

The GCRC at University Park

Unanticipated Problems and Adverse Events Policy

The GCRC has adopted the Office of Research Protections Standing Operating Procedure for Reporting of Unanticipated Problems Involving Risks to Participants or Others (see IRB SOP Addendum), which states that the investigator is responsible for reporting all problems associated with research protocols to the IRB. Reporting requirements vary according to the type of problem, however, all forms and tracking logs submitted to the IRB should also be submitted simultaneously to the GCRC. In addition, Penn State's Safety Policy SY05 (Persons, Other Than Students or Employees Who Are Injured or Become Ill on University Property) requires that a report of the circumstances of an accident or illness be reported to the Office of Risk Management. The GCRC, on the advice of Penn State's Office of Risk Management, views Adverse Events as qualifying under Policy SY05.

The GCRC staff at times interacts with research subjects in the absence of the PI or a PI team member. Under those circumstances, if the GCRC staff become aware of a possible Unanticipated Problem:

- 1) Any suspected Unanticipated Problem or Adverse Event, as defined in the IRB's SOP Addendum Reporting of Unanticipated Problems Involving Risks to Participants or Others, will be reported by the nursing staff or nutrition staff to the Nursing Manager or Acting Nursing Manager, or to the Nutrition Manager or Acting Nutrition Manager, as soon as is possible without compromising the safety of the subject.
- 2) The Manager or designee will report the same to the PI and a GCRC physician.
- 3) As part of the application process to the GCRC the PI will provide contact information (phone numbers, support staff phone numbers, cell phone numbers, etc.) that will allow the GCRC staff access to the PI or appropriate designee as soon as possible in case of the occurrence of an Unanticipated Problem / Adverse Event.
- 4) All suspected Unanticipated Problems and Adverse Events, and their reporting to the PI and GCRC physician, will be thoroughly documented by the staff involved and by the appropriate Manager (the last may choose to simply countersign the staff note).
- 5) The physician will personally interview and examine the subject unless the physician deems the event to be too minor to require such and will document her / his findings.
- 6) It is up to the PI to determine if an event is an Unanticipated Problem and/or an Adverse Events to be reported to the IRB and, it is the PI's responsibility to do so.

- 7) The PI is requested to send a copy of the Problem Report Form and Problem Accumulative Tracking Log to the GCRC at the time of submission to the IRB and on the same time line as reporting to the IRB. All such reports, prompt or annual, without subject identifying information, will be reported to the GAC at its monthly meeting by the Research Subject Advocate.
- 8) Any difference of opinion between GCRC staff members and the PI as to whether an event should be considered as an Unanticipated Problem or Adverse Event will be resolved by the Research Subject Advocate.
- 9) The Incident Form relating to the Safety Policy SY05 (General Forms Usage Guide-Page 8.5) will be completed by a GCRC staff member. The PI will have an opportunity to review the form before it is sent to the Office of Risk Management.