

DHS-Public Health Division PROTOCOL DEVIATIONS AND NONCOMPLIANCE

Investigators are responsible for conducting human subject's research in accordance with all applicable federal and state regulations, as well as the specific requirements of the DHS-Public Health Division/Multnomah County Health Department Public Health IRB. Once the IRB has reviewed and approved a research protocol and the various forms (consent, assent, data collection, etc), no changes may be implemented without prospective review and approval by the IRB. The only exception to this rule involves emergency action by an investigator to protect subjects from apparent immediate hazards.

During the conduct of the study, investigators must request approval for any changes to the IRB approved protocol and applicable consent forms, questionnaires or other documents prior to implementation using the Project Revision/Amendment Form (PRAF). Changes to the revised protocol and/or applicable forms must be highlighted and deletions shown using strikeout.

Definitions

The following definitions apply throughout this document:

Protocol Deviation: Any alteration or modification in the conduct of the research that has NOT been approved by the IRB prior to its initiation or implementation.

- **Minor deviation** is a deviation that does not have a significant impact on the research participant's rights, safety or welfare; the integrity of the data; nor substantially alter risks to subjects as determined by the IRB.
- **Major deviation** is a deviation that may impact the subject's rights, safety and welfare; the integrity of the data; or may substantially alter risks to research participants as determined by the IRB.

Noncompliance: Failure to comply with federal regulations or the requirements or determinations of the IRB.

- **Continuing noncompliance** is repeated instances of noncompliance by the investigator.
- **Serious noncompliance** are instances that pose an increased risk to the safety, rights and welfare of research participants, when investigators either avoid or ignore IRB policies, significant failure to comply with federal regulations, or failure to comply with IRB requirements or determinations.

Reporting Requirements

Major deviations must be reported to the IRB within five (5) working days of their occurrence or within five (5) working days of the investigator becoming aware of their occurrence using the Protocol Deviation form.

Minor deviations must be reported to the IRB within ten (10) working days of their occurrence or within ten (10) working days of the investigator becoming aware of their occurrence using the Protocol Deviation form.

It is the responsibility of the investigator to determine whether a deviation is minor or major and to ensure proper reporting to the IRB. Reports of protocol deviations should be submitted to the sponsor as outlined in the sponsor's protocol.

IRB Review and Action

- Protocol Deviation reports will be submitted by investigators to the IRB Coordinator using the Deviation/Noncompliance report form.
- Upon receipt of the report, the IRB coordinator will E-mail the report to the IRB Chair and/or Vice Chair.
- The IRB Chair and/or Vice Chair will review or have a designee review the information submitted and compare it to the approved protocol. The investigator may be invited to respond to questions to determine possible course of action by the IRB. The IRB Chair and/or Vice Chair or designee will then make a conclusion regarding the seriousness of the deviation and what corrective action, if any, to take. Recommended actions may include but not limited to:
 - termination of the study,
 - suspension of the study until corrective action is taken,
 - increased reporting requirements, or
 - other actions as determined by the IRB.
- In the case of minor deviations, the IRB Chair and/or Vice Chair will notify the investigator in writing what must be done, if anything, to correct the situation that lead to the violation. Investigators will have 30 calendar days to respond. Non-response will constitute non-compliance and subject recruitment may be suspended. A summary of the deviation and conclusions will be presented at the next scheduled Board meeting. The full IRB may initiate further action.
- Major deviations may lead to immediate protocol suspension by the IRB Chair and/or Vice Chair. A summary of the violation, process, facts, and conclusions will be presented at the next scheduled Board meeting for further discussion and action. The IRB Chair and/or Vice Chair will notify the investigator in writing what must be done to correct the situation that lead to the violation and will also notify institutional officials of the deviation, including the IRB's corrective action. Investigators will have 15 calendar days to respond. Non-response will constitute non-compliance and the research may be terminated or suspended.

The IRB will report to the federal Office for Human Research Protections (OHRP), and any other sponsoring federal department or agency head, any serious or continuing noncompliance with the regulations or requirements of the IRB.

Applicable Regulations

45 CFR 46.103 and 46.113

21 CFR 56.113