Protocol Deviations

A protocol deviation occurs when there is a variance in a research study between the IRB approved protocol and the implementation of study activities. Protocol deviations may be minor or major, as defined below.

a). Minor deviations

- The deviation has no substantive effect on the risk to research subjects
- The deviation has no substantive effect on the value of the data collected (i.e., the deviation or violation does not confound the scientific analysis of the results), AND
- The deviation did not result from willful or knowing misconduct on the part of the investigator(s) or study staff

b). Major deviations

- The deviation has harmed or posed a significant risk of substantive harm to research subject
- The deviation has damaged the scientific integrity of the data collected for the study
- There is evidence of willful or knowing misconduct on the part of the investigator(s) and/or study staff; OR
- The investigator(s) and study staff demonstrated other serious or continuing noncompliance with federal, state, or local regulations

Reporting protocol deviations

a). Minor deviations

Minor protocol deviations occurring during the period of approval must be tabulated and reported at the time of continuing review. If there is a question as to whether or not the deviation qualifies as minor, the IRB Chair may be consulted. The IRB Chair or full board may request from the investigator any further information or documentation deemed necessary to assist in the review.

b). Major deviations

Major protocol deviations occurring locally must be reported to the IRB within two days of awareness of the event (or no later than Monday if awareness occurs on Friday). Do not delay reporting because of a lack of information regarding the event. Follow-up reports can be submitted to complete the report as necessary.

Investigator(s) are to complete a Protocol Deviation form when reporting these types of events to the IRB. The form is used to document the investigator's opinion as to whether the event adversely affected the subject, why the deviation occurred, and what steps are being taken to prevent a future occurrence. The IRB Chair or full board may request from the investigator any further information or documentation deemed necessary to assist in the review.

For these types of events, the Adverse Event Committee will conduct a review of the submitted deviation prior to the full IRB review. If the Adverse Event Subcommittee determines no immediate action is necessary, the event will be placed on the agenda for the next scheduled meeting of the IRB for review. If immediate suspension or termination of the study is necessary, the Subcommittee can call an emergency meeting of the full board. If additional changes are required by the full board, a letter will be sent to the investigator.

If fact-finding, inquiry, or review support that scientific misconduct has also occurred, the matter will also be referred by the IRB Chair to the Research Integrity Officer, who may initiate further action under the Scientific Misconduct Policy.

Deviations reported by non-investigators

Occasionally, instances of protocol deviations or other situations of noncompliance come to the attention of the IRB via mechanisms other than investigator reporting. In this event, written documentation must be submitted to the IRB by the reporting party, either via a Protocol Deviation Reporting Form or memorandum.

Appeal of IRB decision

If an investigator disagrees with the findings and/or requirements arising from a protocol deviation report and action, he/she may appeal the decision to the IRB Chair and Institutional Official in writing. The IRB Chair and Institutional Official will consider the appeal request along with any additional information the investigator provides. The decision of the IRB Chair and Institutional Official will be final.