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Submissions of New Applications and Opinions To DSREC

1- Definitions / Key Terms:*

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

1-2 Principal Investigator (PI): An individual charged to conduct objective research that generates independent, high quality, and reproducible results

1-3 GCP: Good Clinical Practice

1-4 ICH: The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

2- Purpose:

2-1 To provide guidance to the Investigators and other stake holders involved in research for the submission of the application

3- Scope of application

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

4- Applicable To:

4-1 Investigators and other stake holders involved in research

5- Responsibilities

5-1 Refer SOP: DHA/DG/MERD/SOP/001

6- Operational Resources*

6-1 Refer SOP: DHA/DG/MERD/SOP/001

7- Policy:

7-1 N/A

8- Procedure/Steps:

8-1 **Submission procedure of new application**

8-1-1 All Applications for ethical review should be submitted 14 days prior to DSREC scheduled regular meeting.

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8-1-2 An assessment fee will apply to be all applications submitted to DSREC. The charges will be according to the published fees guideline outlined in the DSREC's Fee Policy

8-2 Required Documentation for Initial Submission:

For a thorough and complete review, the following documents for all research proposals should be submitted as two hardcopies- one (1) original and one (1) copy of the research proposal- in addition to one electronic version using Microsoft word document.

The required documents are as follow:

1. Completed and appropriately signed and dated Application form for ethical approval of a Research Project - **Appendix 2.1**. Application form needs to be signed by Head of Department/Institution the study site and Principal Investigator.

   NOTE:

   - ü *If the Principal Investigator is the Head of the department, in this case a higher authority must sign the form under the section Head of the department. (CEO OR the Medical Director of the study site).*
   - ü *Any Incomplete applications shall not be considered for the review.*

2. Study Protocol/Protocol Amendments, if any.
3. For any drug / device under trial, all relevant pre-clinical animal data and clinical trial data from other centers (Investigators' brochure) within the country / internationally and/or Investigational Medicinal Product Dossier (where applicable). The Ministry Of Health (MOH-UAE) declaration for trial drug/device entry in the country and the detailed process of provision of the trial drug/device at the study site.

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4. For late phase studies, Summary of product characteristics should be submitted.
5. Informed consent process, including patient information sheet and informed consent form. An Arabic transition of this document to be submitted as per the local requirement. *Please refer to Patient Information sheet section.*
6. Curriculum vitae of the Principal investigator with relevant publications in last five years, if any, and the Co-Investigators, study staff listed on the application form.
7. Case Report Form/Data collection tool.
8. All patients' materials, including but not limited to *questionnaires, diaries, emergency cards. An Arabic transition of these documents to be submitted as per the local requirement.

   **For the translated questionnaires the proof of validation must be provided.*
9. Insurance certificate and/or agreement, where applicable.
10. Source of funding and financial requirements for the project (*Final Draft of Word document for the study contract should be provided).*
11. Disclosure of any Conflict of interests.
12. Disclosure of any financial interests.
13. Signed and dated Confidentiality Agreement-Patient information form (Signed by the Principal Investigator) **Appendix 2.2**
14. Other Important information relevant to the study to support the submission.
15. International and Local EC/Regulatory approvals, if available.
16. Any prior approval/ documentation pertaining to Diagnostic services e.g. lab, radiology etc. , if applicable.

17. ICH GCP training certificate.

8-3 Patient Information Sheet:

- ü Ethically and legally, consent is not considered to be informed unless the investigator(s) disclose all those facts, risks, and discomforts that might be expected to influence an individual's decision to willingly participate as a volunteer in a research project.
- ü All Informed Consent forms submitted for DSREC review should include the mandatory ICF elements in accordance with ICH GCP and should be consistent with the DSREC Consent form checklist. **Refer to Appendix 2.3**.
- ü Informed consents should be available in a language, which is understood to the study participant. Where research involves persons unfamiliar with the Participant Information sheet primary language, the DSREC will ensure that it is properly translated into the participant's language, where applicable.
- ü In case of anticipated communication difficulties upon ICF discussion and for patients who understand the ICF primary language but might still have some difficulties in understanding the medical terms or may need further explanation in their mother language, Competent translators could be used to help overcome similar communication difficulties and to ensure the Patient Information sheet is well understood by the study participant prior to signing off the Information sheet.

NOTE:

- ¶ *Translator section should be added as one of the signatory options in the patient information sheet provided one might be needed at the time of consenting.*

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¶ *The committee may request a brief supplementary site specific information sheet, if required.*

8-4 Handling Multi-center Research submissions to DSREC:

¶ In case of Multi-center research study in UAE including less than three sites falling under DHA Jurisdiction, submission will occur for each site independently.

¶ In case of Multi-center research study in UAE including Three (3) and more sites falling under DHA Jurisdiction, a Coordinating investigator must be assigned for the study and coordinating investigator will be the DSREC point of contact for the study.

¶ The coordinating investigator must submit the following documents along with an agreement between the Coordinating investigator and the sponsor for this role.

Study documents in common will need to be submitted only once, but every site will still need to submit the DHA DSREC following site-specific forms:

1. Signed Confidentiality Agreement-Patient information form.
2. Completed and appropriately signed and dated Application form for ethical approval of a Research Project - **Appendix 2.1**. Application form needs to be signed by Head of Department/Institution the study site and Principal investigator.

NOTE:

¶ *If the Principal Investigator is the Head of the department, in this case a higher authority must sign the form under the section Head of the department. (CEO OR the Medical Director of the study site).*

¶ *Any Incomplete applications shall not be considered for the review.*

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3. Curriculum vitae of the Principal investigator with relevant publications in last five years, if any, and the Co-Investigators listed on the application form.
4. ICH GCP training certificate.
5. Disclosure of any Conflict of interests.
6. Disclosure of any financial interests.
7. Source of funding and financial requirements for the project (Word document for the study contract should be provided).

8-5 Processing of applications for review:

1. Applications will be reviewed and checked for their completeness by the Research coordinator prior to their acceptance onto the agenda. Incomplete applications will be returned to the applicant.
2. The research coordinator will acknowledge acceptance of the application for initial and in-depth review, only after checking the completeness of the application, by stamping as Received on the submitted application/cover letter.
3. The application will be included on the agenda for the next available DSREC meeting, provided it is received by the relevant closing date (2 weeks prior to the meeting) and is complete.
4. If the number of applications exceeds the capability of the committee to deal with in one meeting, some of the applications may be deferred to the following DSREC meeting. If this occurs, priority should be given to those applications that were received first and/or urgent applications at the discretion of the Chairperson.
5. Elements of review:

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a) Scientific design and conduct of the study.

b) Approval of other scientific review committees (if any).

c) Examination of predictable risks/harms.

d) Examination of potential benefits.

e) Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and recruitment of study subjects.

f) Management of research related injuries, adverse events.

g) Compensation provisions.

h) Justification for placebo in control arm, if any.

i) Patient information sheet and informed consent form in local language.

j) Protection of privacy and confidentiality.

k) Involvement of the community, wherever necessary.

l) Plans for data analysis and reporting.

m) Adherence to all regulatory requirements and applicable guidelines.

n) Competence of investigators, research and supporting staff.

o) Facilities and infrastructure of study sites.

p) Criteria for withdrawal of patients, suspending or terminating the study.

q) Financial aspects of the study (payment to PI and Institutional overhead).

6. If required, the application will be assigned to two (2) members of the DSREC for revision and presentation at the meeting. The Chairperson, or designee, assigns protocols to the reviewer with the relevant scientific or scholarly expertise based upon the reviewer's specialty. If no

reviewer has the necessary expertise to perform an appropriate in-depth review, consultation will be sought. Such consultation may be sought either within or outside the DHA.

7. The DSREC will ethically assess each application in accordance with the DHA code of ethics & the ICH-GCP guidelines. The DSREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make an ethical assessment.

8. The DSREC, after consideration of an application at a meeting will make one of the following decisions:

- ü It will approve the project as being ethically acceptable, with or without conditions.
- ü It will defer making a decision on the project until the clarification of information or the provision of further information to the DSREC.
- ü It will request modification of the project.
- ü It will reject the project.

9. The DSREC will endeavor to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision will be carried by a majority of two-thirds of the members including chair and/or Deputy Chair, any significant minority view (i.e. Two (2) or more members) shall be noted in the minutes.

10. In order to facilitate consideration of an application, the DSREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions.

11. For projects where the DSREC has requested clarification, the provision of further information, or modification of the project, the DSREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following:

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¶ Chairperson alone; or chairperson, in oral or written consultation with one or more named members that were present at the meeting or who submitted written comments on the application; or

¶ A sub-committee of the DSREC.

In such circumstances, the DSREC shall be informed at the next available meeting, of the final decision taken on its behalf, including the applicant's response and the reason for the decision taken.

12. Exceptionally, the DSREC may decide that the information should be considered at a further meeting of the DSREC.

13. Independent consultants: DSREC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the DSREC.

8-6 Expedited Review:

The DSREC may conduct expedited review of projects as follows:

1. The DSREC may establish an Executive, consisting of at least the Chairperson or the Deputy Chairperson or a delegated DSREC member with the DSREC research coordinator. The Executive may undertake expedited review of research projects in the following circumstances:

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¶ Questionnaires on non-controversial, non-personal issues.

¶ Research which is being conducted primarily at another institution/Health Service and has been approved by another ethics committee, but which involves a minimal risk component at the Health Service applying to the DSREC for review.

Note:

¶ Expedited review of research projects may be undertaken between scheduled meetings at the discretion of the Chairperson. The Executive may seek advice from other DSREC members or suitably qualified experts, as appropriate, before reaching a decision. The decision of this review must be tabled for ratification at the next DSREC meeting.

¶ The Executive may consider other items of business that are considered to be of minimal risk to participants such as appropriate adverse events, project reports, minor amendments and the like.

2. The minutes of Executive meetings will be tabled for ratification at the next DSREC meeting.
3. Research with the potential for physical or psychological harm should generally not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.
4. Where the Chairperson considers that research may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol must be considered by the full DSREC and cannot be dealt with by expedited review.

8-7 Range of DSREC decisions:

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Approved: The project and its study tools, including the informed consent documents, are approved as submitted. Once the investigator receives the DSREC approval letter, the study may begin.

Approved with Major Revisions: The project requires major revisions, which the DSREC can list as part of the motion. These must be addressed and re-reviewed before the DSREC can grant approval. The PI will be provided with comments explaining rationale for the decision and given an opportunity to respond.

Approved with Minor Revisions: A vote such as this incorporates all the noted contingencies. The project requires minor revisions that must be addressed before final approval can be granted. Minor revisions may be reviewed and approved through the expedited process.

Disapproved: The project has serious deficiencies in submitted protocol affecting the safety and welfare of the projected subject population. These must be addressed in a new protocol and be reviewed by the convened DSREC before the DSREC can grant approval. The PI will be provided with comments explaining rationale for the decision and given an opportunity to respond. The response will be reviewed by the convened DSREC.

Suspended for Cause: An action taken by the DSREC to stop temporarily some or all research procedures until the outlined requirements are met. The DSREC can, at its discretion, make a range of motions regarding the conduct of a given protocol in order to better secure the protection of participants.

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Terminated for Cause: An action taken by the DSREC to stop permanently some or all research procedures. The DSREC can, at its discretion, make a range of motions regarding the conduct of a given protocol in order to better secure the protection of participants.

8-8 Communication of DSREC Decisions for New applications:

1. The DSREC will report in writing to the principal investigator, advising whether the application has received ethical approval (including any conditions of approval), or further information, clarification or modification might still be needed. This will occur within 7 working days of the meeting, unless otherwise notified.
2. If the requested information is not received from the applicant within Three (3) months or Two (2) meetings (whichever occurs sooner), the project will be dismissed and the applicant will be required to re-submit the project at a later date.
3. The DSREC shall endeavor to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues. The DSREC may nominate one of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant DSREC meeting.
4. The DSREC will notify the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval will be in writing, and will contain the following information:

    ¶ Title of project

    ¶ Name of the Principal investigator/ Coordinating Investigator

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¶ Unique DSREC project identification number

¶ The version number and date of all documentation reviewed and approved by the DSREC including Clinical Protocols, Patient Information Sheets, Consent Forms, advertisements, questionnaires etc.

¶ Date of DSREC meeting at which the project was first considered

¶ Date of DSREC approval; and

¶ Conditions of DSREC approval, if any

¶ Date of expiry of DSREC approval, (one (1) year from date of issue)

¶ List of DSREC members who voted for the study. DSREC List of members shall be kept confidential and will not be disclosed. The List of DSREC members who voted will be only referred to by professions.

¶ Research projects may not commence until **written notification** that confirms this has been received.

5. If the DSREC determines that a project is ethically unacceptable, the notification of the DSREC's decision will include the grounds for rejecting the project.

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Appendix 2.1

Application form for ethical approval of a Research Project

Instructions :

1) Submit one (1) original and one (1) copy of the research proposal, in addition to one electronic copy to office of the Dubai Scientific Research Ethics Committee (DSREC)
2) Instructions to fill the application form
   a) The application must be clearly legible
   b) Typing is recommended
   c) The modification of the original content of the form is strictly prohibited.
   d) All sections of the application form must be completed
   e) Write "Not Applicable" wherever appropriate

1) Project Title :

Full Title

Short Title/Protocol Number (If applicable):

2) Is the study required to be recorded in Electronic Medical Record (EMR) system of Dubai Health Authority (DHA)?

Yes ☐ No ☐

If yes, please provide:

i. EMR Title:

ii. *EMR Description:

(Do not exceed more than 200 words)

NOTE:

***EMR Description: Is a description of a study, which can be viewed by all Salama Access users in DHA.**

****Applicable to ONLY prospective studies conducted by DHA Staff**

3) Type of the Project :

☐ Drug Study ☐ Device Study ☐ Chart/Records Review

☐ Biomedical Research ☐ Health Related Research ☐ Community-Based

☐ Social and Behavior Research ☐ Other: ----------

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4) Principal Investigator (only one researcher should be appointed as PI):

Title/Name

Designation

Unit/Department Institution

Email

Contact No. *Office:* *Mobile:* ☐ ***CV attached***

Note: Students cannot be principal investigators on a study

4) Co-Investigators and study site staff:

Yes ☐ **No** ☐ **if checked NO, provide the reason**

Title	Name	Designation and Role in the study	CV Attached	E-mail & Contact No	Unit / Department	EMR Access Yes/No

5) Site Contact Person:

Title/Name

Tel. Office

Fax

Mobile

Email

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Emergency no.

6) Does investigator or key personnel have any conflict of interest in this study?

☐ Yes ☐ No

If yes, please explain:

7) Has this research proposal been approved by an Institutional Review Board (IRB) or Research Ethics Committee elsewhere?

☐ Yes ☐ No

If 'Yes', please provide the following information: (Please attach a copy)

a. Name of institution that reviewed this research proposal

b. Address of reviewing institution

8) Has this study been done elsewhere?

☐ Yes ☐ No

If 'Yes', how does this differ from the ones done earlier.

9) Proposed starting date of the study	**Proposed completion date of the study**

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10) Is this a multicenter trial?

☐ **Yes** ☐ **No**

If yes, which are the other centers involved?

Location(s) within UAE where the research is to be conducted:

11) Will this study/research involve human subjects?

☐ **Yes** ☐ **No** ☐ **Not applicable**

If 'Yes', will you have direct contact or intervention with them?

(e.g., as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?)

☐ Yes ☐ No

12) Goals of the research

Summarize the background and hypothesis of the study.

a) What are the primary and secondary objectives of the study?

b) Why is this research important? What contributions will it make?

13) Participants

a) Research population and sample size calculation

b) Expected total number of participants in the study and expected total number of participants at DHA site.

c) Age range of participants

d) How will participants be included in the study?

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(If randomization is used, please explain how this will be done)

e) How much time will a subject have to dedicate to the project beyond that needed for standard Treatment?

f) If normal volunteers are involved, please explain how many will be selected and the method of selection employed?

14) This project will involve the following subject types: (check mark types to be studied)

☐	Normal Volunteers	☐	Subjects Incapable of giving Consent
☐	In Patients	☐	Prisoners or Institutionalized Individuals
☐	Out Patients	☐	Fetuses
☐	Patient Controls	☐	Infants (0 -3 Y)
☐	Students	☐	Children (3-12Y)
☐	Cognitively Disabled	☐	Minors (Under Age 18)
☐	Physically Disabled	☐	Over Age 60
☐	Pregnant Women	☐	Other Potentially Elevated Risk Populations

15) What are the inclusion criteria?

16) What are the exclusion criteria?

17) Does this project call for: (Check mark all that apply to this study)

☐ Use of Voice, Video, Digital, or Image Recordings?

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☐ Advertising for subjects?

☐ More than Minimal Risk?

☐ More than Minimal Psychological Stress?

☐ Extra Costs to the subjects (tests, hospitalization, etc.)?

18) Does the project require the examination or the use of patient's medical records?

☐ **Yes** ☐ **No**

19) Are there any predictable risks to the subjects of physical or psychological pain or discomfort, or risk of injury of any kind?

☐ Yes ☐ No ☐ Cannot predict

If 'Yes' or "Cannot predict", describe the possible areas of risk. Outline briefly any steps taken to minimize the possibility of pain, discomfort or injury and procedures for determining levels of discomfort at which you will terminate the participation by the subject in the research:

20) This project involves the use of:(Check mark all that apply to this study)

a. ☐ An Investigational New Drug (IND) or an approved drug for an unapproved indication. Drug name and company

b. ☐ An Investigational Medical Device or an Approved Medical Device For An Unapproved Use Device name and manufacturer

c. ☐ Radiation or Radioisotopes

d. ☐ Blood: Total Amount of Blood

Over Time Period (days)

e. ☐ rDNA or Biohazardous materials

f. ☐ Human Tissue or Cell Lines

21) If a drug or a device will be used for the study:

1. Is the drug or the device approved (registered) by DHA or MOH?

☐ Yes ☐ No

If No,

¶ is the drug or the device approved by any major International Organizations, e.g. FDA, EMEA.

☐ Yes ☐ No

¶ is the documentation on the provision of the unregistered drug or the device to the site is submitted

☐ Yes ☐ No (If no please provide the explanation)

¶ is the MOH UAE declaration for the entry of the unregistered drug or the device is submitted

☐ Yes ☐ No (If no please provide the explanation)

2. Provide details of any known side effects, which may result from the investigational drug or device.

3. If it is a drug, what phase of research the drug has reached to date?

☐ Phase 3 ☐ Post marketing study

22) Is this a double-blind study

☐ Yes ☐ No

If yes,

a) Is the code for unblinding in case of emergency available at both the investigator (e.g hospital) and sponsor sites?
b) Format in which code breaks for clinical trials are supplied

☐ Sealed envelopes

☐ Scratch cards

☐ Tear off label on the drug container which will be removed when dispensing the trial drug and place on the drug accountability form

☐ Interactive voice response system – user identity and password is required to access such a system

☐ 24 hour telephone number provided by the sponsor

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23) Please specify any incentives, compensation or treatment the participants will receive through participation in this study.

24) Does the project require special data collection (e.g., interview, questionnaire, case record forms)?

☐ Yes ☐ No

If yes, please attach a copy.

25) What special training or qualifications are required for data gatherers? Who will provide training?

☐ ICH GCP Certificate provide Yes ☐ No ☐

☐ NIH Certificate provide Yes ☐ No ☐

☐ Other (Specify) Certificate provide Yes ☐ No ☐

26) Data Handling

a. Who will have access to the data?

b. Will all personally identifying data be held confidential?
☐ Yes ☐ No

c. Does the project require the linkage of project data on available subjects with other individually identifying data from outside the facility or division?
☐ Yes ☐ No

If yes, describe the other data sources and types of data used:

d. What steps are being taken or will be taken to ensure that no information that may identify an individual be released?

e. How will the subjects' rights to privacy and safety be protected? Describe measures that will be taken to protect the confidentiality of data containing patient-identifying information.

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f. Will any patient identifiable information be provided to an external study sponsor?
☐ Yes ☐ No ☐ N/A, there is no external study sponsor

g. What are the plans for future use of the data (beyond that described in the protocol, if any).

27) Do you anticipate that this research will be used for a commercial purpose?

☐ Yes ☐ No

(If "yes", explain how you will describe this to the participants in the consent process and to the DSREC

28) Anonymity and Confidentiality

a) Will the anonymity (*protection of the identity of participants*) of participants be protected?
☐ Yes (completely) ☐ Yes (partially) ☐ No