Cleveland Clinic Akron General

Standard Operating Procedure
Unanticipated/Serious Adverse Event Report for Human Subjects Research

PURPOSE

To provide investigator guidance on the documentation and reporting of unanticipated problems and/or serious adverse events that may occur during the course of human subjects' research.

APPLICABILITY

The procedures in this document apply to all investigator(s) and research personnel conducting human subjects' research at Akron General Medical Center (AGMC) or its affiliates.

DEFINITIONS

Serious Adverse Event: an undesirable experience associated with the use of a medical product in a patient that results in death, is life-threatening, requires hospitalization or prolonged hospitalization, results in a disability or permanent damage, results in congenital anomaly or birth defect, and/or the event jeopardizes the patient and may require intervention to prevent the other outcomes.

Unanticipated Problems: any incident, experience, or outcome that meets all of the following criteria: 1) Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, and (b) the characteristics of the subject population being studied; 2) Related or possibly related to participation in research; and 3) Suggests that the research places the subject or other at greater risk of harm than was previously known or recognized.

RESPONSIBILITY

It is the responsibility of all investigator(s) and research personnel conducting human subjects research at Akron General Medical Center (AGMC) and its affiliates to follow the procedures set forth in this document.

The Internal Research Review Board (IRRB) at AGMC is responsible for reviewing and reporting any unanticipated problems and serious adverse events as required by the HHS and FDA federal regulations.

PROCEDURES

Internal Events

When an ***internal*** event occurs (i.e. adverse event, protocol deviations, unanticipated event) that could be classified as an adverse event or unanticipated problem, it is required to be reported to the IRRB Office for review.

The Unanticipated/Serious Adverse Event Report for Human Subjects' Research is required to be prepared, reviewed and signed by the Principal Investigator, and submitted to the IRRB Office (IRRB@akrongeneral.org) within 5-days of knowledge of the event. Any protocol and/or informed consent/assent changes proposed as a result of the event should be forwarded with a Request for Amendment/Change form as attachments.

External Events

When report of an ***external*** unanticipated problem is reported to the AGMC Principal Investigator from a sponsor, an electronic copy of the report is required to be forwarded to the IRRB Office (IRRB@akrongeneral.org) to be placed in the study file.

Federal regulations do not require distribution to local IRBs involved in sponsored multi-site research or local IRB review of serious adverse events that are not classified as unanticipated problems. If you are unsure as to whether or not a serious adverse event is an unanticipated problem, submit the event to the IRRB office for further review.

Data safety monitoring reports are required to be forwarded to the IRRB office (IRRB@akrongeneral.org) to be placed in the file.

SUBMISSION

The adverse events/unanticipated problems report is to be emailed to the IRRB Office (IRRB@akrongeneral.org). Please submit a tracked change as well as clean copy of amended protocols and/or informed consent/assent documents as Word documents (.doc,.docx) when applicable. Other documents may be submitted as Word documents or PDFs.

When submitting the report, please verify that all signatures have been obtained (digital signatures that include a time and date stamp are acceptable). The IRRB Secretary will verify that all of the necessary attachments and signatures are present prior to forwarding the report to the IRRB for review.

If additional information or changes are requested, the indicated contact person and the Principal Investigator will be notified of the requests. Please submit a tracked change copy as well as a clean copy of all changes.

Once the submission has been successfully completed, the IRRB Coordinator will notify the contact person and the Principal Investigator of the progress of the review and if any further action is required by letter.