December, that in its time was a noteworthy legislative novelty of our legal regulation and was a recognised as a reference in comparative law, is a consequence of this.

The title is structured in two chapters. The first regulates the conditions for the donation of human embryos and fetuses, among which are the prohibitions that the interruption of a pregnancy can have as a final purpose a donation and that the professional members of a medical team that perform the interruption intervene in the use of the aborted embryos or fetuses, and establishes that for the donation to be valid there must be a concurrence of the informed consent of the donor and the expulsion in the gestating women of the embryos and fetuses without possibility of maintaining its vital autonomy. The second chapter imposes that the research with live embryos and fetuses in the uterus shall only be undertaken for a diagnostic or therapeutic purpose in its own interest and establishes the requisites for the authorisation of the research projects with embryos, fetuses and their biological structures.

In Title IV, the regulation on the donation, use and research with human embryonic cells and tissues and other similar cells is done in full accordance to that provided 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 requisites on the use of these pre-embryos or their biological structures for research or experimentation. This is notwithstanding the compulsory favourable report which the Guarantees Commission for the Donation and Use of Human Cells and Tissues must issue and to the conditions, guarantees and requisites that are imposed to these effects in the first two chapters of Title IV.

The first chapter of this title expressly prohibits the creation of human pre-embryos or embryos for experimentation and authorises the use of any technique for obtaining human stem cells for therapeutic or research purposes, including the activation of oocytes through nuclear transfer which doesn't entail the creation of a pre-embryo or embryo in the terms defined in this Law. Chapter two regulates the conditions which must be met when researching with biological samples of an embryonic nature. The third chapter establishes the composition and function of the aforementioned Guarantees Commission, which also has the responsibility to provide information on researches that are listed in the Law on stem tissues and cells or others functionally similar or to procedures or techniques for obtaining these, including embryonic stem cell lines from third countries. Lastly, within chapter four, a system for promotion and coordination is established in this ambit of research with human embryonic cells and tissues, highlights the regulation of the National Bank of Cell Lines, which is

afforded a structure as a network with a central node and its appointment to the Institute of Health Carlos III.

Title V regulates other emerging matters related with the current expansive tendency of biomedical research, such as, the undertaking of genetic analysis, the access and use of its results, as well as the obtaining and use of human biological samples. In spite of the enormous difficulties to establish 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 which might be involved in these type of analysis, this Law could not renounce to establish a legal framework in which we must take a stance in the undertaking of genetic analysis for any purpose, including diagnostic.

To this respect, the Law, at the same time that it prescribes a set of guarantees in relation with genetic analysis and biological samples within the ambit of the protection of data of a personal nature, it creates a set of norms in order to provide trust and safety to researches, and the public and private institutions in their acts within the sector, eliminating the current legal uncertainties. Besides other normative principles already mentioned, the guiding principles set are those of accessibility, equity and quality in the processing of data, it requires the previous consent and foresees the scenario of anonymised biological samples. Lastly, specific rules are established in relation with the deceased and with pre-embryos, embryos and fetuses, in respect to which the protection of data is also guaranteed and the duty of confidentiality is established. It is

also noteworthy, that the Law sets out the need to accredit the centres and persons capable to undertake genetic analysis.

The regulation on the obtaining, conservation, use and assignment of biological samples is likewise object of a detailed regulation in chapter three of this title. As is logical, the legal framework turns once again on the consent of the subject source of the samples and on the previous information that must be provided to this respect. In so far as the disjunctive on the possibility to grant a completely generic or a specific consent on the use or latter uses of the sample, the Law has chosen an intermediate and flexible regulation, in that the initial consent may provide coverage, if in the information previously provided to the subject source there has been a provision about later researches related with the initial, including the researches that may be undertaken by third parties and the assignment of the data or of identified or identifiable samples to them. Anyways, a transitory regulation has been established in respect to biological samples obtained for any purpose before the entering into effect of this Law, in order not to hinder their use for research while at the same time looking after the interests of the subject source.

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 sole system of registry is set up, whichever the finality of the bank,

including those for clinical use in patients, in an exclusive or shared manner with those of research, and notwithstanding the specific measures that must be developed by regulation for the functioning of each bank in accordance to its respective nature and purposes. It also establishes that the authorisation for the creation of biobanks shall correspond to the appropriate entities of the autonomous community, except for the initiatives that the Institute of Health Carlos III could take on the creation of national banks of biological samples for research in accordance with the general welfare, in which case the authorisation shall correspond to the Ministry of Health and Consumption.

Title VI establishes a regime of administrative infractions and sanctions that are based on the principles of legality, minimum intervention, proportionality, and subsidiarity regarding the criminal infraction. The specific infractions included in this Law are complemented with those provisions that to this respect are found 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.

Likewise, this Law aims to provide response to the need to have available a State entity such as the Bioethics Committee, basically of a consulting nature on matters related with the ethical, legal and social implications on Medicine and Biology, which also represents Spain in the supranational and international forums and bodies that

are involved in Bioethics and that collaborates with other state and autonomous committees with counselling functions on these matters. Title VII of this Law establishes those provisions on its composition and functioning, which aims 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 regarding the elaboration of 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 a 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 of excellence aimed to resolve the health needs of the population and particularly the 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 the possibility that the research activity becomes an integrating part of the professional career of the statutory personnel. Furthermore, mobility measures are established for the research personnel within the general administration of the state and towards private entities of research through a temporary leave of absence.

Additionally, the cooperation among the public and private sectors is strengthened by among other measures, the collaboration and participation of private entities in the execution of research activities of the National Health System and establishes the possibility that the personnel of these private entities participate in the execution of research programs of projects in the National Health System.

Among those dispositions that conclude the articles of this Law, special mention must be made of the additional second, 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 to which biomedical research is foreseeable headed to in the coming years. It is a normative instrument that while at the same time it complies with its aim to guarantee the legal rights and goods involved in biomedical research, it also constitutes a decisive support for the development of public policies and private initiatives that must provide thrust to a biomedical research that is progressive and competitive in our scientific environment and in a clear legal framework that allows the efficiency and quality in research.

TITLE I

General Provisions

Article 1. *Object and Scope.*

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

a. Researches related with human health that imply invasive procedures.

b. The donation and use of human oocytes, sperm, pre-embryos, embryos and fetuses or of 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 promotion, planning, evaluation and coordination of biomedical research.

2. Likewise and exclusively within the health ambit, 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 to includes basic and clinical research, with the exception of clinical trials with medication and sanitary products, which shall be regulated by its specific regulation.

a. The implantation of organs, tissues or cells of any origin shall be regulated by that established in Law 30/1979 of 27 October, on the Extraction and Transplantation of Organs and other applicable legislation, and are excluded from the scope of application of this Law.

Article 2. Principles and guarantees of biomedical research.

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

a. The protection of the dignity and identity of the human being shall be protected in relation with any research that involves interventions on human beings in the field of biomedicine, thus guaranteeing every person, without any discrimination, the respect to their integrity and to 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 interest of society or science.

c. Research on human biological samples shall be undertaken in a framework of respect towards the fundamental rights and freedoms, guaranteeing the 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 ambit of the biomedical sciences shall be guaranteed.

e. The authorisation and development of any research project on human beings or their biological material shall require the previous and mandatory favourable report of the 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 object of evaluation.

Article 3. Definitions.

The following shall be used when interpreting this Law:

a. “Genetic Analysis”: 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 whose object is to understand the nature and magnitude of genetic variations within a population or among individuals of the same group or different groups.

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

d. “Biobank”: 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 of quality, order and destination.

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

f. “Consent”: manifestation of the free and conscious volition that is validly emitted by a capable person or through an authorised

representative, after adequate information has been provided.

g. “Genetic Screening”: 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 can not 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 a non-reasonable 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”: phase of embryonic development from the moment in which the fertilised ovocyte is found in the uterus of a woman until the beginning of organ genesis 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”: 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”: embryo with human appearance and with its organs formed which is maturing from the 57th day after the moment of fertilising 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. “Anonimised or irreversible disassociated biological sample”: sample which can not be associated to an identified or identifiable person as the nexus which had all the information that identifies the subject has been destroyed or because such association requires an unreasonable effort.

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

r. “Codified or reversibly disassociated biological sample”: 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”: embryo constituted in vitro that is formed by the group of cells that are the result of the progressive division of the

ovocyte 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 a research and whose effects can only be of a minor and temporary nature.

v. “Source subject”: living being, no matter his or her state of health, or 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”: capacity to associate a specific biological material with registered information that makes reference to any step in the chain of its collection as well as through all the process of research.

Article 4. Informed consent and the right to information.

1. The free will of persons that may participate in biomedical research or that could provide their biological samples shall be respected. Their previous express and written consent must be provided once the 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 his or her will.

2. When a person is legally disabled or is a minor, their consent shall be granted through representation, provided that there are no other alternatives to the research.

The conveyance of the consent through representation shall be proportionate to the research to be undertaken and shall be done in accordance with the respect of the dignity of a person and for the benefit of their health.

The disabled and minors shall participate, in so far as it is possible and in accordance to 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 moment, 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. The lack of consent or the revocation of consent that has been previously granted shall not entail any damages in the health care assistance of the subject.

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

There shall be an observance of the right of the person not to know that data, which is referred to in the former paragraph, including unexpected findings that could arise. Nonetheless, when this information, according to the criteria of the doctor in charge, is necessary in order to avoid serious damage to his health or that of his 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 exclusively be limited to the necessary data for 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 the biomedical research shall be guaranteed protection, in accordance with that provided in the Basic Law 15/1999, of 13 December on the Protection of Data of a Personal Nature. The same guarantees shall be applicable to biological samples that are the source of information of a personal nature.

2. The conveyance of data of a personal nature to third parties outside the medical-assistance act or to a 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 family members, the conveyance to thirds 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 has access to data of a personal nature, in the duty of their functions in relation with the providing of a medical health care service or biomedical research, whichever the reach of either, shall be subject to the duty of secrecy.

5. If the publication of the results of a 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 a previous and express consent of 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 able to be discriminated 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 with 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, whichever its specific origin, and the compensations that are provided for in this Law can in no way entail a lucrative or commercial nature.

Likewise, the donation implies the waiver by the donor to any right, of an economic nature or other, on the results that could be directly or indirectly obtained through the

research that takes place with 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 the regulations on quality and safety, abiding by the duty of confidentiality and that provided in Basic Law 15/19999, of 13 December on the Protection of Data of a Personal Nature.

When researching with cells or tissues aimed for their application on the human being, the data to guarantee their traceability must be kept during at least thirty years.

The activities related with 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 with criteria of pertinence, quality, equity and accessibility.

3. Predictive tests of genetic diseases or those that permit to identify the subject as the carrier of a gene responsible for a disease or tests to detect a predisposition to a genetic susceptibility of a disease, shall only be carried out for medical or medical research purposes and with genetic counselling, when indicted, or in the case of a study of inter-individual differences in the response to prescriptions and the 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 criteria of quality, efficacy and equal opportunities.
2. Any biomedical research must be scientifically justified, must comply with the generally accepted scientific criteria and must be undertaken in accordance with the adequate professional obligations and standards, under the supervision of a scientifically qualified researcher. Furthermore, it shall also be evaluated at its conclusion.

Article 11. Entry and exit of biological samples.

The entry and exit, both within EU countries and those outside the EU of biological samples of human origin for those 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 an additional observance of the conditions for a conveyance and safety that are established 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.

The following criteria shall be considered, at least, 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 make up.

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 ponder the methodological, ethical and legal aspects of the research project.

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

- d) To watch over the compliance of the procedures that permit to assure the traceability of samples of human origin, notwithstanding that provided 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 the previous and mandatory favourable report by the Research Ethics Committee.

f) To develop codes of good practices 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 watch over the confidentiality and to exercise whichever other functions that could be assigned by the regulation in the development of this Law.

3. The Research Ethics Committees, in the exercise of their functions, may require all information that they need, and particularly that on the sources and quantity of the financing of the studies and the distribution of expenses.

4. The members of the Research Ethics Committee shall have to 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 the matter being examined.

TITLE II

Research that involves invasive procedures on human beings

CHAPTER I

General principles and requirements on information and consent

Article 13. Consent.

The carrying out of research on a person shall require the express, specific and written consent of the 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 a comparable efficacy.

2. Research shall not involve disproportionate risks or discomforts for the human being in relation with the potential benefits that may be obtained.

3. Notwithstanding what was previously established in the earlier paragraph, when the research doesn't have the possibility to produce results that directly benefit the health of the participating subject, then the research can only begin in case that it entails 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. Those persons who have been asked to participate in a research project shall previously receive the 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) Nature, extent and duration of the procedures that are going to be used, particularly those that affect the participation of the subject.

b) Available preventive, diagnostic and therapeutic procedures.

c) Measures to fight against adverse events that bear upon the

subjects who participate in the research.

d) Measures to assure the respect towards private life 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 access, in the terms provided in article 4.5, to the information that is relevant for the subject that may arise in the research or the total results.

f) Measures to assure an adequate compensation in the event that the subject is damaged.

g) Identity of the professional who is responsible for the research.

h) Any potential future use of the results of the research, including those that are commercial.

i) Financing source of the research project.

In the event that these matters are not known, there is an explicit compromise to complete this information when available.

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

4. Furthermore, the persons that are asked to participate in research shall be informed of the rights and safeguards that are provided in this Law for their protection and specifically, on their right to refuse to 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.*

Every biomedical research that entails an invasive procedure in the human being shall be previously evaluated by the Research Ethics Committee with oversight of the submitted research project and authorised by the corresponding autonomous authority. The evaluation must be previous to the authorisation, 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 that are obtained advise a modification of the project, this modification shall require a favourable report by the Research Ethics Committee and shall be notified to the competent autonomic authority for all practical 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. The carrying out of research shall, in every case, abide by the content of the project which has been granted authorisation.

2. The health authorities shall have at all times faculty to inspect the research, being able to have access to the individual clinical histories of the subjects of the study, which, in every case, they must keep its confidential nature.

3. The autonomous authority shall proceed, on its own instance or on behalf of the Research Ethics Committee, to the temporary suspension of the authorised research in the cases where the

requisites provided by this Law aren't met and when necessary to protect the rights of citizens.

Article 18. Compensation for damages and its assurance.

1. Those persons, who have suffered damages as a consequence of their participation in a research project, shall receive a compensation that corresponds in accordance with that provided in the following sections.

2. The undertaking of a research that entails an invasive procedure in human beings shall require the previous assurance of the general and special damages that could be derived for the person in whom it has been carried out.

3. When, for whatever reason, the insurance policy doesn't fully cover the caused damages, the promoter of the research, the researcher in charge and the hospital or centre in which it was carried out shall be joint and severally liable for them, even if there is no fault, thereby being responsible to bear the burden of proof. Neither the administrative authority nor the report of the Research Ethics Committee shall release them from liability.

4. There is a presumption, unless otherwise proven, that the damages that affect the health of a person subject to research, during its undertaking and the year following its conclusion, have been produced 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 with the liability for the damages and its assurance, that which is provided on 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 shall not produce a direct benefit for her, or embryo, foetus or the child after his birth shall only be authorised if the following conditions are met:

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

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

c) That the research entails a 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, provides their consent in the terms provided in this Law.

2. When research is carried out during the lactation period of a woman, 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 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 health.

b) That a research of comparable efficacy can not be carried out in 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 rights and the limits provided in this Law and in the regulation that further develops it for his 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 are previously expressed by the affected person. Additionally, in these cases, actions must be accordance with that provided 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 an exceptional manner if in addition to the requisites 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. For 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 possible to be undertaken on persons who are not in that emergency situation.

b) That in the event that it is not foreseeable that the research is going to produce beneficial results for the health of the patient, that it has the purpose to contribute 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, always that it entails a minimum risk and discomfort for him.

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 are considered to be those in which the person is not in condition to provide his 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 who live with him is impossible to obtain on time.

4. Persons who participate in a 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, the 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. Besides that provided in article 18, necessary measures shall be taken in order to guarantee the safety of the research and to reduce the risks and discomforts for the individuals who participate.

Medical decisions related with 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 accredit 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 are going to participate in the research have the duty to provide real data about their physical state or their health. In any case, the researcher shall take the necessary measures, which shall include, where appropriate, the consultation to the doctors responsible for the medical assistance of the participants, to

verify such extremes before the beginning of the research, in order to assure that the persons for whom the research entails a special risk are excluded from it.

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

Article 24. Non-interference with necessary clinical interventions.

1. Research must not delay or deprive the participants of the 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 extremes which are referred to in the previous section in the protocol of the trial that 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 an unacceptable risk or damage to the patient.

Article 25. Verifications of the progress of research.

1. The Research Ethics Committee shall take the adequate measures in order to verify that the continuity of the project is justified in light of new knowledge that is reached 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 shall have as its finality to determine:

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

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

c) Whether it is necessary to have an additional consent by the participants.

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

4. Any relevant information on the participation in the 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 the compliance with that established in the previous section, having the duty to report the incidences that are observed by the corresponding authority that provided the authorisation for that research, in order that this may adopt the corresponding measures, in accordance with article 17 of this Law and with full respect to that provided in existing regulations in matters of 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 provided its conformity to the research.

CHAPTER V Management of Information

Article 26. Duty to inform.

According to that provided in article 4.5, if research would provide relevant information for the health of the participants, then this must be made available to them, which shall be done within the framework of assistance that is underway, or for lack of, by providing a specific counselling.

Article 27. Information on the results.

1. Once the 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, always when these request so.

3. The researchers shall make public the general results of their research once these have concluded, taking into account the requirements related 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 could be derived from this research.

TITLE III

On the donation and use of human embryos and fetuses, their cells, tissues or organs.

CHAPTER I

Donation of human embryos and fetuses

Article 28. Donation of human embryos and fetuses.

1. Human embryos that have lost their capacity for biological development, as well as dead human embryos or fetuses, may be donated for biomedical research or other diagnostic, therapeutic, pharmacological, clinical or surgical purposes

2. The interruption of a pregnancy shall never have as its purpose the donation and later use of embryos, fetuses or their biological structures. The procedure and manner of the practice of the interruption of the pregnancy shall be only subject to the legal demands and limitations and the characteristics and circumstances that surround it.

The professionals who are part of the medical team that undertakes the interruption of the pregnancy shall not intervene in the use of the aborted embryos, fetuses 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 a conflict of interests with the medical team.

3. The fetuses that are prematurely and spontaneously expelled shall be clinically treated while they remain biologically viable with the sole purpose to favour their development and vital autonomy.

4. Before proceeding to any intervention on human embryos that have lost their capacity of biological

development or on dead embryos or fetuses, a record shall be made by the corresponding medical personnel that such circumstances have taken place.

Article 29. Requisites on donation.

1. Besides that established in the previous article, the donation of human embryos or fetuses or their biological structures for the purposes provided in this Law shall meet the following requisites:

a) That the donor or donors of the embryos or fetuses have previously granted their express and written consent. If any of them 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 be derived from these interventions.

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

2. In the event that the persons from whom the embryos or fetuses come from are 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 an express opposition by those that exercised, in the life of the former, their legal representation.

CHAPTER II
Conditions for biomedical
research with human embryos
and fetuses

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

Interventions on the live embryo or foetus in the uterus shall be exclusively authorised when their purpose is diagnostic or therapeutic in its own interest, notwithstanding what is legally established on the voluntary interruption of a pregnancy.

Article 31. *Requisites on the use.*

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

a) That the embryos or fetuses fit within any of the situations established in section 1 of article 28 of this Law.

b) That the conditions provided in article 29 on the donation of the embryos and fetuses that are going to be used are taken into account.

c) That a project is drafted on the expected use and that it has a favourable report by the Guarantees Commission for the Donation and use of Human Cells and Tissues.

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

2. The team responsible for the authorised project must

communicate its result both to the entity that provided the authorisation to the submitted project, as well as to the Guarantees Commission for the Donation and use of Human Cells and Tissues.

TITLE IV
On the obtaining and use of
cells and tissues of human
embryonic origin and other
similar cells

CHAPTER I
On the use of oocytes and pre-
embryos

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

1. Research with oocytes and pre-embryos must have the consent of the persons from whom they come from, who can revoke it at any moment without affecting the research undertaken.

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

In the case of oocytes, the consent of the donors shall make express reference to its authorisation for the use of a specific technique or techniques that are going to be applied to the oocytes that are object of the donation. For that purpose, the health professionals who are responsible for the obtaining of these oocytes shall provide the donors the appropriate information before the granting of the consent, leaving clear written record of all of this.

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, always when it does not entail the creation of a pre-embryo or an embryo exclusively for this purpose, in 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 requisites for research.

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

a) That the research abides by ethical principles and the applicable legal regime, especially that provided in this Law and the regulation that develops it, and that it follows the principles of relevance, feasibility and suitability, particularly of the main researcher, of the research team and of 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 autonomous authority, after having a favourable report 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 at least the following elements:

a) The authorisation by the management of the centre in which the research is going to take place as well as the favourable report of the corresponding Research Ethics Committee.

b) The disclosure of the common relations and interests that exist, of whatsoever nature, or the absence of such, between the team and the centre that has undertaken each of the processes of assisted reproduction that have generated pre-embryos or that have intervened in the obtaining of the oocytes.

c) The written compromise to provide the corresponding public authority the data that permit 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 compromise of the gratuitous conveyance of cell lines that could be obtained in the development of research for its 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 previous favourable report 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 with 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 in whole or in part, human biological samples, 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.

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

2. The authority that granted the authorisation to 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 the 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 the 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 the research and experimentation with human embryonic biological samples and to contribute to the updating and dissemination of the 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 with the research mentioned in article 35 and to annually evaluate their results.

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

c) To provide a compulsory report on research projects that require the entry or exit of embryonic material. In case of 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 the 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 specialists of well-known prestige 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 criteria of 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 by the Minister of Health and Consumption from among its members.

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, who will have a say but no vote.

6. The members of the Commission shall have access to the detailed information on the research project 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 with embryonic biological samples shall be the responsibility of the Ministry of Health and Consumption, through the Institute of Health Carlos III, notwithstanding the powers that may

correspond to the autonomous communities.

2. The corresponding authority, via the Institute of Health Carlos III, through the procedure that may be established by regulations, 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.

Article 41. Registry of projects.

The Institute of Health Carlos III shall be responsible for the maintenance of the registry of research projects, whose 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 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, protocols that are going to be used 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 the authorisation to undertake research granted by the corresponding authority with power to do so.

e) At the end 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 its competence, shall keep the confidentiality of the data and other demands in reference to those acts that it carries out, in accordance with that established 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 an order of the Minister of Health and Consumption, shall see to it that the access to cell lines for the execution of research projects is undertaken within those scientifically, ethical and legal principles in force and must have available updated information on the registry of embryos and cell lines that are available in the centres for in vitro fertilisation and in the banks of cell lines.

Article 43. Use of cell lines.

The use of cell lines or of biological samples that are derived from the research that is referred to in this title shall comply with that provided 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:

- 1st.** To establish the requirements that must be followed by institutions and persons that carry out genetic analysis and that process or store genetic data of a personal nature and biological samples.
- 2nd.** To see to the correct use of biological samples for biomedical research.
- 3rd.** To establish the requirements that must be followed by biobanks for their creation and functioning.
- 4th.** To assure the gratuity throughout the process of donation, assignment, storage and use of biological samples, both for source subjects as well as for those who deposit, notwithstanding the compensation for the costs.

Article 45. Specific guiding principles.

Besides 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 requisites related to possible personal options.
- b) Protection of data: the right to privacy and to the respect of the will of a subject shall be guaranteed in matters of information, as well as

the confidentiality of genetic data of a personal nature.

c) Gratuity: all the process of donation, assignment, storage and use of biological samples, both for the source subjects as well as for those who deposit, shall be devoid of a financial gain or profit. Personal genetic data shall not be used for commercial purposes.

d) Consent: the written consent of the subject source, or where appropriate, of his legal representatives must be obtained previous 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 response to a specific treatment.

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

Notwithstanding what is provided on the legislation on the protection of data of a personal nature, before the subject provides his consent in the

terms provided in article 48, he must receive the following written information:

- 1st.** Purpose of the genetic analysis for which he is consenting.
- 2nd.** Place of the undertaking of the analysis and the destination of the biological sample at the end of it, whether it is the disassociation of the identifying data of the sample, its destruction or other destinations, for which the consent of the subject source must be requested in the terms provided in this Law.
- 3rd.** Persons who will have access to the results of the analysis when those are not going to undergo a process of disassociation or anonimisation.
- 4th.** A warning about the possibility of unexpected findings and its possible transcendence for the subject, as well as his faculty to take a stance in relation to receiving this communication.
- 5th.** Warning about the implication that the information that could be obtained can have for his family members and the convenience for that person, where appropriate, to convey that information to them.
- 6th.** Compromise to provide genetic counselling, once the results of the analysis are obtained and evaluated.

Article 48. Consent.

- 1.** The express and specific written consent shall be necessary for the undertaking of a genetic analysis.
- 2.** In the health ambit, samples of deceased persons may be obtained and analysed always when it may be of interest for the protection of health, except when the deceased has expressly prohibited it during his life and can be proven. To this effect, the documents of previous instructions and, for lack of, the

criteria of the closest family members of the deceased shall be consulted.

The 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 a genetic screening, there must be an explicit and written consent of the person interested. The Research Ethics Committee shall determine the situations in which the consent may be expressed verbally. In any case, when the screening includes non-curable diseases or the benefits are scarce or uncertain, the consent shall always be written.

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.

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

Article 49. Right to Information and right not to know.

1. The subject source shall be informed on the genetic data of a personal nature that are obtained in the genetic analysis according to the terms in which he manifested his volition, notwithstanding the right to access that is established in the legislation on the protection of data of a personal nature, which could entail the revocation of the previously granted manifestation of free volition.

2. When the subject source has exercised his 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 a serious damage for the health of his biological family, then the affected 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 the establishment that stores the clinical history of the patient shall have access to the data recorded in it in so far as it is relevant for 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 education purposes when the interested subject has expressly provided his consent or when this data has been previously anonymised.
3. In exceptional cases and of general health interest, the corresponding authority, after a favourable report by the authority on data protection, may authorise the use of codified genetic data, always when assuring that third parties may not be able to associate 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 subject to the duty of secrecy in a permanent manner. The disclosure of personal genetic data to third parties is only permitted with the express written consent of the person from whom these proceed.

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

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

Article 52. Conservation of data.

1. Personal genetic data shall be kept during a period of no less than five years from the date in which they were obtained, after which the interested party may solicit its cancellation.
2. If there is no request by the interested party, the data shall be kept during 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 with him.
3. Outside these events, data shall only be kept, for research purposes, in an anonymised manner, without there being the possibility to identify 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 with any other biological samples that may contain genetic information of the person who provided his own biological material for the obtaining of such.

Article 54. Genetic screening.

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

2. The health authorities shall determine based on objective criteria, the relevance of the genetic screening in accordance with the diseases to be prevented or treated. Likewise, they shall ensure a universal and equitable access of the screening to 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. For the undertaking of the screening, the psycho-social aspects and its integration into the health system shall be taken into account. 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 follow-up and evaluation of the program.

5. The participation in a 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 prior to this consent shall be written and shall make reference to:

a) The sought characteristics and objectives of the screening.

b) The voluntary nature of the participation.

c) The validity and reliability of the screening tests and of the diagnostic tests of a second level.

d) The possibility to obtain false positives and, in turn, the need to confirm or discard the diagnosis.

e) The time periods 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 could be derived from the diagnostic process, including those associated to the taking of samples and to 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, then an appropriate genetic counselling must be guaranteed to the interested person, in a manner that shall be established by regulation, always abiding by the criteria of the person interested.

2. The professional who carries out or coordinates the genetic counsel must provide adequate information and counselling, in relation to both the transcendence of the resulting genetic diagnosis as well as the

possible alternatives that the subject may choose.

Article 56. Quality Requirements.

The entire process of genetic counsel and of the practice of genetic analysis for health purposes must be undertaken by qualified personnel and must be carried out in accredited centres that meet the requirements of quality that are 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, public or private, that may perform genetic analyses and that, in every case, must comply with that provided in articles 46 through 57 of this Law.

CHAPTER III

Use of human biological samples for biomedical research

Article 58. Obtaining of samples.

1. The obtaining of biological samples for biomedical research shall be undertaken solely when the previous written consent has been obtained from the subject source and after being informed about the consequences and risks that this can entail for his health. The consent shall be revocable.

2. The consent of the subject source shall always be necessary when the aim is to use biological samples for biological research that have already been obtained for a different purpose, irrespective of whether there is an anonymisation.

Notwithstanding this, in an exceptional manner, codified or

identified samples for biomedical research may be used without the consent of the subject source when the obtaining of this consent is not possible or it entails a non-reasonable effort to the effects provided in article 3.i) of this Law. In these cases, the favourable opinion of the corresponding Research Ethics Committee shall be necessary, which must take into account, at least, the following requisites:

a) That the research is of general interest.

b) That the research is undertaken by the same institution that requested the consent for the obtaining 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 of the subject source.

e) That personal data is guaranteed confidentiality.

3. Notwithstanding that provided in article 7, an economic compensation may be established for the physical discomforts, expenses and other inconveniences that may be derived from the taking of the sample.

4. For health reasons, the subject source or his family may use the samples when in need, always that these are available and are not anonymised.

5. The obtaining 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 risk of the intervention is minimal for the subject source.

b) That relevant knowledge on a disease or on the situation that is object of research and which are of vital importance to understand, palliate or heal it may be obtained from the research.

c) That this knowledge may not be appropriate, shall in turn entail the obtained in another manner. compliance with the requirements

d) That the authorisation is obtained from provided in this Law. In case that the legal representatives of the minor or that these extremes are not known at disabled person or that, where appropriate that moment, the compromise to there are guarantees on the correct consent inform about it as soon as is known of the subject source. shall be established.

6. Studies of genetic diversity shall g) Right to know genetic data that always respect the local and ethnic obtained from the analysis of traditions, always avoiding practices of donated samples. stigmatisation and discrimination.

h) Guarantee of confidentiality of the information obtained, indicating the identity of the persons who shall have access to the data of a personal nature of the subject source.

i) Warning on the possibility that information relative to their health may be obtained as derived from the genetic analysis that are undertaken on their biological sample, as well as on their faculty to take a stance in relation to its communication.

j) Warning on the implication of the information that could be obtained for his family members and the convenience that the person, where appropriate, transmit this information to them.

k) Indication on the possibility to get in contact with him-her, for which information on the way to do so may be solicited.

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

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

a) Purpose of the research or the line of research for which he is providing the consent.

b) Expected benefits.

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

d) Identity of the person responsible for the research.

e) Right to revoke the consent and its effects, including the possibility of the destruction or the anonimisation of the sample and that to this end it shall not be applicable to the rest of the research data that has already taken place.

f) Location of the undertaking of the analysis and the destination of the sample at the end of the research: disassociation, destruction or other research, and where

2. In the event of the use of samples that are going to be anonimised, 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. The consent on the use of the biological sample shall be granted either in the act of obtaining the sample or later in a specific manner for a specific research.

2. The specific consent may provide for the use of a sample for

other lines of research related with that initially proposed, including those undertaken by third parties. If this is not the case, the subject source shall be requested to grant, if deemed appropriate, a new consent.

3. The consent may be revoked, totally or for specific purposes, at any time. When the revocation makes reference to any use of the sample, then it shall be immediately destroyed, notwithstanding the keeping of the resulting data of the research that would have been previously undertaken.

Article 61. Conservation and destruction of samples.

1. In case that the sample is kept, the subject source shall be informed in a written manner of the conditions of its conservation, objectives, future uses, assignment to third parties and conditions in order to be able to take them back or ask for their destruction. Nonetheless, the biological samples used in biomedical research shall be solely kept as long as they are necessary for the purposes that justified its collection, except if the subject source has granted his explicit consent for other later uses.

2. The aforementioned in the previous section is understood to be applicable in so far as the identification data of the sample has not been subject to anonimisation in accordance with that provided in this Law.

Article 62. Report of the Research Ethics Committee.

In every case, the favourable report of 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 when the use of biological samples that come from deceased persons has been foreseen or when 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 competence for the creation of national banks of biological samples that are deemed convenient 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 or legal person, public or private, that holds ownership of a biobank shall be responsible for it.

2. If there is a change in the ownership of the person responsible for the biobank, or the modification or broadening of the objectives of it, then that event shall be communicated to the corresponding authority, who, where appropriate, shall grant a new authorisation.

Article 66. Organisation of the biobank.

1. The biobank shall have a scientific director, a person responsible for the files and shall be assigned to two external committees, a science and an ethics, respectively that will assist the director of the biobank in 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, this shall be made available to the authority that granted the authorisation for the creation of the biobank.

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

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

g) To draft a descriptive memory that compiles the characteristics of the collections, 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 to the samples.

3. The person responsible for the files shall attend all requests in the exercise of the rights to access, rectification, cancellation or opposition that are made by the subject source, in accordance with that provided in the existing legislation on the protection of data of a personal nature.

Article 67. National Registry of Biobanks.

1. Once the 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 of the Institute of Health Carlos III. Before that, they must register in the Spanish Agency for the Protection of Data in accordance with existing legislation. The data in this Registry shall be based in that provided by the competent authorities 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 register in the National Registry of Biobanks. This requisite 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 the 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 during 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. Obtaining and assignment of samples.

1. The obtaining of samples shall be done in accordance with that provided in Chapter III of this Title.

2. The stored samples in a biobank shall be assigned freely to third parties who need them for use in biomedical research. Samples shall only be assigned for requests that come from research projects that have 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. It must contain the approval by the scientific and ethical committees of the bank.

3. The costs of obtaining, maintenance, handling, shipping and other costs of a similar nature related with the samples may be passed on with the assignment 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 obtaining, 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 assignment of samples may be accompanied by the associated clinical information, in which case the data shall be protected in accordance with that provided 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. That provided in the articles of Chapter III of this title in relation with the obtaining, previous information, consent, confidentiality, assignment, conservation of data and samples, access to data and the right not to know shall be applicable to biological samples deposited in biobanks.

2. Notwithstanding that provided 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, always when the source subject, or where appropriate, his legal representatives have provided their consent in these terms.

Article 71. Closure or closing of a biobank.

1. The competent authority may decide the closure or closing of a biobank, on its own motion or as requested and through a motivated resolution, in those cases in which there is non-compliance with the requisites established in this Law for its creation, organisation and function, or when its owner

manifests his will not to continue with its activity.

2. This resolution shall likewise provide the destination of the stored samples of the biobank that is going to be closed or closed.

TITLE VI

Infractions, sanctions and compensations for damages

Article 72. General Dispositions.

1. The infractions provided in this Law related with the obtaining and use of human cells and tissues, on the use of invasive procedures in biomedical research, as well as personal genetic data shall be the object of the corresponding administrative sanctions, after the charges are compiled in a case, notwithstanding the civil, criminal or other type of liability that may also arise.

2. The sanctioning authority regulated in this Law shall be exercised, in those cases not provided in this Law, it shall be in accordance with that provided in Law 30/1992 of 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 by the Administration, the infraction could be an offence or misdemeanour, the administrative entity shall pass it on 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 always when it is imposed for the same acts and in relation to the same protected public interests, though all other responsibilities that can be deduced from other acts or infractions that concur must be enforced.

If the decision is that there hasn't been an offence or misdemeanour, then the administration shall continue with its sanctioning proceeding, 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 safe keep the right to the protection of health and safety of the people shall be kept as long as the judicial authority doesn't make a pronouncement on such.

5. Very serious offences shall prescribe after three years, serious, after two and minor after six months. The sanctions imposed for very serious offences shall prescribe after three years, those for serious offences after two and those for minor offences after a year.

Article 73. Responsibilities.

1. The author shall be responsible for the different infractions.

2. When in accordance with the obligations provided in this Law, the compliance of the obligations corresponds to several persons jointly, then they shall be held joint and severally liable 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 norm shall be applicable to the directors of the centres or services for the non-compliance with the aforementioned obligations by the biomedical professionals who are under their responsibility.

Article 74. *Infractions.*

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

2. Besides that provided 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 infractions shall be considered as minor serious and very serious:

A) Minor infractions are:

Those that entail the non-compliance of any obligation or the violation of any prohibition that is provided in this Law, always when in accordance with the criteria provided in this section they can't be classified as serious or very serious infractions.

B) Serious infractions are:

a) Non-observance of the prescriptions, conditions, requisites or previous authorisations that are provided in this Law for the functioning of the registries provided in this Law.

b) The omission of data, consents 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 the data of the donors established in this Law.

e) The non-fulfilment of the gratuity of the donation of pre-embryos, embryos and fetuses 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 infractions are:

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

b) To continue with the development in vitro of the pre-embryos beyond the limit of 14 days after the fertilisation of the oocyte, taking away from that time that which in which it may have been cryopreserved.

c) To keep living embryos and fetuses outside the uterus for any purpose other than procreation.

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

e) Non-fulfilment of that provided in article 33.

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

g) The non-observance of the previous prescriptions, conditions, requisites or authorisations that are established in this Law for the obtaining and use of cells and tissues of human embryonic origin or other that is functionally similar.

Article 75. Sanctions.

1. Minor infractions, as provided in this Law, shall be sanctioned with a fine of up to 600 euros, serious with a fine from 601 euros up to 10.000 euros, and the very serious from 10.001 up to 1.000.000 euros.
2. The amount of the sanction that is imposed, 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 infractions against this Law.
3. In every case, when the amount of the fine is less than the benefit obtained due to the commission of the infraction, the sanction shall be increased up to double the amount in which the offender has been benefited.
4. If one act can be grounds for two or more classified infractions in this or other Laws, then only that which has the greatest sanction shall be taken into account.
5. The amounts of the fines shall be periodically revised and updated by the Government, taking into account the variation of the consumer price indexes.
6. Notwithstanding the sanctions provided in this article, the serious or very serious infractions shall entail the 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. For the imposition of this measure, the following shall be taken into account: the generated risk, the social repercussion of the infraction and the benefit obtained by the offender of the sanctioned behaviour and the previous commission of one or more infractions against 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, independent and of a consulting nature on matters related with 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 related with the ethical and social implications of Biomedicine and the Health Sciences.

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

d) Represent Spain in the supranational and international forums and organisations that deal with Bioethics.

e) Draft an annual memory of activities.

f) Any others that are attributed in the regulations that develop this Law.

2. The reports, proposals, recommendations and other documents drafted by the Spanish Committee on Bioethics may be published for the general knowledge and diffusion, in full compliance with the 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 the communication among them, 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 among persons who are accredited and qualified in the

scientific, legal and bioethical world. The aim for its composition should be the balanced presence of the different disciplines involved in the bioethical reflections.

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 to 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:

1st) One by the Ministry of Justice.

2nd) One by the Ministry of Education and Science.

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

4th) Three by the Ministry of Health and Consumption.

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

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 say but no vote.

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

1. The members of the Committee 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 renovation.

2. Half of the members shall be renewed every two years, except the first time, which shall be by draw.

3. The members of the Committee shall cease for the following reasons:

a) Expiration of their mandate.
 b) Resignation, which shall take effect by the 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 for the exercise of their function, serious non-fulfilment of his obligations, unexpected incompatibility or the processing for 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 with independence from the authorities who proposed or named them 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, at least, the following matters:

a) Frequency of meetings, which shall be, at least, every three months.

b) Procedures of deliberation and the taking of decisions.

c) Extension and limits of the duty of confidentiality of its members.

d) Independence of its members and 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. The Ministry of Health and Consumption in the drafting of the Sectorial Initiative on Health Research, integrated in the Plan for Scientific Research, Development and Technological Innovation, 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 improvement 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 the 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 the 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 the health training and education in biomedicine.
3. In the ambit of the regulation on research compiled 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 the research networks.
4. Public entities of research which are dependent of the General Administration of the State and of the autonomous communities,

whether they belong to the National Health System or not, 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 of an international nature.

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 R&D 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 the research training of the personnel of the National Health System.

1. The Public Administrations shall provide backing to the training in the field of biomedical research through the development of those measures provided in this Law, scholarships and financial aid programs and the improvement of their working conditions.
2. The National Council of Specialties in the Health Sciences shall promote the 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 to the health services of research personnel in a statutory regime.

The incorporation of research personnel in the case of centres associated to the new management methods of the National Health System according to Law 15/1997, of 25 April, shall be done according to its applicable legal regime.

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

2. The centres of the National Health System 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 the Diploma of Advanced Studies or an administrative document which substitutes it in accordance with the new structure of education adapted to the European Space for Higher Learning, for a maximum period of two years, that must be those following the obtaining of 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 perfection, who shall be doctors or specialists who have achieved the specialised health training and who shall be hired for tasks of research in the conditions provided in article

17.1.b of the Law of 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 proper of the scientific community.

4. The activities undertaken in accordance with that provided in section 2 of this article, shall be included in the 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 the professional promotion within the National Health System.

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

6. In the ambit regarding health services, the necessary measures to ease the compatibility between the assistance activity and the scientific 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 in the different centres within the national

framework, the European space of research and of the reciprocal cooperation agreements with other States shall be promoted.

The civil servants who belong to research entities or registries may be authorised to undertake works related with scientific and technical research outside the organic ambit to which they are appointed, through mobility mechanisms established in the regulation of public functions.

2. Always when an enterprise of a technological basis is created through patents or results generated by research projects which are fully or partially financed with public funds and undertaken in research centres, the civil servants or statutory personnel who justify their participation in the mentioned 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 that, in every case, shall only 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 would not solicit the return to active service, then he or she shall be officially declared on its own motion in voluntary leave for private purposes.

Article 87. Temporary appointment of specialists.

The Ministry of Health and Consumption, after the authorisation by the corresponding entity, shall be

able to temporarily appoint, 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 the civil servants or labour personnel which is applicable, in each case.

The part time appointment of the previously mentioned personnel shall be compatible with that undertaken, likewise in a part time manner, in the 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 that established in article 15.1, subsection a, of the Worker's Statute and in conformance with that provided in 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. To the effects of 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 that provided in article 42.2 of Law 30/1992, of 26 November, of 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 to shall be of twelve months.

Article 89. Cooperation among the public and private sectors.

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

2. To comply with the objective of this first section, the centres of the National Health System, the public institutions and entities that research in biomedicine and the health sciences and the universities, may reach agreements with private entities that undertake activities of scientific research and technological development. These agreements may establish the possibility that the personnel of 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 the investment in biomedical research.

4. Likewise, measures shall be taken that contribute to promote adequate returns to the National Health System in relation to the investments undertaken in the ambit 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 them through those 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 that are managed by the Ministry of Health and Consumption shall fit that provided to the national plan of Research & Development & Innovation, even when 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 for therapeutic purposes of any biological material of human origin which is referred to in this Law 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 them, notwithstanding that provided in Title II of this Law in those cases where it is applicable.

**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 amount to be paid 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 with 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 doesn't 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 of Promotion and General Coordination of Scientific and Technical Research, the 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 the 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 is going to 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, which is referred to in Royal Decree 2132/2004 of 29 October, establishing the requisites 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 and ff of this Law. The former shall look after the compliance of the guarantees and requisites 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 the favourable ruling of the appropriate Research Ethics Committee, which must take into account, at least, the following requisites:

- 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 from the moment in which the 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 the competences of these.

**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, whichever their rank which are contrary to that 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 the 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 requisites of accreditation and authorisation of the centres, services and biomedical teams related with the obtaining 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 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