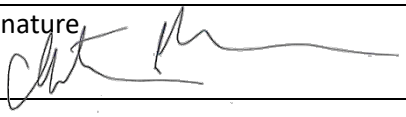
OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #405.1 Revision 1	**TITLE: Reporting of Protocol Deviations**	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature 	Date 3/1/2019
Approved By: IRB Chair	Signature 	Date 3/1/2019

PURPOSE
To describe the policies and procedures for researcher reporting of minor protocol deviations.

REVISIONS FROM PREVIOUS VERSION
Update regulatory reference and administrative corrections

POLICY
Federal regulations and institutional policy require the IRB to review and approve proposed changes to research projects before initiation of these changes, except when changes are "necessary to eliminate apparent immediate hazards to the subject" [45 CFR 46.108(a)(3)(iii)]. Most proposed changes are reviewed through submission of amendments. Any changes that are made to eliminate apparent immediate hazards to a participant should be reported as soon as possible after they occur as a protocol deviation. Deviations range in seriousness according to how the changes may impact participant safety, the degree of noncompliance with federal and state regulations, and the degree of foreknowledge of the event. Deviations must be reported to the IRB with a description of the deviation, its impact on participant safety (if any) and a description of how similar events will be avoided in the future. Once reported, the IRB can make a decision regarding an appropriate response or remedial action. Note that repeated deviations of the same type may be an indication that an amendment is needed to permanently change the project.

Major protocol violations (involve risk or increase in risk)
Accidental or unintentional protocol violations that involve risks to participants or others must be reported to the IRB according to the IRB SOP 401 Reporting and Review of Events Involving Risks to Participants or Others. A **major violation** is one that may impact participant safety or alter the risk/benefit ratio, compromise the integrity of the research data, and/or affect participants' willingness to participate in the project. Major violations require prompt reporting and should be reported to the IRB **within 7 calendar days** of the researcher's knowledge of the deviation. Reports should be made using the Event Form.

Minor protocol deviations (involve <u>no</u> risk or increase in risk)
Minor protocol deviations are defined as a one-time deviation from the IRB-approved protocol that **involve no risks to participants or others**. A minor deviation is one that does **not** impact participant safety, compromise the integrity of the research data, or affect participants' willingness to participate in the project. Examples of minor deviations could include:

- Missing pages of signed consent form.
- Inappropriate documentation of informed consent, including:
    - missing researcher signature and/or date;

  - copy not given to the person signing the form;
  - someone other than the participant dated the consent form;
  - individual obtaining informed consent not listed on IRB approved project team list.
- Use of invalid consent form, i.e. outdated/expired consent form.
- Failure to follow approved research procedures that, in the opinion of the PI, does not affect participant safety or data integrity:
  - Research procedures conducted out of sequence;
  - Omitting an approved portion of the protocol;
  - Failure to perform a required lab test;
  - Enrollment of ineligible participants (e.g. participant's age was 6 months above age limit);
  - Researcher procedure conducted outside of required timeframe.
- Over-enrollment.

RESPONSIBILITIES

Execution of SOP: Researchers.

PROCEDURE

Researcher Reporting Requirements for Minor Protocol Deviations

1. Members of the research team must immediately report the occurrence of a protocol deviation to the Principal Investigator (PI).
2. All minor deviations should be recorded by the research team and summarized for the IRB at the time of continuing review or administrative check-in using the Protocol Deviations Report (available on the OIRB website and IRBNet). The OIRB may also review deviations during the conduct of post approval monitoring activities.
3. Additional reporting requirements to federal agencies, sponsors, or other entities also may be required as determined by the PI.
4. The IRB may request more stringent requirements for reporting protocol deviations for individual research projects if it is deemed necessary.

REFERENCES

45 CFR 46.108(a)(4)(i)