Institutional Review Board
HUMAN SUBJECTS PROTECTION OFFICE

Penn State College of Medicine
Penn State Milton S. Hershey Medical Center

IRB Information Sheet
Protocol Deviations

The following information outlines the requirements for reporting protocol deviations to the IRB.

Background

It is the investigators' responsibility to conduct the research according to the IRB-approved research protocol, except when necessary to protect the safety, rights or welfare of participants. Any departure or deviation from the IRB-approved protocol is called a protocol deviation.

Should I get prior IRB approval for an anticipated protocol deviation?

If an investigator knows in advance that he/she will be deviating from the approved protocol for a single individual, he/she should request prior IRB approval/acceptance of the deviation using the Protocol Exception Request Form which can be found on the IRB web site at http://www.hmc.psu.edu/irb/forms/studies/index.htm.

Do I need to report accidental or unintentional protocol deviations to the IRB?

Reporting requirements for accidental or unintentional deviations depend on whether or not the deviation represented a problem involving risks to participants or others as determined by the investigator.

- For accidental or unintentional protocol deviations that involved no risks
  If the deviation is a one-time deviation from the IRB-approved protocol and it involved no risks, it does not need to be reported to the IRB. Some examples of accidental or unintentional protocol deviations involving no risks include: 1) a participant is seen outside of the visit "window"; 2) a safety lab test is inadvertently omitted at one study visit and this lab test is not known to be adversely affected by the study intervention; or 3) a participant forgets to take one dose of study medication. If the sponsor of the research requires that this type of protocol deviation be reported to the IRB, the deviations may be submitted using the Protocol Deviation Report Form which can be found on the IRB web site at http://www.hmc.psu.edu/irb/forms/studies/index.htm

- For accidental or unintentional protocol deviations that involved risks
  Accidental or unintentional protocol deviations that involved risks must be reported to the IRB according to the IRB Standard Operating Procedure (SOP) Addendum – Reporting and Review of Unanticipated Problems Involving Risks to Participants or Others. Some examples of accidental or unintentional protocol deviations that involved risks include: 1) dosing errors; or 2) enrolling subjects outside the entry criteria.

Do emergency protocol deviations taken without prior IRB review to eliminate apparent immediate hazard to research participants need to be reported to the IRB?

Emergency protocol deviations must be reported to the IRB according to the IRB Standard Operation Procedure Addendum – Reporting and Review of Unanticipated Problems Involving Risks to Participants or Others.

Examples of emergency protocol deviations include: 1) immediate reduction in the study drug dose due to new safety information or serious side effects; or 2) closure of a study arm due to lack of efficacy.

For additional information see the on-line resources, including the IRB Information Sheet – Reporting of Unanticipated Problems.