IRB Tip: Examples of Serious or Minor Protocol Violations

*IRB guidance for implementing federal and institutional IRB policies*

The following provides guidance to help investigators distinguish whether a violation is serious or minor, as described in the Reporting and Managing Protocol Violations Procedure:

1. Serious protocol violations include, but are not limited to:

1.1 Omission of safety lab work with clinical concern or required lab work that has been repeatedly missed.

1.2 Enrollment of participants who did not meet the eligibility requirements, even if approved by the sponsor.

1.3 Failure to obtain informed consent prior to any study-specific tests/procedures, or as approved by the IRB.

1.4 Failure to follow protocol procedures that specifically relate to the primary safety or efficacy endpoints of the study.

1.5 Failure to follow IRB-approved method for obtaining informed consent. This includes, but is not limited to: use of expired consent form, consent by telephone (unapproved), no documentation of informed consent, informed consent is obtained after initiation of study procedures, missing subject signature, missing investigator signature, missing signature of person obtaining consent, or missing witness signature.

1.6 Individual obtaining informed consent is not listed on the IRB-approved study personnel list.

1.7 Performing a study procedure that is not approved by the IRB.

1.8 Study visit conducted outside of required time frame that, in the opinion of the PI, may affect subject safety.

1.9 Drug/study medication dispensing or dosing error.

1.10 Implementation of unapproved recruitment procedures.

1.11 Over-enrollment.

2. Minor protocol violations include, but are not limited to:

2.1 Routine safety lab work for a participant without new clinical concerns and a history of previously normal lab values is inadvertently omitted at a study visit or performed outside the protocol-defined window. The lab will be performed at the next opportunity and is expected to remain within normal limits.

2.2 Investigators miss giving a study required self-administered quality of life questionnaire to a participant.

2.3 Missing original signed and dated consent form (only a photocopy available).

2.4 Failure of subject to return study medication.

2.5 Failure to obtain subject’s initials on each individual page of the consent form, or failure to obtain time of consent.