Oak Valley Health	Reporting Protocol Deviations
Document Owner: Manager, Office of Research	**Original Approval Date:** 04 May 2021
Approved By: Chair, Oak Valley Health REB	**Latest Version:** 19 Aug 2021

1 PURPOSE

The purpose of this guideline is to describe the requirements for reporting deviations to the Research Ethics Board (REB).

2 POLICY STATEMENT

The Principal Investigator is responsible for conducting the study in compliance with the protocol that was approved by the REB. Should an unanticipated or unintentional deviation from the expected conduct of an approved study occur, the PI may be required to report it to the REB. The REB recognizes that deviations from the protocol can be both minor and major, and distinguishes between those that must be reported to the REB and those that should not. All deviations that were implemented to eliminate immediate hazard(s) to a study subject(s) and/or that impacted the safety, welfare, comfort or rights of study subject(s), whether they were intentional or unintentional, are considered major and must be reported to the REB. Protocol deviations that involve only logistical or administrative aspects of the study are considered minor and should not be reported to the REB (e.g., study participant missed appointment, change in appointment date).

In accordance with GCP Article 4.5.2, *investigators should not implement any deviation from, or changes of, the protocol without agreement by the sponsor and prior review and documented approval from the REB of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g. change in monitor(s), change in telephone number(s)).*

Further, GCP Article 4.5.4 states that *the investigator may implement a deviation from, or a change in, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favorable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:*

a) To the IRB/IEC for review and approval/favorable opinion;
b) To the sponsor for agreement and, if required;
c) *To the regulatory authority(ies)*

3 PROCEDURES

3.1 Reportable Protocol Deviations to the REB

The following are considered types of protocol deviations that meet the requirements of reporting to the REB:

- Changes to the study procedures(s) initiated to eliminate immediate hazards to research participants;
- Enrollment of a participant who did not meet the inclusion/exclusion criteria;
- Over-enrollment exceeding the number of participants approved by the REB;
- Deviation on the consent form (i.e., missing documentation on the ICF, failure of obtain consent, used an unapproved or wrong consent form, etc.);
- Performance of a study procedure not approved by the REB;
- Deviation on study procedure (i.e., failure to perform a study procedure that may affect patient safety, procedure or visit performed outside the time frame specified in the protocol, etc.);

- Study drug or intervention errors (i.e., incorrect dosing);
- Potential breach of confidentiality (i.e., missing documents, digital security breach, misplace of USB, etc.).

3.2 Submitting Protocol Deviations

All available information about the deviation must be reported to the REB within **15 calendar days** of the investigator becoming aware of the protocol deviation. Deviations should be reported to the REB using the currently approved Protocol Deviation Form. The Protocol Deviation Form directs the Principal Investigator to provide detail on:

- whether the protocol deviation affects the safety/increases the risk(s) to study subjects(s);
- whether corrective measures have been made to ensure that similar deviations do not occur;
- whether the deviation affects the integrity of the study data;
- whether a protocol amendment will be submitted to the REB for review and approval as a result of the deviation.

The REB will not accept Protocol Deviation reports without an original signature from the PI. This signature attests that the PI is aware of the deviation and its safety implications and has assessed the impact of the deviation on the study procedures.

All protocol deviations should be documented in study files. The investigator is required to explain and sign off on all protocol deviations using the Protocol Deviation Form. Further, the investigator must report all protocol deviations to the Sponsor, if applicable.

3.3 Review Process

The REB office will assess protocol deviations and will contact the PI when further information is needed. The REB may make recommendations to amend the protocol in order to eliminate such occurrences in future.

Generally, the REB will not acknowledge receipt of the protocol deviation report form and will generally not contact the PI unless further action is required.

3.4 Protocol Deviations That Lead to Study Amendments

A protocol deviation may result in the need for an amendment to the study. In the event that a protocol deviation results in the need for an amendment, the deviation must be reported to the REB and an amendment must be submitted to the REB for review and approval. If the amendment has already been implemented to eliminate an immediate hazard, indicate this by answering 'Yes' to the question that asks this on the amendment form. The deviation and amendment must be submitted to the REB together to facilitate the review process.

3.5 Protocol Deviations That Are Also Serious Adverse Event(s)/Unanticipated Problem

If a protocol deviation resulted in an internal adverse event/unanticipated problem, the Internal Serious Adverse Event/Unanticipated Problem Reporting Form must be submitted together with the deviation report to the REB.