Structure and Function of Dubai Scientific Research Ethics Committee

1- Definitions / Key Terms:*

1-1 **Dubai Scientific Research Ethics committee (DSREC):** Is a Central Scientific and Ethical Committee for the Emirates of Dubai.

1-2 **GCP:** Good Clinical Practice

1-3 **ICH:** The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

1-4 **Principal Investigator (PI):** An individual charged to conduct objective research that generates independent, high quality, and reproducible results.

1-5 **Research:** Is an original investigation undertaken in order to contribute to knowledge and understanding.

1-6 **Research Ethics:** Research that involves human subjects or participants raises unique and complex ethical, legal, social and political issues. Research ethics is specifically interested in the analysis of ethical issues that are raised when people are involved as participants in research. There are three objectives in research ethics. The first and broadest objective is to protect human participants. The second objective is to ensure that research is conducted in a way that serves interests of individuals, groups and/or society as a whole. Finally, the third objective is to examine specific research activities and projects for their ethical soundness, looking at issues such as the management of risk, protection of confidentiality and the process of informed consent.

1-7 **Inspection**: The act by a regulatory authority (ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority (ies) to be related to the clinical trial and that may be located at the site of the trial.

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1-8 **Research Coordinator:** A Research coordinator is a DHA staff assigned to the committee who has an appropriate qualification in Science or healthcare field along with a knowledge and certification of ICH GCP.

1-9 **Pharmaceuticals Research Phase 3:** This process takes place after the completion of the Phase a and Phase 2, where the gathering of additional information/data related to the safety and effectiveness of the medicine is expanded through conducting detailed studies and surveys on varying residential areas to test doses of the medicine (under trial). This is done by giving different dosages and observing their impact on the various sick cases and simultaneously using other licensed medicine. In this Research Phase 3 the medicine is selected randomly, then the impact and the effectiveness are monitored on the larger number of participants than in the previous types, ranging between 300-3000 individuals. Studying such research can be conducted through several different health care centers to provide an infographic clarification for the pharmaceutical substance (As per the circular no #56)

1-10 **Pharmaceutical Research Phase 4:** This type is usually a post-marketing of the medicine, awareness phase, or pharmaceutical control. This type includes the studies conducted after obtaining an approval of the medicine by the competent authority in the UAE after make sure the competent internal authorities license medicines. These studies to be conducted after marketing the medicine via collecting and obtaining addition information about the medicine safety, effectiveness and the best method of use. The competent authorities can withdraw the medicine from the market if they believe if it has adverse effects a negative side effects that may causes damages to users. (As per the circular no #56)

2- Purpose:

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2-1 To provide guidance to the members of DSREC, Investigators and other stake holders involved in research. Adherence to these guidelines would help to promote and maintain the standards towards ethical conduct of research, and protect the rights and wellbeing of research participants and communities

3- Scope of application

3-1 This applies to the members of DSREC, Investigators and other stake holders involved in research planned at the institutions governed by DHA; or institutions that are within the jurisdiction of DHA in the Emirates of Dubai. It does apply to interventional, non-interventional studies including medical devices.

4- Applicable To:

4-1 Members of DSREC, Investigators and other stake holders involved in research.

5- Responsibilities

5-1 Specified below in Section 8

6- Operational Resources:*

6-1 DSREC Members

6-2 Research policies

7- Policy:

7-1 Medical Research Section Policies

8- Procedure/Steps:

8-1 **DSREC Responsibilities and Functions**

The formation of this committee aims to encourage ethical scientific studies related to human wellbeing in the Emirate of Dubai. The primary objective of the DSREC is to provide independent and timely review of research projects involving human subjects in addition to ongoing ethical

oversight, monitoring and advice to protect the mental, physical welfare, rights, and safety of participants of research. This is in accordance with the DHA code of ethics, the ICH-GCP guidelines, and ethical principles described in the Declaration of Helsinki and Code of Federal Regulations. Legal, Religious, local and Cultural factors are also considered when taking decisions

8-2 **Scope of DSREC Responsibilities:**

The committee will review:

- Research proposals by Individuals working in any of the institutions governed by DHA; or institutions that are within the jurisdiction of DHA.
- Research proposals for institutions/organizations outside DHA jurisdiction provided that an agreement exists between the DHA and the external institution/organization that defines the role of the DSREC in providing ethical approval and ethical monitoring of the research and the role of the external institution/organization in giving approval for the research to take place within its organization. The agreement shall specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the DSREC, and shall specify that the institution/organization is responsible for liabilities arising from the conduct of the research.
- Research proposals including but not limited to, research involving pharmaceuticals (Phase 3 and Phase 4 only), medical devices, medical radiation and imaging, surgical procedures, biological samples, access to health information, as well as epidemiological, social, and psychological investigations.

8-3 **DSREC Membership composition:**

1. The minimum number of members of the DSREC are seven members, being men and women, comprising:
    a. a chairperson;
    b. at least one (1) member who is a lay person, and who is preferably from the community in which the institution is located;

c. at least one (1) member with knowledge of, and current experience in, the areas of research that are regularly considered by the DSREC (e.g. health, medical, social, psychological, epidemiological, as appropriate);

d. at least two(2) members with knowledge of, and current experience in, the professional care, or treatment of people (e.g. medical practitioner, clinical psychologist, social worker, nurse, as appropriate);

e. At least one (1) member who is familiar with applicable laws, regulations, Standards and Policies and standards of ethical and professional conduct associated with Research Activities.

f. At least one (1) member who has no affiliation to the organization.

2. If DHA appoints additional members it should ensure that, the membership continues to reflect both the diversity of the categories of members listed above.
3. Where required, the DSREC may seek advice and assistance from appropriate experts to assist with the review of a project. However, the DSREC must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter.

8-4 **Appointment and Orientation of members:**

1. DHA may recruit members for DSREC in such a manner and shall appoint them for such a period and on such terms and conditions as it determines.
2. Members are to be appointed for their expertise and not in a representative capacity.
3. Members must receive a formal notice of appointment and assurances that the institution or organization will provide legal protection in respect of liabilities that may arise in the course of bona fide conduct of their duties as committee members
4. Members are appointed by Director General of Dubai Health Authority in consultation with the Committee chairperson.
5. Upon appointment, members shall be provided with the following documentation:

- DSREC Terms of Reference;
- DSREC Standard Operating Procedures;
- Up-to-date list of members' names and contact information;
- Any previous reports on the DSREC's activities; and
- Any other relevant information about the DSREC's processes, procedures and protocols.

6. New members are expected to attend education and training sessions as soon as practicable after their appointment. Reasonable costs associated with attendance at training and education sessions will be met by the DHA.

- Training of DSREC staff and members of the committee is to fulfill its mandate to protect the rights and welfare of human subjects. DSREC staff, members and others charged with the responsibility to review, approve, oversee the human subject research should receive detailed training on the DHA Research Regulations, Standards, Policies and Procedures and any other guiding regulations and policies applicable to human research.
- All new Chairs and members are required to complete an Orientation Program provided by DSREC and training requirements listed below before beginning term on the committee. Chairs and members are also required to meet the continuing education requirements by attending human research protection related conferences, workshops, online courses, seminars, or lectures at least once every two years for continuing members. The DSREC should maintain the training records for the DSREC chairs and member
- Below are the links for the training programs suggested for the members:
- Protecting Human Research Participants offered by the National Institute of Health (NIH).

http://phrp.nihtraining..scom/users/login.php

Or

- Equivalent CITI training (Collaborative IRB Training Initiative)

http://www.citiprogram.org

7. For Orientation purposes, new members could be invited to attend DSREC meetings as Observers or attend informal meetings with Chairman and Deputy Chairman to explain their responsibilities and the DSREC processes and procedures.

8-5 **Membership requirements:**

a. The duration of appointment is initially for a period of 3 years.
b. At the end of 3 years, as the case may be, the committee is reconstituted, and 25 percent of the members will be replaced by a defined procedure.
c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
d. A member can tender resignation from the committee with proper reasons to do so.

8-6 **Duties of the Chairperson:**

The chairperson's duties may include reviewing protocols submitted for exempt or expedited review, assigning studies to DSREC reviewers, determining the DSREC committee agenda, convening and conducting DSREC meetings, summarizing DSREC review recommendations to be sent to investigators, reviewing and signing letters generated from committee actions, reviewing investigator responses to committee requests that are minor, reviewing correspondence from investigators and responding when appropriate, reviewing SAE and safety reports and determining if a study needs to be sent for safety review or full committee review.

When the chairperson is not available, the vice-chairperson (deputy) will assume the responsibilities of the chairperson during the period of his/her absence.

8-7 **Duties of the Deputy Chairperson:**

The Deputy-chairperson assumes the duties of the chairperson for the committee when the chairperson is not available or has a conflict of interest. The Deputy Chairperson may review

protocols submitted for exempt or expedited review. Usually this is done at the request of the chairperson or for meetings in which the Deputy-chairperson will be conducting a committee meeting.

8-8 **Duties of Members:**

A DSREC member's duties include reviewing studies for risk/benefit and protection of human subjects for new studies and for studies at continuing review, evaluating Investigators' requests for changes in studies. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.

8-9 **DSREC Meetings**

8-9-1 ***Preparation of Agenda:***

The Research Coordinator will prepare the meeting agenda and associated documents and circulate them to all DSREC members at least 7 days prior to the next meeting. Agenda and documentation shall remain confidential.

Documentation received after the closing date will be included on the agenda and/or tabled at the meeting at the discretion of the Chairperson.

Agenda items will include at least the following items:

- Apologies
- Minutes of the previous meeting and relative business.
- Conflicts of interest
- New applications
- Amendments to approved protocols
- Correspondence
- Other business
- Closure
- Miscellaneous

8-9-2 ***Conduct of meetings:***

a. The DSREC shall meet on a regular basis, which will normally be every Six (6) - Eight (8) weeks intervals, except July and August. Meeting dates and agenda closing dates shall be publicly available. The DSREC Chairperson can call for unscheduled additional meetings.

b. A quorum must be present in order for the DSREC to reach a final decision on any agenda item. There must be at least 50% +1 members physically present to achieve quorum, provided that a representative of each of the following categories is present: Chairperson/Deputy Chairperson, one non-clinical person, researcher familiar with the types of proposals that are normally reviewed by the DSREC.

- In circumstances where the members cannot be present, they may provide written comments in lieu of attendance. These should normally be received at least 3 working days prior to the meeting.
- Should the quorum fail during a meeting (*e.g.*, loss of a majority through abstention of members with conflicting interests or early departures, or absence of a nonscientist member); the DSREC may not take further actions or votes unless the quorum can be restored. The Chairperson shall decide if can proceed only in exceptional circumstances.
- DSREC may invite the researcher(s) to be present for discussions of the research protocol. The researcher should not be present during the final decision voting for the study.
- Handling of conflicts of interest by DSREC members:

c. An DSREC member shall, as soon as practicable during the DSREC meeting, inform the Chairperson if he/she has a conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the DSREC.

d. The DSREC will determine if this results in a conflict of interest for the member and if so, the member will withdraw from the meeting until the DSREC's consideration of the relevant matter has been completed. The member shall not be permitted to adjudicate on the research.

All declarations of conflict of interest and the absence of the member concerned will be minuted. **For details: refer to Appendix 1.1**

8-9-3 ***Preparation of minutes:***

a. The Research Coordinator will prepare and maintain minutes of all meetings of the DSREC.

b. The Minutes will include at least the following items:

- Present and absent members.
- The decision of the DSREC on the applications, summary of discussions and Views expressed by absent members or significant minority view [Two (2) members or less]
- New applications; Ethical considerations raised, requests for additional information.
- Any conflict of interests declared and the decision of the Committee on the participation of the member concerned.

c. To encourage free and open discussion and to emphasis the collegiate character of the DSREC, particular views should not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.

d. The minutes will be produced as soon as practicable following the relevant meeting and will be checked by either the Chairperson and/or the Deputy Chairperson, for accuracy.

e. The minutes will be circulated to all members of the DSREC as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the minutes prior to their ratification. The minutes will be formally ratified at the next DSREC meeting.

f. The original copy of each meeting's minutes will be retained in a confidential 'Minutes' file and shall be forwarded to the Director of MERD and shall be provided to Director General of DHA upon request.

8-10 **Record keeping:**

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a. The Research Coordinator will prepare and maintain written records of the DSREC's activities, including agendas and minutes of all meetings of the DSREC.

b. DSREC Research Coordinator will prepare and maintain a confidential electronic and/or paper record for each application received and reviewed and shall record the following information:

- Unique project identification number/Title of the project.
- The curriculum vitae of the principal investigator(s);
- Institution or organization name.
- Signed copy of the protocol, amendments and a sample of the case report form (CRF)
- Clinical trial agreement between concerned parties.
- Information given to human subjects, informed consent, and any written information provided to patients, patient diary, and advertisement for subject recruitment.
- Sample of label attached to investigational container, instruction for handling of investigational products.
- Certificate of analysis of shipped investigational products.
- Decoding procedures for blinded trials and master randomization list, where applicable.
- Initial and subsequent Ethical approval or non-approval with date; determining if any was expedited.
- All relevant documents submitted to the DSREC supporting the study progress (SAEs, Progress Reports, Clinical Study Reports, study communication...Etc.)
- The paper file shall contain a hard copy of the application, including signatures.

c. The Research Coordinator will be responsible for archiving and maintaining DSREC relevant documents as confidential files, this includes the following:

- Curriculum Vitae (CV) of all members of DSREC.
- Agendas and Minutes of all meetings duly signed by the Chairperson.
- Copy of all existing relevant national and international guidelines on the research ethics and laws along with amendments.
- Copy of all correspondence with members, researchers and other regulatory bodies.

d. To ensure confidentiality, all documents provided to DSREC members, which are no longer, required, are to be disposed of in a secure manner, such as shredding or placed in confidential bins. Members who do not have access to secure disposal should leave their documents with the Research Coordinator for disposal.

e. Data pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period for retention for non-clinical research is at least 6 years after the date of publication or completion of the research or termination of the study. For clinical research, 15 years shall apply.

8-11 **DSREC internal reporting:**

1. The DSREC shall provide an annual report to the Director General of Dubai Health Authority at the end of each calendar year on its progress, including:

- membership/membership changes
- number of meetings
- number of projects reviewed, approved and rejected
- monitoring procedures for ethical aspects of research in progress and any
- problems encountered by the DSREC in undertaking its monitoring role
- description of any complaints received and their outcome
- description of any research where ethical approval has been withdrawn and
- the reasons for withdrawal of approval; and
- General issues raised

2. The DSREC Terms of Reference, Standard Operating Procedures and Membership will be available upon request to the general public, and will be posted on the DHA website.

8-12 **Subcommittees:**

A sub-committee may be formed at the request of the chairperson to address policy issues, to review research proposals, or to investigate issues related to specific studies or investigations that require more information than can be obtained in written communications.

8-13 **Authority of the DSREC:**

A. The DSREC has the authority to:

1. Approve, disapprove, or require modifications of all human research activities;
2. Request progress reports from the investigators and conduct Inspections and oversee the conduct of the studies;
3. Suspend or terminate approval of an ongoing study;
4. Reopen terminated/closed protocols;
5. Observe or have a third party observe the consent process and the research.

B. In its review of human participant research, the DSREC has jurisdiction over all aspects of the research including, but not limited to:

- Methods of identifying and contacting potential subjects
- Materials to recruit subjects and proposed compensation
- Pilot studies
- Proposals to use or provide stored blood, tissues, or confidential data
- Surveys and questionnaires

- The protocol, Informed consent process and summary of the research
- Evaluation of risks and benefits to subjects
- Unanticipated problems involving risk to subjects
- Proposed changes to the research and Continuing reviews
- Use of investigational drugs and devices in emergencies

8-14 **Appendix 1.1**

Conflict of Interest

Definitions:

1. **Conflict:** Exists when a DSREC Reviewer also has a Financial Interest, or any other Professional or Personal Relationship, which may make it difficult for the DSREC Reviewer to exercise independent judgment in safeguarding the rights and welfare of Research Subjects.
2. **Financial Interests:**
    a. Any ownership interest in a publicly traded company held by the DSREC Reviewer or his/her Immediate Family. This excludes interest arising solely by reason of investment in a business by a mutual, pension, or other institutional investment fund over which the DSREC Reviewer or his/her Immediate family does not exercise control;
    b. Any interest in a non-publicly traded company held by the DSREC Reviewer or his/her Immediate Family;

c. A position held by the DSREC Reviewer or his/her immediate family as employee, director, officer, partner or any position of management;

d. Any income (e.g. consulting, salary to the DSREC Reviewer or his/her Immediate Family) received or promised;

e. Any loan to the DSREC Reviewer or his/her Immediate Family; and

f. Any gift to the DSREC Reviewer or his/her Immediate Family.

3. **Immediate Family:** (1) spouse of the DSREC Reviewer, (2) minor children of the DSREC Reviewer, and (3) parents, children and spouses of children, brothers and sisters, or spouses of brothers and sisters of the DSREC Reviewer, if such individuals reside in the same household as the DSREC Reviewer or if the DSREC Reviewer has knowledge of such an individual's Financial Interests.
4. **DSREC Reviewer:** Includes appointed DSREC Members and any Consultants asked to assist the DSREC.
5. **Personal Relationship:** Exists when a DSREC Reviewer has had or continues to have an interaction with the Investigator that would make it difficult to review his/her study with a non-biased eye.
6. **Professional Relationship:** Exists when a DSREC Reviewer is involved in the design, conduct and reporting of the research study. This would include but not be limited to such roles such as investigator, coordinator, or data manager.

7. **Policy:** For purposes of this policy, the DSREC's review includes all aspects of review, including the review of continuing review reports, adverse event reports, and similar reports, and is not limited to the review of new protocols.

- Except as requested and then only to provide information necessary for the review, DSREC Reviewers are prohibited from participating in the review of any study in which they, or their Immediate Family, have direct Financial Interest in:
  - The Sponsor or Funding Source of any research project which the DSREC is reviewing;
  - The provider of any product being investigated through any research project, which the DSREC is reviewing;
  - Other entities whose financial interests would reasonably appear to be affected by the outcome of any research, which the DSREC is reviewing.
  - Any Personal or Professional Relationship with the Principal Investigator or Co-Investigator of a study up for review.

8-15 **Procedure:**

- DSREC Reviewers:

1. Prior to any meeting in which a study is to be reviewed which poses a Conflict, DSREC Reviewers must promptly and fully disclose to the DSREC Chair/Designee:

All direct and indirect Personal and Professional Relationships and Financial Interests which may pose a Conflict or potential Conflict.

- If DSREC Reviewer is not able to notify the Chair prior to the meeting, the DSREC Reviewer will notify the Chair prior to the review of the study in which the Conflict exists.

2. Complete an annual disclosure questionnaire.

➢ <u>DSREC Chair/Designee and DSREC Staff Role</u>:

- Individual Study Conflicts:
  - ➢ DSREC Reviewer will be asked to leave the room during the discussion and vote on the Study forming the basis of the Conflict. Upon the request of the Committee, the Reviewer may be asked to provide additional information relating to the study.
  - ➢ The DSREC shall determine any action to be taken on the Study by a vote of the non-I interested DSREC members present.
  - ➢ The minutes of all DSREC meetings involving Conflicts shall include the names of the persons who disclosed the existence of a Conflict. In addition, the minutes shall set forth the names of the persons who were present for discussions and/or votes relating to the research project forming the basis of the Conflict; the content of those discussions; and a record of the vote.
  - ➢ The DSREC shall take appropriate disciplinary action against any DSREC Reviewer who violates this policy.

9- Deployment of Structure and Function of Dubai Scientific Research Ethics Committee

☒Announcement

Structure and Function of Dubai Scientific Research Ethics Committee

☒Awareness

☐Training

☐On Job Training

10- Measures of Structure and Function of Dubai Scientific Research Ethics Committee:

10-1 Percentage of eligible application approved by the DSREC	Target/Threshold 70.0%

11- List of Risks of Structure and Function of Dubai Scientific Research Ethics Committee:

11-1 Conducting research-related activities outside of the requirements without getting the approval can lead to compromise/breach the rights, safety and wellbeing of the human participants in the research studies	Risk Level 1-3 LOW
11-2 Delay in finalizing the research related policies and procedure can be a hindrance to determine what process was being utilize to track, monitor the research related activities	Risk Level 4-6 MODERATE

12-Audit, Improvement & Development of Structure and Function of Dubai Scientific Research Ethics Committee:

12-1 Internal audit for compliance with the document content

12-2 Corrective actions for non-conformities with the document content

13- Records of Structure and Function of Dubai Scientific Research Ethics Committee *

13-1 Circular

13-2 Attendance log

14- Annexes of Structure and Function of Dubai Scientific Research Ethics Committee *

14-1 N/A

N.B.: "*" Put "N/A" if there is nothing to write.

(the document) to be replaced by document title