AAHRPP®

Association for the Accreditation of
Human Research Protection Programs, Inc.®

Bylaws of the General Health Law in the Matter of Health Research Mexico

Date:

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Domain I: Organization	
Standard I-2: The Organization ensures that the Human Research Protection Program has resources sufficient to protect the rights and welfare of research participants for the research activities that the Organization conducts or oversees.	
	Description of the resources available for the management of medical emergencies. • The professional history of the principal investigator, including his or her education, representative scientific production and clinical practice or experience in the area of research proposed. • The education and experience of the medical and paramedical staff and other experts that will participate in research related activities.
Standard I-7: The Organization has and follows written policies and procedures to ensure that the use of any investigational or unlicensed test article complies with all applicable legal and regulatory requirements.	
Element I.7.C. The Organization has and follows written policies and procedures for compliance with legal and regulatory requirements governing emergency use of an investigational or unlicensed test article.	For emergency treatment under life-threatening conditions, when it is considered necessary to use the research medicine or a known medicine using indications, doses and means of administration that are not established, the physician must obtain the favorable opinion of the research committee of the healthcare institute and a letter of informed consent from the research subject or, his or her legal representative, as allowed under the circumstances, in accordance with the following requirements: • The research committee and the ethics committee shall be informed of the use of the research medicine beforehand if the investigator may anticipate its use in emergency situations, and retrospectively, if the use of medicine, the indication, dose or means of administration arise due to unforeseen circumstances. In both cases, the committees shall approve or reject the planned use or the unforeseen repeated use of the medicine, and the head of the healthcare institute shall make sure that the Secretariat authorize its use, and • The letter of informed consent will be obtained from the research subject, or from his or her legal representative, or from a member of his or her family, except when the condition of the subject prevents him or her from giving said consent, when the legal representative or relation are not available and stopping using the research medicine represents a virtual risk of death.
Domain II: Institutional Review Board or Ethics Committee	
Standard II-2: The IRB or EC systematically evaluates each research protocol or plan to ensure the protection of participants.	
Element II.2.G. The IRB or EC has and follows written policies and procedures for suspending or terminating IRB or EC approval of research, if warranted, and for reporting these actions, when appropriate.	The healthcare institute shall submit a report to the Secretariat within 15 days of the day of the agreement to suspend or cancel the study, which must specify the adverse effect, the measures taken and the consequences of the effect.

Element II.4.D.	
Standard II-3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.	
Element II.3.F. The IRB or EC has and follows written policies and procedures to evaluate the consent process and to require that the researcher appropriately document the consent process.	If there exists some type of dependence, ascendancy, or subordination of the research subject to the researcher that prevents him or her from freely conferring of his or her consent, consent should be obtained by another member of the research team who is completely independent of the researcher-subject relationship. Required elements of informed consent: • The commitment to provide research subjects all up-to-date information obtained during the study, even if this affects the willingness of the subject to continue participating in the study. • That any additional expenses shall be covered by the research budget. The consent document shall specify the names and addresses of two witnesses and their relationship with the research subject. • The consent document must be signed by two witnesses and by the research subject, or by his or her legal representative. If the research subject cannot sign, he or she shall place his or her thumbprint and another person appointed by him or her shall append his or her signature. • The consent document shall be issued in duplicate, with the research subject or his or her legal representative retaining one copy.
Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.	
Element II.4.A. The IRB or EC has and follows written policies and procedures for determining the risks to prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance.	Laws/regulations concerning minors apply except when it concerns minors who are 16 years of age and who are emancipated. When research is carried out on children, similar studies have first been carried out on adults and in young animals, except with regard to studying conditions that are inherent to the neonatal stage or specific afflictions of certain ages. In research classified as greater-than-minimal risk that are conducted in women of child-bearing age, the following measures should be taken: • Certify that women are not pregnant before they agree to be research subjects, and • Diminish to the extent possible the possibilities of pregnancy during their participation in the research. Research conducted in pregnant women should be preceded by studies carried out in non-pregnant women and that demonstrate their safety, with the exception of specific studies that require this condition. Research carried out on pregnant women that requires an experimental intervention or procedure that is not related to pregnancy, but does provide the woman therapeutic benefit, such as cases of pre-eclampsia, diabetes, hypertension and neoplasias, among others, should not expose the embryo or fetus to a risk greater than the minimum, except when the use of the procedure is justified so as to save the woman's life.

	Research carried out on pregnant women that provides therapeutic benefit related to pregnancy shall be allowed when: • Its purpose is to improve the health of pregnant women, with minimum risk to the embryo or fetus. • Its purpose is to increase the viability of the fetus, with minimum risk to the pregnant woman. During research carried out on pregnant women: • Investigators shall have no authority to decide upon the time, method or procedure used to terminate pregnancy, nor shall be involved in any decision concerning the life of the fetus. • The method to terminate pregnancy for research purposes may only be authorized by the ethics committee when any such change implies minimum risk to the health of the mother and does not present any risk to the survival of the fetus. • It is prohibited in all cases to provide any monetary compensation or any other type of compensation to interrupt pregnancy due to the interests of the research study or for other reasons. The consent document for research during labor should be obtained prior to the initiation of labor and cite expressly that consent may be withdrawn at any time during labor. Research carried out on women during the puerperium stage shall be allowed when the health of the mother and the newborn is not affected. Research carried out on women during lactation shall be authorized when there is no risk to the breast-feeding child or when the mother decides not to breast-feed, if another method of feeding the child has been ensured, and the letter of informed consent is obtained according to requirements in the General Health Law. Fetuses may only be subject to research if the techniques and methods used provide both fetuses and pregnant women maximum safety. Newborn babies may not be subject to research until it has been established with certainty whether they are live births, except when the purpose of the research is to increase the probability of survival up to the viability stage, the study procedures do not cause the cessation of their vital functions or when, without any other risk being added, the intention is to obtain important general knowledge that may not be obtained in any other way. Live births may be subject to research if all of the provisions concerning research on children specified in the General Health Law are met. Research with embryos, dead fetuses, fetuses, stillbirths, macerated fetal material, and the cells, tissues, and organs extracted from these, will be conducted according to the General Health Law. Research on assisted fertilization is only admissible when it is applied to solve fertility problems that cannot be resolved in another manner, respecting the moral, cultural, and social viewpoints of the couple, even if these differs from those of the researcher. Subordinate groups are understood as the following: students, laboratory

	and hospital workers, employees, members of the Armed Forces, inmates in prisons or in social readaptation centers, and other special population groups in which informed consent can be influenced by an authority. • When research is carried out on subordinate groups, the ethics committee must include one or more representatives of the population being studied, who may represent the moral, cultural and social values of the group in question and ensure that: o The participation or rejection of subjects or withdrawal of their consent during the study does not affect their education, job, military situation or anything related to any legal process in which they are involved and the conditions of or complying with their sentence, if applicable. o Results of the research are not used to the detriment of research subjects. o The healthcare institute and sponsors take responsibility for the medical treatment of any harm caused and, if applicable, for paying any indemnity to which subjects are entitled if any harm is caused during research.
Element II.4.B. The IRB or EC has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.	When it is necessary to establish the mental capability of an individual for him or her to give his or her consent, the principal investigator must assess his or her capability of understanding, reasoning and logic, according to the parameters approved by the ethics committee. When it is assumed that the mental ability of a subject has varied over the course of time, the consent of said subject, or of his or her legal representative, must be certified by a group of professionals with recognized scientific and moral experience in the specific area of research, and by an observer who is not involved with the project, to ensure the suitability of the procedure for obtaining consent, and its validity throughout the research study. When a psychiatric patient is interned in an institution because he or she is subject to interdiction, the prior approval of the authority hearing the case must be given, and the requirements established in the preceding article must be shall be met.