Cleveland Clinic Akron General

FOR IRRB USE ONLY
IRRB Number:_____
IRRB Reviewer:_____
☐ Exempt ☐ Expedited ☐ Full

Institutional Research Review Board Akron General Medical Center
Unanticipated/Serious Adverse Event Report for Human Subjects Research

Please type all of the required information. HAND WRITTEN FORMS WILL NOT BE ACCEPTED. Submit an electronic copy of the completed and signed form with all required attachments to the Institutional Research Review Board (IRRB) IRRB@akrongeneral.org. Questions regarding IRRB submissions can be directed to (330) 344-6947, or by emailing IRRB@akrongeneral.org.

Project Title:

Principal Investigator

Name/Degree: Department:
Email: Phone:
Address:

Study Contact Person

Name: Department:
Email: Phone:
Address:

SERIOUS ADVERSE EVENT

Date of Occurrence: **Date Reported to IRRB:**

***NOTE: Only internal unanticipated problems/serious adverse events should be reported on this form.**

Describe the adverse event:

1) The event meets the definition of a serious adverse event because (choose all that apply):

☐ The event resulted in death while enrolled in the study.
☐ The event was/is life threatening.
☐ The event required/requires inpatient hospitalization and/or a prolonged hospitalization.
☐ The event resulted/results in a significant disability or incapacity.
☐ The event resulted/results in a congenital anomaly and/or birth defect.
☐ The event may result in a future adverse event that, based on appropriate medical judgment, may jeopardize the subject's health and/or may require future medical or surgical intervention to prevent further events.

2) The event meets the definition of an unanticipated problem because (choose all that apply):

☐ The event was *unexpected* (i.e. not expected based on information contained in the investigator brochure, protocol, and/or consent documents);
☐ The event was *related* or *possibly* related to participation in the study; and
☐ The event may place subjects or others at more risk of harm than what was previously expected

If the event is an *unanticipated problem*, describe how subject safety for continuing research activities is being ensured, and describe any corrective actions taken to ensure the safety of both current and future subjects:

Does the study protocol require a change due to the unanticipated/adverse event? ☐ Yes ☐ No
If 'yes', submit a tracked change and clean copy of the amended protocol as well as the Request for Amendment form.

Does the informed consent/assent document(s) require change due to the unanticipated/adverse event?
☐ Yes ☐ No
If 'yes', submit a tracked change and clean copy of the amended consent/assent form as well as the Request for Amendment form.

List all internal personnel, institutions, sponsors, and/or agencies to who you have reported this unanticipated/adverse event:

REPORT PREPARATION

_____ _____
Report Preparer's Signature Date

_____ _____
Report Preparer's Printed Name Department

I have reviewed all of the information included in this report, and confirm it is accurate based on the information available.

_____ _____
Principal Investigator's Signature Date

_____ _____
Principal Investigator's Printed Name Department

IRRB Review – For Office Use Only

☐ Report reviewed; no further action required at this time.
☐ Report and proposed corrective actions approved; protocol and consent changes to be reviewed separately.
☐ Report and proposed corrective actions reviewed; recommend further review by full board.
☐ Report and proposed corrective actions reviewed; further information required from Principal Investigator.

Information requested:

_____ _____
Reviewer's Signature Date

_____
Reviewer's Printed Name