



**Instructions for Completing the  
Protocol Deviations / Violations Report Form**

This form was created for the use of reporting protocol deviations/violations to the Ethical Review Committee (ERC). Protocol deviations should be reported within 5 working days of awareness by the study team. A protocol deviation is any action that does not abide by the ERC approved protocol.

**Section A: Project and Site Information**

Please complete this section in full. If you are unaware of your protocol and/or ERC# please contact either the sponsor or the ERC. Please indicate how many subjects have been consented since the initial approval. Consented includes any and all subjects that have signed an informed consent form, regardless if they did or did not qualify to participate.

**Section B: Description**

Please list the subject's initials and/or their subject ID number.

Please indicate the date of occurrence, as well as, the date of awareness by the study team. If you are reporting the event *after 5* working days of awareness, explain the reason for the delay in reporting.

The ERC requires recognizing how the study team identified the deviation and what type of deviation occurred. The following are definitions of the types of deviations that may occur that require reporting:

- Out of window** - PI sees Subject before or after the allotted period of time as described in the protocol.
- Intentional change** - The protocol must be altered to eliminate immediate hazard to the subjects or others.
- Enrollment deviation** - Enrollment of a subject who did not meet all inclusion/exclusion criteria; a minor who signed as an adult; enrollment took place after suspension or expiration of the protocol; implementation of recruitment procedures before approval.
- Consent deviation** - Failure to obtain consent; consent obtained by someone other than the authorized individual(s); inappropriate documentation, i.e. missing any required signature(s) or date(s); copy not given to subject; use of invalid consent.
- Procedural deviation** - Performing a procedure that is not included in the approved protocol by the ERC; increasing or decreasing the number of procedures; procedures performed by unauthorized personnel: incorrect randomization; failure to perform required procedural tests.
- Device/Drug deviation** - Use of expired drug; use of commercial inventory rather than study; dosing error; implant of incorrect device; implant by unapproved personnel.

The ERC requires the description of the deviation in full detail.

**Section C: Study Deviation Action**

The ERC requires an explanation of the action taken as a result of the event.

The following are definitions of the actions that can be selected:

- PI discontinued** - The PI made the determination to discontinue the subject.
- Subject discontinued** - The subject made his/her own determination to discontinue.
- Sponsor discontinued** - The sponsor made the determination to discontinue the subject.
- Sponsor waiver** - The sponsor allowed deviation and the subject continued in the study.
- Event discovered following study completion** - The event was not discovered until after completion.

Drug Deviations:

- Drug continued** - The drug was continued at the study dose or an altered dose after awareness.
- Drug interrupted** - The drug was discontinued due to deviation; once determination of severity was determined, the drug commenced.
- Drug discontinued** - The drug was discontinued as a result of the deviation and the subject was withdrawn from the study.

**Section D: Corrective Action**

The ERC requires a description of any and all measures taken to assure the deviation will not reoccur.

The following are definitions of the actions that can be selected:

- Site/Subject education** - An educational lesson regarding compliance of the protocol.
- Site/Subject counseled** - A one-on-one discussion session regarding compliance of the protocol.
- Note to file** - Documentation of the deviation will be stored within the file.
- Subject re-consented** - In order to comply with the protocol as well as regulations, each subject must be correctly consented.