

INSTRUCTIONS FOR REPORTING PROTOCOL DEVIATIONS AND WAIVERS

DEFINITIONS

A. Protocol Deviation:

The term protocol deviation is not well defined by regulations or guidelines, but a deviation is any unplanned, unanticipated, or unintentional departure from the current HiREB-approved protocol, consent document, study addenda, or research activity. A deviation is different from an amendment in that it is generally applied to a single occurrence or participant, and is not intended at the time to modify the entire protocol.

Previously the term *protocol violation* was also used for certain situations. However, the terms *protocol deviation* and *protocol violation* may now be used interchangeably. The HiREB uses the term *protocol deviation* to refer to all such occurrences.

NOTE: The only acceptable protocol deviation is when urgent action is required to eliminate an immediate hazard to a subject. This type of deviation must still be reported to the HiREB as outlined below.

The following protocol deviations are considered MINOR and need NOT be reported to the HiREB:

- a. Deviations that do not significantly affect the safety/well-being of the participant(s)
- b. Deviations that do not increase the risk or decrease the benefit of the study
- c. Deviations that do not significantly affect the integrity of the research data

The Researcher MUST report to the HiREB any SIGNIFICANT deviations defined by the following criteria:

- a. Deviations that in the opinion of the Researcher jeopardize the safety of research participants, or that jeopardize the research efficacy or data integrity
- b. Any sponsor-approved waivers to the participant eligibility criteria
- c. Any change in the approved process for obtaining consent
- d. Any deviations that lead to an SAE or unanticipated problem

A protocol deviation must be reported to the HiREB **within 7 business days** of its discovery by using the HiREB **Protocol Deviation Report**. A copy of the sponsor protocol deviation or waiver form should be appended to the form. Other supporting documentation should be retained by the Researcher and be made available upon request.

B. Waiver:

An enrollment waiver that, in the opinion of the Researcher, is minimal risk, i.e., has no potential for negative impact on the health and safety of the participant, may be implemented without **prior** HiREB approval. This waiver should still be reported to the HiREB within 7 business days of its occurrence.

NOTE: The HiREB will not give retroactive approval of a deviation.