AAHRPP®

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

Belgium

Addendum to the

Evaluation Instrument for Accreditation

Supplement to Evaluation Instrument

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 a written plan for its Human Research Protection Program appropriate for the volume and nature of the research involving human participants conducted under its auspices.	Interventional clinical trials must receive authorization by a competent authority (generally the Federal Public Health Service).
Element I.1.B: The 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.	
Element I.1.C: The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.	
Element I.1.D: The Organization has and follows written policies and procedures for working with sponsors, investigators, research participants, and the Research Review Unit to uphold ethical standards and practices in research.	
Standard I-2: The Organization assures the availability of resources sufficient to protect the rights and welfare of research participants, taking into consideration the research activities in which they were asked to participate.	
Element I.2.A: The Organization provides resources to the Human Research Protection Program sufficient for conducting the activities under its jurisdiction.	
Element I.2.B: The Organization provides the appropriate number of IRBs for the volume and types of human research to be reviewed, so that reviews are accomplished in a thorough and timely manner. An Organization may use the IRBs of another Organization to meet the needs of its research program.	
Element I.2.C: The Organization provides resources that are necessary for human research protection, care of research participants, and safety during the	

conduct of the research.	
Element I.2.D: The Organization provides for communication and interaction for its units that might be involved in the conduct of human research.	The EC must notify the investigator within 15 days on receipt of a valid application of the grounds for non-acceptance of an application for a mono-centre phase I trial.
Standard I-3: The Organization monitors compliance of all those involved in the research process.	
Element I.3.A: The Organization has and follows written policies and procedures governing research with research participants that are available to investigators and research staff affiliated with the Organization.	
Element I.3.B: The Organization has and follows written policies and procedures that allow the Research Review Unit to function independently of other organizational entities in its role in protecting research participants.	
Element I.3.C: The Organization has and follows written policies and procedures for determining when studies meet the regulatory definitions of human research.	
Element I.3.D: The Organization has and follows written policies and procedures for determining when studies are exempt from applicable federal, state, and local regulations and the Organization's policies and procedures. Such policies and procedures indicate that exemption determinations are not to be made by investigators or others who might have an apparent or real conflict of interest regarding the studies.	
Element I.3.E: The Organization has and follows written policies and procedures for addressing protection of participants in research exempt from applicable federal regulations.	
Element I.3.F: The Organization includes in its Human Research Protection Program policies and procedures regarding the areas in which federal and state law differ, and provides guidance about regulatory compliance.	
Element I.3.G: The Organization has and follows written policies and procedures to identify, manage, and minimize individual conflicts of interest of investigators. The Organization	

works with the IRB regarding conflicts of interest, when appropriate.	
Element I.3.H: The Organization is developing written policies and procedures for recognizing and managing institutional conflicts of interest.	
Element I.3.I: The Organization has and follows written policies and procedures for addressing allegations and findings of non-compliance with Human Research Protection Program requirements.	
Element I.3.J: The Organization has and follows written policies and procedures for addressing unanticipated problems involving risks to research participants or others.	
Element I.3.K: The Organization maintains and supports an assurance of compliance that identifies how the Organization protects research participants, when applicable.	
Element I.3.L: The Organization implements a plan to measure and improve Human Research Protection Program effectiveness, quality, and compliance with organizational policies and procedures and applicable federal, state, and local laws.	
Element I.3.M: The Organization has and follows written policies and procedures so that investigators may bring forward to the Organization concerns or suggestions regarding the Human Research Protection Program, including the IRB review process.	
Standard I-4: The Organization ensures that all personnel reviewing, conducting, or supporting human research demonstrate and maintain sufficient knowledge of the ethical principles and federal, state, and local requirements for protecting research participants.	
Element I.4.A: The Organization evaluates and contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.	
Element I.4.B: The Organization has and follows written policies and procedures requiring all individuals involved with the Human Research Protection Program to understand and apply their obligation to protect the rights and welfare of research	

participants.	
Standard I-5: The Organization has and follows written policies and procedures that use of any investigational or unlicensed test article complies with all federal, state, or local regulations.	
Element I.5.A: The Organization secures assurances from the sponsor that the manufacture and formulation of investigational or unlicensed test articles conform to federal regulations.	
Element I.5.B: The Organization has policies and procedures to ensure that the handling of investigational or unlicensed test articles meets organizational standards relating to pharmacy, inventory control, and documentation.	
Element I.5.C: The Organization has and follows written policies and procedures for compliance with federal regulations governing emergency use of an investigational or unlicensed test article.	
Domain II: Research Review Unit, Including IRBs	
Standard II-1: The structure and composition of the Research Review Unit are appropriate to the amount and nature of the research reviewed.	
Element II.1.A: The Research Review Unit has and follows written policies and procedures requiring protocols to be reviewed by individuals with appropriate scientific or scholarly expertise.	
Element II.1.B: The IRB has a process for obtaining additional expertise when reviewing a specific protocol.	
Element II.1.C: The Research Review Unit has and follows written policies and procedures so that IRB members and consultants do not participate in the review of protocols in which they have a conflict of interest, except to provide information requested by the IRB.	At the time of appointment, members of the EC submit a written declaration to the minister stating any direct or indirect connections with the sponsor. Members who are dependent on the sponsor of the concerned study, on the basis of the declaration, cannot participate in a valid manner in the deliberation and examination of the concerned study. They can provide information on the request of the EC, if they are a participating investigator. Direct or indirect connections are not defined by law and must be defined locally. The definition must include financial interests.
Element II.1.D: The IRB has a qualified IRB chair, members, and staff whose membership and composition are periodically reviewed. The IRB administrator,	The hospital EC is composed of a minimum of 8 and maximum of 15 members.

staff, chair, and members have knowledge, skills, and abilities appropriate to their respective roles.	A majority of members must be hospital-based physicians. There must be at least one general practitioner, one nurse, and one lawyer. Membership must not be gender-biased. The Hospital Director, Chief Physician, The President of the Medical Council, and the Head of Nursing cannot be members of the EC. The term of membership is limited to four years, but membership is renewable. Members are appointed by the management of the hospital.
Element II.1.E: The IRB membership roster includes sufficient information about members to permit appropriate representation at the meeting for each protocol under review. One or more unaffiliated members were represented on the IRB and one or more members can represent the general perspective of participants.	
Element II.1.F: The IRB meets regularly and members have sufficient time to review materials prior to meeting.	The EC must review 20 protocols (from any source, not just Pfizer) a year. The EC must meet at least once per quarter, behind closed doors. The EC must review the application and protocol of a phase I trial within a maximum of 15 calendar days. This period can be extended to 30 days in the case of trials involving medicinal produce for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms. The term may be extended by another 90 days in the event of consultation with the Advisory Council for Biosecurity.
Standard II-2: The Research Review Unit systematically evaluated each research study to ensure the protection of participants.	
Element II.2.A: The Research Review Unit has and follows written policies and procedures for conducting initial and continuing review, and procedures for handling modifications to research studies.	Additional review criteria under Belgium law: Review the information contained in the investigator brochure. Assess whether the evaluation of the anticipated benefits and risks as required is satisfactory and whether the conclusions are justified, in particular on a therapeutic and public health level. Assess the suitability of the participating investigators and supporting staff as well as the quality of the facilities. Assess the insurance or indemnity to cover the liability of the investigator and sponsor. Special protections for participants enrolled in phase I trials: Individuals cannot simultaneously participate in more than one phase I. The protocol must determine an exclusion period in which the participant cannot participate in another phase I trial. The length of period differs according to the nature of the research.
Element II.2.B: The Research	

Review Unit has and follows written policies and procedures to conduct reviews by the expedited procedure.	
Element II.2.C: The Research Review Unit receives and reviews the relevant information to evaluate research studies during initial review.	
Element II.2.D: The Research Review Unit receives and considers relevant information to conduct continuing reviews of research studies and, when appropriate, requests changes.	
Element II.2.E: The Research Review Unit receives and considers the relevant information to evaluate proposed amendments to research studies.	
Standard II-3: The Research Review Unit maintains documentation of its activities.	
Element II.3.A: The Research Review Unit maintains a complete set of materials relevant to review of the research study in each protocol file.	
Element II.3.B: The Research Review Unit retains required records for a period of time sufficient to meet federal, state, and local regulations, sponsor requirements, and organizational policies and procedures.	
Element II.3.C: The IRB documents pertinent discussions and decisions on research studies and activities.	
Standard II-4: The Research Review Unit systematically evaluated risks to participants and potential benefits as part of the initial review and ongoing review of research.	
Element II.4.A: The Research Review Unit has and follows written policies and procedures for identifying and analyzing potential sources of risk and measures to minimize risk, including physical, psychological, social, legal, or economic risks. The analysis of risk includes a determination that the risks to participants were reasonable in relation to potential benefits to participants and to society.	
Element II.4.B: The Research Review Unit reviews the plan for data and safety monitoring in research protocols, when applicable, and determines that the plan provides adequate protection for participants.	
Element II.4.C: The Research	

Review Unit has and follows written policies and procedures for determining the risks to vulnerable populations as defined in applicable federal regulations, and specifically for determining the required risk categories in protocols involving children and prisoners.	
Element II.4.D: The Research Review Unit has and follows written policies and procedures for suspending or terminating previously approved research if warranted by findings in the continuing review or monitoring process.	
Standard II-5: The Research Review Unit systematically evaluates recruitment and participant selection practices.	
Element II.5.A: The Research Review Unit has and follows written policies and procedures to evaluate the equitable selection of participants from various populations and sub-populations, when applicable, and considers whether inclusion and exclusion criteria impose fair and equitable burdens and benefits.	
Element II.5.B: The Research Review Unit reviews proposed participant recruitment methods, advertising materials, and participation payment arrangements, and permits them when fair, honest, and appropriate.	
Standard II-6: The Research Review Unit systematically evaluates the protection of privacy interests of research participants and the confidentiality of data in proposed research.	
Element II.6.A: The Research Review Unit has written policies and procedures to evaluate the proposed arrangements for protecting the privacy interests of research participants during and after their involvement in the research.	
Element II.6.B: The Research Review Unit has written policies and procedures to evaluate proposed arrangements for protecting the confidentiality of identifiable data, when appropriate, during and after the conclusion of the investigation.	
Standard II-7: The Research Review Unit has and follows written policies and procedures that required informed consent to be solicited from participants or their legally authorized representatives, and it verifies that this requirement is met.	
Element II.7.A: The Research Review Unit evaluates compliance	

with policies and procedures on seeking informed consent from participants or their legally authorized representatives, and assent, when possible, from participants who cannot give consent.	
Element II.7.B: The Research Review Unit has and follows written policies and procedures requiring that prospective participants whose decision-making capacity is in question be appropriately protected.	
Element II.7.C: The Research Review Unit reviews the content of the consent process, including the consent document, and the process through which informed consent is obtained from each participant, focusing on measures to improve participant understanding and voluntary decision-making.	
Element II.7.D: The Research Review Unit has and follows written policies and procedures requiring that the investigator has and follows a procedure for properly documenting informed consent.	
Element II.7.E: The Research Review Unit has and follows written policies and procedures for approving waiver or alteration of the consent process and the waiver of consent documentation.	
Element II.7.F: The Research Review Unit has and follows written policies and procedures for making exceptions to informed consent requirements in protocols for emergency situations, and appropriately reviews such protocols.	
Element II.7.G: The Research Review Unit has procedures for observation of the informed consent process in ongoing research, when appropriate.	
Standard II-8. The Research Review Unit has procedures for review and oversight of research conducted at multiple sites.	
Element II.8.A: The Research Review Unit has and follows policies and procedures for communication among IRBs, when appropriate, for research conducted at multiple sites (e.g., multi-site clinical trials, epidemiology studies, or	

educational surveys).	
Element II.8.B: The Research Review Unit has and follows policies and procedures for management of information obtained in multi-site research that may be relevant to the protection of research participants, such as reporting of unexpected problems or interim results.	
Domain III: Investigator	
Standard III-1: The Organization uses policies, procedures, and education programs to help Investigators carry out research studies ethically. In addition to following applicable federal, state, and local regulations, Investigators follow ethical principles and standards appropriate for their discipline. In designing and conducting clinical trials, Investigators follow Good Clinical Practice guidelines defined by the Food and Drug Administration. In designing and conducting research studies, Investigators have the protection of the rights and welfare of research participants as their primary concern.	
Element III.1.A: The Investigator and research staff consider conflicts of interest that might affect the relationship with the research participant or the outcome of the research and, with the Organization, identify and manage them.	
Element III.1.B: The Investigator employs sound study design in accordance with the standards of the discipline, and implements reporting mechanisms that provide information to monitor the rights and welfare of participants enrolled in the research.	
Element III.1.C: In research involving greater than minimal risk to participants, the Investigator provides the IRB with plans for promptly detecting harm and mitigating potential injuries.	
Element III.1.D: The Investigator or research staff recruits participants in a fair and equitable manner, weighing the potential benefits of the research to the participants against their vulnerability and the risks to them.	
Element III.1.E: The Investigator determines that the resources necessary to protect participants are present before conducting the research study.	
Element III.1.F: The Investigator develops an informed consent process and method of documentation appropriate to the type of research and the study population, emphasizing the importance of participant	

comprehension and voluntary participation.	
Element III.1.G: The Investigator and research staff respond to participants' complaints or requests for information.	
Standard III-2: Investigators meet requirements for conducting research with participants and comply with all applicable federal, state, and local regulations and the Organization's policies and procedures for protecting research participants.	
Element III.2.A: Investigators and research staff are qualified by training and experience for their research roles, including knowledge of applicable federal, state, and local regulations; relevant professional standards; and the Organization's policies and procedures regarding the protection of research participants. Investigators understand the definition of human research and seek guidance when appropriate.	
Element III.2.B: Investigators assess and report unanticipated problems occurring during a research study in accordance with applicable federal, state, and local regulations and the Organization's policies and procedures.	A case of death must be reported directly to the EC.
Element III.2.C: Principal Investigators maintain appropriate oversight of their research protocols and research staff including recruitment, selection of study participants, and study conduct, and they appropriately delegate research responsibilities.	
Element III.2.D: The Investigator designs and carries out research studies with adequate data and safety monitoring during the research, when appropriate.	
Domain IV: Sponsor	
Standard IV-1: The Organization applies its Human Research Protection Program to all sponsored research.	
Element IV.1.A: The Organization has a written agreement with the sponsor that the Organization will use procedures that protect research participants.	
Element IV.1.B: The Organization has a written agreement with the sponsor that addresses medical care for research participants with a research-related injury.	
Standard IV-2: Before the initiation of the research study, Investigators or the Organization arrange for the timely communication of information with sponsors that might affect the ongoing oversight of a protocol by the IRB.	

Element IV.2.A: In studies where sponsors bear responsibility for monitoring of the research, the Organization has a written plan with the sponsor that the sponsor promptly reports to the Organization findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study.	
Standard IV-3: The Organization works with sponsors to ensure that the benefits of knowledge obtained through research are realized and that the interests of current and future research participants are protected.	
Element IV.3.A: Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that investigators and sponsors will play in publication or disclosure of results.	
Element IV.3.B: When participant safety or medical care could be directly affected by study results, the Organization addresses in the written agreement with the Sponsor how results will be communicated to study participants.	
Domain V: Participants	
Standard V-1: The Organization responds to the concerns of research participants.	
Element V.1.A: The Organization has and follows written policies and procedures that require each protocol to provide a procedure for research participants to ask questions and voice concerns or complaints to the Investigator.	
Element V.1.B: 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 was unaffiliated with the specific research protocol.	
Standard V-2: The Organization offers educational opportunities to participants, prospective participants, or their communities to enhance their understanding of research involving human participants.	

Element V.2.A: The Organization conducts activities (e.g., distribution of pamphlets, public relations, or community speaking engagements) designed to enhance understanding of human research by participants, prospective participants, or their community, when appropriate.	
Element V.2.B: The Organization periodically evaluates its outreach activities and makes changes when appropriate.	