Report on Occurrence of Unanticipated, Adverse Events Related to Human Subject Research

This form is to be used to report any unanticipated adverse events. Please follow the instructions below if such an event occurs:

- All research activities must be suspended immediately and the Investigator must inform the Institutional Review Board (IRB) by filling out this form and sending it to irb@dohainstitute.edu.qa
- The adverse event must satisfy the following conditions:
  - Serious: puts the subject at a greater risk than originally assessed
  - Unanticipated: was not foreseen within the originally anticipated risks
  - Related to the research being conducted
- You **cannot** resume your research until you obtain a decision letter from the IRB

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

1) Please explain the date, time and location of the adverse event.

2) Please explain the details of what happened.

3) How did you deal with the event?

4) Provide details on the implications of this adverse event on the research.

5) 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.