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## Handling of Complaints

### 1- Definitions / Key Terms:\*

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

### 2- Purpose:

2-1 DHA is committed to observing the highest standards of research integrity and the education of all its constituents regarding these standards so that they may act in accordance with the behavior required.

### 3- Scope of application

3-1 This applies to the 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.

### 4- Applicable To:

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

### 5- Responsibilities

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

### 6- Operational Resources:\*

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

### 7- Policy:

7-1 N/A

### 8- Procedure/Steps:

#### 8-1 Complaints about the conduct of a research project:

1. Any complaints from research participants, researchers or other interested persons about the conduct of approved research projects must be send to [DSREC@dha.gov.ae](mailto:DSREC@dha.gov.ae) also the contact must be included in the Patient Information Sheet and/or Consent Form for each project.

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2. The committee will send a letter of acknowledgement to the complainant and a letter of notification to the principal investigator, outlining the complaint and the mechanism for investigating the complaint, as set out below.
3. Where the complaint concerns a serious matter within the jurisdiction of the DHA, the chairperson of DSREC shall consider referral of the complaint to the appropriate body.
4. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the DSREC on the appropriate course of action. This investigation shall take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist. If the complaint is substantiated, action may include:
  - Suspension of the project;
  - Termination of the project; or
  - Other action to resolve the complaint.
5. The complainant shall be informed of the outcome of the Chairperson's investigation.
6. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can apply once more to the DSREC. The committee will call upon the investigator to present his proposal.

### **8-2 Complaints concerning the DSREC's review process:**

1. Any concern or complaint about the DSREC's review process should be directed to the [DSREC@dha.gov.ae](mailto:DSREC@dha.gov.ae), detailing in writing the grounds of the concern or complaint.
2. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the DSREC on the appropriate course of action. This investigation shall

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take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist. Also, the justification on complain should be sent to the complainant and the higher authority.

### 8-3 Complaints concerning the DSREC's rejection of an application:

1. A person with a concern or complaint about the DSREC's rejection of their application should detail the grounds of the concern or complaint in writing and bring it to the attention of the Chairperson of the DSREC.
2. Should the DSREC be requested to review its decision by the researcher, then the outcome of this review by the DSREC will be final.

### 9- Deployment of Handling of Complaints: (Check all that apply)

- Announcement  
 Awareness  
 Training  
 On Job Training

### 10- Measures of Handling of Complaints

10-1 NA

Target/Threshold

### 11- List of Risks of Handling of Complaints:

11-1 NA

Risk Level

### 12-Audit, Improvement & Development of Handling of Complaints:

12-1 Internal audit for compliance with the document content

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

### 13- Records of Handling of Complaints \*

13-1 Complaint form

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13-2 All the complaints and their corresponding investigations and outcomes will be kept in DSREC files for 2 years (proposed) from the closing date of the complaint

### 14- Annexes of Handling of Complaints \*

14-1 N/A

N.B.: “\*” Put “N/A” if there is nothing to write.

*(the document)* to be replaced by document title