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

ADDENDUM

State of Qatar

General Overview

The State of Qatar ("Qatar") Addendum to the *Evaluation Instrument for Accreditation* ("*Evaluation Instrument*") is intended for use by:

- organizations in Qatar seeking accreditation,
- AAHRPP peer reviewers evaluating organizations in Qatar, and
- accredited organizations in the US that conduct or oversee research in Qatar.

This Addendum includes Standards and Elements where Qatari law, regulations, and guidelines require significant additional protections beyond those defined in the *Evaluation Instrument*, or are significantly different from requirements in the *Evaluation Instrument*, and is intended to be used in conjunction with the *Evaluation Instrument*.

The Addendum focuses on the laws most relevant to human research protection programs, including research ethics committees. However, it is not an exhaustive account of all requirements covering research involving human participants in Qatar.

The Addendum is based on a review of the Qatar laws, policies, and guidance including, but not limited to:

- Policies, Regulations and Guidelines for Research Involving Human Subjects
- Standards of Good Clinical Practice - Standards of the International Council for Harmonization's E6 (Revision 1 and 2) "Good Clinical Practice" (ICH-E6 GCP)
- Guidelines on Reviewing and Reporting Unanticipated Problems Involving Risks to Subject or Others and Adverse Events

Requirements when following good clinical practice are included below.

This Addendum represents AAHRPP's current understanding of additional requirements covering organizations conducting or reviewing research in Qatar.

We appreciate questions, concerns, and suggestions to improve this document. Please email accreditation@aahrpp.org.

Domain I: Organization

Standard I-1: The organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the organization are knowledgeable about and follow the policies and procedures of the Human Research Protection Program.

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 should incorporate Essential Requirements under (1)(a), but not other requirements under this Element.

- AAHRPP will not request that organizations in Qatar add US FDA definitions to policies.

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.

When following Good Clinical Practice:

- Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with good clinical practice and the applicable regulatory requirements.

Element I.1.F. 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.

When following Good Clinical Practice:

- The available nonclinical and clinical information on an investigational product is adequate to support the proposed clinical trial.

Standard I-5: The organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.

Element I.5.D. The organization has and follows written policies and procedures for addressing allegations and findings of noncompliance with Human Research Protection Program requirements. The organization works with the Institutional Review Board or Ethics

Committee, when appropriate, to ensure that participants are protected when noncompliance occurs. Such policies and procedures include reporting these actions, when appropriate.

Qatar law does not appear to define serious or continuing noncompliance, and does not appear to define reporting requirements to a government office.

Policies should include the organization's definition of noncompliance, serious noncompliance, and continuing noncompliance.

Policies should define reporting requirements for researchers to the IRB/EC and organizational officials.

Policies should define review by the organization of serious and/or continuing noncompliance.

Standard I-6: The organization has and follows written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated.

Element I.6.B. The organization has and follows written policies and procedures to identify, manage, and minimize or eliminate individual financial conflicts of interest of researchers and research staff that could influence the conduct of the research or the integrity of the Human Research Protection Program. The organization works with the Institutional Review Board or Ethics Committee in ensuring that financial conflicts of interest are managed and minimized or eliminated, when appropriate.

Qatar law does not appear to define researcher and research staff conflict of interest requirements.

Policies should define equivalent protections.

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.B. The organization has and follows written policies and procedures to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements.

When following Good Clinical Practice:

- Where allowed or required, the researcher may assign some or all duties for accountability of investigational articles at the trial sites to an appropriate pharmacist or another appropriate individual who is under the supervision of the researcher.
- The researcher, pharmacist, or other designated individual will maintain records of the product's delivery to the trial site, the inventory at the site, the use by each participant, and the return to the sponsor or alternative disposition of unused products. These records will include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial participants.
- Researchers should maintain records that document adequately that the participants are provided the doses specified by the protocol and reconcile all investigational products received from the sponsor.
- If the researcher serves as a sponsor-researcher, the researcher is responsible for ensuring manufacturing, handling, and storage in accordance with applicable good manufacturing practice.

Standard I-9: The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected.

Policies must meet requirements under Standard I-9(1). AAHRPP will not request that organizations in Qatar add items under Standard I-9(2-7), except where the organization is required to follow these requirements under regulation.

Research collaboration with foreign institutions must provide IRB/EC approval from the foreign institution as well as IRB/EC approval from the Qatari institution to the funding body.

- Policies should describe who is responsible for ensuring IRB/EC approval from foreign institutions has been obtained and document this approval.

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.

IRB/EC rosters and membership must meet Essential Requirements under (1)(a) and (b).

Standard II-2: The IRB or EC systematically evaluates each research protocol or plan to ensure the protection of participants.

Element II.2.A. The IRB or EC has and follows written policies and procedures for determining when activities are exempt from applicable laws and regulations, when permitted by law or regulation and exercised by the IRB or EC. Such policies and procedures indicate that exemption determinations are not to be made by researchers or others who might have a conflict of interest regarding the studies.

Qatar allows certain research to be exempt from IRB/EC review. Exemption categories appear to be different from the revised US Common Rule, and do not allow exemptions under US FDA regulations. Review for conformity with the following exemption categories. AAHRPP will not request that organizations in Qatar add additional exemption categories in the *Evaluation Instrument*.

Category 1

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - Research on regular and special education instructional strategies, or
  - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - Information obtained is recorded in such a manner that human participants can be identified, and
  - Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Category 3

- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that participants cannot be identified.

Category 4

- Research and demonstration projects which are designed to study, evaluate, or otherwise examine:
  - Public benefit or service programs.
  - Procedures for obtaining benefits or services under those programs.
  - Possible changes in or alternatives to those programs or procedures.
  - Possible changes in levels of payment for benefits or services under those programs.

Category 5

- Taste and food quality evaluation and consumer acceptance studies if:
  - Wholesome foods without additives are consumed, or
  - A food is consumed that contains a food ingredient at or below the level found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe.

Element II.2.C. The IRB or EC has and follows written policies and procedures to conduct limited review by the IRB or EC, if such procedures are used.

Policies should not allow limited IRB/EC review.

AAHRPP will not request that organizations in Qatar add this to policies, except where the organization is required to follow these requirements under regulation.

Element II.2.F. The IRB or EC has and follows written policies and procedures to conduct reviews by an expedited procedure, if such procedure is used.

Continuing review at least annually is required for all non-exempt research, including minimal risk research.

Policies describe expedited criteria for research activities that present no more than minimal risk to human participants, and involve only procedures listed in one or more of the following categories:

Category 1

- Clinical studies of drugs and medical devices only when cleared/approved for marketing and the medical use.

Category 2

- Collection of blood samples by finger stick, heel stick, ear stick, or vein puncture.

Category 3

- Prospective collection of biological specimens for research purposes by noninvasive means.

Category 4

- Collection of data through noninvasive procedures.

Category 5

- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.

Category 6

- Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7

- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Expedited review may also be used to review:

- Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.
- For multicenter, multinational research projects which have been approved by the IRBs/ECs in their relevant countries, the

institutional Qatari IRB/EC may carry an expedited review provided that a copy of relevant research ethics information as approved by the other IRBs/ECs is submitted (see Standard I-9).

AAHRPP will not request that organizations in Qatar add US expedited review categories under the revised Common Rule or FDA regulations.

Element II.2.G. The IRB or EC has and follows written policies and procedures for addressing unanticipated problems involving risks to participants or others, and for reporting these actions, when appropriate.

Policies define an unanticipated problem involving risks to participants or others:

- The event is unexpected in terms of nature, severity, or frequency as given in the IRB/EC-approved research protocol and informed consent document.
- There is a reasonable possibility that it is related or possibly related to participation in the research; and
- The event suggests that the research places participants or others at a greater risk of harm than was previously known or recognized.

Policies define adverse event as:

- Any unfavorable medical occurrence including any abnormal sign, symptom, or disease temporally associated with the participant's participation in the research, whether or not considered related to the participant's participation in the research.

Policies define serious adverse event as any adverse event that:

- Results in death.
- Is life-threatening.
- Results in inpatient hospitalization or prolongation of existing hospitalization.
- Results in a persistent or significant disability/incapacity.
- Results in a congenital anomaly/birth defect; or based upon appropriate medical judgment, may jeopardize the participant's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Policies define timelines for reporting unanticipated problems involving risks to participants or others to the IRB/EC, organizational officials, the Department of Research at Qatar Ministry of Public Health, and the funding body:

- Unanticipated problems that are serious adverse events should be reported to the Ministry of Public Health within one week of the researcher becoming aware of the event.
- Any other unanticipated problem should be reported within two weeks of the researcher becoming aware of the problem.
- All unanticipated problems should be reported to appropriate organizational officials (as required by an institution's reporting procedures), the funding body, and the Department of Research at Qatar Ministry of Public Health within one month of the IRB's/EC's receipt of the report of the problem from the researcher.

When following Good Clinical Practice, problems researchers must report to the IRB/EC include:

- New information that might adversely affect the safety of the participants or the conduct of the clinical trial.
- Any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.

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.

Policies must include the basic and additional elements of consent. (See Table II.3.F.1.)

When following Good Clinical Practice:

- The IRB/EC determines that the following consent disclosures are included:
  - The approval or favorable opinion by the IRB/EC.
  - The probability for random assignment to each treatment.
  - The participant's responsibilities.
  - The alternative procedures or treatment that might be available to the participant, and their important potential benefits and risks.
  - When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
  - The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the participant.

    - When there is no intended clinical benefit to the participant, the participant should be made aware of this.
    - A statement that the monitors, the auditors, the IRB/EC, and the regulatory authorities will be granted direct access to the participant's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally authorized representative is authorizing such access.
    - A statement that if the results of the trial are published, the participant's identity will remain confidential.
- Documentation of the consent process includes:
    - Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the participant or by the participant's legally acceptable representative.
    - Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the person who conducted the informed consent discussion.
    - If a participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion.
        - After the written consent document and any other written information to be provided to participants is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the consent document, the witness should sign and personally date the consent document.
        - By signing the consent document, the witness attests that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that consent was freely given by the participant or the participant's legally acceptable representative.

- Prior to participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated written consent document and any other written information provided to the participants.

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.

The IRB/EC may waive or alter the consent process provided the IRB/EC finds and documents that:

- The research project is to be conducted by or subject to the approval of the Ministry of Public Health officials and is designed to study, evaluate, or otherwise examine:
  - Public benefit or service programs.
  - Procedures for obtaining benefits or services under those programs.
  - Possible changes in or alternatives to those programs or procedures; or
  - Possible changes in methods or levels of payment for benefits or services under those programs.
- The research involves no more than minimal risk to the participants.
- The waiver or alteration will not adversely affect the rights and welfare of the participants.
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

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.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.

Pregnant women or fetuses may be involved in research when:

- Scientifically appropriate, preclinical studies (including studies on pregnant animals), and clinical studies (including studies on

non-pregnant women), have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

- The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.
- Any risk is the least possible for achieving the objectives of the research.
- If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, consent is obtained.
- If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions described above except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
- For children as defined above who are pregnant, assent and permission are obtained.
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; except as a part of an approved randomized clinical trials in which a decision about timing, method, or procedure of delivery will be made by randomization; and
- Individuals engaged in the research will have no part in determining the viability of a neonate, except as a part of randomized clinical trial (RCT) in which the decision will be made by randomization.

Neonates of uncertain viability and nonviable neonates may be involved in research when:

- Scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- Individuals engaged in the research will have no part in determining the viability of a neonate.

Research involving neonates of uncertain viability may be involved in research only when the IRB/EC determines the following additional requirements are met:

- The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
- The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and,
- When the neonate survives as a result of any research intervention, they will be at a very high risk of adverse neuro-developmental outcome later in their life. This must be clearly explained to the parents at the time of obtaining their consent.
- Legally effective informed consent is obtained, and it is suggested that the individual researcher, IRB/EC, and the institution should have indemnity against the legal consequences of this outcome.

Research involving nonviable neonates may be conducted when the IRB/EC determines the following additional requirements are met:

- Vital functions of the neonate will not be artificially maintained.
- The research will not terminate the heartbeat or respiration of the neonate.
- There will be no added risk to the neonate resulting from the research.
- The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
- Legally effective informed consent has been obtained.

Research involving human tissue obtained after delivery, including the placenta, the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable laws and regulations regarding such activities.

- If information associated with material described above is recorded for research purposes in a manner that living

individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and all other requirements in the Addendum are applicable.

Prisoners may may be involved in research when:

- A majority of the IRB/EC (exclusive of prisoner members) shall have no association with the prison involved, apart from their membership on the Board; and
- At least one member of the IRB/EC shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board. Only one Board needs satisfy this requirement.
- The IRB/EC determines and documents the following additional determinations:
    - The research under review represents one of the categories of research permissible.
    - Any possible advantages accruing to the prisoner through their participation in the research are not of such a magnitude that their ability to weigh the risks of the research against the value of such advantages is impaired.
    - The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
    - Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal researcher provides to the Board justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
    - The consent form information is presented in language which is understandable to the participant population.
    - Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research, and each prisoner is clearly informed in advance that participation in the research will have no effect on their parole; and
- Where the IRB/EC finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of

individual prisoners' sentences, and for informing participants of this fact.

- The institution shall certify to the funding body and the Ministry of Public Health that the duties of the IRB/EC under this section have been fulfilled.

In addition to the requirements above, prisoners may may be involved in biomedical research when:

- The institution responsible for the conduct of the research has certified that the IRB/EC has approved the research; and
- In the judgment of the funding body and the Ministry of Public Health, the proposed research involves solely the following:
    - Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants.
    - Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants.
    - Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Ministry of Public Health has consulted with appropriate experts; or
    - Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB/EC to control groups which may not benefit from the research, the study may proceed only after the Ministry of Public Health has consulted with appropriate experts, of the intent to approve such research.

Children may may be involved in research when:

- For research not greater than minimal risk:
    - The IRB/EC finds that no greater than minimal risk to children is presented, and
    - Only if the IRB/EC finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

- Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants may be approved if the IRB/EC finds:
    - Research involves more than minimal risk to children but the intervention or procedure holds out the prospect of direct benefit for the individual participant, or
    - Research involves a monitoring procedure that is likely to contribute to the participant's well-being.
    - The IRB/EC determines:
        - The risk is justified by the anticipated benefit to the participants.
        - The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches; and
        - Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

Children may participate in research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition when the IRB/EC makes protocol-specific determinations that:

- The risk represents a minor increase over minimal risk.
- The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
- The intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition; and
- Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

Children may participate in research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children only if:

- The IRB/EC finds and documents protocol-specific determinations that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- The Ministry of Public Health, after consultation with a panel of experts, has determined:

- The research in fact satisfies the conditions applicable in this policy, or
- The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.
- The research will be conducted in accordance with sound ethical principles.
- Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

When children are involved in research, the IRB/EC shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB/EC the children are capable of providing assent. In determining whether children are capable of assenting, the IRB/EC shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB/EC deems appropriate. If the IRB/EC determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB/EC determines that the participants are capable of assenting, the IRB/EC may still waive the assent requirement under circumstances in which consent may be waived as described above.

- The IRB/EC shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB/EC may find that the permission of one parent is sufficient for research to be conducted.
- In addition to the provisions for waiver of consent, if the IRB/EC determines that a research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and provided further that the waiver is not inconsistent with current laws. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk

and anticipated benefit to the research participants, and their age, maturity, status, and condition.

- Permission by parents or guardians shall be documented in accordance with and to the extent required by this policy.
- When the IRB/EC determines that assent is required, it shall also determine whether and how assent must be documented.
- If the research requires making videos or photographs of women and/or children, the IRB/EC should strictly scrutinize this and eliminate every possibility of any misuse of these videos or photographs for any purpose.

When following Good Clinical Practice for studies involving adults unable to consent, the IRB/EC determines:

- A non-therapeutic clinical trial (i.e., a trial in which there is no anticipated direct clinical benefit to the participant) should be conducted in participants who personally give consent and who sign and date the written consent document.
- Non-therapeutic clinical trials may be conducted in participants with consent of a legally acceptable representative provided the following conditions are fulfilled:
    - The objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally.
    - The foreseeable risks to the participants are low.
    - The negative impact on the participant's wellbeing is minimized and low.
    - The clinical trial is not prohibited by law.
    - The opinion of the IRB/EC is expressly sought on the inclusion of such participants, and the written opinion covers this aspect.
    - Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

Element II.4.C. The IRB or EC has and follows written policies and procedures for making exceptions to consent requirements for planned emergency research and reviews such exceptions according to applicable laws, regulations, codes, and guidance.

Qatar law does not appear to have provisions for planned emergency research without consent.

When following Good Clinical Practice, consent of the participant or permission of a legally authorized representative must be obtained as soon as practicable if participants are enrolled in research without consent.

Domain III: Researcher and Research Staff

Standard III-1: In addition to following applicable laws and regulations, Researchers and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers and Research Staff have the protection of the rights and welfare of research participants as a primary concern.

Element III.1.C. Researchers employ sound study design in accordance with the standards of their discipline. Researchers design studies in a manner that minimizes risks to participants.

When following Good Clinical Practice:

- During and following a participant's participation in a clinical trial, the researcher ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the clinical trial.
- The researcher follows the clinical trial's randomization procedures, if any, and ensures that the code is broken only in accordance with the protocol. If the clinical trial is blinded, the researcher promptly documents and explains to the Sponsor any premature unblinding.
- A qualified physician (or dentist, when appropriate), who is a researcher or a co- researcher for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions.
- Researchers inform participants when medical care is needed for other illnesses of which the researchers become aware.

Element III.1.E. Researchers and Research Staff recruit participants in a fair and equitable manner.

When following Good Clinical Practice:

- The researcher informs the participant's primary physician about the participant's participation in the clinical trial if the participant has a primary physician and if the participant agrees to the primary physician being informed.

- Although a participant is not obliged to give their reasons for withdrawing prematurely from a clinical trial, the researcher makes a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

Standard III-2: Researchers and Research Staff meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.

Element III.2.A. Researchers and Research Staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the organization's policies and procedures regarding the protection of research participants.

When following Good Clinical Practice:

- The researcher provides evidence of their qualifications through up-to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB/EC, or the regulatory authority.
- The researcher is familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator's brochure, in the product information, and in other information sources provided by the sponsor.
- A qualified physician (or dentist, when appropriate), who is a researcher or a co-researcher for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions (not applicable to independent IRBs/ECs).
- During and following a participant's participation in a clinical trial, the researcher ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the clinical trial (not applicable to independent IRBs/ECs).
- The researcher ensures the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.
- The researcher permits monitoring and auditing by the sponsor and inspection by the appropriate regulatory authority.
- The researcher maintains the clinical trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirements.

- Essential documents are retained until at least two years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least two years have elapsed since the formal discontinuation of clinical development of the investigational product.

Element III.2.B. Researchers maintain appropriate oversight of each research study, as well as Research Staff and trainees, and appropriately delegate research responsibilities and functions.

When following the Good Clinical Practice:

- The researcher must maintain a list of appropriately qualified persons to whom they have delegated significant clinical trial-related duties.

Element III.2.D. Researchers and Research Staff follow reporting requirements in accordance with applicable laws, regulations, codes, and guidance; the organization's policies and procedures; and the IRB's or EC's requirements.

When following the Good Clinical Practice:

- The researcher reports all serious adverse events (SAEs) to the sponsor except for those SAEs that the protocol or other document (e.g., investigator's brochure) identifies as not needing immediate reporting. The researcher follows regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the IRB/EC.
- The researcher reports adverse events or laboratory abnormalities identified in the protocol as critical to safety evaluations to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.
- For reported deaths, the researcher supplies the sponsor and the IRB/EC with any additional requested information (e.g., autopsy reports and terminal medical reports).
- The researcher provides written reports to the sponsor, the IRB/EC, and, where applicable, the organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.
- If the researcher terminates or suspends a clinical trial without prior agreement of the sponsor, the researcher informs the organization, sponsor, and the IRB/EC.

- If the IRB/EC terminates or suspends approval of the clinical trial, the researcher promptly notifies the sponsor.
- Upon completion of the clinical trial, the researcher informs:
    - The organization.
    - The IRB/EC with a summary of the trial's outcome; and
    - The regulatory authority with any reports required.