University of South Carolina
Institutional Review Board

Guidelines - Protocol Deviations

A Protocol Deviation is any departure from the procedures and treatment plans as outlined in the protocol version submitted and approved by the USC Institutional Review Board (IRB). Protocol deviations have the potential to place participants at risk and can also undermine the scientific integrity of the study thus jeopardizing the justification for the research.

Protocol deviations are unplanned and unintentional events. Anticipated changes to a protocol should always be submitted to the IRB as a study amendment before the changes are initiated.

The IRB recognizes that some protocol deviations pose no conceivable threat to participant safety or scientific integrity. Therefore, the IRB only requires that **Major Protocol Deviations** be **promptly** reported to the IRB.

1. Major Protocol Deviations

A protocol deviation is considered **major** if it:

- Is intended to eliminate apparent immediate hazard to a research participant,
- Impacts the health, safety or welfare of subjects or places subject at increased risk of harm (physical psychological, economic, or social),
- Concerns possible serious or continued non-compliance (see USC IRB Guidance re: Non-Compliance at: http://www.orc.research.sc.edu/PDF/Non-compliance.pdf).

Some e**xamples** of Major Protocol Deviations are:

- A subject received the wrong treatment or incorrect medication dose.
- Enrollment of a subject who did not meet all inclusion/exclusion criteria.
- Failure to obtain informed consent (including lack of appropriate documentation of informed consent), including:
  - Missing subject signature
  - Use of an invalid or outdated/expired consent form (if changes impact safety, rights or welfare of subject)
  - Informed consent obtained after subject has already undergone study procedures
- Enrollment of a subject from a federally-defined "vulnerable population" (i.e., children, prisoners, pregnant women and fetuses) without prior approval.
- Failure to perform a required lab test that, in the opinion of the PI, may affect subject safety or data integrity.
- Failure to follow the data safety monitoring plan.
- Breach of confidentiality that may place subjects at increased risk of harm

2. Minor Protocol Deviations

A protocol deviation is considered **minor** if it does NOT:

- Impact the health, safety or welfare of subjects or alters the risk/benefit ratio,
- Compromise the scientific integrity of the data collected for the study,
- Affect subjects' willingness to continue participating in the study.

Some **examples** of Minor Protocol Deviations:

- Failure of a subject to appear for a scheduled study visit.
- Failure of subject to return unused study drug.
- Over-enrollment (depending on nature of study).

Minor Protocol Deviations are **not** required to be reported to the USC IRB. If the investigator would like to report minor deviations, the preferred manner would be to maintain a deviation log, which may be uploaded to the yearly Continuing Review application. If an investigator is uncertain whether a deviation is major or minor, (s)he may seek advice from the USC Office of Research Compliance (803) 777-7095.