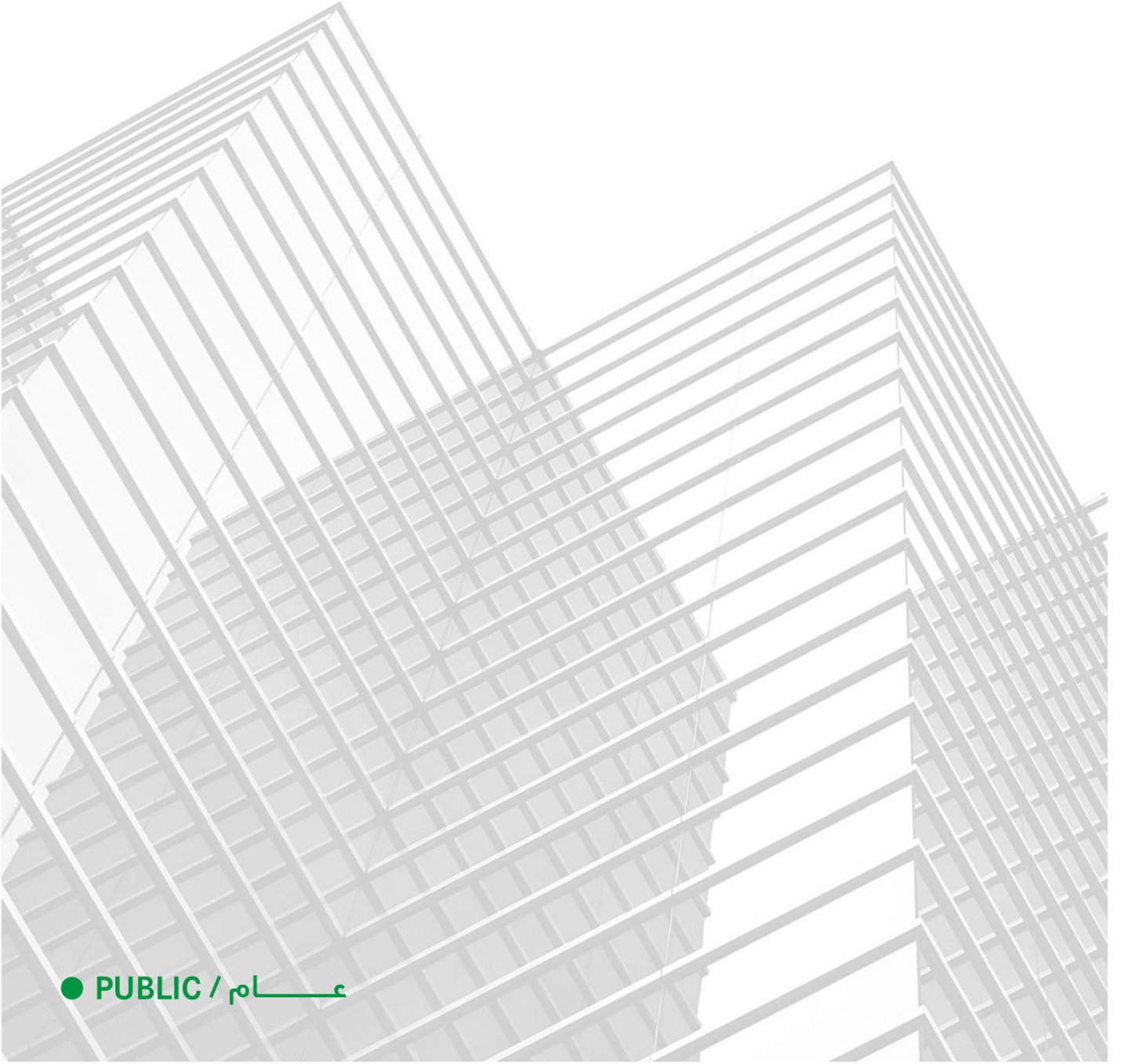




Standard for Biomedical Research



Document Title:	Standard for Biomedical Research		
Document Ref. Number:	DoH/SD/HLSS/SBR/V1/2026	Version:	V1
New / Revised:	New		
Publication Date:	April 2026		
Effective Date:	<p>Effective Immediately for all provisions of the standard excluding application to correct the ongoing Biomedical research as per the new scope according to following</p> <ol style="list-style-type: none"> 1. Starting 3 months from issuance and 2. Grace period of 15 months from issuance 		
Document Control:	DoH Strategy Sector		
Applies To:	<ul style="list-style-type: none"> - DoH licensed Healthcare Providers involved in Biomedical Research - Academic institutions involved in Biomedical research - Research Facilities and Institutes include, but not limited to, sites, research and development centers, pharmaceutical companies, laboratories - Sponsors of Biomedical Research like marketing authorization holders, medical technology developers and startups. - Contract research organizations, and site management organizations - Bioequivalence Centers - Researchers and investigators up- taking / involved/ supervising Biomedical research - Biobanks - Health / genomic data bases custodians 		
Owner:	Health Life Science Sector		
Revision Date:	Sept 2026		
Revision Period:	6 months		
Contact:	Medical Research and Development medical.research@doh.gov.ae		

1. Standard Scope and Purpose

1.1 Purpose

- 1.1.1 The purpose of this standard is to define the regulatory requirements for the conduct of biomedical research in the Emirate of Abu Dhabi, ensuring adherence to ethical, scientific, and legal standards.
- 1.1.2 This standard explicitly delineates the functions, responsibilities, and requisite qualifications of the key parties involved in the conduct of biomedical research.
- 1.1.3 Furthermore, this standard acknowledges and incorporates the roles of ancillary entities involved in the formulation of protocols, ongoing monitoring, and comprehensive review of trial data and outcomes. Such entities include, but are not limited to, patient advocacy groups and Data Safety Monitoring Boards (DSMB) / Independent Data Monitoring Committees (IDMC).
- 1.1.4 This standard emphasizes the importance of the structured integration of all entities involved, which serves to augment oversight mechanisms, reinforce participant safeguarding protocols, and ensure the integrity of data generated throughout the biomedical research process.

1.2 Scope:

- 1.2.1 The Standard for Biomedical Research is designed to align with the expanded definition delineated within Federal Decree-Law No. 38 of 2024, governing Medical Products, Pharmacist and Pharmaceutical Establishments¹.
- 1.2.2 The scope includes all types of biomedical research such as but not limited to clinical research including clinical trials, non-interventional clinical research, observational studies, registries and other forms of biomedical research.
- 1.2.3 This standard applies to the following
 - 1.2.3.1 DoH licensed Healthcare Providers involved in Biomedical Research
 - 1.2.3.2 Academic institutions involved in biomedical research
 - 1.2.3.3 Research Facilities and Institutes include, but not limited to, sites, research and development centers, pharmaceutical companies, laboratories
 - 1.2.3.4 Sponsors of Biomedical Research like marketing authorization holders, medical technology developers and startups.
 - 1.2.3.5 Contract research organizations, and site management organizations
 - 1.2.3.6 Bioequivalence Centers
 - 1.2.3.7 Researchers and investigators up- taking / involved/ supervising biomedical research
 - 1.2.3.8 Biobanks
 - 1.2.3.9 Health / genomic databases custodians

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	ADEK	Department of Education and Knowledge, the Education Sector regulator across the Emirate of Abu Dhabi, work closely with all privately owned Nurseries, Private Schools, Higher Education and co-manage charter Schools within the Emirate of Abu Dhabi
2.2	Adverse Device Effect (ADE)	An adverse event related to the use of an investigational medical device.
2.3	Adverse Drug Reaction (ADR)	<p>Any noxious and unintended response to the intervention at any level at any dose / use level as applicable should be considered an adverse reaction.</p> <p>In case of a drug/ medicinal product the term used is adverse drug reaction. The term “<i>response to a medicinal product</i>” indicates that a causal relationship between the product and the adverse event is at least reasonably possible, meaning the relationship cannot be ruled out.</p> <p>For marketed authorized medicinal products, an adverse drug reaction is defined as a noxious and unintended response to a drug that occurs at doses normally used in humans for prophylaxis, diagnosis, treatment of disease, or modification of physiological function.</p>
2.4	Adverse Event (AE)	Any unfavorable medical occurrence in a trial participant administered the investigational product, which does not necessarily have a causal relationship with the treatment. It encompasses all undesirable experiences associated with the use of a medical product / intervention, irrespective of whether they are considered related.
2.5	Adaptive Clinical Trial Designs	<p>An adaptive clinical trial design is a clinical trial methodology that allows for prospectively planned modifications to one or more aspects of the study design or statistical procedures based on an analysis of accumulating data from subjects within the trial itself.</p> <p>The purpose is to make clinical trials more flexible, efficient, and faster by, for example, adjusting the sample size, changing the randomization ratio, or stopping the trial early for efficacy, futility, or safety reasons, while still maintaining the study's validity and integrity</p>
2.6	Assent	Affirmative written and signed agreement of a minor to participate in clinical study. The absence of expression of agreement or disagreement should not be interpreted as assent.
2.7	Basket Clinical Trials	A basket clinical trial is a type of master protocol that investigates a single intervention (e.g. targeted therapy) in multiple different disease types or subtypes that all share a common characteristic,

		such as a specific genetic mutation or biomarker. This design is particularly useful in precision medicine and oncology, allowing researchers to efficiently test if a treatment is effective for a particular molecular alteration across various cancers.
2.8	Corrective and Preventive Action (CAPA)	is a systematic quality management process to identify, investigate, and eliminate the root causes of non-conformities or potential problems, ensuring they don't recur by implementing effective corrective (fixing current issues) and preventive (stopping future issues) actions, common in regulated industries like pharma, medical devices, and research. It involves root cause analysis, risk assessment, implementing solutions, and verifying effectiveness for continuous quality improvement.
2.9	Chief Research/Scientific/ Medical Officer (CSO/CMO)	is a top-tier executive leading an organization's research, development, and clinical strategy, overseeing R&D teams, ensuring scientific rigor, aligning innovation with business goals, managing budgets, and navigating regulatory landscapes, with the specific focus shifting from pure science (CSO) to clinical application and patient care (CMO)
2.10	Clinical Research	<p>It is research conducted in a group(s) of people or the study of their data, samples, or tissues for understanding health and disease, for the most important reasons:</p> <ol style="list-style-type: none"> 1. Explore the cause of a disease or group of symptoms. 2. Test effectiveness, efficiency and quality on a specific Medical Product that are conducted in groups of humans to determine how it is absorbed, metabolized, distributed, and eliminated from the body, to identify basic effects, side effects, and adverse interactions thereof. With the aim of confirming the effectiveness, efficiency, quality, and safety of using the Medical Product within the approved uses in accordance with the Marketing Approval granted to the Medical Product, or for new uses or drugs under research and development. 3. Testing the effectiveness of a therapeutic procedure in treating symptoms or conditions. 4. Learn how a particular intervention or factor affects people's health. Clinical Research consists of two basic types of research: <ol style="list-style-type: none"> 1. Clinical Trial (see definition). 2. Other Clinical Research: Any Research Projects that do not fall within Clinical Trials and include: <ol style="list-style-type: none"> a. Research Projects on humans that involve procedures for taking samples of biological material or collecting personal health data on individuals, such as health survey projects of various types. b. Research Projects involving the further use of biological materials or personal health data of individuals

		<p>c. Research Projects carried out on deceased persons.</p> <p>d. Research Projects carried out on stillbirth.</p>
2.11	Clinical Trial	<p>A type of clinical research that studies new interventions either at their investigational phase or after their approval with a purpose to evaluate their safety, quality and efficacy to achieve defined human health outcomes in comparison with other gold standard or status. A clinical trial's main purpose is to generate reliable data required to get a formal authorization or to enhance/ support an existing authorization to further evaluate its effectiveness and safety post the authorization.</p> <p>Clinical trials are considered as interventional investigations in human participants carefully designed, reviewed and completed.</p> <p>Clinical trials design to achieve the requested authorizations or to meet post authorization commitments need to be approved by the concerned health authorities before they can start.</p>
2.12	Clinical Trial/Study Report (CSR)	<p>A documented description of a clinical study report of any investigational products or device conducted in human participants, in which the clinical and statistical description, presentations and analyses are fully integrated into a single report.</p>
2.13	Co-investigator	<p>A Co-investigator(s) refers to a key investigator(s) involved in a clinical study who does not have the overall responsibility and authority of the Principal Investigator. A Co-Investigator is expected to devote a specified amount of time to the project, make significant contributions, and may be involved in development and/or carrying out the project.</p>
2.14	Consent	<p>A legally and ethically required process in which a research participant voluntarily confirms their willingness to participate in a specific study, after being informed of all relevant aspects. This includes the study's purpose, procedures, potential risks and benefits, alternatives, and data handling practices.</p>
2.15	Contract Research Organization (CRO)	<p>An organization (commercial, academic or other) that provides a service used during the conduct of a clinical trial or clinical research to either the sponsor or the principal investigator to fulfil one or more of their trial or clinical/translation research-related activities.</p>
2.16	Current Good Manufacturing Practice (cGMP)	<p>Current Good Manufacturing Practice (cGMP) is a set of enforced regulations ensuring the quality, safety, and purity of products like drugs, medical devices, and supplements by controlling manufacturing processes, facilities, and quality systems. The "current" signifies the need to update these standards with technologic advancements and science, requiring robust documentation, trained personnel, and processes to prevent contamination and mix-ups, guaranteeing products meet their labeled strength and quality from batch to batch.</p>

2.17	Decentralized Clinical Trials (DCTs)	A study design where some or all trial-related activities occur at locations other than a traditional, central clinical trial site (e.g., at a participant's home or a local health care facility). DCTs leverage digital health technologies (DHTs), such as telemedicine, wearable devices, and direct-to-patient drug shipments, to improve patient accessibility and convenience, increase the diversity of participants, and allow for continuous data capture in real-world settings. Most DCTs use a hybrid model combining remote and in-person visits
2.18	Department of Health (DoH)	The regulative body of the Healthcare Sector in the Emirate of Abu Dhabi, Established based on law No. (10) of 2018.
2.19	Data Safety Monitoring Board (DSMB)	An independent data monitoring committee (e.g., data safety monitoring board) that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints and to recommend to the sponsor whether to continue, modify, or stop a trial. DSMB is also known as the Independent Data Monitoring Committee (IDMC) in some jurisdictions.
2.20	Department of Health Institutional Review Board (DoH IRB)	An oversight committee established by the DoH to review and support critical biomedical research conducted by public and private healthcare providers in Abu Dhabi. It advises on and promotes health research across the emirate and is also known as the Abu Dhabi Health Research and Technology Committee (ADHRTC).
2.21	Dual Use	Dual-use research in science involves well-intentioned research, knowledge, or technology that can be easily misused for harmful purposes, such as creating biological weapons, threatening public health, or causing environmental damage, even if intended for beneficial applications like disease treatment. It presents an ethical dilemma for researchers, balancing scientific advancement with potential misuse, often requiring careful assessment, restrictions, and compliance with export controls for dissemination.
2.22	Emirates Drug Establishment (EDE)	The UAE federal authority responsible for regulating all medical and pharmaceutical products. This includes also medical devices, blood derivative products, genetically modified organisms, stem cells, medicated cosmetics, veterinary medications, and agriculture products.
2.23	First In Human (FIH) clinical Trial	A type of clinical trial in which a new drug, procedure, or device is tested in humans for the first time. FIH studies take place after the new treatment has been tested in laboratories or in animals and are usually done as phase I clinical trials.
2.24	Good Clinical Practice (GCP)	A standard for the planning, initiating, performing, recording, oversight, evaluation, analysis and reporting of clinical trials and clinical research that provides assurance that the data and reported results are ethically collected, reliable and that the rights, safety and well-being of trial participants are protected.

2.25	Good Practice Standards (GXP)	Refers to a set of several guidelines each defining the minimum requirements for a particular practice or field, such as Good Manufacturing Practices (GMP) or Good Clinical Practices (GCP). These standards, often created by professional bodies or regulatory agencies, serve as benchmarks for ensuring quality, safety, and ethical conduct. The "x" in this context acts as a placeholder for the specific field or industry
2.26	Biomedical Research	Any research that falls under the definition of a-non-clinical research and b-clinical research as defined by Federal Decree-Law No. (38) of 2024 Governing Medical Products, Pharmacists and Pharmaceutical Establishments.
2.27	In Silico	Refers to experiments, analyses, or models conducted via computer simulation or computational methods, rather than in vivo (in living organisms) or in vitro (in test tubes or culture). In silico approaches are widely used in biomedical research for tasks such as: <ol style="list-style-type: none"> 1. Drug discovery and design 2. Predicting biological processes 3. Modelling disease progression 4. Analysing large datasets (e.g., genomics, proteomics, epigenomics, phenomics, etc.) These computational models enable rapid hypothesis testing and can reduce the need for laboratory or animal experiments.
2.28	Investigational Device Exemption (IDE)	A temporary regulatory designation for an investigational device that permits its use in a clinical study to collect safety and effectiveness data until its full approval. This exemption allows devices that have not yet received marketing approval to be shipped and used in human subjects without complying with other requirements that typically apply to approved commercial devices.
2.29	Independent Data Monitoring Committee (IDMC)	A group of independent experts established by the sponsor to periodically review accumulating trial data to ensure the safety of participants, the validity and integrity of the data, and the continued scientific relevance of the trial.
2.30	Incapacitated adult	Participant, who is, for reasons other than the age of legal competence, to give informed consent, incapable of giving informed consent according to the law of the UAE.
2.31	Investigational New Drug (IND)/ Investigational Medicinal Product (IMP)	A drug or biological product (Medicinal Product in EU) that has not been approved for general use or marketing by the reference regulatory authorities but is authorized for use in a clinical investigation in human subjects. The term "Investigational New Drug" is often used interchangeably with the Investigational New Drug (IND) application process, which is the mechanism by which a pharmaceutical company or sponsor obtains DoH's approval to start human clinical trials and legally import the experimental product (with appropriate approvals).

		<p>It can apply to new drugs or approved products being studied for new indications, populations, dosages, or administration routes. In general, the application requires non-clinical study data, manufacturing information, and clinical trial plans.</p>
2.32	Institutional Review Board (IRB)	<p>An independent body (a review board or a committee, institutional, regional, national or supranational) constituted of medical professionals and non-medical members whose responsibility it is to ensure the protection of the rights, safety and well-being of human participants involved in a trial and to provide public assurance of that protection by, among other things, reviewing and approving/providing favourable opinion on the trial protocol, the suitability of the investigator(s), the facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial participants. The legal status, composition, function, operations and regulatory requirements pertaining to IRBs may differ among countries but should allow the IRB to act in agreement with GCP. IRB is also known as the Research Ethics Committee (REC) in certain jurisdictions.</p>
2.33	International Conference on Harmonization – Good Clinical Practice (ICH GCP E6 R3)	<p>Is an international ethical and scientific quality standard for the design, conduct, recording, and reporting of clinical trials involving human participants. The primary purpose of the ICH GCP E6 guideline is to provide a unified, globally accepted framework that ensures:</p> <ol style="list-style-type: none"> 1. The rights, safety, and well-being of trial participants are protected and prevail over the interests of science and society. 2. The data and reported results of the clinical trial are credible, accurate, and reliable. <p>This standard facilitates the mutual acceptance of clinical trial data by regulatory authorities in different countries, which helps streamline the global drug development process.</p>
2.34	Investigational Intervention	<p>A defined intervention being tested or used as a reference in a clinical trial. This broad category can be further classified based on the nature of the intervention:</p> <ol style="list-style-type: none"> 1. Investigational Medicinal Product (IMP): This term is used by most jurisdictions and is also used in the UAE. It is similar to the term Investigational New Drug (IND) in some jurisdictions. (See definition in this standard) 2. Investigational Medical Device (IMD): This refers to any device undergoing a clinical investigation or study to determine its safety and/or effectiveness for a specific use. Like IMPs, these devices are not yet cleared or approved for commercial use in the context of the study or being tested for new uses not previously approved. <p>Health Care / Public Health Solution: healthcare bundle, clinical pathway, or integrated healthcare / public health solution: These terms refer to structured and defined approaches / set of interventions that combine multiple interventions or products to</p>

		achieve a specific medical purpose or significantly improve patient outcomes, public health outcomes or economic outcomes.
2.35	Investigator's Brochure (IB)	Is a comprehensive regulatory document that summarizes all the clinical and non-clinical data available on an investigational intervention subject of the clinical trial and its components that are relevant to its study in human subjects.
2.36	Investigator-Initiated Trial (IIT)	Clinical trials in which the investigator assumes the role of both sponsor and investigator, taking full responsibility for the trial's design, conduct, oversight, and compliance with regulatory and ethical requirements. An internationally recognized standard for designing, conducting, monitoring, and reporting clinical trials including pragmatic clinical trials, decentralized clinical trials, as well as those that incorporate real world data sources. It defines the roles and responsibilities of investigators, sponsors, monitors, and ethics committees, ensuring that trials are scientifically sound, ethically conducted, and that participant rights and data integrity are protected.
2.37	Medical Device	<p>Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, Artificial Intelligence (AI) algorithms / tools, material, or other similar or related articles intended by the manufacturer / developer to be used, either alone or in combination, for/ in human beings for one or more of the following specific purposes:</p> <ol style="list-style-type: none"> 1. Diagnosis, prevention, monitoring, treatment, or alleviation of disease, 2. Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury, 3. Investigation, replacement, modification, or support of the anatomy or a physiological process, 4. Supporting or sustaining life, 5. Control of conception, 6. Disinfection of medical devices, 7. Providing information through in vitro examination of specimens derived from the human body. <p>A medical device does not achieve its primary intended action through pharmacological, immunological, or metabolic means, although it may be assisted in its function by such means.</p>
2.38	Non-Clinical Research	Pharmaceutical research and toxicity research to evaluate the safety of a Medical Product and its readiness for the Clinical Research stage prior to human research. This research yields preliminary information about the efficacy, toxicity, effect of the drug in the body and its level of safety. It is conducted through laboratory experiments (test tube or cell culture in-Vitro) or experiments on animals (in-vivo experiments) or using computer models of interactions between the drug or the targeted treatment (In-Silico).

2.39	Non-Interventional Study	<p>A non-interventional clinical study may involve one or more interventions using medical products with marketing authorization or solutions already established in clinical practice, provided all the following conditions are met:</p> <ol style="list-style-type: none"> 1. The products/solutions are used in the usual manner in accordance with the terms of the marketing authorization if products or the usual practice if solution, 2. The assignment of any participant involved in the study to a particular therapeutic strategy is not decided in advance by a clinical trial protocol, 3. The decision to prescribe/assign a particular medical product/solution is clearly separated from the decision to include the participant in the study, 4. No diagnostic or monitoring procedures are applied to the participants included in the study, other than those which are ordinarily applied during the therapeutic strategy / intervention in question, 5. Epidemiological methods are to be used for the analysis of the data arising from the study.
2.40	Non-substantial Amendment	<p>Amendments that do not have a significant implication on the substantial criteria (see definition of substantial amendment) are considered non-substantial amendments.</p>
2.41	Organoid Models	<p>Three-dimensional (3D) cell culture systems derived from stem cells or organ-specific progenitor cells that self-organize into structures mimicking the architecture and function of real organs. These models recapitulate key physiological and pathological features of human tissues, making them valuable for studying development, disease mechanisms, drug testing, and personalized medicine.</p> <ol style="list-style-type: none"> 1. Organoids can be generated for various organs (e.g., brain, liver, intestine). 2. They provide more physiologically relevant data than traditional two-dimensional cell cultures. 3. They also include patient derived organoids (e.g. in cancers)
2.42	Pharmaceutical grade	<p>A substance meets rigorous purity and quality standards, often >99% pure with no fillers, approved by the FDA for human/animal use, adhering to strict Current Good Manufacturing Practices (CGMP), ensuring consistency, safety, and effectiveness for medicinal purposes, as outlined in references like the United States Pharmacopeia (USP) or European Pharmacopoeia (EP).</p>
2.43	Pivotal clinical trials	<p>Are definitive, well-controlled studies designed to provide the primary evidence of medical intervention's safety and efficacy that is required to support regulatory approval. These trials are typically conducted in later phases of clinical development (usually randomized) and are characterized by rigorous methodology, including randomization, adequate sample size, and predefined endpoints.</p>

2.44	Platform Clinical Trials (Master Protocols)	A platform trial is a type of master protocol that involves a single, overarching study framework (master protocol) designed to investigate multiple investigational treatments simultaneously for a single disease or condition in a continuous, perpetual manner. Treatments can be added to or removed from the platform over time based on pre-specified decision rules, and they typically share a single, common control group, which enhances efficiency and saves time and resources compared to running separate trials for each treatment.
2.45	Pragmatic Clinical Trials	A type of clinical trial designed to evaluate the effectiveness of interventions in real-world, routine clinical practice conditions, rather than under highly controlled, ideal conditions. They typically involve a broader, more diverse patient population, use less stringent inclusion/exclusion criteria, and measure patient-centred outcomes (like quality of life or hospital admissions) that are relevant to patients, clinicians, and healthcare decision-makers. The results are highly generalizable to everyday medical care.
2.46	Principal Investigator (PI)	The researcher, who leads the clinical research/Trial team and, along with the other members of the research team, regularly monitors study participants' health to determine the study's safety and effectiveness. An investigator is primarily responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of clinical research.
2.47	Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a study. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol-referenced documents.
2.48	Protocol Amendment	A documented description of a change(s) to a protocol.
2.49	Reference Safety Information (RSI)	Contains a cumulative list of ADRs that are expected for the investigational product being administered to participants in a clinical trial. The RSI is included in the Investigator's Brochure.
2.50	Regulatory Authorities	Bodies have the power to regulate, including those that review submitted protocols and clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities. Reference regulatory authorities are authorities known for their stringent regulatory review, mainly EDE, US-FDA, EMA, UK MHRA, TGA-Australia, Health Canada, Japan and equivalent(s).
2.51	Regulatory Sandbox	A regulatory sandbox for Biomedical Research / clinical trials is a controlled, temporary testing environment where researchers can develop and test novel medicines, medical devices, or digital health solutions under relaxed or flexible regulations, allowing for real-world experimentation of new technologies (like AI, digital health) that don't fit traditional frameworks, while regulators gain insights

		to adapt rules for patient safety and access. It provides a safe space for "living labs" to assess breakthrough products with safeguards, bridging innovation with established regulatory requirements.
2.52	Seamless Clinical Trials	An adaptive design that combines two or more traditional phases of a clinical trial (e.g., Phase I/II or Phase II/III) into a single, continuous study. This design allows for a more rapid transition between phases without the typical administrative pause, using data from patients enrolled before and after the adaptation in the final analysis to streamline the drug development process and reduce development time
2.53	Serious Adverse Device effect (SADE)	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
2.54	Serious Adverse Event (SAE)	Any unfavourable medical occurrence that is considered serious at any dose / level of utilization of the intervention if it: <ol style="list-style-type: none"> 1. Results in death 2. Life-threatening 3. Requires inpatient hospitalization or prolongation of existing hospitalization results in either persistent or significant disability, incapacity or a congenital anomaly/birth defect or is otherwise considered medically significant by the investigator
2.55	Sponsor	An individual, company, institution, or organization that takes responsibility for the initiation, management, and arrangement of the financing of biomedical research including but not limited to clinical trials, registries and others.
2.56	Standard Operating Procedures (SOPs)	Detailed, documented instructions to achieve uniformity in the performance of a specific activity.
2.57	Sub-investigator	Any individual member of the clinical trial or clinical research team designated and supervised by the investigator to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).
2.58	Substantial Amendment	Amendments to the clinical trial or the clinical research are regarded as "substantial" where they are likely to have a significant impact on: the safety, physical or mental integrity of the participants, the scientific value of the clinical trial/research, the conduct or management of the clinical trial/research, or the quality or safety of any IMP used in the trial
2.59	Suspected/ Unexpected Serious Adverse Reaction (SUSAR)	An adverse reaction that meets three criteria: suspected, unexpected and serious. Suspected: There is a reasonable possibility that the drug caused the adverse drug reaction. Unexpected: An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., the RSI, see glossary term contained within the Investigator's Brochure or alternative documents according to applicable regulatory requirements. Note: See above definition for SAE

2.60	Traditional, Complementary and Alternative Medicine (TCAM)	Medicine including herbal drugs, homeopathic medicine, traditional Chinese medicine, Unani medicine, Ayurveda, functional medicine
2.61	Trial Participant	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.
2.62	Unexpected Adverse Drug Reaction	An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product)
2.63	Unexplainable phenomenon	Also known as anomalous phenomenon, refers to an observable event, effect, or pattern that current scientific understanding or existing theories cannot adequately account for, challenging established knowledge and prompting further investigation
2.64	Urgent Safety Matter (USM)	An action that the sponsor and investigator may take to protect the participants of a study against any immediate hazard to their health and safety.
2.65	Vulnerable Participants	Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of a retaliatory response from senior members of a hierarchy or family members in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and individuals kept in detention. Other vulnerable subjects include patients with incurable diseases, individuals in nursing homes, unemployed or impoverished individuals, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.
2.66	Window Period	The time-period after the onset of an event, based on available scientific evidence, within which the investigational product must be used or administered to have its potential clinical effect.

3. Standard Requirements and Specifications

3.1 Ethics, Bioethics and Responsible Research

3.1.1 Ethics and bioethics are the foundations of human research, influencing the formation and implementation of ethical principles within the framework of human research documents. These principles ensure that participants' rights, safety, and well-being are prioritized throughout the research process. The initial set of guidelines for human research ethics, established in 1964 by the World Medical Association (WMA) within the Declaration of Helsinki, marked the international medical community's first concerted effort in this realm.

3.1.2 Responsible Research: Researchers, industry, companies, startups, academia, individuals, and any other party involved in biomedical research should comply with the following documents:

3.1.2.1 This standard (Standard on Biomedical Research).

3.1.2.2 Global guidance framework for the responsible use of life sciences: mitigating bio risks and governing dual-use research. Geneva: World Health Organization; 2022. License: CC BY-NC-SA 3.0 IGO².

3.1.2.3 Responsible AI Standard³.

3.1.2.4 Abu Dhabi Healthcare Information and Cyber Security Standard (ADHICS)⁴

3.1.2.5 ICH E6 (R2) Guideline for good clinical practice (GCP)⁵

3.1.3 Ethical and Sustainable Handling of Biomedical Waste in Research in clinical trials

3.1.3.1 DoH recognizes the critical value of responsible handling for biomedical waste in general as a key aspect to establish sustainable/ ethical research practices.

3.1.3.2 For general guidelines, research facilities can refer to regulations and standards governing biohazard waste, environmental hazards, hazardous materials and others.

3.1.3.3 It is recommended that ethically challenging biowaste from clinical trials, such as birth associated spare parts (umbilical cord, placental tissue, etc.) and surgical discards, be responsible, processed, and utilized under ethical and scientific guidelines.

3.1.3.4 All institutions engaged in research involving biowaste / human tissues and biospecimen must adhere to the following:

3.1.3.4.1 Ethical Sourcing and Consent: Ensure informed consent protocols are in place for the donation of biological materials, prioritizing transparency and donor rights.

3.1.3.4.2 Compliance with Regulatory Standards: Mandate adherence to cGMP and biosafety protocols to ensure the safety and quality of materials used in research.

3.1.3.4.3 Waste Reduction and Circular Economy: Promote the repurposing of biomedical waste to reduce environmental impact while maximizing its potential in research and development.

3.2 Harmonization with International Standards

3.2.1 Biomedical research shall be conducted in harmonization with international standards governing biomedical research.

3.2.2 The ICH GCP E6 (R3) guidelines, developed by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), serve as a global standard for conducting clinical trials. These guidelines enable the globalization of industry-backed clinical research, allowing data collected in one region

according to ICH GCP standards to support new drug applications in diverse geographical areas.

3.2.3 Other ICH Guidelines:

3.2.3.1 ICH E18 (Guideline on Genomic Sampling and Management of Genomic Data)⁶. Investigators utilizing genomic data in research are guided to follow the principles outlined here.

3.2.3.2 The ISO14155 guidelines⁷ and its updates provide a framework for conducting clinical trials with medical devices, ensuring that these studies are conducted ethically and scientifically.

3.3 Roles and Responsibilities of entities and parties involved in conducting biomedical research:

3.3.1 Authorized/Licensed Facility for “Biomedical Research”

3.3.1.1 Obtain “Biomedical Research” Facility Licensing / Authorization

3.3.1.1.1 Facilities seeking to conduct biomedical research shall be required to consult and comply with the requirements to be issued by the DoH which must be satisfied as a condition precedent to obtaining licensure as a biomedical research facility in the Emirate of Abu Dhabi.

3.3.1.1.2 All facilities/organizations applying to become a DoH-Authorized/Licensed Research Facility must first get Abu Dhabi licensing requirements pertaining to their activity and provided services as applicable.

3.3.1.1.3 Facilities intending to conduct biomedical research must provide the following to get the required DoH authorization / Licensing as a biomedical research facility:

3.3.1.1.3.1 Complete research authorization application submission,

3.3.1.1.3.2 Provide all the required documentation supporting application submission,

3.3.1.1.3.3 At least five voting REC/IRB members’ list from their institution. Exceptions are to be justified by the applicant and contingent upon DOH approval.

3.3.1.1.3.4 Completion of a Research Ethics Training course for Good Clinical Practice (GCP) Certificate or equivalent for all REC/IRB members.

3.3.1.1.3.5 The facility shall submit the name, appointment letter, biography and qualifications of the individual designated by facility authorized management as the “**Chief Research/ Scientific or /Medical Officer**”, or equivalent, who shall be responsible, on behalf of the facility, for ensuring compliance with applicable biomedical research standards and all legal obligations under the laws governing biomedical research. The designated officer shall sign the application form.

3.3.1.1.3.6 Completion of Undertaking Letter for all institution’s REC/IRB members

3.3.1.1.3.7 One community member (non-scientific) should be a member of the institution’s REC/IRB.

3.3.1.1.3.8 Institutional REC/IRB should consist of an odd number of voting members.

3.3.1.1.4 Upon successful validation of the submitted documentation and satisfaction of all conditions applicable to the specific category of biomedical research proposed by the facility, the DoH shall issue to the

- facility a Biomedical Research Facility Authorization Letter or License. Such authorization shall specify the facility's name, its chief research officer's (or equivalent) name, facility address, and the scope of biomedical research activities permitted thereunder.
- 3.3.1.1.5 The licensed/Authorized biomedical Research Facility can update/expand their licensing scope by reapplying and submitting a justification letter and the supportive required documents
 - 3.3.1.1.6 Facilities are advised to refer to www.doh.gov.ae
 - 3.3.1.1.7 Obligations of Licensed / Authorized "biomedical Research Facilities":
 - 3.3.1.1.8 No research facility shall initiate, commence, or permit the conduct of any biomedical research within its premises without first obtaining all requisite approvals for the specific research protocol and securing appropriate institutional authorization and licensure for the facility itself.
 - 3.3.1.1.9 Each human bioresearch facility is mandated to strictly adhere to Good Clinical Practice (GCP) guidelines. This adherence includes, but is not limited to:
 - 3.3.1.1.9.1 The establishment and maintenance of a functioning Institutional Review Board (IRB) to ensure continuous ethical oversight and full compliance with all prevailing regulatory requirements.
 - 3.3.1.1.9.2 Ensure all research activities adhere to internationally recognized GCP standards and local DoH regulations.
 - 3.3.1.1.9.3 Provide ongoing GCP training for investigators and staff.
 - 3.3.1.1.10 Clinical Trial Agreements (CTA):
 - 3.3.1.1.10.1 A Clinical Trial Agreement (CTA) or a clinical study agreement, is a formal, legally binding contract between the healthcare facility (study site) study sponsor outlining all terms for conducting medical research on humans, covering roles, data, patents, confidentiality, indemnification, funding, and regulatory compliance to ensure patient safety and ethical conduct.
 - 3.3.1.1.10.2 CTA with sponsors should be developed in clear and fair manner outlining roles, responsibilities, financial arrangements, and intellectual property (IP) terms.
 - 3.3.1.1.10.3 Avoid requesting exaggerated financial compensation or unjustified IP rights.
 - 3.3.1.1.10.4 Financial terms (direct and indirect) should be in line with internationally acceptable levels
 - 3.3.1.1.11 Data Privacy and Secure Storage:
 - 3.3.1.1.11.1 Safeguard participant data in accordance with UAE data protection laws and DoH guidelines.
 - 3.3.1.1.11.2 Implement secure systems for data collection, storage, and access, ensuring confidentiality and integrity.
 - 3.3.1.1.11.3 For data protection and data transfer, the following regulations and underlying related rules must be observed:
 - 3.3.1.1.11.3.1 Abu Dhabi Healthcare Information and Cyber Security (ADHICS) Standard⁴, and the Ministerial Resolution No. (51) of 2021⁸ should be followed and overrules the local healthcare facility's data privacy rules for international research.

- 3.3.1.1.11.3.2 The Ministerial Resolution No. (51) of 2021⁸, where storing and transferring data that is used as part of scientific research is permitted, provided that such data is encrypted and transmitted using media based on highest security standards.
 - 3.3.1.1.11.3.3 Data transmission as per the Ministerial Resolution No. (51) of 2021⁸ is allowed from the healthcare facilities within Abu Dhabi, only on DOH IRB approved studies, and only at the sites which are officially authorized to conduct healthcare related research.
 - 3.3.1.1.11.3.4 In global studies, the data transmission as per the Ministerial Resolution No. (51) of 2021⁸, will be allowed if fulfilling all requirements as mentioned in 4.25.4, and additionally, all Protected Health Information (PHI/) Personally Identifiable Information (PII) is removed to make it anonymized or pseudonymized.
- 3.3.1.1.12 Support and Recognition for Investigators
- 3.3.1.1.12.1 Encourage and reward physicians/investigators for engaging in research.
 - 3.3.1.1.12.2 Allocate reasonable, protected time for research activities.
 - 3.3.1.1.12.3 Include research contributions in performance appraisals and career advancement.
- 3.3.1.1.13 Facilitation and Timely Review Processes
- 3.3.1.1.13.1 Support the provision and dissemination of clear, informative, and accurate statistics on the facilities capabilities, research conducted, investigators and their specialty, type of diseases / statistics on cases treated up to severity/complexity level etc. to enhance the visibility of the facility's potential to accept research. This transparency will facilitate feasibility assessments by sponsors and other entities considering the facility as a potential site for their research projects, thereby promoting informed decision-making and fostering successful collaborations.
 - 3.3.1.1.13.2 Support efficient submission and review of research protocols to the IRB
 - 3.3.1.1.13.3 Adhere to reasonable timelines (based on international benchmarks) for IRB reviews and approvals to avoid unnecessary delays. The timelines should be communicated in the application for licensing and to be adhered with.
- 3.3.1.1.14 Transparent Communication with Authorities
- 3.3.1.1.14.1 Promptly notify the DoH of any concerns, suspensions, administrative holds, or issues affecting ongoing research.
 - 3.3.1.1.14.2 Maintain open channels for compliance reporting and regulatory updates.
- 3.3.1.1.15 Research Facilitation and Infrastructure
- 3.3.1.1.15.1 Provide adequate infrastructure, resources, and administrative support to enable high-quality research.

- 3.3.1.1.15.2 Foster a research-friendly environment within the facility.
- 3.3.1.1.15.3 Commits to uptake research projects in acceptable proportion for the capabilities and resources under the facility's control.

3.3.1.1.16 Ethical Oversight and Participant Safety

- 3.3.1.1.16.1 Ensure all research is conducted with the highest ethical standards, prioritizing participant safety and rights.
- 3.3.1.1.16.2 Assign a responsible qualified person (either as a dedicated chief research officer, or to assign responsibilities to other senior personnel ex: the chief medical officer, chief scientific officer) to monitor / supervise conducted research for compliance and ensure prompt actions are taken to address any adverse events or protocol deviations.

3.3.2 Investigator:

3.3.2.1 General term

- 3.3.2.1.1 The Principal Investigator (PI) is the primary individual responsible for the preparation, conduct, and administration of a biomedical research project at a study/trial site in compliance with applicable laws and regulations and facility policy governing the conduct of research.

3.3.2.2 Qualifications and requirements to authorize/license the Investigator:

- 3.3.2.2.1 All investigators, including the PI, must provide proof of a valid Good Clinical Practice (GCP) Certificate issued within the preceding 3 years from the submission date. Certificates older than 3 years at the time of submission will not be accepted. This certification ensures that investigators are trained in ethical and scientific quality standards for clinical trials.
- 3.3.2.2.2 The Investigator could be from any health specialty including but not limited to physician, dentist, nurse, ancillary health staff, pharmacist, scientist, etc
- 3.3.2.2.3 The investigator's specialty must align with the research area under investigation
- 3.3.2.2.4 The PI must be affiliated with an Emirate of Abu Dhabi authorized / licensed biomedical research facility and will be the designated Investigator on all DoH and REC/IRB forms.
- 3.3.2.2.5 For multicenter (International) studies where a Coordinating/Global Investigator is identified, the UAE Investigator shall be the named Investigator on all DoH and REC/IRB forms
- 3.3.2.2.6 For multicenter studies in Abu Dhabi, the DOH mandates one investigator per site.

3.3.2.3 Regulatory obligations of the Investigator conducting biomedical research are as follows:

- 3.3.2.3.1 The Investigator is the "point of contact person" for communicating with the REC/IRB for all applications (review/approvals/amendments etc.).
- 3.3.2.3.2 The Investigator is responsible for ensuring that clinical trials/clinical research are conducted in compliance with the protocol, standard operating procedures (SOPs, GCP and applicable regulatory requirements.
- 3.3.2.3.3 Conduct clinical research including clinical trials and Real-World Evidence (RWE) collection in compliance with the protocol, applicable regulations, the principles of GCP and the SOPs relevant to the clinical research.
- 3.3.2.3.4 Conduct biomedical research at the location(s) specified and approved in the biomedical research application.

- 3.3.2.3.5 Ensure that all medical/dental/pharmacy care and decisions relating to the trial participants are provided to participants as required and necessary to protect their health and under supervision of a qualified medical practitioner.
- 3.3.2.3.6 For interventional clinical research, ensure that the investigational Intervention and its alternates are discussed in depth with subjects/patients by a medical professional.
- 3.3.2.3.7 Ensure that any individual to whom a research-related activity is delegated is qualified by education, training, and experience to perform the delegated trial-related activity.
- 3.3.2.3.8 Maintain a list of appropriately qualified people to whom significant trial-related activities have been delegated.
- 3.3.2.3.9 Ensure that informed consent requirements are compiled to as per the ICH GCP R3 and local requirements.
- 3.3.2.3.10 Keeps adequate essential research documents for the specified period, dictated as per the DoH rules and regulations.
- 3.3.2.3.11 Declare every financial or non-financial interest, including that of any person assisting the Investigator, to REC/IRB
- 3.3.2.3.12 Report serious adverse events within stipulated timelines to sponsor, and/or to the REC/IRB if required. For Sponsor initiated Interventional Studies, the reporting of serious adverse events in line with the regulatory requirements for pharmaco-vigilance (PV) is a joint responsibility of the investigator and the Sponsor.

3.3.3 Sponsor

- 3.3.3.1 The sponsor may be one of the following:
 - 3.3.3.1.1 A pharmaceutical or biotechnology company,
 - 3.3.3.1.2 An academic institution,
 - 3.3.3.1.3 A government agency, including DoH.
 - 3.3.3.1.4 Or any entity initiating, managing, and financing the clinical trial.
- 3.3.3.2 Biomedical research may have one or several sponsors permitted under regulatory requirements. All sponsors have the responsibilities of a sponsor. In accordance with regulatory requirements, sponsors may decide in a documented agreement setting out their respective responsibilities. Where the agreement does not specify to which sponsor a given responsibility is attributed, that responsibility lies with all sponsors.
- 3.3.3.3 If a clinical trial / pivotal clinical trial is proposed to evaluate an unauthorized intervention, or to expand the authorized indications or methods of use of intervention to other unauthorized indications and/or unauthorized methods of use, the sponsor shall be required to obtain prior approval from the DoH to conduct such clinical trials. This approval may include a prior step, as applicable, as a separate application to get the designation of the investigational intervention as an Investigational New Drug (IND), Investigational Medical Device (IMD), investigational treatment technology as applicable or the granting of an exemption.
- 3.3.3.4 Register all interventional clinical trials on a publicly accessible database such as www.clinicaltrials.gov. or equivalent
- 3.3.3.5 Obtain approval for substantial amendments to biomedical research.
- 3.3.3.6 In case of clinical trials / interventional biomedical research to ensure that the information in the Investigator's Brochure (IB) is current and not more than one year old at the time of submission.
- 3.3.3.7 Ensure biomedical research is conducted by adequately qualified Investigators at sites with resources to meet the needs of the protocol.
- 3.3.3.8 implement and maintain quality assurance and quality control systems to ensure that clinical research activities are conducted in compliance with the protocol, standard operating procedures, ICH GCP E6 (R2)⁵ and applicable regulatory requirements.
- 3.3.3.9 The Sponsor should provide a PV system and Risk Management Plan (RMP) for the intervention if includes the testing / use of medical product under study as applicable and in line with the approved PV system and RMP by the reference regulatory authorities.
- 3.3.3.10 The sponsor of the study must provide an insurance scheme that adequately and proportionately covers potential risks to patients, and risks to the research facility.
- 3.3.3.11 In case of clinical trials to ensure appropriate investigational product's labelling and package artworks are in line with the relevant regulatory approvals / conditions as applicable for the investigational medicinal products / Medical Device.
- 3.3.3.12 In case of clinical trials to ensure that the products tested are manufactured in line with the regulatory approval of the investigational product and by facilities granted valid relevant GMP certifications issued by the concerned regulatory authorities.
- 3.3.3.13 Notify DoH of the research study status (including the suspension, termination and/or conclusion of the trial especially in the case of global trials),

serious breaches and urgent safety measures taken to protect trial participants against immediate hazard within the stipulated timelines.

3.3.3.14 Report unexpected serious adverse drug reactions and medical devices adverse events within the stipulated timelines.

3.3.3.15 Submit the final report within the stipulated timelines.

3.3.4 Undergraduates and postgraduates conducting biomedical research:

3.3.4.1 An undergraduate or postgraduate can take on the responsibility of a Principal Investigator along with a co-investigator at a licensed healthcare facility. The course or thesis supervisor may or may not choose to be a co-investigator.

3.3.4.2 The course/thesis advisor(s) of the postgraduates and undergraduates along with the undergraduate / post graduate investigators involved in any human data acquisition or analysis (whether de-identified or not) must obtain GCP certification.

3.3.4.3 For studies with international and local participants, the DoH IRB can only approve the participants enrolled / part to be conducted within the Emirate of Abu Dhabi.

3.3.5 Contract Research Organization (CRO):

3.3.5.1 A CRO is a person or an organization to which a sponsor may transfer or delegate one or more of its trial-related duties and functions (as defined in ICH GCP E6 Section 5.2.1). Accordingly, the ultimate responsibility for the quality and integrity of the trial data always resides with the Sponsor.

3.3.5.2 Any delegation of sponsor obligations must be documented in a formal written agreement.

3.3.5.3 The CRO shall implement and ensure quality assurance and quality control systems for all delegated activities and ensure compliance with the protocol, SOPs, ICH GCP E6, and all applicable regulatory requirements, including those of the Abu Dhabi DoH.

3.3.5.4 Licensure requirements: As per Pharmacy law no. 38 for year 2024¹, the CRO must hold a valid regulatory authority license/permit to perform its duties as a CRO. In case the CRO

3.4 Institutional Review Board IRB / Research Ethics Committee REC

3.4.1 IRB Role and Function

3.4.1.1 A Research Ethics Committee is an independent body appointed by the biomedical research facility to review, approve/ reject, and monitoring research involving human participants. IRB/ REC shall review all biomedical research regardless of the research design or the nature of research subjects.

3.4.1.2 IRB/ REC primary responsibilities include:

3.4.1.2.1 Assessing the ethical acceptability of research proposals to ensure that ethical standards are upheld.

3.4.1.2.2 Protecting the rights, safety, and well-being of research participants including the collection and analysis of their data.

- 3.4.1.2.3 Ensuring that research complies with local laws, regulations, and international guidelines (such as ICH-GCP E6 [R3]).
- 3.4.1.3 IRB / REC can provide ethical opinions on research projects without requiring prior DoH IRB approval. If substantial changes are requested by DoH IRB after the ethical opinion of the facility IRB/ REC is issued, then a substantial amendment shall be submitted to the facility's IRB/REC.
- 3.4.1.4 In all instances the research shall not commence unless both Facility IRB / REC and DoH-IRB approvals are formally granted to the final protocol intended for implementation.
- 3.4.1.5 For investigational interventions, the sponsor and investigator should perform initial and ongoing assessments on the safety and efficacy of the intervention and provide comprehensive information to the IRB revision, while the IRB provides independent ethical oversight and final determination of whether the study's risks are justified by its potential benefits to participants or society. Ethical assessments shall focus on potential risks and benefits to participants, measures to minimize risks, and the clarity and adequacy of participant information sheets and consent forms.
- 3.4.1.6 Review and discuss ongoing compliance findings internally and share them with the DoH for potential further action.
- 3.4.1.7 Provide post-approval support to researchers by evaluating and assisting in managing post-approval events through on-site reviews and directed investigations.

3.4.2 Establishing facility IRB/REC and Authorization

- 3.4.2.1 A facility seeking DoH authorization to conduct biomedical research in Abu Dhabi must establish and maintain an IRB/REC.
- 3.4.2.2 IRB/REC structure and membership need to be authorized (accredited) by DoH as part of the research facility authorization / licensing as biomedical Research Facility.

3.4.3 IRB/REC Composition, Minimum Membership, Representation and Structure

- 3.4.3.1 The facility IRB/REC shall be established within a single clinical establishment, and its composition shall be specified by an order from the institution head.
- 3.4.3.2 The IRB/REC shall consist of members with the qualifications and experience necessary to evaluate the scientific, medical, and ethical aspects of proposed / potential biomedical research to be conducted within the facility or under its affiliates.
- 3.4.3.3 The IRB/ REC shall include at least five members.
- 3.4.3.4 At least one member shall have non-scientific discipline (lay member).
- 3.4.3.5 The IRB / REC shall include members of both genders.
- 3.4.3.6 The number of voting members shall always be an odd number.
- 3.4.3.7 At a minimum, an IRB/REC shall include members from departments actively engaged in clinical research, ensuring that it is multi-representative and multidisciplinary.
- 3.4.3.8 The IRB/REC may engage external experts as needed to support its work.

3.4.4 Leadership and Review of Membership

- 3.4.4.1 An IRB/REC shall have qualified leadership (e.g. Chairperson), competent members and staff.
- 3.4.4.2 Membership and composition of the IRB/REC shall be periodically reviewed and adjusted as appropriate.

3.4.4.3 The term of office for members, as well as the rules for renewing membership, shall be clearly defined in writing

3.4.5 Membership Records and Conflicts of Interest

3.4.5.1 All IRB/REC members shall sign a statement of conflict of interest.

3.4.5.2 The IRB/REC shall retain its membership list, including the names and occupations or affiliations of its members.

3.4.6 IRB / REC Meetings, Decision-Making and independence

3.4.6.1 The IRB/REC shall conduct its meetings in closed sessions. Where necessary, the Chairperson of the IRB/REC may invite the sponsor or investigator or CRO to participate in specific discussions.

3.4.6.2 The IRB/REC shall schedule meetings at least once a month, and the meeting schedule can be published and communicated within the facility.

3.4.6.3 The IRB/REC shall make decisions only in scheduled meetings where the required quorum, as defined in its written SOPs, is present.

3.4.6.4 Only IRB/REC members who are not directly involved in the specific trial and who are independent from the sponsor and investigator, both administratively and financially, shall be allowed to vote and participate in deliberations.

3.4.6.5 When reviewing clinical research involving minors, the IRB/REC shall ensure the involvement of a pediatrician, either as a regular member or an external expert.

3.4.6.6 When reviewing research involving vulnerable participants, the IRB/REC shall include individuals who are knowledgeable about or experienced in working with such populations.

3.5 Procedure for Issuing a “Biomedical Research” Approval:

3.5.1 Preliminary Application Submission (by facility/sponsor/Investigator):

3.5.1.1 Upon receiving notification of an applicant with a determination to conduct/continue to conduct biomedical research activities within / under Abu Dhabi licensed biomedical research facilities, the DoH Medical Research Department will provide guidance to the applicant within 5 (five) working days on the correct pathway, application form(s) and supporting documents required to obtain/renew a DoH Research Approval Letter.

3.5.1.2 The DoH provided guidance on the appropriate pathway is dependent on the completeness, accuracy and clarity of the information and documents submitted by the applicant regarding the biomedical research project’s scope purpose and description.

3.5.2 Investigational Intervention evaluation:

- 3.5.2.1 This step is only applicable for clinical trials including pivotal clinical trials, where investigational intervention is tested.
- 3.5.2.2 The full process and requirements are described in section 3.8 of this standard below.
- 3.5.2.3 Upon completion of the evaluation, the investigational status designation for the intervention shall be granted, together with, as applicable, additional designations such as breakthrough intervention, orphan product, priority review, or other relevant regulatory classifications in accordance with international guidance for clinical trials. In such cases, the sponsor shall be required to submit comprehensive data on the intervention as specified by the DoH and any applicable international regulatory standards.
- 3.5.2.4 In cases where an “exempted investigational intervention” status is granted, the sponsor or investigator shall be exempted from submitting the full dossiers for the intervention. However, the evaluation process for granting this exemption remains mandatory and must be completed in accordance with applicable regulatory requirements.
- 3.5.2.5 For biomedical research that doesn’t include the use of an investigational intervention, the applicant will go to the next step of submitting the biomedical research application directly.

3.5.3 Biomedical Research Application Submission and Validation:

- 3.5.3.1 Application submission: The applicant (Sponsor, Investigator, Facility) is required to fill in the relevant application form and the required documents and submit to DoH IRB and facility REC/IRB review concurrently.
- 3.5.3.2 The submission requirements for both IRB / Facility REC/ IRB should be identical and in line with the preliminary preview advice considering the following:
 - 3.5.3.2.1 Administrative Documentation.
 - 3.5.3.2.2 Research Application form filled and signed
 - 3.5.3.2.3 Conflict of Interest Form signed
 - 3.5.3.2.4 Patient Informed Consent Form drafts must be provided in both Arabic and English languages, and both should have same text (descriptions).
 - 3.5.3.2.5 Information about participants.
 - 3.5.3.2.6 Documentation concerning the trial protocol.
 - 3.5.3.2.7 Documentation regarding the intervention if applicable (i.e. medicinal product, medical device or solution under investigation:
 - 3.5.3.2.7.1 Similar documentation submitted for the IND review (refer to section 3.8.5 of this standard below)
 - 3.5.3.2.7.2 Comparator and its description if any.
 - 3.5.3.2.8 Investigational brochure
 - 3.5.3.2.9 Documentation about the technical qualifications and the Principal Investigator and key research staff.
 - 3.5.3.2.10 Information about funding sources and the administrative organization structure of the trial.
 - 3.5.3.2.11 Clinical Contract Agreement between the sponsor and the facility if applicable.
 - 3.5.3.2.12 Submission of documents evidencing insurance, indemnity, and compensation coverage, as applicable.
 - 3.5.3.2.13 Monitor information (Name and address), appointment letter and qualifications (if CRO a copy of the license to be attached).

- 3.5.3.2.14 All supportive documents must be in English. In cases where supportive documents are not originally in English, a copy of the document in its original language, accompanied by an authenticated translation in English shall be submitted.
- 3.5.3.3 Submission to DoH IRB via the designated platform
- 3.5.3.4 The facility REC/IRB specific procedure for submission should be followed.
- 3.5.3.5 Upon submission of documentation and administrative validation, the DoH will issue a receipt (signed check list) for documents submitted.

3.5.4 Administrative Review:

- 3.5.4.1 DoH's Medical Research Department will commence validation of the application upon receipt of documents.
- 3.5.4.2 In general, an application should be accepted as valid if it meets the following criteria:
 - 3.5.4.2.1 Mandatory documents as per the specified checklist have been provided
 - 3.5.4.2.2 The correct application form has been completed and has been signed and dated by the authorized person on behalf of the applying facility
 - 3.5.4.2.3 Applicable supporting documents as required have been provided.
 - 3.5.4.2.4 All text is in English, and the print is clearly legible
- 3.5.4.3 It is the responsibility of the applicant who is submitting the application to provide a completed application form and to ensure the accuracy of all information provided.
- 3.5.4.4 In the case of incomplete applications, DoH's Medical Research Department will notify the facility identifying the information that has not been provided and the timeframe within which the application may be resubmitted. If the application is not resubmitted within the time specified, the application will be withdrawn, or rendered invalid, and the applicant will need to submit a new application request.
- 3.5.4.5 Once an application has been validated by the DoH's Medical Research Department and deemed complete:
 - 3.5.4.5.1 The application, together with the outcomes of the investigational intervention review (if applicable), shall be forwarded for consideration at the next scheduled meeting of the DoH Institutional Review Board (IRB) within the prescribed number of 10 (ten) working days.
 - 3.5.4.5.2 Notification of application validity will be issued via formal email within 5 (five) working days from receipt of documents or via online software.

3.5.5 DoH IRB Review Step

- 3.5.5.1 The DoH IRB will review the submitted applications and accordingly the decision will be formally communicated to the applicant once concluded.
- 3.5.5.2 When evaluating the documentation, the DoH-IRB or facility REC/IRB may require, on a one-off basis, the applicant to provide additional documentation, which may delay the commencement of the trial.
- 3.5.5.3 The applicant is required to promptly notify the DoH Institutional Review Board (IRB) of any decisions and requests for information issued by the facility REC / IRB, as well as the applicant's corresponding responses.
- 3.5.5.4 Decision of the DoH-IRB and REC/IRB could include:
 - 3.5.5.4.1 Approval.
 - 3.5.5.4.2 Rejection (justification for refusal will be provided), OR
 - 3.5.5.4.3 Conditional Approval (request some modification as a condition for obtaining full approval).

- 3.5.5.5 Any DoH IRB decision should be considered a single opinion of the DoH IRB members.
- 3.5.5.6 Upon fulfillment of all requirements and receipt of approval from the Institutional Review Board (IRB), the research approval or response letter shall be issued within 28 working days from the date on which all requests for information from the DoH IRB have been satisfied.
- 3.5.5.7 The letter of approval to conduct biomedical research must contain the following information:
 - 3.5.5.7.1 Name of the authorized Research Facility as per the submitted license.
 - 3.5.5.7.2 Name of the Investigator, CROs
 - 3.5.5.7.3 Ref no. of the protocol (or attach the protocol)
 - 3.5.5.7.4 Details / description of the investigational intervention (ex: IND / IMD / solution) as applicable
 - 3.5.5.7.5 Effective date of the approval letter.
 - 3.5.5.7.6 Term of the approval letter (365 calendar days in most cases).
 - 3.5.5.7.7 Authorized Research Activity that the authorized Research Facility intends to conduct.
 - 3.5.5.7.8 Where applicable: any terms, conditions, or restrictions may be specified by DoH.
 - 3.5.5.7.9 Authorized Research Site address where the DoH reserves the right to conduct site assessment visits to ensure the site is suitable for the Authorized Research Activity and for ongoing quality checks; and
 - 3.5.5.7.10 Research approval reference number which will be generated by DoH.
- 3.5.5.8 Appeal of DoH-IRB and REC/IRB Decision
 - 3.5.5.8.1 Where the opinion / decision of the DoH IRB is “rejection”, the investigator may, within a period of 28 working days of the date of notification, appeal its decision.
 - 3.5.5.8.2 The opinion of the DoH IRB upon appeal review should be final and binding.
- 3.5.5.9 Withdrawals of Application
 - 3.5.5.9.1 If the applicant wishes to withdraw the clinical research application before the DoH has reached its decision on the application due to unexpected events or additional information, the applicant should inform the DoH in written as soon as possible of the intention to withdraw the application.
 - 3.5.5.9.2 A formal letter of withdrawal providing a brief description of the reasons should be provided.

3.5.6 Non-industry Sponsored Biomedical Research

- 3.5.6.1 IT is also known as Investigator-Initiated Trial (IIT)
- 3.5.6.2 Staff members or postgraduate students (residents, fellows) planning research projects involving biomedical research shall initiate the review process by submitting the application for approval of biomedical research form to the Chair of the DoH-IRB and facility’s REC/IRB, through its secretary.
- 3.5.6.3 Researchers shall submit a fully developed research plan and accompanying documentation (e.g., questionnaires, interview scripts, informed consent forms).
- 3.5.6.4 For research conducted by residents, fellows, Master or PhD students, applications shall be approved by their program director or the institute’s Designated Institutional Official (or equivalent) before submission to the DoH IRB and the facility IRB / ERC.

3.5.7 Pharmaceutical/Biotech Sponsored Biomedical Research

3.5.7.1 For biomedical research applications under pharmaceutical, biotech or MedTech companies' sponsorship - intended to use hospital / research facility resources (laboratory, pharmacy, diagnostic equipment)- shall be submitted by the sponsor to both the DoH-IRB and facility's REC/IRB, and research director, or equivalent to be approved before commencement.

3.5.8 Other studies:

3.5.8.1 In case of retrospective studies and case reports coming from a single institution: only this facility IRB / REC approval is required.

3.5.8.2 In case of genomic or pandemic / endemic epidemiology studies regardless of the design if retrospective or prospective and involving human subjects must be approved by both facility IRB /ERC and DoH-IRB.

3.6 DoH-IRB/ Facility IRB level of review and decision making

3.6.1 Level of Review by facility IRB / REC

3.6.1.1 The DoH-IRB / facility IRB/REC shall categorize all applications for biomedical research into one of three review tiers: Exempt, Expedited, or Full.

3.6.1.2 The DoH-IRB / facility IRB/REC determines the level of review, even if the Investigator believes the research is exempt.

3.6.2 Exempt Review

3.6.2.1 Research may qualify for exemption from full facility IRB/REC review; non-exhaustive examples are below:

3.6.2.1.1 If the research uses existing data, documents, records, or biological specimens that are publicly available or recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

3.6.2.1.2 Research on Educational Practices: Research conducted in established or commonly accepted educational settings involving normal educational practices, such as instructional strategies or classroom management methods.

3.6.2.1.3 Research Involving Minimal Risk and Non-Sensitive Topics: Non-clinical research involving the use of educational tests, surveys, interviews, or observation of public behavior, provided that the information obtained is recorded anonymously and disclosure would not place subjects at risk of harm.

3.6.2.1.4 Activities designed for quality assurance, program evaluation, or improvement purposes, where the intent is not to contribute to generalizable knowledge.

3.6.2.2 Exemption does not mean the research is free from all ethical oversight; it may still require administrative review or notification.

3.6.2.3 The determination of exempt status is the responsibility of the facility IRB/REC, not the researcher. The researcher will be responsible for providing enough information and details to assist the facility IRB in ruling out the exempt review decision for the proposal.

3.6.2.4 For biomedical research proposals exempted by the facility IRB/ REC from full review are exempted from further / dual submission to the DoH-IRB approvals.

3.6.2.5 Research involving vulnerable populations (e.g., children, prisoners, refugees, pregnant women etc.) is rarely exempt.

3.6.2.6 For exempt research, the IRB/REC Chair/Co-Chair shall review the proposal and inform the Investigator of the decision.

3.6.3 Expedited Review

3.6.3.1 Research that poses only minimal risk to participants may be reviewed through the expedited process.

3.6.3.2 “Minimal risk” means that the probability and magnitude of harms or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during routine physical or psychological examinations.

3.6.3.3 For expedited research, the DoH-IRB / facility IRB/REC Chair and one other IRB/REC member shall review the proposal and inform the Investigator of the outcome.

3.6.4 Full Board Review

3.6.4.1 Research that does not qualify as exempt or expedited shall undergo full board review. The proposal shall be reviewed by both DoH-IRB / Facility IRB/REC in their convened meetings, during which discussion may occur.

3.6.4.2 A majority of facility IRB/REC members, including specifically the Emirates of Abu Dhabi community members, shall be present at the meeting to form a quorum and deliberate on the proposal.

3.6.4.3 The following research proposals should mandate full review:

3.6.4.3.1 Includes challenging (ethically, scientifically) concepts:

3.6.4.3.1.1 Embryonic based cells / tissues

3.6.4.3.1.2 Brain-Computer Interface

3.6.4.3.1.3 Interfering or manipulating a natural process

3.6.4.3.1.4 Includes unexplainable phenomenon

3.6.4.3.1.5 Includes ultra specialized non explicit unexplainable methods (AI, Gene manipulation)

3.6.4.3.2 Subject and material of the research impose uncontrollable risks if wrongly used or uncontrolled:

3.6.4.3.2.1 Dual Use objects/materials are involved

3.6.4.3.2.2 Activities implying high risks of Biosafety as a great concern

3.6.4.3.3 Clinical Trials:

3.6.4.3.3.1 Including interventions that are still at investigational phase or for unauthorized indications or method of use.

3.6.4.3.3.2 Testing combination of technologies, products, solutions difficult to classify under an explicit archetype

3.6.4.3.4 Presents ultra risk:

3.6.4.3.4.1 Requiring real-time monitoring and decision making for managing serious health issue(s)

3.6.4.3.4.2 Conclusions/test thesis are expected or have the potential to impact large population at a time.

3.6.4.3.4.3 Success will have a massive disruptive impact.

3.6.4.4 Applications considered for full review

3.6.4.4.1 Shall require the DoH IRB review and approval before commencement.

3.6.4.4.2 At the discretion of the DoH IRB, may require special arrangements for monitoring (ex: regulatory sandbox arrangements)

3.6.5 Duration of Ethical Opinion

- 3.6.5.1 The DoH-IRB / Facility IRB/REC's favorable ethical opinion remains valid for 365 calendar days and must be renewed annually through the renewal application unless suspended or terminated, provided the IRB/REC may review its opinion at any time.
- 3.6.5.2 If the study extends beyond the originally approved duration, the Investigator shall notify the DoH-IRB / Facility IRB/REC with reasons for the extension and continue submitting annual progress reports.
- 3.6.5.3 Extensions alone are not considered substantial amendments unless they involve other significant changes, and formal approval is not required unless substantial amendments are proposed.

3.6.6 Reviewing Reports

- 3.6.6.1 The DoH-IRB / Facility IRB/REC's shall receive the following reports from the Investigator: progress reports, final reports, periodic safety reports, and findings and recommendations from the DSMB/IDMC, where applicable.
- 3.6.6.2 Progress reports and the final report shall be reviewed at least by the Chair or Co-chair of the DoH-IRB / Facility IRB/REC's, at the Chair's or Co-chair's discretion, by one or more members of the committee or a scientific officer.
- 3.6.6.3 Annual periodic safety reports shall be reviewed at least by the DoH-IRB / Facility IRB/REC's Chair/Co-Chair and, unless the Chair has appropriate expertise, by an expert member or referee. The review of periodic safety reports shall:
 - 3.6.6.3.1 Check the accuracy of the risk/benefit analysis as described in the participant information sheet
 - 3.6.6.3.2 Consider the possible need for new information to be given to participants and their consent sought to continue in the study
 - 3.6.6.3.3 Consider the possible need for new information to be given to participants and their consent sought to continue in the study
 - 3.6.6.3.4 Consider any other issue that may be relevant to the ethics of the trial or clinical research study
 - 3.6.6.3.5 Where concerns arise about any of the above, the DoH IRB/ facility IRB/REC may contact the Investigator or sponsor to express its concerns, request further information, and may invite the Investigator to attend a meeting of the committee to discuss the concerns of the IRB/REC.
 - 3.6.6.3.6 Findings and recommendations from the DSMB/IDMC shall be reviewed in the same way as periodic safety reports.

3.6.7 Monitoring / review of Research IRB/ REC Decisions

- 3.6.7.1 The IRB/REC shall monitor its favorable ethical opinion by reviewing regular annual progress reports and any significant developments in the research.
- 3.6.7.2 The IRB/REC may review its favorable ethical opinion of a study at any time. This may be prompted by safety reports, progress reports, or any other information received about the conduct of the study.
- 3.6.7.3 The Investigator or sponsor may ask the IRB/REC to review its opinion or seek advice from the IRB/REC on any ethical issue relating to the study.
- 3.6.7.4 The facility's IRB/REC may review its opinion considering new ethical concerns following any new information received about the trial or clinical research study. Any such review shall be based on a decision taken at a quorate meeting of the full committee.
- 3.6.7.5 Where the IRB/REC decides that it no longer has a favorable opinion of a trial and other studies, the Chair/Co Chair shall inform the DoH DoH-IRB. Facility's REC/IRB

may recommend that consideration be given to suspending or terminating the trial approval.

3.6.7.6 The IRB/REC is not responsible for proactive monitoring of research; this responsibility lies with the sponsor and the employing organization.

3.6.8 Suspension or Termination of biomedical research

3.6.8.1 Favorable ethical opinion on a non-interventional study all clinical/translational research studies may be suspended or terminated by the committee due to serious concerns about one of the following:

- 3.6.8.1.1 Scientific validity of the trial/Clinical Research
- 3.6.8.1.2 Health or safety of participants
- 3.6.8.1.3 Competence or conduct of the investigator(s)
- 3.6.8.1.4 Serious or repeated breach of approval conditions
- 3.6.8.1.5 A delay of at least two years in the commencement of the study, leading to doubts about the continuing validity of the ethical opinion given on the original application
- 3.6.8.1.6 Adequacy of the site or facilities

3.6.9 Potential Fraud and Misconduct

3.6.9.1 Where the IRB/REC receives information suggesting that any kind of fraud or misconduct may have occurred in relation to an application for ethical review or the conduct of research, the Chair or IRB/REC coordinator shall pass the information confidentially to the facility management, sponsor, and DoH.

3.6.9.2 The IRB/REC shall consider whether any action needs to be taken in relation to the ethical opinion of the research, where there could be an immediate risk to the safety of participants. The opinion on a non-interventional study may be suspended pending the outcome of further investigation by other bodies. Such a decision shall only be taken after careful consideration of the implications for research participants already recruited.

3.6.9.3 A member of the facility's IRB/REC who becomes aware of possible fraud or misconduct in research shall report this to the Chair and coordinator of the IRB/REC, who shall be responsible for reporting the matter to the DoH DoH-IRB

3.6.10 Suspension or termination of regulatory approval for the study

3.6.10.1 A decision by the IRB/REC to suspend or terminate a favorable ethical opinion shall be taken only at a quorate meeting of the full committee.

3.6.10.2 Before taking this decision, the IRB/REC shall carefully weigh the implications for any research participants already recruited.

3.6.10.3 The Investigator shall be notified of the decision by the Chair or co-chair.

3.7 Insurance, Indemnity & Compensation

- 3.7.1 In clinical trials conducted in Abu Dhabi the primary responsibility to provide insurance for research-related injury or harm rests with the research sponsor; in case of interventional clinical trials, insurance is mandatory. The sponsor must ensure that appropriate insurance or indemnity arrangements are in place to cover potential liabilities for research participants. This coverage should include compensation for medical expenses and other related costs.
- 3.7.2 The research facility (site) may also be required to maintain its own institutional liability insurance, but the sponsor's insurance specifically addresses participant injuries directly resulting from the trial. The Investigator or physician malpractice insurance does not equate to the clinical research insurance, and both must be finalized before commencing the clinical research.
- 3.7.3 This requirement mandated by DoH is a standard expectation under ICH-GCP E6(R3).
- 3.7.4 Research facilities, investigators and sponsors are responsible for ensuring through the Clinical Trail agreements that insurance cover is adequate to protect the investigators and the institutions from legal liability in case of injury or death to any of the study participants.
- 3.7.5 Documentation proving insurance coverage must be submitted as part of the research application to the Ethics Review Committee (ERC) of the facility /and to DoH IRB.
- 3.7.6 The costs of investigational and experimental interventions tested/ studied in clinical trials shall be covered by the sponsor and are generally excluded from reimbursement by insurance. This exclusion is in accordance with the Health Insurance Law General.

3.8 Clinical Trials (Interventional Biomedical Research)

3.8.1 General terms:

3.8.1.1 As the definition implies, Clinical trials are a form of biomedical research in which participants consent to test investigational, typically unauthorized interventions (such as drugs, devices, artificial intelligence solutions, technologies, approaches, or combinations of these) to evaluate their safety and efficacy, with the main goal of satisfying regulatory requirements to obtain marketing authorization or supplement / expand an existing marketing authorization for the intervention being tested.

3.8.2 Phases of Clinical Trials: Clinical Trials as a regulatory requirement are phased according to the following order⁵

- 3.8.2.1 **Phase 0:** are micro-dosing clinical trials. Participants, receiving sub-therapeutic doses, face reduced risks compared to conventional phase I trials but necessitate close monitoring.
- 3.8.2.2 **Phase I:** A phase I trial marks the initial stage of human testing. Certain phase I trials, particularly the "first-in-human" (FIH) and dose-escalating trials, are linked to higher risk of potential harm compared to other trial phases. For rare diseases, a natural history lead-in study into phase 1 trials is allowed and encouraged.
- 3.8.2.3 **Phase II:** Phase II clinical trials are conducted to evaluate the safety and efficacy of an investigational drug in a larger group of individuals affected by the targeted disease or condition.
- 3.8.2.4 **Phase III:** Phase III trials confirm the efficacy and safety of an investigational drug by comparing it to the current standard of care. Before starting this phase of trial, a formal discussion with the DOH is required to define the comparator arm, especially when choosing between placebo and active control for trial designation, based on the clinical standards practiced within Abu Dhabi

Outcomes utilizing hierarchical composite endpoints (e.g. win ratios) are acceptable and encouraged when designing randomized clinical trials.

3.8.2.5 **Phase IV:** Phase IV clinical trials are conducted after a drug has received regulatory approval (and is available in the market).

3.8.3 The research / study protocol:

3.8.3.1 The use of novel study /trial designs are encouraged including adaptive trial designs, platform trials (master protocols), pragmatic trials, decentralized clinical trials, seamless trials, and basket trials, to increase research efficiency is encouraged (see definitions for each in section 2).

3.8.3.2 Protocols for various clinical designs should include guidelines or predetermined rules for interim analyses, decision-making processes, and data monitoring.

3.8.3.3 The use of real-world data and digital health technologies, such as electronic health records (EHRs), telemedicine, and wearables etc.:

3.8.3.3.1 Are allowed by the DoH

3.8.3.3.2 Protocol shall comply with the relevant guidelines to ensure ethical use and regulatory compliance.

3.8.3.3.3 Details of the protocol shall address data privacy, security, and the ethical considerations of digital data collection.

3.8.3.3.4 Procedures should ensure that these technologies are used responsibly, and that data is handled in accordance with privacy laws and regulations. Electronic consenting by participants is allowed.

3.8.3.4 First, in human trials originating from drug development from stem cell derived (or tumor derived) organoid models are allowed. Clinical research into which the drug origins are utilizing computer-assisted methodologies (e.g. In-silico approaches) are allowed. In all instances the research needs to be approved by DoH according to the set procedures above. Organoid is a 3D, self-organized, miniature tissue grown from stem cells in a lab that mimics the structure, complexity, and functions of a human organ.

3.8.3.5 Any deviations or violations from protocol need to be:

3.8.3.5.1 Handled effectively, maintaining the trial's integrity and protecting participant's safety.

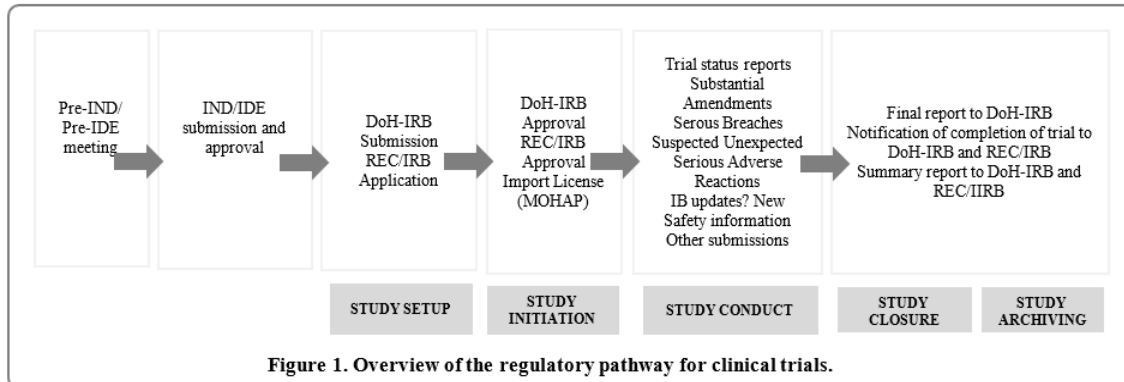
3.8.3.5.2 To conduct an impact assessment, root cause analysis and implementation of corrective and preventive actions (CAPA) are required.

3.8.3.5.3 To be recorded and documented.

3.8.3.5.4 If substantial, to be notified to the facility responsible in charge of clinical trials, to the IRB / REC of the Facility and to the DoH IRB.

3.8.4 Regulatory pathway for Interventional Clinical Trials

3.8.4.1 An overview of the regulatory roadmap for clinical research from study set-up to study archival is summarized in Figure 1 below:



3.8.4.2 The sponsor (Principal Investigator in selected cases) shall first apply to obtain an IND or IDE from the DoH.

3.8.4.3 Then the sponsor (Principal Investigator in selected cases) shall submit the application to conduct clinical research, in parallel to both the DoH IRB and the institutional IRB.

3.8.4.4 Approval from DoH's IRB is valid for 365 calendar days and an annual renewal is required within 30 calendar days of the expiration date.

3.8.4.5 For clinical trials requiring an import license for the IMP or device, EDE would be the responsible body, but DoH IRB approval is mandatory BEFORE applying for the import permit.

3.8.5 Pre- Investigational Intervention (Pre-Investigational Medical Product (IMP) submission meeting:

3.8.5.1 Before initiating any interventional clinical trial / pivotal clinical trial regardless of the phase, a pre-Investigational meeting is required (Pre-IND, Pre-IMD/IDE)

3.8.5.2 In this meeting and according to the phase of the study the sponsor is expected to provide clear, accurate and comprehensive relevant information about the intervention in the following manner:

3.8.5.2.1 Scientific background, rationale and discovery path.

3.8.5.2.2 Discuss with the DoH on preclinical studies, pharmacology/toxicology or good laboratory practice (GLP) toxicology, or device safety.

3.8.5.2.3 Provide information on the IND / IVD description, intended use, mechanism of action, formulation and form, and method of use

3.8.5.2.4 Manufacturing information / processing including GMP / ISO certification information as applicable

3.8.5.2.5 History of the intervention and previous experience, previous clinical trials.

3.8.5.2.6 Burden of the disease / healthcare challenge as applicable and potential impact on patients/ healthcare/ economic outcomes and public health outcomes.

3.8.5.2.7 World-wide regulatory status including approvals so far and designations.

3.8.5.2.8 The phase of the trials proposed and the main features of the proposed protocol, including risks and risk management plan (RMP).

3.8.5.2.9 Other aspects the sponsor find it important to justify the trial.

3.8.5.3 The pre-IMP meeting may be followed by more questions and request for information, including more meetings with experts, or a specialized panel.

3.8.6 Investigational Intervention documents and evaluation:

- 3.8.6.1 After the pre-IMP meeting, an IND/IDE submission is required:
- 3.8.6.2 The minimum required documents for this submission are:
 - 3.8.6.2.1 Intervention description, its intended uses to be tested.
 - 3.8.6.2.2 History of intervention, previous experience, and previous decisions by regulatory authorities.
 - 3.8.6.2.3 Documentation on reference country approvals if any.
 - 3.8.6.2.4 Mechanism of action
 - 3.8.6.2.5 For medicinal investigational products and pharmaceutical dosage form classified as medical devices: Chemistry, Manufacturing and Control as applicable (preferably using CTD format).
 - 3.8.6.2.6 For medical devices and MedTech: the full design , quality assurance/ quality control and specifications.
 - 3.8.6.2.7 Manufacturing sites: GMP, ISO certification as applicable
 - 3.8.6.2.8 Artwork, pictures and other diagrams clearly describing the intervention.
 - 3.8.6.2.9 Preclinical and toxicology studies and references.
 - 3.8.6.2.10 Clinical studies (including pharmaco- dynamics and pharmaco- kinetics) and references
 - 3.8.6.2.11 PV system, plan and risk management plan (RMP).
 - 3.8.6.2.12 The IND application must include potential environmental impact of a clinical trial and its associated activities. If a genetically modified organism (GMO) is involved in a clinical trial.
 - 3.8.6.2.13 A GMO risk assessment submission for IND is required (if applicable)
 - 3.8.6.2.14 Investigation plan and rationale
- 3.8.6.3 Once the IND / IDE or exemption is granted, the IRB submissions may be made.

3.8.7 Phase 1 / first in Human Clinical Trial Submission

- 3.8.7.1 Phase I clinical trials shall be permitted in:
 - 3.8.7.1.1 Participants suffering from serious diseases or conditions (such as cancers, cardiovascular diseases, neurological disorders, infectious diseases, autoimmune diseases, rare diseases etc.).
 - 3.8.7.1.2 Healthy participants ONLY if the institution is officially designated or permitted by the DoH to conduct Phase I trials or having a No-Objection-Certificate to conduct phase 1 clinical trials
- 3.8.7.2 In the case of animal studies, the DoH can guide during pre-IND or IND meetings whether one or more species are sufficient to allow a FIH clinical trial.
- 3.8.7.3 For FIH clinical trials conducted in Abu Dhabi, the DoH shall have the discretion to determine, in the case of novel interventions, whether the design, approval, and conduct of animal studies and toxicological studies must be discussed with, approved by, and conducted under the oversight of the DoH or another relevant regulatory authority.

3.8.8 Innovative Diagnostic and Therapeutic Studies:

- 3.8.8.1 Studies evaluating machine learning models for diagnostic or therapeutic purposes are permitted and require a full DoH REC/IRB review.
- 3.8.8.2 Refer to DoH policy on Bioconvergence.

3.8.9 Traditional, Complementary and Alternative Medicine (TCAM)

- 3.8.9.1 TCAM investigations with any active pharmaceutical ingredient to be used commercially must undergo clinical trials.
- 3.8.9.2 The active pharmaceutical ingredient of TCAM should be produced in a cGMP facility before human use, and it should be of pharmaceutical grade (e.g. USP grade or equivalent).

- 3.8.9.3 This guidance document is applicable to all TCAM products involving an active pharmaceutical ingredient (plant based or animal based).
- 3.8.9.4 The World Health Organization (WHO) states that a full range of toxicological tests may not be necessary. Instead, tests which examine effects that are difficult or even impossible to detect clinically should be encouraged. WHO recommends at a minimum the following tests:
 - 3.8.9.4.1 Immunotoxicity (e.g. tests for allergic reactions),
 - 3.8.9.4.2 Genotoxicity
 - 3.8.9.4.3 Carcinogenicity and reproductive toxicity,
 - 3.8.9.4.4 Renal and Liver toxicity tests,
 - 3.8.9.4.5 Hematological toxicity tests

3.8.10 Clinical Trial process post IMP (IND/ IMD/ investigational Intervention) status granting:

- 3.8.10.1 The submission process for the DoH IRB and institutional IRB may take place simultaneously as per the sponsor's choice.
- 3.8.10.2 The same principles for IRB / REC review process discussed for general biomedical research in section 3.5 above will apply.
- 3.8.10.3 Clinical trials with interventional design may begin when all the following conditions are fulfilled:
 - 3.8.10.3.1 The DoH IRB has issued a written approval.
 - 3.8.10.3.2 The institutional IRB has provided written approval.
 - 3.8.10.3.3 Drug Control Department at The Emirates Drug Establishment (EDE) has issued an import license for the intervention (if applicable).
 - 3.8.10.3.4 Clinical trial insurance letter to sponsor is obtained and valid throughout the duration of the trial.
 - 3.8.10.3.5 A DSMB or IDMC (see section 3.8.11) is established for monitoring the clinical trial.
- 3.8.10.4 The Sponsor must ensure that every clinical trial must be registered in a publicly accessible database before recruitment of the first subject (such as www.clinicaltrials.gov or equivalent).

3.8.11 DSMB/ IDMC

- 3.8.11.1 **General term:** The DoH mandates the principal investigators to have an ethical obligation to develop a DSMB/IDMC for interventional clinical trials research to ensure the safety of participants and the integrity of the data. An exemption from the establishment of the DSMB/IDMC may be requested in cases of low-risk interventions with justifications and it is up to the DoH to approve the request (see below).
- 3.8.11.2 **Procedures for Establishing a DSMB/IDMC**
 - 3.8.11.2.1 Develop a DSMB/IDMC charter outlining the roles, responsibilities, procedures, and frequency of meetings. This charter shall be agreed upon by all DSMB/IDMC members prior to the trial initiation.
 - 3.8.11.2.2 Select DSMB/IDMC members who are independent of the trial sponsor, CRO, and participating institutions, ensuring no conflicts of interest.
 - 3.8.11.2.3 Schedule regular DSMB/IDMC meetings to review accumulated data, with the frequency of meetings based on the risk profile and complexity of the trial.

- 3.8.11.2.4 Maintain detailed records of all DSMB/IDMC meetings, decisions, and recommendations, and ensure timely communication of DSMB/IDMC recommendations to the trial sponsor and the DoH.
- 3.8.11.3 **Composition of the DSMB/IDMC**
 - 3.8.11.3.1 The DSMB/IDMC shall consist of independent, multidisciplinary experts who are not affiliated with the trial sponsor or the institutions where the trial is conducted.
 - 3.8.11.3.2 The DSMB/IDMC shall include the following members, as appropriate:
 - 3.8.11.3.2.1 Clinical experts relevant to the therapeutic area
 - 3.8.11.3.2.2 Biostatisticians with experience in clinical research data analysis
 - 3.8.11.3.2.3 Ethics experts, where appropriate, provide guidance on ethical considerations
 - 3.8.11.3.2.4 Patient representatives, when appropriate, to offer perspectives on patient
 - 3.8.11.3.2.5 safety and trial conduct
- 3.8.11.4 **Responsibilities of the DSMB/IDMC**
 - 3.8.11.4.1 Regularly reviewing safety data, as specified in the DSMB/IDMC charter for the study, to identify any adverse trends or safety concerns.
 - 3.8.11.4.2 Periodically assessing efficacy data, as specified in the DSMB/IDMC charter for the study, to determine whether the trial objectives are being met.
 - 3.8.11.4.3 Recommending modifications to the trial protocol, including dose adjustments or early termination if necessary for safety reasons.
 - 3.8.11.4.4 Providing independent recommendations to the trial sponsor and investigators regarding the continuation, modification, or termination of the trial.
- 3.8.11.5 **Types of Studies Requiring a DSMB/IDMC**
 - 3.8.11.5.1 The DoH mandates the establishment of a DSMB/IDMC for the following types of clinical research:
 - 3.8.11.5.1.1 Trials involving novel or high-risk interventions, including but not limited to gene therapy, stem cell therapy, cellular therapy, and biologics.
 - 3.8.11.5.1.2 Studies involving vulnerable populations, such as children, pregnant women, the elderly, or individuals with severe comorbid conditions
 - 3.8.11.5.1.3 Multi-center phase II/III or seamless trials with large participant populations, particularly those intended to support marketing authorization applications
 - 3.8.11.5.1.4 Trials investigating treatments for life-threatening conditions or diseases with significant morbidity and mortality rates
 - 3.8.11.5.1.5 Trials with complex designs, such as adaptive trials, that require ongoing data review and interim analyses
 - 3.8.11.5.1.6 Traditional, Complementary, and Alternative Medicine (TCAM) trials
 - 3.8.11.5.1.7 All phase I / first-in-human trials on patients
 - 3.8.11.5.1.8 All clinical research with invasive devices includes surgeries and or procedures.
 - 3.8.11.5.1.9 All clinical research with a combination of device and a drug

3.8.11.6 Seeking Exemptions from DSMB/IDMC Requirements

3.8.11.6.1 Although it is the sponsor's responsibility to assess the need for and establish a DSMB/IDMC, the DoH recognizes that certain trials may not require a DSMB/IDMC based on their risk profile and complexity. Sponsors may seek exemptions from DoH formally and DoH will response back with the following conditions:

3.8.11.6.1.1 Risk Assessment Justification: Provide a comprehensive risk assessment justifying why a DSMB/IDMC is not necessary for the specific trial. This assessment shall include details on alternative safety monitoring strategies that will be implemented

3.8.11.6.1.2 Discussion with DoH: Submit a formal request for exemption to the DoH's Medical Research Department, including the trial protocol, risk assessment, and proposed monitoring plan

3.8.11.6.1.3 DoH Review and Decision: The DoH shall review the exemption request and may approve, reject, or request additional information. Sponsors shall be notified of the decision in writing

3.9 Reporting responsibilities

3.9.1 Suspected Adverse Reaction (SAE)/ Suspected Unexpected Serious Adverse Reaction (SUSAR)

3.9.1.1 Principal Investigator has to report to the sponsor within 24 hours of becoming aware.

3.9.1.2 The sponsor has to report to the DoH SAEs/SUSAR within 7 calendar days of being aware.

3.9.1.3 A SUSAR is a serious adverse reaction to an investigational medicinal product in a clinical trial that is both suspected to be related to the product and is unexpected based on existing information, requiring expedited reporting to authorities.

3.9.1.4 SUSAR has significant regulatory importance. The purpose of SUSAR reporting is to ensure the ongoing safety of trial participants and to allow timely risk assessment of investigational products.

3.9.1.5 Both initial and follow-up reports of SAE/SUSAR, shall be submitted to the DoH IRB/ accompanied by a cover letter on the company's or CRO letterhead.

3.9.1.6 The sponsor should inform the investigators carrying out the clinical research with an investigational medicinal product of any SAE/SUSAR associated with the tested medicinal product, irrespective of its origin / place/ clinical trial.

3.9.1.7 The minimum criteria for initial expedited reporting of SAEs/SUSARs shall include:

3.9.1.7.1.1 Suspected Investigational Intervention

3.9.1.7.1.2 Identifiable participant (e.g. study participant code number)

3.9.1.7.1.3 An adverse event assessed as serious and/or unexpected, and for which there are reasonable suspected causal relationship (s).

3.9.1.7.1.4 An identifiable reporting source

3.9.1.7.1.5 The required administrative details for clinical safety data management include the unique case identifier (e.g., sponsor's case identification number, if applicable), the study protocol number (e.g., DoH IRB number), or the sponsor's trial protocol code number, where applicable.

3.9.1.7.1.6 Information on the final description and evaluation of an adverse reaction report may not be available within the required time frames for reporting.

3.9.1.8 SAE/SUSAR Follow-up Reports

- 3.9.1.8.1 In case of incomplete information at the time of initial reporting, all the appropriate information for an adequate analysis of causality should be actively sought from the reporter or other available sources.
- 3.9.1.8.2 The sponsor should report further relevant information after receipt as follow-up reports.
- 3.9.1.8.3 In certain cases, it may be appropriate to conduct follow-up of the long-term outcome of a particular reaction.

3.9.2 Reporting Non-Intervention Related Serious Adverse Event (SAE)s

- 3.9.2.1 The PI must report Non-Intervention Related Serious Adverse Event, which should be notified to the IRB/REC using the DoH Adverse Drug Reaction Reporting Form.

3.9.3 Reporting Serious Breaches of GCP or the Protocol

- 3.9.3.1 A serious breach is a breach during clinical research which is likely to affect to a significant degree:
 - 3.9.3.1.1 The safety, or physical or mental integrity, of any participant in clinical research.
 - 3.9.3.1.2 The scientific value of clinical research.
- 3.9.3.2 The sponsor must notify the Facility IRB/ REC and DoH of any serious breach of the study (research protocol) within 5 working days of the sponsor becoming aware of the serious breach via email or online.
- 3.9.3.3 The facility IRB/REC / DoH IRB shall be notified of serious breaches of the conditions or principles of GCP as set out in the regulations.
- 3.9.3.4 Any such report shall be considered at a meeting of the IRB/REC.
- 3.9.3.5 There is no statutory provision for the IRB/REC to approve proposed deviations from the research protocol for individual participants.
- 3.9.3.6 It is the responsibility of the sponsor and/or investigator to determine whether research protocol or Informed Consent Form amendments are required: Where the amendment is substantial, it shall be notified to the IRB/REC.

3.9.4 Post-Clinical Trial Safety Reporting

PV after clinical trials specifically during the period between the conclusion of clinical trials and before the drug enters the market is crucial to ensuring the ongoing safety and efficacy of investigational products. Both the DoH and Sponsors shall fulfil distinct yet complementary responsibilities during this phase, as follows:

- 3.9.4.1 The DoH shall oversee the collection and evaluation of safety data from extended clinical trials and compassionate use programs, ensuring that any adverse events are thoroughly investigated.
- 3.9.4.2 The DoH shall ensure that any potential risks identified during this phase are appropriately managed, in support of the safe transition of the drug to market approval.
- 3.9.4.3 Sponsors shall maintain rigorous pharmacovigilance systems, including the prompt reporting of adverse reactions and the continuous assessment of safety data.
- 3.9.4.4 Sponsors shall confirm with the DoH whether any specific DoH SAE reporting forms are required for the collection and submission of safety data.

3.9.4.5 Sponsors and the DoH shall collaborate to identify, assess, and mitigate risks effectively before market approval.

3.9.5 Periodic Safety Reporting

3.9.5.1 The Sponsor shall provide DoH DoH-IRB and facility's REC/IRB with an annual report on the safety profile of the IMP.

3.9.5.2 Periodic safety reports shall be accompanied by a line listing all suspected serious adverse reactions occurring in the trial during the year, including both expected and unexpected reactions.

3.9.5.3 Periodic safety reports shall be sent to DoH DoH-IRB and facility's REC/IRB as soon as practical after the end of the reporting period.

3.9.5.4 The minimum content of the periodic safety reports is as per the PV guidance documents issued by DoH and EDE.

3.9.6 Urgent Safety Measures

3.9.6.1 The sponsor or the investigator may undertake urgent safety measures to protect the participants of clinical research against any risks appearing on sudden basis to their safety and health.

3.9.6.2 In such cases, the sponsor shall immediately notify DoH-IRB and REC/IRB facility of the action undertaken and the reasons for those actions.

3.9.7 Unanticipated Events

3.9.7.1 Any unanticipated events shall be reported to DoH-IRB and facility's REC/IRB.

3.9.7.2 In general, the following occurrences shall be reported to DoH-IRB and facility's REC/IRB,:

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

3.9.7.2.2 Post-study SUSARs that occur after the participant has completed a trial and are reported by the Investigator to the sponsor

3.9.7.2.3 A new event, related to the conduct of the trial or the development of the IMP, that is likely to affect the safety of participant, such as:

3.9.7.2.4 A SAE which could be associated with the trial procedures, and which could modify the conduct of the trial (for example, an SAE occurring during the run-in period)

3.9.7.2.5 A significant hazard to the participant population such as lack of efficacy of an IMP used for the treatment of a life-threatening disease

3.9.7.2.6 A major safety finding from a newly completed animal study (such as carcinogenicity)

3.9.7.2.7 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.

3.9.7.2.8 The conclusions or recommendations of the DSMB/IDMC, where relevant for the safety of participant

3.9.7.2.9 Any information that materially alters the current risk/benefit assessment of the IMP, or merits changes in the way the IMP is administered, or in the overall conduct of the trial, shall also be reported to DoH-IRB and facility's REC/IRB using the DoH Adverse Drug Reaction Reporting Form.

3.10 Investigator's Brochure (IB)

3.10.1 For the IB details and content, applicants can refer to the GCP ICH E6 (R3)

3.10.2 Every 365 calendar days, the Investigator shall submit to DoH DoH-IRB and facility's REC/IRB an updated IB or other relevant information concerning the safety profile of the investigational product if applicable

3.11 Informed Consent:

3.11.1 General Principles of Informed Consent

3.11.1.1 Securing informed consent from participants is a fundamental ethical and legal obligation in clinical research, upholding the autonomy and rights of participants.

3.11.1.2 For general informed consent form, the recommendations by the ICH GCP E6 (R3) shall be followed.

3.11.2 Research Requiring Consent

3.11.2.1 For all clinical trials including Phase I, II, III, device trials, or artificial intelligence interventions (e.g., AI chatbots) informed consent must be obtained exclusively by DoH-licensed clinicians, such as pharmacists, nurses, or physicians. These individuals must be qualified to explain not only the IMP/IMD and its potential side effects, but also alternative treatment options as outlined in the consent documentation.

3.11.2.2 For observational studies, non-interventional clinical studies etc. (which comprise most studies reviewed by the DoH, DoH-IRB, post-doctoral researchers and scientists may obtain consent, provided no medical discussion is required.

3.11.2.3 For observational studies in school children, with appropriate IRB and ADEK approvals, DoH-licensed practitioners are not required to obtain individual consent unless psychological assessments are involved, or otherwise mandated by the IRB.

3.11.2.4 For psychological or behavioral studies, informed consent must be obtained by DoH-licensed healthcare professionals.

3.11.2.5 For public health studies that do not involve clinical interventions, informed consent may be obtained by trained research staff rather than healthcare professionals in certain cases. Additionally, for studies involving secondary use of de-identified data or aggregate data collection with minimal risk, an informed consent waiver may be granted by the IRB/REC.

3.11.3 Informed Consent Process

3.11.3.1 The elements of an informed consent form are outlined in the ICH GCP guidelines and must be incorporated accordingly.

3.11.3.2 The informed consent form must be approved by the facility's IRB/REC prior to use and written in clear, practical, and understandable language that is non-technical and non-exculpatory.

3.11.3.3 Participants or their legally acceptable representatives must be given ample time and opportunity to ask questions, consider participation, and decide freely, without coercion, duress, or undue influence.

3.11.3.4 Informed consent must be obtained by the Investigator or a qualified, trained, and experienced study team member delegated by the Investigator.

3.11.3.5 The informed consent process must emphasize three principles: providing sufficient information, ensuring comprehension, and obtaining voluntary agreement. Care and patience are essential to achieve meaningful understanding.

3.11.3.6 The informed consent form must be personally signed and dated by:

- 3.11.3.6.1 The trial participant or legally acceptable representative
- 3.11.3.6.2 The individual obtaining consent
- 3.11.3.6.3 An impartial witness, if the participant is unable to read, sign, or date the form personally
- 3.11.3.7 A signed and dated copy of the informed consent form must be provided to the participant or legally acceptable representative, and the original must be filed in the investigator site file.

3.11.4 Informed Consent for Minors - ASSENT

- 3.11.4.1 Minors (individuals under 18 years of age) cannot legally provide consent to participate in research.
- 3.11.4.2 Consent for minors must be obtained from a parent or legally acceptable representative, acting in the best interests of the minor.
- 3.11.4.3 Assent from the minor must also be sought, appropriate to their age and capacity, and documented as part of the consent process.
- 3.11.4.4 Age-appropriate information must be provided and discussed with the minor to enable them to understand the study and voluntarily agree to participate.
- 3.11.4.5 A written assent form is appropriate for children aged 8 years and above and should be signed by the minor if capable of doing so.
- 3.11.4.6 The minor's capacity to provide assent must be assessed by the investigator prior to obtaining assent.
- 3.11.4.7 Supporting documentation of the minor's status must be retained in the study file:
 - 3.11.4.7.1 Birth certificate if consent is given by a parent.
 - 3.11.4.7.2 Certified court order letter if consent is given by a legal guardian.
- 3.11.4.8 If the minor reaches the age of legal capacity to consent during the trial, the investigator must:
 - 3.11.4.8.1 Provide a full explanation of the trial to the participant.
 - 3.11.4.8.2 Seek the minor's informed consent to continue participation at the earliest opportunity.
 - 3.11.4.8.3 For minors' enrolment in clinical research, one parent's written informed consent is acceptable for low-risk studies if both parents are married with no legal disputes, while both parents' consent (verbal and written) is required for high-risk trials, and the same rules apply to legal guardians as determined by the court.

3.11.5 Informed Consent for Adults Lacking Capacity

- 3.11.5.1 An adult lacking capacity is an individual who, at any given time, is unable to make independent decisions because of an impairment or disturbance in the functioning of the mind or brain.
- 3.11.5.2 An individual is considered unable to make decisions if they cannot:
 - 3.11.5.2.1 Understand relevant information
 - 3.11.5.2.2 Retain the information
 - 3.11.5.2.3 Use or weigh the information as part of their decision-making
 - 3.11.5.2.4 Communicate their decision by any means (speech, sign language, or other)
 - 3.11.5.2.5 Consent for adults lacking capacity must be provided by a legally acceptable representative, who must act in the best interests of the participant.
 - 3.11.5.2.6 If the legally acceptable representative is under 18 years of age, The investigator must determine that the representative has sufficient understanding and intelligence to provide informed consent.
 - 3.11.5.2.7 The legally acceptable representative shall be identified in descending order of priority, if no power of attorney has been appointed:

- 3.11.5.2.7.1 Spouse of the adult
- 3.11.5.2.7.2 Adult child of the adult
- 3.11.5.2.7.3 Parent or guardian of the adult
- 3.11.5.2.7.4 Adult sibling of the adult
- 3.11.5.2.7.5 Any other adult previously named by the participant as someone to consult

3.11.5.3 Appropriate information should still be provided to an adult who lacks capacity, to an extent compatible with their understanding, and assent to participate should be sought whenever possible.

3.11.5.4 If capable, the participant should sign and personally date an assent form to document their agreement.

3.11.5.5 If an adult participant regains capacity to consent during the trial, the investigator must:

3.11.5.5.1 Provide a full explanation of the trial and its implications as soon as possible

3.11.5.5.2 Promptly seek the participant's informed consent to continue participation

3.11.5.5.3 If the participant declines, ensure their immediate withdrawal from the trial or research study

3.11.6 Informed Consent in Emergency Situations

3.11.6.1 Emergency clinical research aims to assess the safety or efficacy of an investigational product in trial participants under specific conditions:

3.11.6.1.1 Participants are in a life-threatening situation requiring immediate intervention

3.11.6.1.2 Participants cannot provide consent due to their medical condition

3.11.6.1.3 It is not possible to seek consent from the participants' legally acceptable representatives within the Window Period

3.11.6.1.4 In an emergency, when prior consent of the participant is not possible, consent of the participant's legally acceptable representative should be requested.

3.11.6.1.5 When a participant's legally acceptable representative is not present, enrolment of the participant in the study should proceed in accordance with the process described in the protocol or as otherwise documented and approved by the DoH DoH-IRB and facility's REC/IRB.

3.11.7 Conditions for Enrolment into an Emergency Clinical Trial

3.11.7.1 If consent cannot be obtained from the prospective trial participant or their legally acceptable representative, and no family member has objected to the participant's enrolment (if feasible), the participant may be enrolled in clinical research if the investigator and one independent specialist certify in writing that:

3.11.7.1.1 The participant is confronted by a life-threatening situation necessitating use of the investigational product

3.11.7.1.2 Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the participant due to their medical condition

3.11.7.1.3 There is insufficient time to obtain consent from the participant's legally acceptable representative within the Window Period

3.11.7.1.4 No alternative approved or generally recognized therapy is available that offers an equal or greater likelihood of saving the participant's life

3.11.7.1.5 If, in the Investigator's opinion, immediate use of the investigational product is required to preserve the participant's life, and there is insufficient time to obtain an independent physician's determination, the Investigator may make the determination and administer the investigational product.

3.11.7.1.6 The Investigator must notify the IRB/REC within 5 working days after emergency use, providing a summary of attempts made to contact the participant's legally acceptable representative.

3.11.7.1.7 The research protocol must include conditions designed to protect the rights and safeguard the welfare of the participant.

3.11.8 Re-Consent of Participant Who Regains Capacity to Consent

3.11.8.1 At any time during the emergency clinical research, the participant regains the capacity to provide informed consent, the Investigator must expeditiously provide a comprehensive explanation of the trial and seek the participant's consent to continue participation.

3.11.8.2 If the participant is still unable to consent due to their medical condition, the investigator must, as soon as practicable, make reasonable attempts to contact the participant's legally acceptable representative, providing a full explanation of the trial and requesting consent for continued participation. The legally acceptable representative must act in the best interests of the participant.

3.11.8.3 If the legally acceptable representative cannot be reached, the Investigator must promptly attempt to contact a family member, provide a comprehensive explanation of the trial, and seek consent for the participant's continued participation.

3.11.8.4 All reasonable efforts to contact the participant's legally acceptable representative or family member must be documented in the participant's medical records.

3.11.8.5 If the participant, the legally acceptable representative, or a family member object to the Participant's continued participation in the clinical research, the Investigator must ensure the participant is withdrawn from the trial immediately.

3.11.9 Informed Consent in Illiterate Participants

3.11.9.1 When a participant is incapable of reading and understanding the informed consent form, consent must be obtained in the presence of an impartial witness.

3.11.9.2 The impartial witness must be present throughout the entire consent process, observing the explanation of information and the participant's voluntary agreement to participate.

3.11.9.3 After the informed consent form and any supplementary information are read and explained to the participant or the participant's legally acceptable representative, and they have orally agreed to participate, the following applies:

3.11.9.4 If the participant can do so, they should sign and personally date the informed consent form. A thumbprint is acceptable as a signature if necessary

3.11.9.5 The impartial witness must contemporaneously sign and personally date the consent form

3.11.9.6 The impartial witness's signature attests that:

3.11.9.7 The information in the informed consent form was accurately explained to the participant or legally acceptable representative

3.11.9.8 The participant or legally acceptable representative appeared to understand the information provided

3.11.9.9 The decision to participate was made voluntarily, without coercion or undue influence

3.11.10 Incidental Findings

3.11.10.1 The informed consent form must clearly address the possibility of incidental findings that may arise during the research study period. Participants shall be informed, in clear and understandable language, whether clinically

relevant incidental findings will be disclosed to them, the circumstances under which such disclosure may occur, and the process for communicating these findings. The consent form must describe the limitations of the research procedures in detecting health conditions, clarify that the research is not intended to replace routine clinical care, and outline any recommended follow-up or referral pathways where appropriate. Decisions regarding the disclosure of incidental findings must be consistent with ethical principles, participant welfare, applicable regulations, and the approval of the IRB/REC

3.11.11 Use of Translators

- 3.11.11.1 Ensuring that all participants fully understand the informed consent process is critical to the ethical conduct of clinical research. This includes providing information in a language that the participant can understand. The use of translators is essential when dealing with participants who do not speak the primary language of the trial.
- 3.11.11.2 During initial contact, each potential participant's language proficiency should be assessed to determine if a translator is necessary for the informed consent process. Participants should be made aware they have the right to request a translator if they are more comfortable communicating in a different language.
- 3.11.11.3 Translators must be fluent in both the language of the informed consent document and the participant's preferred language. Translators must possess knowledge of relevant medical terminology to convey complex concepts accurately and be culturally competent to ensure translations are appropriate and sensitive. Translators may be part of the study team.
- 3.11.11.4 Translators should receive training in the informed consent process, including the ethical and legal implications. Whenever possible, certified translators should be used to ensure high-quality translations.
- 3.11.11.5 The use of a translator must be documented in the participant's trial records, including the translator's name, qualifications, and relationship to the participant (if any).
- 3.11.11.6 The translator should be present throughout the entire informed consent process to ensure the participant fully understands the information. They should facilitate questions from the participants and ensure comprehensive answers are provided by the trial team. Verification of understanding can be achieved through a back-translation process. Ensure the translator is available for ongoing communication throughout the participant's involvement in the trial.
- 3.11.11.7 Ensure the use of translators respects the participant's dignity and privacy. Confirm that participants are comfortable with the presence of the translator and consent to their involvement.

3.11.12 Special Consent Procedures for Vulnerable Populations

- 3.11.12.1 For research involving neonates and individuals with intellectual disabilities, specific consent procedures must be followed.
- 3.11.12.2 For viable neonates, consent from one parent is sufficient (unless high risk clinical trial)
- 3.11.12.3 For non-viable neonates, consent from both parents is required.
- 3.11.12.4 If neither parent can provide consent due to unavailability or incapacity, a legally designated Substitute Consent Giver should be consulted.

4. Key stakeholder Roles and Responsibilities

4.1 Internal to DoH stakeholders:

- 4.1.1 Healthcare facilities licensing and Audit sections / Healthcare Quality Sector
- 4.1.2 Health workforce licensing section
- 4.1.3 Digital Health
- 4.1.4 Information and Cybersecurity

4.2 External Stakeholders

- 4.2.1 Ministry of Higher Education: ensure Universities and educational institutions a under their scope of authority and their biomedical research activities are compliant with the licensing requirements
- 4.2.2 Department of Economic Development (DED): to get the DoH required NOCs and Licensing approvals as applicable for the facilities involved in biomedical research such as but not limited to:
 - 4.2.2.1 CRO companies
 - 4.2.2.2 Bioequivalence centers
 - 4.2.2.3 Standalone biomedical Research Labs
 - 4.2.2.4 Others as need arise, DoH will coordinate with the DED
- 4.2.3 Emirates Drug Establishment EDE:
 - 4.2.3.1 To issue the import license for the investigational medical products
 - 4.2.3.2 To coordinate the Investigational medical products reviews and communicate to DoH upon request.
 - 4.2.3.3 To provide visibility on status of clinical trials approved by EDE for marketing authorization applications.
 - 4.2.3.4 To provide visibility on the biomedical research facilities and CROs licensed and their status
- 4.2.4 Ministry of Health and Prevention (MoHAP) and other Local Health Authorities in UAE:
 - 4.2.4.1 To provide visibility on status of clinical trials approved

5. Monitoring and Evaluation

5.1 Effective dates and compliance:

5.1.1 Facilities, investigators, researchers and sponsors need to comply with the updated version of this effective standard immediately,

5.1.2 Currently ongoing approved biomedical research applications are allowed to continue based on their original approval,

5.1.3 For biomedical research activities that didn't get the required approvals as per the new scope of this standard, facilities, researchers and sponsors need to apply for necessary approvals starting from March 2026 along with CAPA plan

5.1.4 The concerned entities listed in 5.1.1 and researchers will be granted a grace period of 15 months from the issuance of this standard to correct their current licensing status / and their biomedical research status. Corrective applications to start 3 months after this standard issuance date. For new facilities and new research this standard is effective immediately.

5.2 Monitoring

5.2.1 This standard must be updated according to the changes made in the DoH documents cited in this standard and under prior authorization of the DoH.

5.2.2 The following are the key success factors along with relevant stakeholders aimed to be monitored and evaluated periodically and ensure continuous improvement to the healthcare ecosystem.

Key Success Factor	Stakeholder	Responsibility to monitor
No. of DoH approved biomedical research applications per type: <ul style="list-style-type: none"> Interventional Applications Non-Interventional biomedical research 	Biomedical Research facilities (academic, laboratories, Bioequivalence centers, Clinics / Hospitals).	DoH Medical Research and Development – Health Life Science Sector
No. of patients enrolled in DoH approved biomedical research applications per type: <ul style="list-style-type: none"> Interventional Applications Non-Interventional biomedical research 	biomedical research facilities (academic, laboratories, Bioequivalence centers, Clinics / Hospitals).	DoH Medical Research and Development – Health Life Science Sector
% DoH approved biomedical research applications commenced within 6 months of the approval from DoH and completed per type: <ul style="list-style-type: none"> Interventional Applications Non-Interventional Biomedical research 	biomedical research facilities (academic, laboratories, Bioequivalence centers, Clinics / Hospitals).	DoH Medical Research and Development – Health Life Science Sector
% of non-compliant Biomedical Research facilities with the standard out of all Biomedical research facilities licensed in Abu Dhabi Emirate	Facilities conducting or supervising Biomedical Research (academic, laboratories, Bioequivalence centers, Clinics / Hospitals).	DoH Audit – Healthcare Quality Sector

- 5.2.3 Licensing / authorizing (as applicable):
 - 5.2.3.1 Qualifying / licensing as applicable of Biomedical Research Centers
 - 5.2.3.2 Qualifying the Biomedical Research Centers' IRB / ERC committees
 - 5.2.3.3 Licensing / privilege personnel to be authorized to conduct Biomedical research
 - 5.2.3.4 The Licensed Biomedical research facility shall report the data on a quarterly basis through the Medical Research and Development Division.
 - 5.2.3.5 DoH monitors compliance with the normative established in this standard through audits that prepare supervision lists and reports evaluating the results and the impact of this standard on accreditation of laboratories for genomic-related services and devices.
 - 5.2.3.6 Audits and inspections will assess compliance with:
 - 5.2.3.6.1 Approved study protocols
 - 5.2.3.6.2 Applicable ethical standards
 - 5.2.3.6.3 Local and international regulatory requirements
 - 5.2.3.6.4 compliance with the relevant GXP (good Practice Standards)
 - 5.2.3.6.5 DoH Audit will ensure compliance with this document after preparing a checklist generated based on this standard for the following:
 - 5.2.3.6.5.1 Scheduled audits
 - 5.2.3.6.5.2 Unscheduled inspections
 - 5.2.3.6.5.3 Detailed audit procedures and possible sanctions will be outlined and communicated to all stakeholders.
 - 5.2.3.6.5.4 Non- compliance may result in various sanctions, such as:
 - 5.2.3.6.5.4.1 Penalties and disciplinary actions
 - 5.2.3.6.5.4.2 Temporary or permanent suspension of research activities
 - 5.2.3.6.5.4.3 Revocation of research approval(s) legal actions (in case of serious, repeated, or intentional non-compliance with applicable regulations, standards, or laws)
- 5.2.4 To uphold the integrity, quality, and ethical standards of biomedical research, the DoH will implement a comprehensive compliance monitoring system.

6. Enforcement and Sanctions

6.1 DoH may impose sanctions in relation to any breach of requirements under this Standard in accordance with the Disciplinary regulation of the Healthcare Sector.

6.2 All involved in Biomedical Research shall comply with all regulatory requirements including the federal laws, DoH issued regulations as well as accreditation body requirements that shall be monitored by scheduled and ad-hoc audits/inspections, data reporting including KPIs reporting and documentation to ensure the ethical, safe, and equitable implementation of clinical practices.

7. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1	2024	Federal Decree-Law No. 38 of 2024, governing Medical Products, Pharmacist and Pharmaceutical Establishments	https://uaelegislation.gov.ae/en/legislations/2751/download
2	2022	WHO. Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research	https://www.who.int/publications/i/item/9789240056107
3	2025	DoH. Responsible AI Standard	https://www.doh.gov.ae/en/resources/standards
4	2024	Abu Dhabi - Healthcare Information and Cyber Security Standard	https://www.doh.gov.ae/en/resources/standards
5	2016	ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)	https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
6	2017	ICH E18 Guideline on Genomic Sampling and Management of Genomic Data	https://database.ich.org/sites/default/files/E18_Guideline.pdf
7	2020	ISO 14155- Clinical investigation of medical devices for human subjects — Good clinical practice	https://32352161.s21i.faiusr.com/61/ABUIABA9GAAgtNGisQYousW_ggY.pdf
8	2021	Ministerial Resolution No. (51) of 2021	https://uaeph1.mohap.gov.ae/en/health-policies-and-legislations-advocacy/health-legislations?itemId=726efdef-580e-4817-bf5a-fbf8e53fddfc
9	2024	WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects	https://www.wma.net/policies-post/wma-declaration-of-helsinki/
10	2021	ICH E8(R1) General Considerations for Clinical Studies	https://database.ich.org/sites/default/files/ICH_E8-R1_Guideline_Step4_2021_1006.pdf
11	2009	ICH M3(R2) Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals	https://database.ich.org/sites/default/files/M3_R2_Guideline.pdf
12	2012	ICH E3: Structure and Content of Clinical Study Reports – Questions & Answers (R1)	https://database.ich.org/sites/default/files/E3_Q%26As_R1_Q%26As.pdf
13	2017	Department of Health – Abu Dhabi: Healthcare Regulator Manual	https://www.doh.gov.ae/-/media/B8AE2259EF7B4F819BE5F908EB8BB699.ashx

14	2026	DoH Abu Dhabi: Pharmacovigilance Reporting Service	https://www.doh.gov.ae/en/resources/Reporting
15	2006	CIOMS Working Group VII: Development Safety Update Report (DSUR) – Harmonizing the Format and Content for Periodic Safety Report during Clinical Trials	https://cioms.ch/publications/product/development-safety-update-report-dsur-harmonizing-format-content-periodic-safety-report-clinical-trials-report-cioms-working-group-vii/
16	2025	Ich Harmonised Guideline Guideline For Good Clinical Practice E6(R3)	https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
17	2022	Data Safety Monitoring Boards	https://irb.emory.edu/includes/documents/sections/dsmb-guidance.pdf