CHAMBER OF DEPUTIES OF THE H. CONGRESS OF THE UNION
General Secretary
Secretariat for Parliamentary Services

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REGULATION OF THE GENERAL HEALTH LAW REGARDING RESEARCH TO HEALTH

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CURRENT TEXT
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In the margin a seal with the National Shield, which says: United Mexican States.- Presidency of the Republic.

MIGUEL DE LA MADRID H., Constitutional President of the United Mexican States, in exercise of the power conferred on the Federal Executive by section I of Article 89 of the Political Constitution of the United Mexican States and based on articles 1, 2 ., section VII, 3rd. section IX, 4th, 7th, 13 section "A" sections I, IX, X, section "B" sections I and VI, 96, 97, 98, 99, 100, 101, 102, 103 and others related to the General Health Law, and

CONSIDERING

That by virtue of the Decree by which Article 4o. Constitutional Law, published in the Official Gazette of the Federation on February 3, 1983, the Right to Health Protection was enshrined as a social guarantee;

That on February 7, 1984, the General Health Law, regulating the third paragraph of Article 4, was published in the Official Gazette of the Federation. of the Political Constitution of the United Mexican States, beginning its validity on the 1st. July of the same year;

That the aforementioned Law established and defined the bases and modalities for access to health services, as well as the distribution of powers between the Federation and the Entities
Federal in General Health Matters, for which it is pertinent to have the necessary regulatory instruments for the effective exercise of its powers;

That within the programs provided for in the National Development Plan 1983-1988, is that of
Health, which, as strategic guidelines, completes five major policy areas, the last being "Education, Training and Research" aimed primarily at promoting the biomedical, medical-social and health services areas, hence the National Program of Health 1984-1988 develops the Research Program for health, among others, as support for the consolidation of the
National Health System in substantial aspects, with the specific objective of contributing to national scientific and technological development aimed at finding practical solutions to prevent, attend to and control priority health problems, increase the productivity and efficiency of services and reduce the technological dependency from abroad;

That the General Health Law has established the guidelines and general principles to which scientific and technological research for health must be subject, corresponding to the
Ministry of Health guide its development;

That research for health is a determining factor to improve actions aimed at protecting, promoting and restoring the health of the individual and of society in general; to develop Mexican technology in health services and to increase their productivity, in accordance with the bases established in said Law;

That conducting research for health must attend to ethical aspects that guarantee the dignity and well-being of the person subject to research;

That the development of research for health requires the establishment of technical criteria to regulate the application of procedures related to the correct use of the resources allocated to it;

That without restricting the freedom of researchers, in the particular case of research that is carried out on human beings and that uses materials or procedures that carry a risk, it is necessary to abide by the scientific, ethical and safety standards generally accepted, and

That research in human beings of new prophylactic, diagnostic, therapeutic and rehabilitation resources must be subject to control to obtain greater efficacy and avoid risks to people's health, I have seen fit to issue the following

REGULATION OF THE GENERAL HEALTH LAW REGARDING RESEARCH FOR HEALTH

FIRST TITLE
General disposition

UNIQUE CAPITULE

ARTICLE 1.- This Ordinance aims to provide, in the administrative sphere, compliance with the General Health Law in relation to research for health in the public, social and private sectors. It is applicable throughout the national territory and its provisions are of public order and social interest.

ARTICLE 2.- For the purposes of this Regulation, when mention is made of the "Law" to the "Secretariat" and to the "Research", it shall be understood as referring to the General Health Law, to the Ministry of Health and to the Research for Health, respectively.

ARTICLE 3.- Research for health includes the development of actions that contribute:

I. To the knowledge of biological and psychological processes in human beings;

II. To the knowledge of the links between the causes of disease, medical practice and the social structure;

III. To the prevention and control of health problems;

IV. To the knowledge and evaluation of the harmful effects of the environment on health;

V. The study of the techniques and methods that are recommended or used for the provision of health services, and

SAW. To the production of health supplies.

ARTICLE 4.- The application of this Regulation corresponds to the Secretariat and the governments of the federal entities, including the Federal District, within the scope of their respective competencies and

under the terms of the Coordination Agreements that are signed to formalize the actions that are intended to promote and promote the development of research.

ARTICLE 5.- The powers referred to in the previous article, will be distributed according to the following:

A. It corresponds to the Secretariat:

I. Issue the technical standards to which the conduct of health research will be subject throughout the national territory and verify its compliance;

II. Organize and operate research activities in their administrative units;

III. Promote, guide, encourage and support research activities by the governments of the federal entities;

IV. Carry out, within its competence and in coordination with the corresponding Units and Entities, the general evaluation of the investigation activities throughout the national territory, and

V. Coordinate research within the framework of the National Health System.

B. In matters of General Health, as local authorities, it corresponds to the governments of the federal entities, within their respective territorial jurisdictions and in accordance with the applicable provisions:

I. Organize, operate, supervise and evaluate research activities for health;

II. Formulate and develop their research programs;

III. Prepare and provide the information on investigation requested by the authorities competent federal;

IV. Monitor compliance with the Laws, Regulations and Technical Standards that refer to research, and

V. Collaborate with the coordination of research within the framework of the National Health System.

ARTICLE 6.- The Secretaries of Health and Public Education, in the sphere of their respective competences, may enter into collaboration or concertation agreements with the educational institutions that carry out health research, so that these, without prejudice to the autonomy that by law correspond to them contribute to the aforementioned Units in the development of actions aimed at promoting health research, as well as for compliance with the provisions of Title Five of the Law.

ARTICLE 7.- The coordination of the investigation, within the framework of the National Health System, will be in charge of the Secretariat, who will be responsible for:

I. Establish and conduct the national policy on Health Research, in the terms of the applicable Laws, of this Regulation and other provisions;

II. Promote research activities within the institutions that make up the National Health System;

III. Promote the deconcentration and decentralization of research activities;

IV. Determine the frequency and characteristics of information on health research that they must provide the dependencies and entities that carry it out;

V. Support coordination between health and educational institutions to promote research activities;

SAW. Assist with the competent agencies to regulate and control the transfer of technology in the health area;

VII. To help ensure that the training and distribution of human resources for research is consistent with the priorities of the National Health System;

VII. Promote and encourage the participation of the community in the development of research programs;

IX. Promote the permanent updating of legal provisions on research, and

X. The other attributions related to the previous ones that are required for the fulfillment of the research objectives of the National Health System.

ARTICLE 8.- In the formulation of research policies and in the coordination of actions for their execution and development, the Secretariat of Public Education and the Secretariat will have the Interinstitutional Commission for Health Research as a consultation body.

ARTICLE 9.- The Secretariat, in coordination with the Secretariat of Public Education and with the collaboration of the National Council for Science and Technology and higher education institutions, will carry out and keep updated the national inventory of research in the area of its competence.

ARTICLE 10.- For the purposes indicated in the previous article and in the terms of article 99 of the Law, the Secretariat must carry and keep updated on an annual basis, an inventory of the investigation that is carried out in the institutional system of the Secretariat, which will include the registration of:

I. The centers where research is carried out;

II. The researchers;

III. The scientific publications of the researchers, and

IV. The performance of the researchers.

Article amended DOF 04-02-2014

ARTICLE 11.- The Secretariat will establish, in accordance with the participants, the bases for interinstitutional and intersectoral coordination, as well as those of a technical nature of the international agreements and treaties on research.

A report of said instruments will be sent to the Secretariat, which must include, among other points, the origin and destination of the financial resources involved, including those of those sponsored investigations that are related to the development of inputs, technologies and other application processes. , susceptible to patents or commercial development, among others, that are carried out in human beings.

Excepted from the foregoing are those involving higher education institutions and the National Council of Science and Technology in which it will proceed by consensus of the subscribers.

ARTICLE 12.- The General Health Council will have the power to issue complementary provisions on areas or modalities of research in which it deems necessary, as well as give an opinion on research programs and projects.

SECOND TITLE
On the Ethical Aspects of Research on Human Beings

CHAPTER I
Common Provisions

ARTICLE 13.- In all research in which the human being is the subject of study, they must prevail the criterion of respect for their dignity and the protection of their rights and well-being.

ARTICLE 14.- Research carried out on human beings must be carried out in accordance with the following bases:

I. It must adapt to the scientific and ethical principles that justify medical research, especially with regard to its possible contribution to the solution of health problems and the development of new fields of medical science;

Section reformed DOF 04-02-2014

II. It will be based on previous experimentation carried out on animals, in laboratories or in other scientific facts;

III. It should be carried out only when the knowledge that is intended to be produced cannot be obtained by other suitable means;

IV. The probabilities of the expected beneficiaries must always prevail over the risks predictable;

V. It will have the informed consent of the subject on whom the investigation will be carried out, or of their legal representative, in the event of their legal incapacity, in terms of the provisions of this Regulation and other applicable legal provisions;

Section reformed DOF 04-02-2014

SAW. It must be carried out by health professionals referred to in article 114 of this Regulation, with knowledge and experience to care for the integrity of the human being, under the responsibility of a health care institution that acts under the supervision of the authorities. competent health authorities that have the necessary human and material resources to guarantee the well-being of the research subject;

VII. It will have the favorable opinion of the Research, Research Ethics and Biosafety Committees, in the cases that correspond to each of them, in accordance with the provisions of this Regulation and other applicable legal provisions;

Section reformed DOF 04-02-2014

VII. It will be carried out when you have the authorization of the head of the health care institution and, where appropriate, of the Secretariat, in accordance with articles 31, 62, 69, 71, 73, and 88 of this Regulation;

Section reformed DOF 04-02-2014

IX. The investigation must be suspended immediately by the main investigator, in the event of the risk of serious injury, disability or death of the subject in whom the investigation is carried out, as well as when requested, and

Fraction added DOF 04-02-2014

X. It will be the responsibility of the health care institution in which the research is carried out to provide medical care to the research subject who suffers any damage, if it is directly related to the research, without prejudice to the compensation that legally corresponds.

Fraction added DOF 04-02-2014

ARTICLE 15.- When the experimental design of an investigation carried out on human beings includes several groups, random selection methods will be used to obtain an impartial assignment of the participants in each group and the pertinent measures must be taken to avoid any risk or damage. to the research subjects.

ARTICLE 16.- In research on human beings, the privacy of the individual will be protected research subject, identifying him only when the results require it and he authorizes it.

ARTICLE 17.- Research risk is considered to be the probability that the research subject suffers some damage as an immediate or late consequence of the study. For the purposes of this Regulation, investigations are classified into the following categories:

I. Research without risk: These are studies that use retrospective documentary research techniques and methods and those in which no intentional intervention or modification is carried out in the physiological, psychological and social variables of the individuals participating in the study, among which The following are considered: questionnaires, interviews, review of clinical files and others, in which they are not identified or sensitive aspects of their conduct are not addressed;

II. Research with minimal risk: Prospective studies that use the risk of data through common procedures in physical or psychological examinations for routine diagnosis or treatment, among which are considered: weighing the subject, hearing acuity tests; electrocardiogram, thermography, collection of excreta and external secretions, collection of placenta during childbirth, collection of amniotic fluid when membranes rupture, collection of saliva, deciduous teeth and permanent teeth extracted for therapeutic indication, dental plaque and stones removed by prophylactic procedure not invasive, hair and nail cutting without causing disfigurement, blood extraction by venipuncture in adults in good health, with a maximum frequency of twice a week and a maximum volume of 450 Ml. in two months, except during pregnancy, moderate exercise in healthy volunteers, psychological tests to individuals or groups in which the behavior of the subject will not be manipulated, research with commonly used drugs, wide therapeutic margin, authorized for sale, using the indications, doses and routes of administration established and that are not the investigational drugs that are defined in article 65 of this Regulation, among others, and

III.- Research with risk greater than the minimum: These are those in which the probabilities of affecting the subject are significant, among which are considered: radiological and microwave studies, tests with medications and modalities that are defined in article 65 of this Regulation, trials with new devices, studies that include surgical procedures, extraction of blood greater than 2% of the circulating volume in neonates, amniocentesis and other invasive techniques or major procedures, those that use random methods of assignment to therapeutic schemes and those that have placebo control, among others.

ARTICLE 18.- Repealed.

Article repealed DOF 04-02-2014

ARTICLE 19.- Repealed.

Article repealed DOF 04-02-2014

ARTICLE 20.- Informed consent is understood as the written agreement, through which the research subject or, where appropriate, their legal representative authorizes their participation in the research, with full knowledge of the nature of the procedures and risks involved. that will submit, with the capacity of free choice and without any coercion.

ARTICLE 21.- For the informed consent to be considered as existing, the research subject or, where appropriate, their legal representative must receive a clear and complete explanation, in such a way that they can understand it, at least, on the following aspects:

I. The justification and objectives of the investigation;

II. The procedures to be used and their purpose, including identification of procedures that are experimental;

III. The expected inconveniences or risks;

IV. The benefits that can be obtained;

V. The alternative procedures that could be advantageous for the subject;

SAW. The guarantee of receiving an answer to any question and clarification of any doubt about the procedures, risks, benefits and other matters related to the research and treatment of the subject;

VII. The freedom to withdraw your consent at any time and stop participating in the study, without creating prejudices to continue their care and treatment;

VII. The assurance that the subject will not be identified and that the confidentiality of the information will be maintained. information related to your privacy;

IX. The commitment to provide you with up-to-date information obtained during the study even if it could affect the subject's will to continue participating;

X. The availability of medical treatment and the compensation to which he would legally be entitled, by the health care institution, in the case of damages that warrant it, directly caused by the investigation, and

XI. That if there are additional expenses, these will be absorbed by the research budget.

ARTICLE 22.- The informed consent must be formulated in writing and must meet the following requirements:

I. It will be prepared by the main researcher, indicating the information referred to in the article above and in accordance with the other applicable legal provisions;

Section reformed DOF 04-02-2014

II. It will be reviewed and, where appropriate, approved by the Research Ethics Committee of the research institution. health care;

Section reformed DOF 04-02-2014

III. It will indicate the names and addresses of two witnesses and the relationship that they have with the subject of research;

IV. It must be signed by two witnesses and by the research subject or his legal representative, if applicable. If the research subject does not know how to sign, he will print his fingerprint and another person designated by him will sign on his behalf, and

V. It will be issued in duplicate, leaving a copy in the possession of the research subject or his legal representative.

ARTICLE 23.- Repealed.

Article repealed DOF 04-02-2014

ARTICLE 24.- If there is any type of dependence, ancestry or subordination of the research subject towards the researcher, which prevents him from freely granting his consent, it must be obtained by another member of the research team, completely independent of the researcher-subject relationship. .

ARTICLE 25.- Repealed.

Article repealed DOF 04-02-2014

ARTICLE 26.- Repealed.

Article repealed DOF 04-02-2014

ARTICLE 27.- When a psychiatric patient is interned in an institution for being subject to interdiction, in addition to complying with what is stated in the previous articles, it will be necessary to obtain the prior approval of the authority that knows the case.

Threat II
From Research in Communities

ARTICLE 28.- Research related to human health in communities will be admissible when the expected benefit for it is reasonably assured and when studies carried out on a small scale have not produced conclusive results.

ARTICLE 29.- In community research, the principal investigator must obtain the approval of the health authorities and other civil authorities of the community to be studied, in addition to obtaining the letter of informed consent of the individuals included in the study, informing them of the information referred to in articles 21 and 22 of this Regulation.

In the case of communities that, due to their economic or social conditions, are in a situation of vulnerability, including indigenous communities and peoples, it will also be required that the Research Ethics Committee of the institution to which the principal investigator belongs, give an opinion favorably conducting the research.

Added paragraph DOF 2014-04-02

ARTICLE 30.- Repealed.

Article repealed DOF 04-02-2014

ARTICLE 31.- Experimental investigations in communities may only be carried out by establishments that have the prior authorization of the Secretariat to carry them out, without prejudice to the powers that correspond to other dependencies of the Federal Executive, and have complied, as the case may be. , with toxicity studies, according to the characteristics of the products and the risk they imply for human health.

ARTICLE 32.- In all research in communities, the experimental design must offer practical protection measures for individuals and ensure that valid results will be obtained, involving the minimum number of subjects so that it is representative.

ARTICLE 33.- In any community research, the ethical considerations applicable to research on individuals must be extrapolated to the community context in the pertinent aspects.

Threat III
Of the Investigation in Minors or Disabled

ARTICLE 34.- In addition to the general ethical provisions that must be complied with in all research involving human beings, research carried out on minors or incapacitated persons must satisfy the provisions of this chapter, except in the case of emancipated persons over 16 years of age.

ARTICLE 35.- When research is intended to be carried out on minors, it must be ensured that similar studies have previously been carried out on people of legal age and on immature animals, except when it comes to studying conditions that are typical of the neonatal stage or age-specific ailments.

ARTICLE 36.- To carry out investigations on minors or incapacitated persons, in any case, a written informed consent must be obtained from those who exercise parental authority or legal representation of the minor or incapacitated person in question.

When two people exercise parental authority over a minor, the consent of one of them will only be admissible if the other is irrefutably or manifestly unable to provide it or in the event of imminent risk to the health or life of the minor or incapacitated person.

ARTICLE 37.- When the mental capacity and psychological state of the minor or incapable allow it, their acceptance to be the subject of the investigation must also be obtained, after explaining what is intended to be done. The Research Ethics Committee may waive compliance with these requirements for justified reasons.

Article amended DOF 04-02-2014

ARTICLE 38.- Research classified as risky and likely to benefit directly for the minor or the incapable, will be admissible when:

I.- The risk is justified by the importance of the benefit that the minor or incapacitated person will receive, and

II.- The benefit is equal to or greater than other alternatives already established for diagnosis and treatment.

ARTICLE 39.- Research classified as risky and without direct benefit to the minor or the incapable, will be admissible according to the following considerations:

I. When the risk is minimal:

A). The intervention or procedure must represent for the minor or the incapacitated person a reasonable experience comparable to those inherent to their current or expected medical, psychological, social or educational situation, and

B). The intervention of the procedure must have a high probability of obtaining generalizable knowledge about the condition or illness of the minor or the disabled person, which is of great importance to understand the disorder or to achieve its improvement in other subjects.

II. When the risk is greater than the minimum:

A). The research should offer a high probability of understanding, preventing or alleviating a serious problem that affects the health and well-being of children or the disabled, and

B). The head of the health care institution will establish strict supervision to determine if the magnitude of the foreseen risks increases or others arise and will suspend the investigation at the moment in which the risk could affect the biological, psychological or social well-being of the minor or of the incompetent

Threat IV

From research on Women of Reproductive Age, Pregnant, during Labor, Puerperium, Lactation and Newborns; of the use of Embryos, Obitus and Fetuses and of Assisted Fertilization

ARTICLE 40.- For the purposes of this Regulation it is understood as:

I. Women of childbearing age.- From the beginning of puberty to the beginning of menopause;

II. Pregnancy.- It is the period from the fertilization of the ovum (evidenced by any presumptive sign or symptom of pregnancy, such as suspension of menstruation or medically accepted positive pregnancy test) until the expulsion or extraction of the fetus and its annexes;

III. Embryo.- The product of conception from the fertilization of the ovum until the end of the twelfth week of management;

IV. Fetus.- The product of conception from the beginning of the thirteenth week of gestation until their expulsion or extraction;

V. Fetal Obito.- The death of the fetus in the uterus;

SAW. Live birth.- It is the expulsion or complete extraction of the product of conception, from the maternal womb, when after said separation it breathes and the heart beats, the umbilical cord has been cut or not and the placenta is detached or not;

VII. Stillbirth.- It is the complete expulsion or extraction of the product of conception, from the maternal womb, when after said separation it does not breathe or beat the heart, the umbilical cord has been cut or not and the placenta is detached or not;

VII. Labor.- It is the period from the beginning of uterine contractions (with progressive characteristics of intensity, irrigation and duration) and that ends with the expulsion or extraction of the fetus and its annexes;

IX. Puerperium.- It is the period that begins with the expulsion or extraction of the fetus and its annexes until achieve involution of gestational changes (approximately 42 days);

X. Lactation.- It is a physiological phenomenon in which milk secretion occurs from the expulsion or removal of the fetus and its appendages, and

XI. Assisted fertilization.- It is the one in which the insemination is artificial (homologous or heterologous) and includes in vitro fertilization.

ARTICLE 41.- In addition to the general ethical provisions that must be complied with in all research involving human beings, those that include the subjects referred to in this chapter must satisfy the provisions of articles 42 to 56 of these Regulations.

ARTICLE 42.- In investigations classified as risk greater than the minimum, which is performed on women of childbearing potential, steps should be taken to:

I. Certify that the women are not pregnant, prior to their acceptance as research subjects, and

II. Reduce as much as possible the chances of pregnancy during the development of the investigation.

ARTICLE 43.- To conduct research on pregnant women, during labor, puerperium and lactation; in live or still births; of the use of embryos, deaths or fetuses; and for assisted fertilization, it is required to obtain a letter of informed consent from the woman and her spouse or partner in accordance with the provisions of articles 21 and 22 of these Regulations, prior information on the possible risks to the embryo, fetus or newborn in your case.

The consent of the spouse or common-law partner may only be waived in the event of irrefutable or manifest incapacity or impossibility to provide it; because the concubinage does not take care of the woman or, well, when there is imminent risk to the health or life of the woman, embryo, fetus or newborn.

ARTICLE 44.- The investigations carried out in pregnant women must be preceded by studies carried out in non-pregnant women that demonstrate their safety, with the exception of specific studies that require said condition.

ARTICLE 45.- Research without therapeutic benefit in pregnant women, whose objective is to obtain generalizable knowledge about pregnancy, should not represent a risk greater than the minimum for the woman, the embryo or the fetus.

ARTICLE 46.- Research in pregnant women that involves an intervention or experimental procedure not related to pregnancy, but with therapeutic benefit for women, such as in cases of toxemia gravidarum, diabetes, hypertension and neoplasms, among others, should not expose the embryo or fetus at more than minimal risk, except when the use of the intervention or procedure is justified to save the life of the woman.

ARTICLE 47.- Research in pregnant women, with therapeutic benefit related to pregnancy, will be allowed when:

I. Are intended to improve the health of the pregnant woman with minimal risk to the embryo or fetus,

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II. Are aimed at increasing the viability of the fetus, with minimal risk to the pregnant woman.

ARTICLE 48.- During the execution of investigations in pregnant women:

I. The researchers will not have the authority to decide on the moment, method or procedure used to terminate the pregnancy, nor will they participate in decisions about the viability of the fetus;

II. Only with the authorization of the Research Ethics Committee may the method to terminate pregnancy be modified for research purposes, when such modifications mean a minimal risk to the health of the mother and do not represent any risk to the survival of the fetus, and

Section reformed DOF 04-02-2014

III. In any case, it is strictly prohibited to grant monetary or other incentives to interrupt the pregnancy, for the interest of the investigation or for other reasons.

ARTICLE 49.- The letter of informed consent for research during labor must be obtained in accordance with the provisions of articles 21, 22, and 43 of these Regulations, before it begins and must expressly indicate that the consent It can be removed at any time during labor.

ARTICLE 50.- Research in women during the puerperium will be allowed when they do not interfere with the health of the mother and the newborn.

ARTICLE 51.- Research in women during lactation will be authorized when there is no risk to the infant or when the mother decides not to breastfeed, her feeding is ensured by another method and the letter of informed consent is obtained in accordance with the provisions of the Articles 21, 22 and 43 of this Regulation.

ARTICLE 52.- The fetuses will be subjects of research only if the techniques and means used They provide maximum security for them and the pregnant woman.

ARTICLE 53.- Newborns will not be subjects of research until it has been established with certainty whether or not they are live births, except when the purpose of the research is to increase their probability of survival until the viability phase, the study procedures do not cause the cessation of its vital functions or when, without adding any risk, it seeks to obtain important generalizable knowledge that cannot be obtained in any other way.

ARTICLE 54.- Live births may be subjects of research if they comply with the dispositions on investigation in minors, indicated in this Regulation.

ARTICLE 55.- Research with embryos, deaths, fetuses, stillbirths, macerated fetal matter, cells, tissues and organs extracted from them, will be carried out in accordance with the provisions of the Fourteenth Title of the Law and in these Regulations.

ARTICLE 56.- The research on assisted fertilization will only be admissible when it is applied to the solution of sterility problems that cannot be solved in another way, respecting the moral, cultural and social point of view of the couple, even if it differs with that of investigator.

CHAPTER V
Of Research in Subordinate Groups

ARTICLE 57.- Subordinate groups are understood as the following: students, laboratory and hospital workers, employees, members of the armed forces, inmates in prisons or

social rehabilitation centers and other special groups of the population, in which informed consent may be influenced by some authority.

ARTICLE 58.- When investigations are carried out in subordinate groups, the representatives of the affected nucleus or of the users who participate in the Research Ethics Committee, in terms of the provisions of the second paragraph of article 41 Bis of the Law, will monitor :

Paragraph amended DOF 04-02-2014

I. That the participation, the refusal of the subjects to intervene or the withdrawal of their consent during the study, does not affect their school, work, military situation or that related to the judicial process to which they were subject and the conditions of compliance with the sentence, in your case;

II. That the results of the research are not used to the detriment of the participating individuals,
Y

III. That the health care institution and the sponsors are responsible for the medical treatment of the damage caused and, where appropriate, for the compensation that legally corresponds for the harmful consequences of the research.

CHAPTER VI

Of the Research in Organs, Tissues and their Derivatives, Products and Corpses of Human beings

ARTICLE 59.- The research referred to in this Chapter includes that which includes the use of organs, tissues and their derivatives, products and corpses of human beings, as well as the set of activities related to their obtaining, conservation, use, preparation, supply and final destination.

ARTICLE 60.- The investigation referred to in this Chapter must observe, in addition to respect, dignity and consideration for the human corpse, the provisions of this Regulation and the provisions of Title Fourteen of the Law and other applicable legal provisions.

Article amended DOF 04-02-2014

THIRD TITLE

From the investigation of new Prophylactic, Diagnostic, Therapeutic and rehabilitation

CHAPTER I

Common Provisions

ARTICLE 61.- When research is carried out in human beings, on new prophylactic, diagnostic, therapeutic and rehabilitation resources or it is intended to modify those already known, the provisions of the previous articles must be observed, where applicable, and the provisions of this Title.

ARTICLE 62.- Those interested in carrying out the investigations referred to in this Title must obtain the authorization of the Secretariat. To this end, they will submit their request in writing, attaching the following documentation:

Paragraph amended DOF 04-02-2014

I. Research protocol that must contain an objective and complete analysis of the risks involved, compared with the risks of the diagnosis and treatment methods

established and the expectation of the living conditions of the subject with and without the proposed procedure or treatment;

II. Acceptance letter from the head of the institution where the research would be carried out, as well as from the principal investigator responsible for it;

Section reformed DOF 04-02-2014

III. Favorable opinion of the Research and Research Ethics Committees and, where appropriate, of Biosafety;

Section reformed DOF 04-02-2014

IV. Description of available resources, including areas, equipment and auxiliary services of laboratories and cabinets;

V. Description of the resources available for handling medical emergencies;

SAW. Professional history of the principal investigator, including his academic preparation, representative scientific production and clinical practice or experience in the area of the proposed investigation;

VII. The one that proves the academic preparation and experience of the medical, paramedical and other experts who will participate in the research activities;

Section reformed DOF 04-02-2014

VII. The one with which, where appropriate, the information is accredited, indicated in articles 69 and 73 of this Regulation, and

Section reformed DOF 04-02-2014

IX. The others indicated by the applicable legal provisions.

Section reformed DOF 04-02-2014

Interested parties may submit with their request for authorization the opinion issued by a third party authorized for this purpose by the Secretariat, which must contain the technical report on the safety and scientific validity of the corresponding research protocol, in accordance with the applicable legal provisions, same that will be valued by the Secretariat, in order to determine if it is appropriate to grant the authorization. In this case, the Secretariat will resolve the appropriate, within a period of thirty business days, counted from the day following the filing of the request.

Added paragraph DOF 2014-04-02

ARTICLE 63.- When there is sponsorship or other forms of remuneration, the necessary measures must be established to prevent them from causing conflicts of interest to the principal investigator in the protection of the rights of the research subjects, even if they have given their consent in the preservation of the veracity of the results and in the allocation of resources.

ARTICLE 64.- In the development of the investigations contemplated in this Title, the following obligations must be fulfilled:

I. The principal investigator will inform the Research Ethics Committee of any adverse effect that is probable or directly related to the investigation;

Section reformed DOF 04-02-2014

II. The head of the institution, in turn, will notify the Secretariat of the presence of any adverse effect, within a maximum period of 15 business days following **(sic DOF 01-06-1987)** to its presentation;

III. The principal investigator, the Research Ethics Committee, the authorized officials of the health care institution in question or the Secretariat, must suspend or cancel the investigation in the presence of any adverse effect that is an impediment from the point of view of ethical or technical view to continue with the study;

Section reformed DOF 04-02-2014

IV. The health care institution will submit a report to the Secretariat within 15 business days following the day in which the suspension or cancellation of the study was agreed, specifying the effect noticed, the measures adopted and the consequences produced, and

V. Others indicated by the applicable legal provisions.

Section reformed DOF 04-02-2014

Threat II
Pharmacological Research

ARTICLE 65.- For the purposes of this Regulation, pharmacological research is understood as scientific activities aimed at the study of drugs and biological products for use in humans, with respect to which there is no previous experience in the country, which have not been registered by the Secretariat and, therefore, are not distributed commercially, as well as registered and approved medications **(sic DOF 01-06-1987)** for sale, when their use is investigated with modalities, indications, doses or routes of administration different from those established, including their use in combinations.

ARTICLE 66.- Drug research in clinical pharmacology comprises the sequence of studies that are carried out from the time they are first administered to humans until data are obtained on their efficacy, quality and therapeutic safety in large population groups. For this purpose, the following phases are considered:

Paragraph amended DOF 04-02-2014

PHASE I.- It is the administration for the first time of a research drug to a healthy human being, without diagnostic or therapeutic benefit, in single or multiple doses, in small hospitalized groups, to establish initial pharmacological parameters in man;

PHASE II.- Is the administration of a research medication to the sick human being, in single or multiple doses, in small hospitalized groups, to determine its initial efficacy and other pharmacological parameters in the sick organism;

PHASE III.- It is the administration of an investigational drug to large groups of patients (generally external), to define its therapeutic usefulness and identify adverse reactions, interactions and external factors that may alter the pharmacological effect, and

PHASE IV.- These are studies that are carried out after the medicine is granted registration and authorization for its sale, and its purpose is to generate new information on the safety of the medicine during its widespread and prolonged use.

ARTICLE 67.- All investigations in clinical pharmacology that are carried out must be preceded by complete preclinical studies that include physical-chemical characteristics, pharmacological activity, toxicity, pharmacokinetics, absorption, distribution, metabolism and excretion of the drug in different animal species; frequencies, routes of administration and duration of the doses studied that can serve as a basis for the safety of their administration in humans; studies on mutagenesis, teratogenicity and carcinogenicity will also be required.

ARTICLE 68.- The preclinical toxicology studies required for each drug will depend on it in particular, on the known potential toxicology of others with a similar chemical structure and on the route and time of administration intended to be used in humans.

ARTICLE 69.- The use of research drugs in human beings during their assessment through phases I to IV of clinical pharmacological research, will be done with the authorization of the Secretariat. To this effect, the institutions must submit the documentation indicated in article 62 of that Regulation, in addition to the following:

I. The basic and preclinical pharmacological information of the medication, and

II. Information previously obtained on clinical pharmacology, in cases of phases II, III and IV and availability tests when required.

ARTICLE 70.- Phase I clinical pharmacology studies of new antineoplastic drugs and others with a very low therapeutic index will be allowed when:

I. They are based on preclinical studies that demonstrate the pharmacological activity of the medication and clearly indicate the characteristics of its toxicity;

II. Are carried out only in volunteer subjects with the specific advanced disease, confirmed by additional diagnostic means, who have not presented a therapeutic response to any other available treatment and in whom the new medicine could offer a therapeutic benefit, and

III. Do not cause expenses to the patient.

ARTICLE 71.- In the emergency treatment in conditions that threaten the life of a person, when it is considered necessary to use an investigational medication or a known medication using indications, doses and routes of administration different from those established, the treating physician must obtain the favorable opinion of the Research and Research Ethics Committees of the health care institution, as well as the letter of informed consent of the research subject or, where appropriate, of their legal representative, as circumstances allow, according to the following bases:

Paragraph amended DOF 04-02-2014

I. The Research and Research Ethics Committees will be informed of the use of the research drug in advance if the researcher can foresee the need for its use in emergency situations. Subsequently, if the use of the medication, the indication, dose or new routes of administration arise as unforeseen needs. In both cases, the Committees will issue an opinion in favor or against approving the planned use or the repetition of the non-planned use of the drug, and

Section reformed DOF 04-02-2014

II. The letter of informed consent will be obtained from the research subject, in his case **(sic DOF 06-01-1987),** of his legal representative or of the closest relative in bond, except when the subject's condition incapacitates him or prevents him from granting it, the legal representative or the relative is not available and the stop using the research drug represents an almost absolute risk of death.

Threat III
From the Research of Other New Resources

ARTICLE 72.- For the purposes of this Regulation, research into other new resources or modalities different from those established is understood as scientific activities aimed at studying materials, grafts, transplants, prostheses, physical, chemical and surgical procedures, instruments devices, artificial organs and other methods of prevention, diagnosis, treatment and rehabilitation that are carried out on human beings or their biological products, except pharmacological ones.

ARTICLE 73.- Any investigation referred to in this Chapter must have the authorization of the Secretariat. To this effect, the institutions must present the documentation indicated in article 62 of these Regulations, in addition to the following:

I. The scientific foundations, information on previous experimentation carried out on animals, in the laboratory, and

II. Previous clinical research studies, when any.

ARTICLE 74.- Research related to the disposal of organs, tissues and cells, including blood and its components, must be subject to the provisions of the Law, this Regulation and other applicable legal provisions.

Article amended DOF 04-02-2014

TITLE THIRD BIS
Authorized Third Parties

Title added DOF 02-04-2014

SINGLE CHAPTER

Added chapter DOF 2014-04-02

ARTICLE 74 BIS 1.- For the purposes of this Regulation, an authorized third party is considered to be the natural or legal person authorized by the Secretariat to issue the opinions referred to in the second paragraph of article 102 of the Law.

Article added DOF 04-02-2014

ARTICLE 74 BIS 2.- The Secretariat will publish in the Official Gazette of the Federation the calls addressed to natural and legal persons interested in acting as an authorized third party, in which the scope, requirements and conditions will be established, among other aspects. for your authorization.

Article added DOF 04-02-2014

ARTICLE 74 BIS 3.- The Secretariat will form a technical committee made up of experts in research on human beings, representatives of chambers and associations and, where appropriate, of the entity of accreditation, whose function will be to give a technical opinion on requests for the granting of third-party authorizations.

The operation and functioning of the technical committee referred to in the previous paragraph, will be in accordance with the operating rules issued for such purpose by said committee.

Article added DOF 04-02-2014

ARTICLE 74 BIS 4.- To obtain authorization as an authorized third party, the interested party must meet the following requirements:

I. Submit an application in the format established by the Secretariat. For this purpose, the Secretariat will make known the corresponding format through publication in the Official Gazette of the Federation;

II. Accompany the documentation that accredits the experience and legal, technical, material, human and financial capacity to issue the opinions referred to in the second paragraph of article 102 of the Law;

III. Have the facilities, equipment and technology to carry out the tests, studies and other activities necessary to issue the opinions referred to in the second paragraph of article 102 of the Law;

IV. Have standard operating procedures that guarantee quality in the performance of their duties;

V. Attach a document stating, under protest to tell the truth, that it is not subject to direct influence by any manufacturer, merchant, natural or legal person, merchant of the research protocols to be determined, and

SAW. Present their proposals for activities to dictate research protocols, as well as describe the services that they intend to provide and the procedures to be used to make said opinions.

Article added DOF 04-02-2014

ARTICLE 74 Bis 5.- Once the request for the authorization of an authorized third party has been submitted, the Secretariat will proceed to carry out the verification visits and, together with the committee referred to in article 74 Bis 3 of this Regulation, will carry out the evaluations that are necessary. to rule on whether the requirements referred to in the previous article are met.

In the event that the opinion issued by the Secretariat is not favorable, a period of up to one hundred and eighty calendar days will be granted to the applicant, counted from the day following the notification of said opinion, to correct the anomalies detected. The term granted may be extended for an equal period, for a single occasion, when the applicant justifies the need for it.

In the event that the applicant does not correct the anomalies detected within the period granted,
In accordance with the provisions of the preceding paragraph, your request will be deemed withdrawn.

Article added DOF 04-02-2014

ARTICLE 74 BIS 6.- The authorization as a third party will be valid for two years, same as
It may be extended for equal periods, at the request of the interested party.

Article added DOF 04-02-2014

ARTICLE 74 BIS 7.- Authorized third parties must:

I. Comply with the provisions contained in the Law, this Regulation and other applicable legal provisions;

II. Refrain from providing their services as an authorized third party, when they are shareholders, advisers, successors in title, attorneys-in-fact, directors, commissioners, or any other type of relationship with the person requesting their services, which may mean a conflict of interest;

III. Immediately inform the Secretariat of any irregularity or non-compliance with the sanitary provisions that are identified during the evaluation of the research protocols.
to do;

IV. Provide the Secretariat with reports on the opinions and technical recommendations that they issue on the research protocols that they evaluate, as well as provide the information that is required by said dependency;

V. Assist the Secretariat in cases of health emergency, and

SAW. Allow verification of their activities by the Secretariat and facilitate their verifiers free access to its facilities.

Article added DOF 04-02-2014

ARTICLE 74 BIS 8.- The result of the tests carried out by the authorized third party shall be recorded in an opinion that shall be signed, under its responsibility, by the person empowered to do so. Said opinions will be valid before the Secretariat in accordance with the functions that have been authorized to the third party.

Article added DOF 04-02-2014

ARTICLE 74 BIS 9.- The Secretariat may, at any time, carry out verification visits to authorized third parties to verify that the conditions under which the corresponding authorization was granted are fulfilled.

Article added DOF 04-02-2014

ARTICLE 74 BIS 10.- If derived from the verification visits, the Secretariat warns that the conditions referred to in the previous article do not subsist, or else, the applicable legal provisions are not complied with, it will prevent the interested party to correct the anomalies found and will grant a period of up to one hundred and eighty days, counted from the day after the said anomalies were notified, to correct them. The foregoing, without prejudice to the fact that when the detected irregularity implies a health risk, the Secretariat may order the temporary suspension of the activities carried out by the authorized third party.

If the authorized third party does not vent the prevention, within the term granted in accordance with the provisions of the previous paragraph, it will be cause for suspension of the authorization granted, in terms of article 412 of the Law, and the Secretariat will grant a new term. ninety days to correct said irregularities. In the event that what is indicated by the Secretariat within the latter is not complied with period, the authorization will be revoked.

Article added DOF 04-02-2014

ARTICLE 74 BIS 11.- The Secretariat will publish in the Official Gazette of the Federation the list of third parties authorized to dictate investigation protocols, as well as the suspensions and revocation of said authorizations.

Article added DOF 04-02-2014

FOURTH TITLE
Of the Biosecurity of the Investigations

CHAPTER I
From Research with Pathogenic Microorganisms or Biological Material that may contain them

ARTICLE 75.- The health institutions referred to in article 98 of this Regulation, in which research is carried out with pathogenic microorganisms or biological material that may contain them, must:

I. Have the facilities and laboratory equipment in accordance with the technical standards issued by the Secretariat for this purpose, which guarantee the appropriate physical containment for the safe handling of such germs;

II. Prepare a manual of procedures for microbiology laboratories and make it available. provision of professional, technical, service and maintenance personnel;

III. Train personnel on the handling, transportation, use, decontamination and disposal of waste;

IV. Determine the need for medical surveillance of the personnel participating in the investigations and, if applicable, implement it;

V. Establish a safety supervision and monitoring program in microbiology laboratories;

SAW. Have updated bibliography and a file on the **(sic DOF 06-01-1987)** equipment safety, the availability of containment systems, rules and regulations, risks involved and other related aspects, and

VII. Comply with the other provisions determined by the Secretariat.

ARTICLE 76.- In the health institutions mentioned in the previous article, the microbiology laboratories will comply with the requirements indicated by the technical standards issued by the Secretariat and will be classified into three types:

I. Basic Microbiology Laboratory;

II. Microbiological Safety Laboratory, and

III. Laboratory of Maximum Microbiological Security.

ARTICLE 77.- The Manual of Procedures referred to in article 75 section II, of this Regulation, will describe the following aspects:

I. Laboratory practices;

II. Personal security of employees;

III. Management and maintenance of insolations and equipment;

IV. Emergency situations;

Section reformed DOF 04-02-2014

V. Entry and transit restrictions;

SAW. Reception and transport of biological materials;

Section reformed DOF 04-02-2014

VII. waste disposal;

VII. decontamination, and

IX. Others considered necessary to achieve microbiological safety.

ARTICLE 78.- The principal investigator, in agreement with his hierarchical superior, the Biosafety Committee and the head of the health care institution, will determine, in accordance with the applicable provisions, the type of laboratory in which he must carry out the investigations. proposals, as well as the respective procedures, taking into account the degree of risk of infection presented by the microorganisms to be used.

Article amended DOF 04-02-2014

ARTICLE 79.- To assess the degree of risk of infection referred to in the previous article, the Secretariat will issue the corresponding technical standard and will classify the microorganisms within four Groups, according to the following criteria:

Risk Group I:
Microorganisms that pose little risk to the individual and the community;

Risk Group II:
Microorganisms that pose moderate risk to the individual and limited risk to the community;

Risk Group III:
Microorganisms that pose a high risk to the individual and a low risk to the community, and

Risk Group IV:
Microorganisms that represent a high risk for the individual and for the community.

ARTICLE 80.- Microorganisms that are classified in risk groups I and II must be handled in basic microbiology laboratories, using safety cabinets when deemed necessary.

ARTICLE 81.- Microorganisms that are classified in risk group III must be handled in microbiological safety laboratories.

ARTICLE 82.- Microorganisms that are classified in risk group IV must be handled in maximum security microbiology laboratories, under the authorization and control of the corresponding health authorities referred to in article 4o. of the law.

ARTICLE 83.- During the development of the investigations referred to in this Chapter, the main investigator will be in charge of:

I. Determine the real and potential risks of the proposed investigations and, in the event that they are approved by the Committees of the health institution, according to their scope of competence, make them known to the associated researchers and other personnel who will participate in the investigation;

Section reformed DOF 04-02-2014

II. Determine the appropriate level of physical containment, select the best microbiological practices and design procedures to deal with possible accidents during the investigation and instruct the participating personnel on these aspects;

III. Monitor that the participating staff complies with the requirements of medical prophylaxis, vaccinations or serological tests;

IV. Supervise that the transport of infectious materials is done appropriately, according to the applicable legal provisions;

Section reformed DOF 04-02-2014

V. Inform the Biosafety Committee about the occurrence of disease among the personnel participating in the research, which could be attributed to transcutaneous inoculation, ingestion or inhalation of infectious materials, as well as accidents that cause contamination that may affect personnel or the environment, Y

Section reformed DOF 04-02-2014

SAW. Inform the Biosafety Committee of difficulties or failures in the implementation of safety procedures, as well as correct work errors that could cause the release of infectious material and ensure the integrity of physical containment measures.

Section reformed DOF 04-02-2014

ARTICLE 84.- The Biosafety Committee of the health institutions must carry out visits with the periodicity that they determine, to evaluate compliance with the safety measures and issue recommendations on laboratory practices, including the temporary or definitive suspension of investigations. that pose an uncontrolled risk of infection or contamination to laboratory workers, the community, or the environment.

Article amended DOF 04-02-2014

Threat II

Of research involving the construction and handling of recombinant nucleic acids

ARTICLE 85.- For the purposes of this Regulation, recombinant nucleic acids **(sic DOF 01-06-1987)** shall be understood as the new combinations of genetic material obtained outside of a living cell, through the insertion of natural or synthetic segments of deoxyribonucleic acid in a virus, bacterial plasmid or other deoxyribonucleic acid molecules, which serve as a vector system to allow their incorporation into a host cell, where they are not found naturally, but in which they will be capable of replication. Also included are the deoxyribonucleic acid molecules resulting from said replication.

ARTICLE 86.- Research with recombinant nucleic acids must be designed in such a way as to achieve the maximum level of biological containment, selecting the ideal host and vector systems that reduce the probability of dissemination of recombinant molecules outside the laboratory, taking into account the origin of the genetic material and the technical standards issued by the Secretariat.

ARTICLE 87.- The principal investigator, in agreement with his hierarchical superior, the Biosafety Committee and the head of the health institution, will determine, in accordance with the applicable legal provisions, the type of microbiology laboratory in which the tests will be carried out. experiments referred to in this Chapter, taking into account the origin of the genetic material to be replicated.

Article amended DOF 04-02-2014

ARTICLE 88.- The authorization of the Secretariat is required to initiate the following types of experimentation:

I. Formation of recombinant deoxyribonucleic acid derived from pathogenic microorganisms that are classified in risk groups III and IV referred to in article 79 of this Regulation, as well as the formation of recombinant genetic material derived from cells that are infected by such agents, regardless of the host and vector system used;

II. Intentional construction of recombinant nucleic acids to induce the biosynthesis of potent vertebrate toxins;

III. International release **(sic DOF 01-06-1987)** into the environment of any microorganism that carries recombinant nucleic acids;

IV. Transfer of antibiotic resistance to microorganisms that do not acquire it in nature, if such transfer could negatively affect the use of the antibiotic in human medicine, and

V. Experiments with microorganisms with recombinant nucleic acids in cultures larger than 10 liters, due to the fact that their physical and biological containment is more difficult, unless the recombinant molecules have been rigorously characterized and the absence of dangerous genes in them is demonstrated. Those processes of an industrial and agricultural nature not directly and specifically related to the activities established in article 3 are excluded. of this Regulation.

Threat III
Research with radioactive isotopes and devices and generators of ionizing and electromagnetic radiation

ARTICLE 89.- Research involving the use of radioactive isotopes and devices that generate ionizing and electromagnetic radiation in human beings for medical purposes, must be carried out in accordance with the laws, regulations and other applicable legal provisions.

Article amended DOF 04-02-2014

ARTICLE 90.- In the health institutions where the investigations referred to in this Chapter are carried out, the Biosafety Committee will ensure that for each study the person responsible for radiological safety is authorized by the National Nuclear Safety Commission and Safeguards, for compliance with the requirements and obligations that arise as the person in charge of radiological safety.

Article amended DOF 04-02-2014

ARTICLE 91.- The responsible person referred to in the previous article must:

I. Define, implement and monitor compliance with radiological and physical safety measures;

II. Prepare, under the terms of the Regulatory Law of Article 27 of the Constitution on Nuclear Matters, a manual of procedures available to all personnel, in which the procedures for the identification and control of radiation sources will be described; permitted and restricted areas; registration and control of the dose equivalent of occupationally exposed personnel and the environment; training and medical examinations for occupationally exposed personnel; emergency plan in case of accidents that contaminate personnel or the environment, among others, and

III. Train personnel on work procedures and the characteristics of the laboratory and equipment.

ARTICLE 92.- The personnel involved directly or indirectly in the investigations referred to in this Chapter, must be adequately informed by the person responsible for radiological safety, about the health risks represented by the radiation doses to which they are exposed. , as well as knowing the basic principles of radiological protection, such as: shielding, exposure time, distance and control of contamination and radioactive waste, among others, in order to guarantee precise knowledge of the radiological protection measures that ensure the biosafety of the procedures used in the investigation, with the corresponding participation of the Secretary of Energy.

Article amended DOF 04-02-2014

ARTICLE 93.- In these investigations, the occupationally exposed personnel must be over 18 years of age. When such personnel are women of childbearing age, the exposures must be distributed as evenly as possible over time, in order to protect, where appropriate, the embryo during the period of organogenesis, before the diagnosis of pregnancy is made.

Pregnant women may only continue work that exposes them occupationally, if it is ensured that the exposures will be distributed as evenly as possible over time and when it is unlikely that they will receive a third of the annual equivalent dose that must be specified in the biosafety standards of the according to the specific radioactive energy. Pregnant or lactating women should not work in places where there is a risk of incorporating radioactive materials.

ARTICLE 94.- The health institution where research with radioactive materials is carried out must appoint a doctor or health care institution that will be responsible for conducting medical examinations of occupationally exposed personnel, in order to:

I. Determine your aptitude, from the point of view of your health, to carry out the work considered, before they are exposed to radiation.

II. Identify changes in your health that could result from exposure to radiation during the performance of your duties, and

III. Detect late effects of radiation, even after exposure has ceased.

ARTICLE 95.- Studies involving exposure of the research subject to radiation will:

I. Be justified because it is not possible to obtain the same information with less risk through research using other techniques, and

II. Be designed optimizing the protection of the subject, so that the radiation received by the subject is reduce to a reasonable minimum that allows obtaining the information sought.

ARTICLE 96.- In research without direct benefit to the research subject, the equivalent dose limits, secondary limits, derived limits as well as authorized limits, must be specified in the research projects, taking into account whether it is external, internal radiation , the tissues in accordance with the biosafety standard, which must coincide with the standards of the National Commission for Nuclear Safety and Safeguards.

Research involving the exposure of pregnant women to materials is prohibited. radioactive or ionizing radiation generating devices.

ARTICLE 97.- In research with direct benefit to the research subject, the criteria for limiting radiation doses must be the same as that applied to other exposures required for medical reasons, such as those due to diagnostic and treatment procedures.

TITLE FIVE
Of the Internal Committees in the Health Institutions

Denomination of Title reformed DOF 04-02-2014

UNIQUE CAPITULE

ARTICLE 98.- For the purposes of this Regulation, a health institution where health research is carried out is considered to be any organically structured unit belonging to a dependency or entity of the Public Administration, or to a social or private institution where health research is carried out. carry out one or more of the activities established in article 5o. of this Regulation.

ARTICLE 99.- In every health institution where health research is carried out, under the responsibility of the respective directors or owners and in accordance with the applicable provisions, the following shall be constituted:

I. A Research Ethics Committee in the event that they conduct research on human beings;

Section reformed DOF 04-02-2014

II. A Biosafety Committee in charge of determining and regulating the use of ionizing radiation or genetic engineering techniques within the institution, based on the applicable legal provisions, and

Section reformed DOF 04-02-2014

III. An Investigation Committee, whose membership will be mandatory for care institutions for health.

Section reformed DOF 04-02-2014

ARTICLE 100.- The general functions of the Committees referred to in the previous article, will be the following:

Paragraph amended DOF 04-02-2014

I. Provide advice to the heads or managers of the institution, to support the decision on the authorization for the development of research;

II. Assist researchers for the optimal performance of their studies, and

III. Monitor the application of this Regulation and other applicable provisions.

ARTICLE 101.- The heads of the health institutions will register the Committees referred to in article 99 of this Regulation before the Secretariat, which will determine the characteristics and the periodicity of the reports that they will have to provide. In the case of Research Ethics Committees, registration will be made before the National Bioethics Commission.

Article amended DOF 04-02-2014

ARTICLE 102.- The head of the health institution, based on the opinions of the Research, Research Ethics and Biosafety Committees, as appropriate, will decide whether to authorize the carrying out of the research that is proposed, except when it is of investigations that require the authorization of the Secretariat, in terms of articles 31, 62, 69, 71, 73 and 88 of this Regulation.

For the purposes of the provisions of the preceding paragraph, the Research Ethics Committees of Research and Biosafety, may meet together.

Article amended DOF 04-02-2014

ARTICLE 103.- The Research and Biosafety Committees will be integrated with a minimum of three scientists, with experience in research.

Article amended DOF 04-02-2014

ARTICLE 104.- The Research Ethics Committees will be made up of medical personnel from different specialties and by people from the professions of psychology, nursing, social work,

sociology, anthropology, philosophy or law that have training in bioethics, being essential to have representatives of the affected nucleus or of users of health services, up to the number agreed by its members, in accordance with the general provisions issued for this purpose the Secretary.

Article amended DOF 04-02-2014

ARTICLE 105.- To constitute the Biosafety Committee, scientists with extensive experience or knowledge in this field will be included, whether or not they are staff members of the health institution, to ensure that research activities are carried out under adequate biosafety measures.

Article amended DOF 04-02-2014

ARTICLE 106.- To constitute the Research Committee, preference will be given to members of the health institution with knowledge and experience in scientific methodology.

Article amended DOF 04-02-2014

ARTICLE 107.- When within the institution it is not possible to bring together the appropriate people to constitute the Committees, the respective holder may request the support and advice of the Committees constituted at the level immediately above his own dependency or outside of it, provided that the aforementioned requirements are met.

Article amended DOF 04-02-2014

ARTICLE 108.- The members of the Committees will remain in office for a period of three years, and may be ratified for an equal period. Likewise, the members of the Committees must excuse themselves from participating in the evaluation or issuance of reports on investigations in which they have participated. The operation of the Research and Biosafety Committees will be subject to the general provisions issued by the Secretariat for this purpose, as well as the operating rules that
formulated by said Committees.

Article amended DOF 04-02-2014

ARTICLE 109.- The Research Ethics Committee will evaluate and rule on the research protocols in human beings, formulating the appropriate ethical recommendations, for which it will review the risks and benefits of the research, as well as the letter of informed consent of the subject that will be the subject of the investigation, among other elements, to guarantee the well-being and rights of the research subjects, as well as to follow up on said recommendations.

Likewise, the Research Ethics Committee will prepare the guidelines and ethical guidelines for the conducting research on human beings of the health institution to which they belong.

Article amended DOF 04-02-2014

ARTICLE 110.- The Biosafety Committee will issue the technical opinion on the biosafety aspects of the proposed investigations, by reviewing the facilities, materials and methods involved, among other elements, in order to guarantee the protection of biological physical integrity occupationally exposed personnel, as well as research subjects, the community and the environment.

Article amended DOF 04-02-2014

ARTICLE 111.- The Research Committee will evaluate the technical quality and scientific merit of the proposed research, formulating the corresponding opinion, and will issue the opinion that, if applicable, must contain the opinion of the Research Ethics and Biosafety Committees. .

Article amended DOF 04-02-2014

ARTICLE 112.- The Committees referred to in this Chapter and the authorities to which they report, will maintain confidentiality on the reports they receive from the investigators,

mainly if the research is related to the development of inputs, technology and other application processes susceptible to patents or commercial development.

Article amended DOF 04-02-2014

SIXTH TITLE
On the Execution of Research in Health Care Institutions

UNIQUE CAPITULE

ARTICLE 113.- The conduct of the investigation will be in charge of a principal investigator, who must be a health professional and have the appropriate academic training and experience to direct the work to be carried out, in addition to being members of the care institution. to health and have the authorization of the head responsible for their assigned area.

ARTICLE 114.- For the purposes of this Regulation, health professionals are considered to be those persons whose activities related to medicine, dentistry, veterinary medicine, biology, bacteriology, nursing, social work, chemistry, psychology, sanitary engineering, nutrition, dietology, pathology and its branches and others established by other applicable legal provisions, require a professional title or certificate of specialization legally issued and registered by the competent educational authorities.

ARTICLE 115.- The investigations will be carried out in accordance with a protocol, which will be prepared in accordance with the technical standard issued by the Secretariat for this purpose and will include the elements that allow the evaluation of the study that is proposed to be carried out.

ARTICLE 116.- The principal investigator will be in charge of the technical direction of the study and will have the following attributions:

I. Prepare the research protocol;

II. Comply with the procedures indicated in the protocol and request authorization for the modification in the necessary cases on aspects of ethics and biosafety;

III. Document and record all data generated during the study;

IV. Create a file on the study that will contain the protocol, the modifications to it, the authorizations, the data generated, the final report and all the documentary and biological material that can be saved, related to the research;

V. Select the personnel participating in the study and provide them with the necessary information and training to carry out their function, as well as keep them informed of the data generated and the results;

SAW. Prepare and present the partial and final reports of the investigation, and

VII. The other related ones that are necessary **(sic DOF 01-06-1987)** to comply with the technical direction of the investigation.

ARTICLE 117.- The main researcher will select the associated researchers with suitable academic training and experience in the scientific disciplines required to participate in the study.

ARTICLE 118.- The main investigator will select the technical and support staff with the necessary experience to ensure their competence in carrying out the activities assigned to them and, where appropriate, will take care that they receive training and qualification to correctly carry out their research tasks. according to the level of supervision that will be available during the conduct of the study.

ARTICLE 119.- At the end of the execution of the investigation, the main investigator has the responsibility to present to the Research Committee of the health care institution, a technical report that includes the elements established by the applicable legal provisions.

Article amended DOF 04-02-2014

ARTICLE 120.- The main researcher may publish partial and final reports of the studies and disseminate their findings by other means, taking care that the confidentiality to which the research subjects have rights is respected, as well as that which has been agreed with the sponsors of the study. study. In addition to giving due credit to the associated researchers and the technical personnel who participated in the investigation, a copy of these publications must be delivered to the Institution's Management.

TITLE VII
Research that includes the use of experimental animals.

UNIQUE CAPITULE

ARTICLE 121.- In experimental research with animals, referring to human health, the requirements established by the standards of the health institutions themselves, authorized by the Secretariat, must be met and the provisions of this Chapter must be met.

ARTICLE 122.- The investigations will be designed in order to avoid the maximum suffering of the animals.

ARTICLE 123.- When it is necessary to sacrifice an experimental animal, a procedure that ensures as far as possible his death without suffering.

ARTICLE 124.- The vivariums must be in accordance with the species, body conformation, habits, postural preferences and locomotor characteristics of the animals, to provide them with comfort, except when the experimental variables justify other situations.

ARTICLE 125.- The production or chronic maintenance vivariums will be supervised by a qualified and competent professional in the matter and must allow the growth, maturation, reproduction and normal behavior of the animals, in accordance with the regulations issued by the institution itself.

ARTICLE 126.- The head of the health institution where the research referred to in this Chapter is carried out, must establish and monitor compliance with the security measures for the care and handling of animals, as well as prophylaxis measures. and vaccination necessary for the protection of occupationally exposed personnel.

TITLE VIII
About security measures

UNIQUE CAPITULE

ARTICLE 127.- The application of the security measures and their procedure, in matters of investigation, will be subject to what is ordered in chapters I and III of Title Eighteen of the Law and to the provisions of this Regulation.

ARTICLE 128.- Corresponds to the health authorities, within the scope of their respective powers, order or execute the following security measures:

I. Isolation;

II. The quarantine;

III. personal observation;

IV. The vaccination of people;

V. Vaccination of animals, as long as it refers to human health;

SAW. The destruction or control of insects and other transmitting and harmful fauna, insofar as it refers to human health,

VII. The suspension of jobs or services;

VII. The seizure and destruction of objects, products or substances;

IX. The vacating or eviction of houses, buildings, establishments and, in general, of any property;

X. The prohibition of acts of use, and

XI. The rest of a health nature determined by the competent health authorities, which may avoid causing or continuing to cause risks or damage to health.

NINTH TITLE
Follow-up and Observance

UNIQUE CAPITULE

ARTICLE 129.- Corresponds to the health authorities, within the scope of their respective powers, monitoring and enforcement of this Regulation and other applicable provisions, in accordance with the provisions of Title Seventeen of the Law.

ARTICLE 130.- Whoever conducts health research that includes the use of human beings, as well as the use of pathogenic microorganisms or biological material that contains them, construction and handling of recombinant nucleic acids, radioactive isotopes and devices that generate ionizing and electromagnetic radiation , in contravention of the provisions of the Law and these Regulations, will be credited with the sanctions that the Law indicates in this regard, without prejudice to those established in the Regulatory Law of Article 27 of the Constitution on Nuclear Matters and the penalties that may be incurred. when they constitute crimes.

ARTICLE 131.- The competent authority may revoke the health authorizations that it has granted to carry out health research, when they do not comply with the provisions contained in the Law, this Regulation and other provisions that derive from it. For the substantiation of

procedure for the revocation of authorizations, the provisions of Chapter II of Title Sixteen of the Law shall be observed.

ARTICLE 132.- Against acts and resolutions of the health authorities that, due to the application of this Regulation, end an instance or resolve a file, the interested parties may file the appeal of disagreement, which will be substantiated in terms of the Chapter IV of Title Eighteen of the Law.

Article added DOF 04-02-2014

ARTICLE 152 (sic DOF 04-02-2014).- Repealed.

Article repealed DOF 04-02-2014

TRANSIENT

FIRST.- This Regulation will enter into force the day after its publication in the Official Gazette. Federation Officer.

SECOND.- The Agreement for the creation of the Investigation and Ethics Commissions, of December twenty-third, nineteen eighty-one, published in the Official Gazette of the Federation on January twenty-six, nineteen eighty-two, and the Decree creating the Biosafety Commissions, dated July 8, 1982, published in the Official Gazette of the Federation on August 4 of the same year. Likewise, the other provisions on the matter that are contrary to this ordinance are repealed.

Given at the Residence of the Federal Executive Branch, in Mexico City, Federal District, on the twenty-third day of the month of December, nineteen eighty-six.- **Miguel de la Madrid H.-** Signature.- The Secretary of Programming and Budget, **Carlos Salinas de Gortari.-** The Secretary of Energy, Mines and Parastatal Industry, **Alfredo del Mazo González.-** Signature.- The Secretary of Public Education, **Miguel González Avelar.-** Signature.- The Secretary of Health, **Guillermo Soberón Acevedo.- Signature .**

TRANSITORY ARTICLES OF REFORM DECREES

DECREE amending, adding and repealing various provisions of the Regulations of the General Health Law in the field of Health Research.

Published in the Official Gazette of the Federation on April 2, 2014

SOLE ARTICLE.- Articles 10 are **REFORMED ;** 14, fractions I, V, VII and VIII; 22, fractions I and II; 37; 48, section II; 58, first paragraph in its header; 60; 62, first paragraph in its header and sections II, III, VII, VIII and IX; 64, fractions I, III and V; 66, first paragraph; 71, first paragraph in its header and section I; 74; 77, fractions IV and VI; 78; 83, fractions I, IV, V and VI; 84; 87; 89; 90; 92; 99, fractions I, II and III; 100, first paragraph in your header; 101; 102; 103; 104; 105; 106; 107; 108; 109; 110; 111; 112; and 119, as well as the name of TITLE FIVE; **Sections** IX and X are ADDED to Article 14; the second paragraph to article 29; the second paragraph to article 62; TITLE THIRD BIS “Authorized Third Parties”, which includes a Single Chapter and includes articles 74 Bis 1 to 74 Bis 11, and article 132, and articles 18 are **REPEALED ;** 19; 23; 25; 26; 30 and 152, of the Regulation of the General Law of Health in the Matter of Research for Health, to be as follows:

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TRANSIENT

SOLE.- This Decree will enter into force the day after its publication in the Official Gazette of the Federation.

Given at the Residence of the Federal Executive, in Mexico City, on March twenty-eight, two thousand and fourteen.- **Enrique Peña Nieto.-** Signature.- The Secretary of Energy, **Pedro Joaquín Coldwell.-** Signature.- The Secretary of Public Education, **Emilio Chuayffet Chemor.-** Signature.- The Secretary of Health, **María de las Mercedes Martha Juan López.- Signature .**