DOHA INSTITUTE
FOR GRADUATE STUDIES

Report on Occurrence of Unanticipated Problems Related to Human Subject Research

Investigators conducting human subject research after obtaining Doha Institute for Graduate Studies Institutional Review Board (DI-IRB) approval must promptly report Unanticipated Problems to the IRB. The Investigator shall fill out this form comprehensively and email it to irb@dohainstitute.edu.qa. Failure to report Unanticipated Problems could result in suspension or termination of the IRB approval for the research study.

The DI-IRB adopts the Qatar Ministry of Public Health (MoPH) definition for Unanticipated Problems. In general, this will include any incident, experience, or outcome that meets **all of the following criteria**:

(1) unexpected in terms of nature, severity, or frequency from what is provided in the IRB approved research protocol and informed consent document;

(2) there is a reasonable possibility that it is related or possibly related to participation in the research; and

(3) suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

Please note that an *adverse event*, defined as a serious and unfavorable occurrence that could encompass physical or psychological harm to research human subjects, must be promptly reported only when it meets the above 3 criteria.

The DI-IRB will promptly review Unanticipated Problem reports and provide feedback to the Investigator on any required course of action. This could include a request for further information or guidance on required changes. The IRB could also suspend or terminate the approval of the research as appropriate and as deemed necessary for the protection of human subjects.

Please fill out the below with as much detail as possible:

Name of Investigator:
Date:
Research Study title:
IRB Approval No.:

1) Who was affected by this Unanticipated Problem?

2) Please explain the date, time and location of the Unanticipated Problem.

3) Please explain the details of what happened.

4) How did you deal with this Unanticipated Problem?

5) Provide details on the implications of this Unanticipated Problem on the research.

6) Does this event require you to modify your research procedures, or consent form? If yes, please describe the proposed changes to the IRB for review. All changes require review and approval of the IRB prior to resuming the research.