Changes in principal investigators and other key personnel may qualify for expedited review of the proposal.

Reporting Requirements

All major protocol violations must be reported to the IRB by letter within five (5) working days of discovery. Minor violations are to be reported at continuing review. It is the responsibility of the Principal Investigator (PI) to determine whether a violation is major or minor and to ensure proper reporting to the IRB. Reports of protocol violations should be submitted to the sponsor as outlined in the sponsor's protocol.

Major Violations

Examples (the list of examples is intended as a guide and is not all-inclusive):

1. Failure to obtain informed consent or research authorization, i.e., there is no documentation of informed consent/research authorization or Informed consent/research authorization obtained after initiation of study procedures
2. Informed consent/research authorization for IND/IDE studies obtained by someone other than individuals authorized by IRB to obtain consent/research authorization, e.g. someone other than a licensed physician investigator or key personnel
3. Inappropriate documentation of informed consent/research authorization, including missing subject signature, missing signature of person who obtained informed consent
4. Enrollment of a subject who did not meet all inclusion/exclusion criteria
5. Performing study procedure not approved by the IRB
6. Failure to report an unanticipated problem or serious adverse event to the IRB and/or sponsor
7. Failure to perform a required lab test that, in the opinion of the PI, may affect subject safety or data integrity
8. Drug/study medication dispensing or dosing error
9. Study visit conducted outside of required timeframe that, in the opinion of the PI, may affect subject safety
10. Failure to follow safety monitoring plan
11. Enrollment of subjects after IRB-approval of study expired
12. Failure to submit continuing review application to the IRB before study expiration
13. Use of invalid consent form, i.e. consent form without IRB approval stamp, or outdated/expired consent form/research authorization
14. Omitting an approved portion of the protocol

Minor Violations

Examples (the list of examples is intended as a guide and is not all-inclusive):

1. Implementation of unapproved recruitment procedures except for the purpose of subject safety
2. Missing original signed and dated consent form/research authorization (only a photocopy available)
3. Missing pages of executed consent form/research authorization
4. Copy not given to the person signing the form/research authorization
5. Someone other than the subject dated the consent form/research authorization
6. Failure to follow the approved study procedure that, in the opinion of the PI, does not affect subject safety or data integrity
7. Study procedure conducted out of sequence
8. Failure to perform a required lab test
9. Missing lab results
10. Enrollment of ineligible subject (e.g., subject's age was 6 months above age limit)