AAHRPP®

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

Addendum: Argentina Law
Governing Research Involving Human Participants
Including Law of Buenos Aires

General Comments

Standards and Elements listed below address areas where policies and procedures must address specific requirements in the following laws describing human participant protections:

- Guidelines for Research involving Human Participants (Guía para Investigaciones con Seres Humanos)
- Good Clinical Practice for Clinical Pharmacology (Buena Práctica Clínica para Estudios de Farmacología Clínica or BPIC).
- Act Nº 3301/09 Protection of the rights of subjects taking part in health research.
- Decree Nº 58/GCABA/11.
- Resolution Nº 485/GCABA/MSGC/11
- Resolution Nº 1035-MSGC/2012

Domain I: Organization

Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program with appropriate leadership.

Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program.	Policies and procedure state that human participant protections apply to all research, whether conducted by public or private sectors, including clinical research, and research involving private information such as in behavioral, social-anthropologic, and epidemiological research.
Element I.1.C. The Organization has and follows written policies and procedures that allow the Institutional Review Board or Ethics Committee to function independently of other organizational entities in protecting research participants.	Policies and procedures describe a process of the organization to ensure that research does not proceed before obtaining approval from the following, in addition to the EC: • The corresponding head of unit, division, or department. • The Committee for Teaching and Research (CODEI) of the hospital. • The hospital director. • The central ethics committee for research.
Element I.1.D. The Organization has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to Sponsors, Researchers, Research Staff, research participants, and the Institutional Review Board or Ethics Committee, as appropriate.	Policies and procedures include the following ethical values: • Cultural and ethical values of the host community must be respected. • Research on vulnerable communities must respond to their health needs and priorities, as a way to prevent their exploitation for most disadvantaged communities. Policies and procedures state that the following activities are not research involving human participants and do not require review by an EC: • Investigations where there is no information regarding human participants, or when using publicly available information that does not identify participants. • Interventions limited to the study of health systems, government programs, public health or public health surveillance activities, provided that there is no possibility of identifying individuals. • Evaluations by a health officer or health service when conducted by the agency necessary to ensure the effectiveness and safety of a facility or process and benefits to people. • Monitoring epidemiological events or side effects of medications or other products.
Element I.1.F. The	Policies and procedures state that no research on human beings may

Organization has and follows written policies and procedures for reviewing the scientific or scholarly validity of a proposed research study. Such procedures are coordinated with the ethics review process.	proceed if other previous suitable experimental paths have not been carried out. Policies and procedures state that an EC may require a scientific advisory expert for advice, but must make its own decision about the scientific validity of the study, based on these consultations.
Element I.1.G. The Organization has and follows written policies and procedures that identify applicable laws in the localities where it conducts human research, takes them into account in the review and conduct of research, and resolves differences between federal or national law and local laws.	Policies and procedures define a child as a person who is under 21 years of age.
Standard I-4: The Organization responds to the concerns of research participants.	
Element I.4.A. The Organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.	Policies and procedures describe that: • No personally identifiable data should be used when a study can be done without them. Where necessary, researchers must describe plans to maintain confidentiality of the data. • Genetic data about a person must not be disclosed or made available to third parties, including employers, insurance companies, educational establishments, or family members of the person concerned. • Generally, the genetic data collected for the purposes of scientific research should not be kept in a manner where it is associated with an identifiable person longer than necessary to carry out the investigation.
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.A. When research involves investigational or unlicensed test articles, the Organization confirms that the test articles have appropriate regulatory approval or meet exemptions for such approval.	Policies and procedures describe the process for registering clinical pharmacology studies and any studies funded by the Ministry of Health with the National Administration for Drugs, Food and Medical Technology (ANMAT) in the National Register on Health Research.
Standard I-8: The Organization works with public, industry, and private Sponsors to apply the requirements of the Human Research Protection Program to all participants.	
Element I.8.A. The Organization has a written	Policies and procedures state that in clinical trials sponsored by a

agreement with the Sponsor that addresses medical care for research participants with a research-related injury, when appropriate.	pharmaceutical company or other business, the EC must verify that the agreement or contract between researcher and sponsor institution: • Does not include clauses that limit or appear to limit the rights of the participants. • Does not contain inconsistencies with the information that will be provided to participants or require actions that oppose the ethical requirements of the EC. • Provides that the costs of the trial, including treatment and study procedures, including full coverage for damage resulting from them, will be covered by the sponsor. • Makes clear that the institution and investigators remain undamaged in any claim for damages caused by participation in the trial, in its responsibilities to the sponsor and, in case of conflict between the parties, they shall be settled in local courts regarding research centers. • The sponsor has insurance or a guarantee subject to the legislation Argentina. • The sponsor provides a realistic estimate of all costs of the assay, that ensures its implementation and payments to the researcher and study team are proportional to the task and do not constitute an undue inducement to engage in ethical failure.
Domain II: Institutional Review Board or Ethics Committee	
Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.	
Element II.1.A. The IRB or EC membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. The IRB or EC has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB or EC regularly reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.	Policies and procedures describe that the composition of the EC meets legal and regulatory requirements: • Each EC has at least seven members and no more than fifteen with varying backgrounds to promote complete and adequate review of research commonly conducted by the organization. • No EC has fewer than 30% of the membership as males, or fewer than 30% as females. • Each EC has at least three members who are not otherwise affiliated with the organization and who are not part of the immediate family of a person who is affiliated with the organization. • Each EC has at least one specialist in research methodology. • Each EC has at least one attorney. • Each EC has at least one physician researcher.
Element II.1.B. The IRB or EC has qualified leadership (e.g., chair and vice chair)	Policies and procedure state: • EC members are appointed for three year terms.

and qualified members and staff. Membership and composition of the IRB or EC are periodically reviewed and adjusted as appropriate.	• The membership of the EC must be renewed periodically to combine the advantages of experience with new perspectives.
Standard II-2: The IRB or EC systematically evaluates each research protocol or plan to ensure the protection of participants.	
Element II.2.C: The IRB or EC has and follows written policies and procedures for conducting meetings by the convened IRB or EC.	Policies and procedures state that EC members must be willing to give out the full name, profession and institutional affiliation, and sign a confidentiality agreement on the details of the investigations and discussions about them. Policies and procedures state: • The EC should establish clearly defined positions to optimize performance, such as a president, secretary and members. • The EC obtains information to evaluate the credentials of the researcher, in addition to the curriculum vitae. Policies and procedures state: • The EC communicates decisions within two weeks. • The EC should arrive at decisions by consensus, rather than a vote.
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.A. The IRB or EC has and follows written policies and procedures for identifying and analyzing risks and identifying measures to minimize such risks. The analysis of risk includes a determination that the risks to participants are reasonable in relation to the potential benefits to participants and to society.	Policies and procedures state that in order to approve research, the EC determines: • All participants in the research have access to optimal or best standards of care, whether for diagnostics, prevention or treatment. • The research is relevant to the needs of the community. When the EC reviews two or more protocols that, due to operative reasons, cannot coexist in the same organization, the EC should give priority to the treatment and approval of that which corresponds to the local and national medical needs. The researcher will explain how the research is related to the local medical needs, which potential benefits exist for the local population and how people will have a reasonable access to the research results and benefits. Policies and procedures state that the EC reviews research to determine participants have access to the resulting benefits from the research: • The sponsor or funding agency responsible for the research shall guarantee the participants the reasonable access to the benefits resulting from the research such as products or technical-scientific procedures. • The researcher shall guarantee, by previous agreement with the sponsoring agency, the continuation of the treatment to the research participants, once completed their participation in the study, and provided the following conditions apply: • That treatment has proved to be beneficial for the participant and the suspension thereof could derive in detriment of his or her health. • That it is the only available alternative. Policies and procedures state that the EC may approve research involving risks to populations or communities if the benefits to the individuals or society clearly outweigh the risks involved, and risks have been minimized

	to the extent possible. Policies and procedures state that when reviewing research that poses risks to communities, the EC must determine: • The research is of sufficient importance to the health of other to justify the risks of the research, such as research involving a transmissible infectious or genetic disease. • Participants in the research have a right to decide whether the community will be informed of the results of the research, and have access to advice from people with appropriate professional expertise. • Whether there benefits from the research, such as: • Training community members in techniques and procedures which can improve care. • Improvement in health services • Dissemination of research results. Policies and procedures state that when reviewing clinical research involving a placebo, in order to approve the research the EC must determine the following mechanisms are in place to minimize risks: • The protocol document clearly states the use of placebo and its risks. • The period of treatment is the minimum possible to reduce exposure to non-treatment. • Participants will be monitored frequently and strictly, and there is a plan to withdraw participants or transfer to active treatment (rescue) treatment failure if detected. • An interim analysis plan and an independent board monitoring data with clear rules for stopping the study for safety reasons. • The study involves a crossover design, where alternating groups receive active treatment or placebo. • When scientifically and medically possible, all participants should receive the standard treatment, adding either the experimental or placebo product. • The EC should pay particular attention to projects that propose the use of placebo in groups or communities without access to standard therapy. The EC should not approve research involving the use of placebo if this is your only basis. Policies and procedures state: The EC should determine that, when research involves a placebo, there is a plan to provide compensation for accidental injuries. • If an investigation would result in damage, the sponsor shall compensate the harmed appropriately depending on the type of damage. • Pecuniary losses should be repaired promptly. In order to approve research involving gene therapy, the EC must determine: • Preclinical studies in animals or other models and previous clinical studies of experimental therapeutic proposal must show convincing evidence of safety and potential therapeutic benefit to justify its use in humans. • The biological characteristics of the intervention and production

	processes must be clearly established. Where applicable, the production must conform to the Good Laboratory Practice, and performed in the appropriate biosecurity. • The proposed clinical trial should provide a safety assessment in the short, medium and, if corresponds, in the long term, with a plan timely and effective reporting of adverse events. • The experimental therapy should be compared with the best available treatment, if any. • The risks of experimental therapy should be identified and minimized when possible. • Potential therapeutic benefits must be realistically defined. • Evaluation and monitoring of the trial protocol requires a detailed, well-defined standard of manufacturing and toxicology laboratory and information. • The experimental therapy, if approved, should be accessible to the local population through available health services. Policies and procedures state that participants are entitled to receive any attention requiring care in case of toxicity, including treatment of tumors that may appear, and compensation for injuries resulting from the research. Given the persistence long-term implanted cell product and the type of experimental intervention, participants must undergo health checks in the long term.
Element II.3.C. The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants. **Element II.3.C.1. The IRB or EC has and follows written policies and procedures to review proposed participant recruitment methods, advertising materials, and payment arrangements and determines whether such arrangements are fair, accurate, and appropriate.**	Policies and procedures state that the EC has the authority to supervise the recruitment process and participant enrollment to guarantee a clear, transparent, and non-coercive procedure. The use of any encouragement by investigators to force by any means the enrollment of participants to a research is prohibited. Policies and procedures state that the EC determines that the sponsor provides compensation to participants for expenses (ordinary and extraordinary) and integral compensations due to disturbances, productivity losses and any other type of damage, either physical or psychic, that derives from their participation in the research. Policies and procedures state that the EC reviews research to determine that, when applicable, there is a plan to provide results in a local database including information about the research, such as the purpose, phase, responsible person, place, and drug used in the research. Policies and procedures state that the EC determines that when research involves communities or groups of people linked by ethnic, geographical, social or common interests, a representative of the community has been consulted. The representative should be chosen according to the nature and traditions of the community, and equivocally represent the interests of the community. • Researchers should consider the desirability of obtaining approval of community leaders prior to individual decisions, when appropriate. Policies and procedures state that in order to approve research involving genetic testing that may have important consequences for health of a person, the EC must confirm that participants are provided with genetic counseling. The counseling advice should be non-coercive, adapted to the

	culture in question, and serve the best interests of the persons involved. Policies and procedures state that in order to approve the research, the EC should ensure: • At the end of the investigation, all participants should share the benefits obtained from the research. • In a clinical trial sponsored by a pharmaceutical company that has shown the experimental product is beneficial, the sponsor should continue to ensure provision of the experimental product to participants by other means. • This requirement should be determined according to relevant considerations, such as o The severity of the medical condition in question and the expected effect of removing or modifying the treatment, for example, leave a sequel or death of the patient. o When it is not comply fully possible, it may be agreed providing an alternative intervention or other appropriate profit, approved by the EC and the terms it decides. Policies and procedures state that in order to approve research, the EC evaluates the impact of the research on the community, considering: • Measures to consult the community or their representatives before and during the study. • The future availability of any successful product research. • The availability of research results to the communities involved.
Element II.3.E. The IRB or EC has and follows written policies and procedures to evaluate proposed arrangements for maintaining the confidentiality of identifiable data, when appropriate, preliminary to the research, during the research, and after the conclusion of the research.	Policies and procedures state that the EC determines that genetic data and samples should not be kept associated with an identifiable person for longer than the need to conduct research.
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.	Policies and procedures state that the EC reviews the process of consent to determine that a summary of information about the research is registered in the clinical history or the professional registers including the date, signature of the prescribing investigator, printed name, and number of the register specifying the principal investigator's name and contact information. The clinical history should document the participant's consent to the proposed research or treatment, as well as the decision by a participant to withdraw from the research if applicable. Policies and procedures indicate that consent is documented using an information sheet and the consent document. The information sheet contains the following: • Sufficient information about the research characteristics, differences with the medical care, and if applies, the special features of the combination of research and medical care. • Statement of the participant's right of not taking part and his/her right to

	receive suitable and effective medical care independently of his/her enrollment in the research. • Title of the proposed research, sponsoring agency, organization that carries out the research, and responsible researcher as well as contact information for the researcher. • Reasons, objectives and procedures of the research and the nature, extension and duration of the research. • Proposed and justifiable treatment for placebo, if apply, together with the criteria of use thereof. • Responsibilities, risks, charges and possible adverse events that may correspond to the participant. • Benefits expected by the participant and the community. • Benefits and risks of the existing alternative methods. • Potential uses, including commercial uses, of the research results. • Financial source of the project. • Guarantee of medical care, name of those responsible thereof, including predicted adverse events, and investigators' way of contact. • Guarantee of access to any new information relevant to the participant including a summary of the final results of the research and name of the person responsible for bringing the information. • Freedom to reject invitation to take part therein or dropout at any phase of the research, without prejudice of suffering any discrimination, penalty or damage. • Guarantee of protection for privacy and confidentiality of personal data explaining the methods to be adopted to do so. • Guarantee of expenses coverage generated for the participation in the research and compensations to be received by the participant. • Insurance guarantee for compensation for possible damages generated during the research, name of the insurance company and policy number. • Information that allows participants to contact the CEI that approves the research for answers to questions about the research. • The name of the insurance company and the policy number for the insurance covering research-related injury. Policies and procedures state that consent documents disclose the risks to standard therapy, in addition to anticipated risks of participation in the research. Policies and procedures state that consent documents must contain the statement specified in regulation that by signing the consent document, participants are not renouncing other rights under Argentina law. Policies and procedures state that consent documents for clinical studies must contain the statement specified in regulation that the clinical pharmacology study is authorized by ANMAT, and that if participants have any questions about the treatment or research, they can consult ANMAT by calling 0800-333-1234 (toll-free). Policies and procedures state that for research funded by industry or commercial sponsors, consent documents include a statement that research procedures are provided at no costs to participants. Policies and procedures state that if biological samples are obtained as part

	of the investigation, the consent reported shall include the following information: • The possible uses, direct or secondary, of biological samples obtained in the study. • The use of biological samples at the end of the study, for example, destruction or storage for future use. The consent document must specify what would be the possible future uses and where, how and how long to store the samples, and that the participant is entitled to decide on these future uses. • A statement that the samples or derived data will not be sold. • When appropriate, the potential for development of a commercial product from samples biological, and whether the participant is expected to receive monetary or other benefits from participating in the research. • The transfer of any sample or biological material intended for scientific research between participant and researcher or between researchers and other shall be free, without prejudice the participant may receive financial compensation for expenses or inconvenience suffered or the receiver should cover the shipping and storage of samples or materials. • A witness to the consent process is required when research involves biological samples. Policies and procedures state that the EC determines that consent documents include a statement that participants have the right to decide to know results about their genetic data and have access to the samples, unless: • All information that would allow the identification of the participants is removed from samples. • There are no significant consequences for the health of the participant. Policies and procedures state that the EC determines that genetic data collected for research purposes must not be used for purposes incompatible with the original consent, unless the researcher obtains a new consent of the participant or his representative. Policies and procedures state that the EC determines that researchers must ensure that the use of the data is not exposed to individuals, families, groups or communities at risk of discrimination or stigmatization. Policies and procedures state that for studies involving gene trials or other cell therapy, in order to approve the research the EC determines consent documents clearly describe: • The foreseeable risks of the proposed experimental therapy. For example, in the case of stem cell therapies, cell proliferation and / or tumor development, exposure to animal materials and the possibility of transmission of viral vectors, and in the gene, the possible effects on gamete cells and offspring. • The potential therapeutic benefits of the experimental intervention and the existence or not therapeutic alternatives. Consent must emphasize the experimental aspect of the intervention to prevent erroneous expectations about its therapeutic potential. • In the case of cell therapy, cell transplantation irreversibility must be explained clearly. The cells, unlike many drug products or devices

	cannot be removed from the body and could continue to generate their effects. • That the participation in this type of research may have adverse effects over the lifetime of a patient. • Potential participants should be asked to give consent to an autopsy to assess the extent of cell implantation and morphological consequences. • The request for an autopsy should be aware of cultural sensitivities and family. The issue is delicate but without access to the material post-mortem information trial would be affected to the detriment of future products or product enhancements. • Recognizing the potential value of new cellular and gene therapies for patients with cognitive impairment and the importance of which they are not excluded from such advances. Policies and procedures state that researchers must develop a procedure for authorized representatives of patients can make a decision on their behalf. The representatives shall be properly qualified and knowledgeable enough to evaluate the test and provide adequate protection.
Element II.3.G. The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.	Policies and procedures state that the process and documentation of consent may be waived in the following circumstances: • When research involves data or samples or information where it is not possible to identify participants, and research involving publicly available information. A probable refusal to participate by individuals should not be considered impracticability criterion to approve the omission of consent. • When research is not greater than minimal risks and it is impracticable or very difficult to obtain consent, where researchers ensure there are appropriate plans to protect the confidentiality of data. • Research involving established and officially recognized records, such as disease registries, provided the recorded data are not linked to people. • When the notice of consent may invalidate the results of the investigation, for example, when studying the behavior of a human group. • Experimental epidemiological investigations in which the intervention involves a group of people or community, or a defined area, such as students in a school or residents in a defined area. Consent may be obtained by a community representative who will assess whether the expected benefits to the community outweigh the risks. Additionally, individuals should be informed about the research and have the opportunity, whenever possible, to refuse participation. • In clinical trials conducted in emergency situations requiring immediate medical intervention. Policies and procedures state that when reviewing requests for secondary use of existing biological specimens, the EC may waive a requirement for consent for secondary use provided the original consent has specified the following: • Whether there will or might have a secondary use for these samples and, if any, which such studies could be made with these materials. • The conditions under which researchers will have to contact participants

	to request additional authorization for secondary use or not yet defined. • The plan, if any, to destroy unused samples or dissociate irreversibly. • The right of participants to request the destruction or dissociation of the samples. Policies and procedures state that when research involves medical data and biological samples, participants have a right to know if their data or samples will be used for research. However, the EC may approve the use of research data or samples from medical care, without the prior consent of the patients, when • The project is scientifically valid. • The research does not involve greater than minimal risk. • Obtaining consent is difficult or impracticable and ensure. • The researcher has made adequate provisions to protect the privacy interests of participants and the confidentiality of participants' data.
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.	Policies and procedures state that research involving vulnerable populations may be carried out only when: • The research provides a direct benefit. • The direct benefit is acceptable in relation to the anticipated risks from the research. Policies and procedures state that research involving participants with psychiatric disorders is not allowed if the research can be conducted in persons without psychiatric disorders. • Participation of people suffering from psychiatric disorders in phase I research is prohibited. Policies and procedures state that in order to approve research involving a vulnerable population that could pose an unequal distribution of burdens and benefits, the EC must determine: • The research could not be done equally well with less vulnerable persons. • The research attempts to obtain knowledge that will lead to improved care for diseases or other health problems characteristic of the group. • The study participants and other vulnerable members of the group will have a reasonable access to products that become available as a result of the investigation. • The risks associated with interventions or procedures without direct benefit to the health participants do not exceed those associated with routine medical or psychological examinations, unless authorized by the EC. • In the case of clinical trials, consent will be obtained in the presence of an independent witness to ensure voluntariness and freedom of the decision to participate. Policies and procedures state that when research involves individuals unable to give consent, in order to approve the research, the EC must determine: • The knowledge to be gained from this research is relevant enough

	regarding foreseeable risks. • The risks of an observational study are only slightly higher than those associated with medical examinations and routine psychological condition such persons under investigation. • The risks of experimental research are similar to those of interventions individuals usually receive by the condition under investigation. • The EC has consulted specialists or experts in that particular group. Policies and procedures state that when research involves participants who are vulnerable due to cultural, education, social or economic circumstances, in order to approve the research the EC determines: • Consent must be obtained in the presence of an independent witness and investigator of his team when the research plans to enroll participants who are: o Unemployed or have only informal employment or unstable employment in the main breadwinner. o Homeless or in poor housing (hotel or boarding house, tenement house or building not taken for housing) or located in unfavorable areas (village or informal settlement). o Without social security coverage (social work or prepaid). o Illiterate or have incomplete primary study. o Indigenous people belonging to an ethnic or whose primary language is not Spanish. o A refugee or displaced person. • The research meets the needs of health and priorities of the population or community and that any benefit accruing from research, whether or product knowledge, reasonably available to benefit of that population or community. If the knowledge gained from the research will use primarily for the benefit of others who may bear the cost of the product once commercialized, the research can be characterized as exploitative and unethical. Policies and procedures state that research involving pregnant women may only be approved when the research is relevant to health problems related to pregnancy and the product of conception, and if properly supported by previous experiments in animals, particularly for establishing the risk of teratogenicity and mutagenicity.
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.	Policies and procedures state that when research involves children older than 14 years of age and there is disagreement between the teenager and the participant's legally authorized representative, the EC or a competent judge will determine what is in the best interest of the participant. Policies and procedures state that when the research involves adult participants who have diminished decision-making capacity and there is disagreement between a participant and the participant's legally authorized representative, the EC or a competent judge will determine what is in the best interest of the participant.
Element II.4.C. The IRB or EC has and follows written policies and procedures for making exceptions to consent requirements for	Policies and procedures state that in emergency situations, if it is not possible to obtain consent, consent should be obtained from the participant's legally authorized representative, or if not available, from a

planned emergency research and reviews such exceptions according to applicable laws, regulations, codes, and guidance.	relative or a close friend of the family. • The EC should review and approve plans for enrollment of participants in emergency situations prior to research starting, and should determine that participation in the research provides a benefit and that there are no other available clinical alternatives. • The participant or the participant's legally authorized representative will be informed as soon as possible about the enrollment in the study and consent will be obtained prior to continuing the research.
Standard II-5: The IRB or EC maintains documentation of its activities.	
Element II.5.A. The IRB or EC maintains a complete set of materials relevant to the review of the research protocol or plan for a period of time sufficient to comply with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.	Policies and procedures state that records must be retained for no fewer than 10 years after the end of the research.