



AAHRPP®

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

United Arab Emirates – Abu Dhabi

Addendum

Domain I: Organization

The United Arab Emirates is a federation of seven monarchies, including the Emirate of Abu Dhabi. There are laws governing research at both the federal- and emirate-level. At the federal-level the Ministry of Health has requirements governing research involving human participants. Department of Health - Abu Dhabi is the regulatory authority for research involving human participants in the Emirate of Abu Dhabi. There are some differences between emirate requirements. As such, this Addendum focuses on Abu Dhabi (see the United Arab Emirates - Dubai Addendum for requirements for research in Dubai).

This Addendum to the Evaluation Instrument for Accreditation is intended for use by organizations in Abu Dhabi seeking accreditation, by site visitors evaluating organizations in Abu Dhabi, and by accredited organizations in the US that conduct or oversee research in Abu Dhabi. This Addendum includes Standards and Elements where Abu Dhabi or United Arab Emirates laws, regulations, and guidelines require significant additional protections beyond those defined 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.

Organizations in Abu Dhabi must comply with the following laws, policies, and guidance:

- United Arab Emirates Ministry of Health
 - Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices (2017)
 - Guidance for conducting Clinical Trials Based on Drugs/ Medical Products & Good Clinical Practice (2006)
 - Federal Law No. (4) of 2016 (requiring insurance for clinical trials)
- Abu Dhabi Department of Health
 - Abu Dhabi DOH Standard on Human Subjects Research (January 2020); the DOH Standard mandates the use of specific forms.
 - Abu Dhabi DOH Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices (January 2020)

- Policy Governing the Ethical Conduct of Human Subjects Research (2010)
- Abu Dhabi DOH/HAAD Research Ethics Committee (REC) Standard Operating Procedures (SOPs) (The DOH/HAAD REC SOPs meet the obligations of DOH/HAAD under UAE Federal Law No. (10) of 2008 regarding Medical Liability and DOH/HAAD policies regulating health research in the Emirate of Abu Dhabi for the operation of the Abu Dhabi Research Ethics Committee (ADREC) and institutional Research Ethics Committees (RECs) to oversee the conduct of clinical trials and other human health research. All institutional RECs authorized by DOH/HAAD must comply with these SOPs.) They also apply to the Abu Dhabi Research Ethics Committee, established under the auspices of the Abu Dhabi Health Research Council.
- Chapter VII of the Health Regulator Manual

All clinical trials must adhere to ICH-GCP (E6)(R2) (required in DOH Standard on Human Subjects Research, 4.2.3. and Chapter VII of the Health Regulator Manual)

This Addendum represents AAHRPP's understanding of additional requirements covering organizations conducting or reviewing research in Abu Dhabi as of the date of publication.

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

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 and procedures include the following definitions:

- Human subject: A living individual about whom an investigator obtains:
 - Data from intervention or interaction with and/or

- Identifiable private information (e.g. examining student records to ascertain grade point averages)
- Research: A “systematic investigation designed to develop or contribute to generalizable knowledge beyond a particular setting.” This includes findings that are presented as a poster or paper at a conference, at Student Symposium, on a website, or that may be published, and student work presented outside of the classroom.
- Human Subject Research: Any activity falling within one or more of the following categories:
 - Studies of a physiological, biochemical or pathological process, or of the response to a specific intervention – whether physical, chemical or psychological – in healthy subjects or in patients.
 - Controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalizable response to these measures against a background of individual biological variation.
 - Studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures.
 - Studies concerning human health-related behavior in a variety of circumstances and environments.
 - Activities that are not considered “research” for the purpose of this Standard include:
 - Research on normal educational practices such as instructional strategies, curricula or classroom management techniques. Experiments with class format and/or use of student evaluation to improve teaching.
 - Journalism: Journalists and investigative reporters who are writing stories for news publications unless ethical approval is required.

(DOH Standard on Human Subjects Research, 3.18, 3.31, 3.32)

- Clinical trial: means any investigation in relation to humans intended:
 - To discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of one or more investigational products;
 - To identify any adverse reactions to one or more investigational products; or

- o To study the absorption, distribution, metabolism and excretion of one or more investigational products; with the objective of ascertaining the safety and/or efficacy of those investigational products. The terms clinical study and clinical trial are synonymous.
- A trial subject (human participant) involved in research: means an individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control. The trial subject can be any of the following:
 - o A healthy volunteer;
 - o A patient whose disease is not related to the administration of the investigational product; or
 - o A patient whose disease is related to the use of the investigational product.

(Guidelines for Conducting Clinical Trials with Investigational Products, 2; Standard Operating Procedures for Research Ethics Committees, Annex B)

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 the steps the organization takes to ensure that for research involving critical subjects, that after approval in principle by the Research Ethics Committee, research does not start until review and approval is obtained from the Abu Dhabi Health, Research and Technology Council (ADHRTC) for:

- Multi-center studies;
- Clinical Trials/studies;
- Any pharmaceutical sponsored research;
- Any research that carries significant or potential risk to human subjects (patients);
- Any research with genetic material;
- Processing of medical data outside UAE for research purpose;
- Genomics-related research;

Clinical trials with interventional design, may begin when the following conditions are fulfilled:

- the Ethics Committee (ADHRTC and REC) has given a positive opinion;
- the Regulatory Committee at the Department of Health (DOH) has issued a written approval and;

Drug Control Department at the Ministry of Health and Prevention (DCD), in addition to drug and medical product department in the Abu Dhabi DOH, has issued an import license.

Clinical trials with non-interventional design may begin when the following conditions are fulfilled:

- the Ethics Committee (ADHRTC or REC/IRB) has given a positive opinion, and
- the Regulatory Committee at the Department of Health (DOH) has been notified in writing prior to
- the first subject being enrolled.

(DOH Standard on Human Subjects Research, Appendix 2)

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.

Human subjects research must conform to generally accepted international principles and values of ethical conduct in research, as described in the Nuremberg Code, Declaration of Helsinki, and the Belmont Report.

Clinical trials must follow the Declaration of Helsinki.

Clinical trials must follow ICH-GCP (E6)(R2)

(Guidelines for Conducting Clinical Trials with Investigational Products, 3.1; Health Authority – Abu Dhabi Policy Governing Research Involving Human Subjects, 11)

Element I.1.E. The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.

Prior to participating in human subjects research, all investigators and research personnel shall receive HAAD certification by successfully completing a research ethics training course accredited by Health Authority – Abu Dhabi, including the Basic Course for the Protection of Human Research Subjects” provided by the Collaborative Institutional Training Initiative (CITI).

Each investigator shall be required to renew DOH/HAAD certification at least every three (3) years by taking a refresher course in research

ethics, such as the CITI “Refresher Course for the Protection of Human Research Subjects.”

(Health Authority – Abu Dhabi Policy Governing Research Involving Human Subjects, 13)

For clinical trials, researchers must have an updated, recent GCP certification, provided by an approved GCP training organization for investigator is expected to have been completed.

(Guidelines for Conducting Clinical Trials with an Investigational Product, 7.7)

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.

A Research Ethics Committee must notify the Abu Dhabi Department of Health where one of the following is suspected:

- Conduct of a trial without regulatory authorization or favorable Research Ethics Committee opinion.
- Provision of false or misleading information to the Research Ethics Committee in relation to an application for ethical opinion or notification of substantial amendment.
- Implementation of a substantial amendment without authorization and/or a favorable opinion as appropriate.
- Failure to notify SUSARs occurring in a trial in an expedited manner or to provide an Annual Safety Report.
- Failure to notify urgent safety measures.
- Failure to notify the early termination or conclusion of the trial.
- A serious breach of ICH GCP or the research protocol. A breach of the conditions and principles of ICH GCP or the research protocol should be regarded as “serious” if it is likely to affect

to a significant degree the safety or physical or mental integrity of the participants or the scientific value of the trial.

- Any other fraud or serious misconduct.
- Consideration should also be given to notifying the authorities where a pattern emerges of repeated minor breaches of ICH GCP or the research protocol.

(DOH Standard on Human Subjects Research, 4.2.6.)

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.

Policies and procedures describe a process for researchers to disclose fully to the REC when submitting its Research Proposal any financial or other conflict of interest that may exist in relation to any of the proposed researchers. The circumstances that must be disclosed include, but are not limited to, the existence of:

- any agreement between an Investigator and any person (including the Institution) under which the value of compensation paid to the Investigator for conducting the Research could be influenced by its outcome;
- any proprietary interest held by an Investigator in any product which is a subject of the Research;
- any financial interest held by an Investigator in a company or body which may benefit from the outcome of the Research (not including his or her employment status with the Institution);
- any non-financial benefits which may be available to an Investigator depending on the outcome of the Research.

Organizations in Abu Dhabi do not need to follow US Public Health Service conflict of interest rules, or other US conflict of interest rules, unless engaged in research studies covered by US regulations.

(Health Authority – Abu Dhabi Policy Governing Research Involving Human Subjects, 9.3)

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 to ensure approval by the Abu Dhabi Department of Health and/or UAE Ministry of Health prior to starting a clinical trial of an investigational medicinal product:

- The sponsor must obtain authorization from DOH and/or MOH before the commencement of the clinical trial.
- Evidence of the authorization should be forwarded to the facility's REC when available (if not already provided to the Committee).
- Where DOH and/or MOH requests significant changes to the research protocol before confirming authorization, or attaches any other condition requiring substantial amendments to be made to the terms of the REC application or the supporting documentation, a Notification of Substantial Amendment form should be submitted to the facility's REC.
- Creating Clinical Trials Registry and include the commenced CTIMP in addition to patients' information registry.

(DOH Standard on Human Subjects Research, 4.2.6.; Guidance for conducting Clinical Trials Based on Drugs/ Medical Products & Good Clinical Practice)

Element I.7.C. The Organization has and follows written policies and procedures for compliance with legal and regulatory requirements governing emergency use of an investigational or unlicensed test article.

Policies and procedures describe the process for "compassionate use" where the immediate use of the investigational product is, in the investigator's opinion, required to preserve the life of the subject:

- The decision should be taken by at least two physicians not involved in the research team and should be documented.

- And if the time is not sufficient to obtain the independent determination specified in under item 19.1.1 in advance of using the investigational product, the determinations of the clinical investigator should be made and, within 5 working days after the use of the product, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. This should be documented.
- The documentation in support of items should be submitted to the IRB/REC within 5 working days after the use of the investigational product.
- The duty of an Investigator to obtain Informed Consent in accordance with the requirements of this Chapter shall not apply in the case of an individual Subject where all of the following conditions are satisfied:
 - o the Subject is confronted by a life-threatening situation necessitating the use of an unproven treatment, medical device or product that is the subject of the Research;
 - o the Subject is incapable of communicating with the Investigator due to his or her medical condition;
 - o there is insufficient time to obtain Informed Consent from the Subject's legally authorized representative;
 - o there is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the Subject; and
 - o both the Investigator and a physician who is not otherwise participating in the Research certify in writing that all of the above conditions are met and submit that certificate to the REC within five (5) working days.

(Guidelines for Conducting Clinical Trials with an Investigational Product, 19; Health Authority – Abu Dhabi Policy Governing Research Involving Human Subjects, 17)

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 agreement with the Sponsor that addresses medical care for research participants with a research-related injury, when appropriate.

See Element II.3.C. in this Addendum.

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.

A facility REC should be set up within one single clinical establishment and its composition should be specified by an order of the Institution Head.

(Guidelines for Conducting Clinical Trials with an Investigational Product, 19)

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.

According to REC rosters:

- Each IRB or EC has at least five members with varying backgrounds to promote complete and adequate review of research commonly conducted by the organization. (See II.2.E., where quorum is defined as at least seven (7) members).
- No IRB or EC has members who are all males or all females.
- No IRB or EC has members who represent a single profession.
- Each IRB or EC has at least one member whose primary concerns are in scientific areas.
- Each IRB or EC has at least one member whose primary concerns are in nonscientific areas.
- Each IRB or EC has at least one member who is not otherwise affiliated with the organization and who is not part of the

immediate family of a person who is affiliated with the organization.

- Each IRB or EC has at least one member who represents the perspective of research participants.

In addition, policies and procedures should include the following guidance:

- Committee members should be selected from departments that have the most active clinical research programs. Committee members must have a research interest and a record of indexed publications to qualify to be a REC member (with exception to the outside/lay member).
- Membership of REC should be multidisciplinary and include to the extent possible: experts from within the facility, members with relevant clinical and/or methodological expertise, lay members and members who are independent of the facility.

(Abu Dhabi DOH Standard on Human Subjects Research, Appendix 3)

Policies and procedures indicate:

- A healthcare provider or facility seeking to conduct human subject research must apply for and have a Facility Research Authorization granted by DOH for that Facility to conduct Human Subject Research.
- A healthcare provider/facility seeking DOH authorization to Conduct Human Subject Research must ensure that a Research Ethics Committee is established and maintained for each facility that holds a Facility Research Authorization.

(DOH Standard on Human Subjects Research, 4.1, 4.2)

Policies and procedures include the following guidance:

The Ethics Committee should consist of:

- medical and scientific professionals with sufficient qualifications and experience
- at least one-third of the members being legal professionals or social workers in non-medical and non-scientific areas.

(Guidance for conducting Clinical Trials Based on Drugs/ Medical Products & Good Clinical Practice, 3.3)

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.

Policies and procedures describe the process for making exemption determinations:

- In the case of Exempt research, REC chair should review the proposal and advise the principal investigator of the outcome.
- The researcher may not determine whether a study is exempt. The following exempt categories are permitted:

Policies and procedures define exempt criteria:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - o research on regular and special education instructional strategies; or
 - o research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - o information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - o any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation.
 - o This exemption only applies to research involving children if the investigator does not participate in the public activities being observed. The exemption does not apply to research involving children where the research involves survey or interview procedures or any direct interaction with participants under observation.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (I)(B) of this policy, if:
 - o UAE or Abu Dhabi law(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- 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 investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs;
 - o procedures for obtaining benefits or services under those programs; or
 - o possible changes in or alternatives to those programs or procedures; or
 - o possible changes in methods or levels of payment for benefits or services under those programs.
- Taste and food quality evaluation and consumer acceptance studies,
 - o if wholesome foods without additives are consumed; or
 - o if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Abu Dhabi Food Control Authority or Abu Dhabi Environment Agency.

The exemptions do not apply to research involving prisoners.

(Abu Dhabi DOH/HAAD Research Ethics Committee (REC) Standard Operating Procedures, 7.7; DOH Standard on Human Subjects Research, 6a)

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.

Limited IRB/EC review as defined in US regulations does not appear to be permitted under Abu Dhabi laws. Even when research is covered by the US Common Rule, Abu Dhabi law supersedes the Common Rule provisions for limited IRB/EC review.

If an application for accreditation includes limited IRB review, contact AAHRPP Staff.

Element II.2.E. The IRB or EC has and follows written policies and procedures to conduct reviews by the convened IRB or EC.

Policies and procedures define quorum:

The quorum for meetings of the REC is seven members, including the following:

- The Chair or, if unavailable, the vice-Chair; and
- At least one expert member, with relevant clinical and/or methodological expertise; and
- One lay member; and
- At least one other member who is independent of the institution or specific location where the research is to take place.

(Abu Dhabi DOH Standard on Human Subjects Research, 4; Standard Operating Procedures for Research Ethics Committees, 3.1)

Policies and procedures indicate the decisions available to the REC:

- Favorable: The Principal Investigator shall be notified within 10 days and the trial shall commence within 12 months
- Unfavorable: The applicant shall be given a full explanation of the REC's reasons and may re-submit a new application taking due account of the REC's concerns
- Provisional opinion with request for further information: The researcher must provide additional information within 60 days.
- No opinion and request for advice from a referee: Where additional expertise is required to review the research.

(Abu Dhabi DOH/HAAD Research Ethics Committee (REC) Standard Operating Procedures, 4)

Our current understanding is that the use of the following forms are mandatory for all projects submitted to REC as full board review, and must be included in applications for accreditation:

- REC form 001 (Application Checklist)
- REC form 002 (Application)
- REC form 003 (Studies with Medical Devices Use)
- REC form 004 (Use of Drugs and/or Biological Products in Research)
- REC form 005 (Use of Stem Cell, Zygotes, Gametes and Fetuses in Research)
- REC form 006 (Study Progress Report)
- REC form 007 (Request to Amend a Currently-Approved Project)
- REC form 008 (ADHRTC Risk Assessment)
- DOH form (Adverse Event Reporting form)
- REC CV template
- Conflict of Interest Form
- Certificate of Confidentiality

(DOH Standard on Human Subjects Research, Appendix 4)

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.

There is no statutory provision for the expedited review of applications; however, a REC may issue an opinion. (Standard Operating Procedures for Research Ethics Committees, 6)

Policies and procedures describe when research is eligible for review using an expedited procedure.

- Research that poses only minimal risk to participants can be handled as Expedited. “Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- In case of Expedited research, the REC Chair and one other member of REC should review the proposal and advise the principal investigator of the outcome.
- Activities approved for Expedited review include:
 - o Collection of biological specimens through non-invasive means; for example, electrocardiography, electroencephalography, thermography, Doppler blood flow, echocardiography, functional magnetic resonance imaging;
 - o Clinically routine non-invasive procedures such as muscular strength testing, moderate exercise, body composition assessment, flexibility testing involving health subjects;
 - o Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, surveys, interviews, and focus groups) as follows:
 - involving adults, where (i) the research does not involve stress to subjects; and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;
 - involving children, where (i) the research involves neither stress to subjects nor obtaining of sensitive information about themselves, or their family; (ii) parents/guardians will complete the usual consent form (i.e. there is no request for a waiver); (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be

- damaging to the financial standing, employability, or reputation of themselves or their family members;
- o Collection of data from voice, video, digital or image recordings, as long as identification of the subjects and/or their responses does not place them at risk for criminal or civil liability, or damage their financial standing, employability or reputation;
- o Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials have been collected prior to the research for a purpose other than the proposed research, confidentiality should be strictly maintained, and information should not be recorded anonymously (e.g., use will be made of audio or videotapes, names will be recorded, even if they are not directly associated with the data);
 - In case where data or human subject's biospecimens, whether collected prospectively or retrospective, banked, are shared outside the supervision of the REC, a data and material sharing agreement should be required between the parties involved with sufficient information with confidential material transfer agreement, both in Arabic and English languages). Furthermore, Certificate of Confidentiality should be signed.
- o Continuing review of non-exempt research previously approved by the REC, where no new subjects will be enrolled or where the research involves no greater than minimal risk.

(DOH Standard on Human Subjects Research, 6b)

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 and procedures describe the following reportable events:

- Adverse reaction/event: In a Clinical Trial of an Investigational Medical Product (IMP) any untoward and unintended response in a subject to an IMP which is related to any dose administered to that subject.
- Unexpected Adverse Reaction: An adverse reaction is considered to be "unexpected" if its nature and severity are

not consistent with the information about the medicinal product set out in the trial documentation.

- Serious Adverse Reaction/Event: is an untoward and unintended response to an IMP at any dose that:
 - Results in death;
 - Is life threatening;
 - Requires hospitalization or prolongation of existing hospitalization;
 - Results in persistent or significant disability or incapacity;
 - Consists of a congenital anomaly or birth defect;
 - Or is otherwise considered medically significant by the investigator.
 - Such events must be reported by the researcher to the REC within seven days.
- Suspected Serious Adverse Reaction (SSAR): An adverse reaction is “serious” if it:
 - Results in death
 - Is life-threatening
 - Requires hospitalization or prolongation of existing hospitalization
 - Results in persistent or significant disability or incapacity
 - Consists of a congenital anomaly or birth defect.
- Suspected unexpected serious adverse reaction (SUSAR): A “suspected unexpected serious adverse reaction” (SUSAR) is a SSAR which is also “unexpected”, meaning that its nature and severity are not consistent with the information about the medicinal product in question as set out:
 - In the case of a product with a marketing authorization, in the summary of product characteristics for that product.
 - In the case of any other investigational medicinal product, in the investigator’s brochure relating to the trial in question.

Policies and procedures specify that the following must be reported to the REC and DOH within 15 days:

- An increase in the rate of occurrence or a qualitative change of an expected serious adverse reaction, which is judged to be clinically important.

- Post-study SUSARs that occur after the patient has completed a trial and are reported by the investigator to the sponsor.
- A new event, related to the conduct of the trial or the development of the IMP, that is likely to affect the safety of subjects, such as:
 - o A serious adverse event which could be associated with the trial; procedures and which could modify the conduct of the trial (for example a SAE occurring during the run-in period);
 - o A significant hazard to the subject population such as lack of efficacy of an IMP used for the treatment of a life threatening disease;
 - o A major safety finding from a newly completed animal study (such as carcinogenicity);
 - o Any anticipated end or temporary halt of a trial for safety reasons where the trial is conducted with the same IMP by the same sponsor in another country;

(DOH Standard on Human Subjects Research, 3, 5.9; Guidelines for Conducting Clinical Trials with an Investigational Product, 41)

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 describe when the REC/IRB may approve the use of a placebo in research by making the following determinations:

A researcher may, in carrying out research involving human participants, withhold from participants a therapy that is known to be superior to an intervention being tested only in cases where there either is no established effective therapy or where:

- withholding an established effective therapy would expose the participants to no more than temporary discomfort or delay in the relief of symptoms;
- the use of an established effective therapy as a comparator would not yield scientifically reliable results; and
- the use of a placebo would not increase any risk of serious or irreversible harm to the participants.

(Abu Dhabi Policy Governing Research Involving Human Subjects, 20)

Element II.3.C. The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants.

Organizations, researchers, and sponsors are responsible for ensuring that insurance cover is adequate to protect the investigators and the institutions from legal liability in case of injury or death.

Applicants and the facilities in which they are conducting the research must show that:

- The financial arrangements, including insurance or indemnity, cover the research study concerned.
- The sponsor, research protocol authors, investigators/collaborators and, where applicable, Site Management Organizations will all be protected by insurance or indemnity arrangements.
- The arrangements will provide adequate cover to meet the potential liability assessed by the sponsor.

(DOH Standard on Human Subjects Research, 5.1; Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices, 11, 12, 29; Guidance for conducting Clinical Trials Based on Drugs/ Medical Products & Good Clinical Practice, 2.6)

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.

Abu Dhabi consent requirements are consistent with the Evaluation Instrument, Table II.3.F.1. and must include:

- the basic elements of consent disclosure
- additional elements of disclosure
- additional requirements when following the ICH-GCP (E6) Guideline

In addition, consent disclosures include a statement addressing any cultural or religious concerns of the Subject.

(Policy Governing the Ethical Conduct of Human Subjects Research, 15-16)

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 indicate that an exception to the duty of a researcher to obtain consent shall not apply in the case of an individual participant where all of the following conditions are satisfied:

- the participant is confronted by a life-threatening situation necessitating the use of an unproven treatment, medical device or product that is the subject of the research;
- the Subject is incapable of communicating with the researcher due to his or her medical condition;
- there is insufficient time to obtain informed consent from the Subject's legally authorized representative;
- there is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the Subject; and
- both the Investigator and a physician who is not otherwise participating in the research certify in writing that all of the above conditions are met and submit that certificate to the REC within five (5) working days.

(Policy Governing Research Involving Human Subjects, 17)

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.

Minors-Clinical trials on minors may be undertaken provided that:

- The protocol has been approved by the IRB/REC after discussion of the clinical, moral and psycho-social of the impact on childhood, in which at least two pediatricians have taken part;
- A direct benefit is expected from the clinical trial for the group of patients that will be included in it;
- The clinical trial is directly related to the clinical condition of the minors;
- The medicinal product tested is intended to be used for diagnosis, treatment or prevention of diseases that are specific to minors;
- The purpose of the trial is to verify data obtained from clinical trials on individuals that are able to give informed consent or data obtained through other research methods, and the results

obtained from clinical trials on adults and their interpretation may not also be considered valid for minors and young persons;

- The trial is planned in a way to minimize pain, inconvenience, fear and other foreseeable risks associated with the disease, and the level of risk and physical pain have been predefined and are constantly controlled during testing;
- No financial or other incentives are provided.

(This is the only permissible circumstance when children may participate in research. Abu Dhabi law supersedes Subpart D in DHHS and FDA regulations; Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices, 21; DOH Standard on Human Subjects Research, 6.7)

In addition, policies indicate that:

- Minors (less than 18 years of age) cannot give legal permission to participate in research. In these instances, the researcher must prepare an Informed Consent form for parents (or legal guardians) to sign on their child's behalf.
- Additionally, children must be assessed by the PI before obtaining consent and they must also agree (assent) to participate in the research study, either in writing or verbally.
- Written assent will typically be appropriate for children aged eight (8) and above.

(Abu Dhabi DOH Standard on Human Subjects Research, 6.7)

Clinical trials on adults unable to consent may be undertaken provided that:

- The IRB/REC, involving specialists with competence in respect to the disease concerned or to the group of patients, has approved the protocol after discussing the clinical, moral and psycho-social aspects of relevance to the particular disease and to the group of patients;
- It may be expected that taking the medicinal product tested would bring benefits exceeding the risks or that risks have been fully eliminated;
- The purpose of the trial is to check data obtained through clinical trials on humans who are able to give informed consent or of data obtained through other research methods;
- The trial is directly connected to a life-threatening or disabling disease or any other diseases of which the adult person concerned who is not able to give informed consent suffers;
- The clinical trials have been planned so that pain, inconvenience, fear and other foreseeable risks associated with the disease have been reduced to a minimum and the level of risk and the

degree of physical pain have been set in advance and are constantly monitored during the trial;

- No financial and other incentives are provided.

(Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices, 22)

Clinical trials on pregnant and breast-feeding women may only be undertaken if the REC determines:

- The medicinal product concerned is required for their treatment and may not be tested on any other group of patients.

(This is the only permissible circumstance when pregnant or breastfeeding women may participate in research. Abu Dhabi law supersedes Subpart C in DHHS regulations; Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices, 23)

Research involving genomics may be undertaken where the REC:

- Provides ethical review of research using human tissue collected, stored and used at the Facility.
- Undertakes ethical review in a proportionate way, taking account of any material risk of harm or distress to donors, their families and other research participants.
- Facilitates valuable research using human tissue of benefit to society, within the legal framework of the UAE.

For genomics studies, the REC must determine:

- Processing and handling of genomic samples and data should be conducted in a manner that protects the confidentiality of subjects' individual data.
- Highest security measures using coding schemata and restriction of access should be implemented at each step of analysis and storage.
- Research proposing storage of genetic data outside the institutional premises (e.g. universities and non-health institutions within UAE) needs approval from ADHRTC.
- Suitable consideration should also be given to data protection and confidentiality legislation and policies from DOH and UAE federal laws.
- When use of genomic samples and data may involve repeated access over time in accordance with the informed consent, the REC must consider:
 - o Strategies and procedures involving systems that ensure strict control of access rights with access logs should be established for all genomic samples and data for each project, similar to that for other clinical data.

- o When outsourcing sample storage, genomic analysis or data storage outside the institutional premises, contractual agreements must specify that the responsible party will supervise the outsourced facility in an appropriate manner to ensure that the samples and/or data are properly safeguarded.
 - o The ADHRTC must be notified of these outsourcing arrangements.
 - o The outsourcing of Genomics analysis or data outside UAE is strictly prohibited.
- The study includes a plan or position that describes transparency and return of findings to subjects and their primary healthcare providers.
 - o The position must articulate whether the intended research findings, incidental findings, neither or both will be communicated. Ideally, the position would describe the timing of such communication (during or after the clinical study) and to whom (subject or in case of children and incapacitated individuals) as appropriate.
 - o The decision on whether to return research results to participants must be made by the study investigator in consultation with REC. This decision, including the format and process for returning results, must be clearly communicated.
 - o If results are agreed to be communicated, it must be communicated by a genetic counsellor accompanied by the principal investigator.
 - o The applied assay and its level of validation must also be considered before communicating any results.
 - o The PI is not to communicate a genomics related results to the affected individual without prior consideration to the short and long term effects and proper consultation with subject matter experts.
 - o The person(s) responsible for communicating the findings will also need consideration and usually this would be the investigator, with a link to the informed consent.
 - o The subject's desire and consent to receive such information or not must be respected.
 - o Arrangements should be in place for appropriate counselling (if required) and offered following disclosure of information to participants.
- The study describes plans for storage of genomic data, in order to assure confidentiality:

- o Identifying information or coding keys must be destroyed as soon as possible. (However, Consent Forms must be kept for a minimum of three years after the research project ends, or more if required by specific authorizing or sponsoring agencies.)
 - o Raw data must be archived in a secure location within the Emirate.
 - o Paper records must be kept in a secure locked file or office.
 - o Portable electronic records (e.g., laptop computer, PDA, flash or zip drive, CD or DVD, external hard drive) must be kept in a locked office or password protected and communicated through secure mail.
 - o Non-portable electronic records (e.g. data accessed via the Web) must be maintained on a Local network with restricted access (e.g., a shared drive).
 - o Storage of genetic analysis raw data outside health facility is not allowed unless permitted by ADHRTC.
 - o Usage of cloud storage solutions is prohibited.
- The study describes which additional individuals, in addition to the principal investigator, will have access to identifiable data.
 - o Each of these individuals must sign a confidentiality form to be kept by the investigator.
 - o In this context, temporary employee, part time employee or an external employee who does not belong to the same institution as that of the PI will not be allowed to have access to the secure identifiable data of the subjects.
- The study describes plans for the reporting of Genomic Data:
 - o Identifiable information about individual subjects should not be disclosed during any phase of the clinical trial without the subject's explicit consent.
 - o Aggregated (grouped) data will be reported with potentially-identifiable information (e.g., demographic descriptors) removed.

(DOH Standard on Human Subjects Research, 6; Health Authority – Abu Dhabi Policy Governing Research Involving Human Subjects, 22)

For research involving human tissues, the following additional requirements apply:

The following research involving human tissues must receive approval from the facility REC and regulatory authority:

- Storing or using the tissue of living or deceased persons for a research project
- Storing or using tissue from the living for a research project without consent where the samples are anonymized to the

researcher, i.e. in circumstances where the researcher is unable to identify the tissue donor and not likely to be able to do so in future.

- Analyzing human DNA in material from the body of a living person (or using the results of DNA analysis) without consent, in circumstances where they are unable to identify the tissue donor and not likely to be able to do so in future.
- Storing or using tissue for a research project where consent is required.

Project-based applications should be made in the following circumstances where research involves human tissues:

- Clinical trials involving storage or use of human tissue.
- Research involving removal of human tissue or other bodily material from the living as part of the protocol (i.e. primarily for research purposes).
- Research involving the use of stored tissue or data in circumstances where the researcher is able, or could be able, to identify the donor(s).
- Research involving any contact with donors or relatives to seek consent, obtain further data or undertake any other research procedure.
- Research involving use of stored tissue from a research tissue bank which does not have ethical approval from a REC.
- Research involving use of stored tissue from a research tissue bank, which has ethical approval from a REC, but (a) the terms of the approval do not extend to generic approval for projects receiving tissue from the bank, or (b) the tissue bank manager requires the researcher to obtain project-specific approval before agreeing to release tissue.
- Research involving stored tissue from a clinical diagnostic archive that is not licensed to store tissue for use in research and is not ethically approved.
- Ethical approval for project-specific applications is confined to the specific project described in the protocol and the application form
 - o It is not acceptable to use the project-specific application form to seek open-ended approval for use of stored tissue in future research programs.
 - o it is not acceptable to submit substantial amendments to approved projects in order to use tissue for another project with a different set of research questions.

For research involving extended tissue storage, where a researcher makes a specific project-based application but also plans to store the

tissue beyond the life of the project for use in further projects, the following options are available:

- At the end of the project, the researcher may make a further project-based application. If the second application is also granted a favorable opinion, continued storage of the tissue for use in this project will be lawful without a license. At the end of the second project the options set out in this paragraph apply in the same way.
- At the end of the project the researcher may make an application for review of a research tissue bank, including details of the plans for further research. The research tissue bank will require a storage license.
- The researcher may hold on to the tissue without a license under the original REC approval provided it is being held as a record of the completed research project, for example to verify research data. Storage for this purpose without a license should continue for no longer than necessary. If the tissue continues to be stored without a license for the purpose of any other research project, further ethical approval should be sought using either the project-specific or research tissue bank application process.

For research involving research tissue banks:

Organizations responsible for the management of research tissue banks (RTB) must apply for a license from the regulatory authority and must seek a favorable opinion from the facility Research Ethics Committee reviewing the arrangements for collection, storage, use and distribution of tissue. A “research tissue bank” (or “biobank”) is defined for the purpose of these SOPs as:

- A collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval.
- Tissue banks storing human tissue for use in as yet unspecified research must obtain a license.

Ethics review of research tissue banks:

- Approval is given for a period of 5 years.
- Option A: For Banks receiving generic approval:
 - o Samples of human tissue or other biological material may be supplied and used in research projects to be conducted within the establishment responsible for the Bank and/or by researchers and research institutions external to the Bank within Abu Dhabi and in other countries in accordance with the following conditions.

- The research project should be within the fields of medical or biomedical research described in the approved application form.
 - The Bank should be satisfied that the research has been subject to scientific critique, is appropriately designed in relation to its objectives and (with the exception of student research below doctoral level) is likely to add to existing knowledge.
 - Where tissue samples have been donated with informed consent for use in future research, the Bank should be satisfied that the use of the samples complies with the terms of the donor consent.
 - All samples and any associated clinical information must be non-identifiable to the researcher at the point of release (i.e., anonymized or linked anonymized).
 - Samples must not be released to any project requiring further data or tissue from donors or involving any other research procedures. Any contact with donors must be confined to ethically approved arrangements for the feedback of clinically significant information.
 - A supply agreement must be in place with the researcher to ensure storage, use and disposal of the samples in accordance with all federal and Abu Dhabi laws and regulations, Health Authority – Abu Dhabi policies and standards, the terms of the ethical approval and any other conditions required by the Bank.
- Option B: For Banks where the applicant has not applied for generic ethical approval for projects receiving tissue or such approval has not been given by the REC:
 - The approval for the Bank does not confer generic ethical approval for specific research projects using tissue supplied by the Bank. Where project approval is required under Health Authority – Abu Dhabi (HAAD) policies, a specific application should be made by the researcher. Such applications should normally be made to the REC.
 - To request generic ethical approval for projects to which tissue is supplied, the Bank should submit a new application rather than a Notice of Amendment

(Standard Operating Procedures for Research Ethics Committees,
Annex G)

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.

Not applicable

Domain III: Researcher and Research Staff

Researchers must meet requirements for ICH-GCP (E6)(R2)