Reporting to the IRB

What is the difference between a violation and a deviation?

Protocol deviation? means an inadvertent act (from the perspective of the PI and study staff) in which the protocol is not followed. Examples of protocol deviations include the accidental destruction of a bone marrow sample intended for phenotyping to characterize the subject's type of leukemia in order to determine study eligibility, or an accidental misread of a laboratory value as being within the reference range when it actually is sufficiently abnormal to preclude study participation by the subject.

Protocol violation? means an intentional act (from the perspective of the PI and study staff) in which the protocol is not followed. Examples of protocol violations include the PI prescribing or administering the wrong drug on the study, or the study subject being scheduled to return for follow-up intervention outside the protocol-dictated window as a convenience to the PI or the study staff.

When do I have to report a protocol deviation or protocol violation to the IRB?

A Protocol Deviation/Violation must be reported to the IRB if it: (i) affects subject rights and welfare, or (ii) affects subject safety; or (iii) affects the integrity of study data; or (iv) affects the subject's willingness to continue in the study; or (v) is specifically requested by a government agency, internal/external auditor, medical monitor, or the IRB.

When do I have to report an adverse event to the IRB?

An Adverse Event must be reported to the IRB if it: (i) is more likely than not related to study activities; and (ii) represents a new risk; and (iii) is unanticipated. In addition, an expected event that is occurring at a frequency or intensity greater than originally anticipated must be reported to the IRB.

What are the reporting requirements regarding adverse events?

- Immediately (within 24 hours) upon learning of an unanticipated study-related death, study personnel will notify the IRB via e-mail or fax by providing a brief summary of the event. Then, within 1 week (five business days), study personnel will send to the IRB a Safety Event submission in the eIRB.
- For a reportable serious adverse event, study personnel will notify the IRB within five business days of the investigator becoming aware of the event. Study personnel will
send a Safety Event submission in the eIRB.

- For any other problem or event requiring prompt reporting to the IRB, within ten business days of the investigator becoming aware of the event, study personnel will send to the IRB a Safety Event submission in the eIRB.

Click Here for Actual Policy

**What does UPIRTSO stand for?**

Unanticipated Problem Involving Risk to Subjects or Others