Reporting Problems in Human Subjects Research to the IRB

Consider any emergency procedures required for participant protections.
Report to the IRB within 48 hours of learning in the event. Submit a written report within 5 business days to irb@purdue.edu.

See SOP 409
Submit the form

found here. Do not include any identifiable participant information.

Is this a Serious Adverse Event?

Does the problem/event result in an outcome that is fatal, lifethreatening, requires or prolongs hospitalization, produces a disability/incapacity; results in congenital anomaly/birth defect, requires medical intervention to prevent one of the above conditions?

Yes



Is the Event Unanticipated?

Does the problem, event, or outcome affect subjects or others (nonsubjects) in a way not described as a potential risk in the consent form, IRB protocol or study materials, not part of an underlying disease or condition, or described as a risk, but the event or outcome has occurred with unexpected frequency or severity?

Yes



Was the problem anticipated, but occurring with Unexpected Severity or Frequency?

Is the problem, event or outcome listed as a risk in the consent form and/or approved protocol but occurs more frequently than anticipated or with unexpected severity?

Yes

No

The IRB encourages prompt self-disclosure of any problems by the research principal investigator and/or research team to assist in confirmation of the determination. Submit the information as a memo to the IRB. Do not include any identifiable participant information.

Investigators must report during any IRB protocol renewal processes.

If you are a study participant, or concerned study observer, you may report to the IRB directly at irb@purdue.edu, or (765) 494-5942. To anonymously report via Purdue's Hotline, see http://www.purdue.edu/hotline/