IRB FORM X

BALDWIN WALLACE UNIVERSITY INSTITUTIONAL REVIEW BOARD

NONCOMPLIANCE REVIEW FORM

Investigators are responsible for conducting human subject's research in accordance with all applicable federal and state regulations. 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. Changes to the revised protocol and/or applicable forms must be highlighted and deletions shown using strikeout.

This form should only be used to report **observed or apparent** noncompliance. **Noncompliance** is defined as any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with federal or state regulations or institutional policies governing human subjects research or the requirements or determinations of the IRB including minor protocol deviations. **Minor protocol 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. Examples include, but are not limited to, failure to obtain IRB approval, inadequate supervision, failure to follow recommendations made by the IRB, failure to report unanticipated problems or protocol changes, etc.

SECTION I: PRINCIPLE INVESTIGATOR INFORMATION

Category (Check one): [ ] Expedited [ ] Exempt

Date of Review_____ Date(s) of noncompliance_____

Principle Investigator:

Title of Project:

Academic Department:

Campus Address:

Telephone:

SECTION II: NONCOMPLIANCE INFORMATION
Seriousness of deviation: (Check one)

____ This report is a minor protocol deviation. (A deviation from the IRB approved protocol that DOES NOT have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.)

____ This report is a protocol violation. (A deviation from the IRB approved protocol that may affect the subject's rights, safety, or well being and/or the completeness, accuracy and reliability of the study data.)

A. This protocol violation resulted in:

___ no impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data (only select if the report is a minor protocol deviation)

___ actual harm to the research subject (if checked, submit NIH adverse event report);

___ potential harm or significant or substantive risk of harm to the research subject;

___ a compromise to the scientific integrity of the data collected for the study;

___ a willful or knowing breech of human subject protection regulations, policies, or procedures on the part of the investigator(s);

___ a serious or continuing noncompliance with federal, state, local or institutional human subject protection regulations, policies, or procedures;

B. Provide an explanation of the facts surrounding the noncompliance, including a timeline of occurrence of noncompliance and discovery.

C. Provide an assessment of the increased risk (if any) to subjects resulting from the noncompliance.

D. Explain the corrective measures taken in response to the noncompliance and explain any preventive measures that will be taken to prevent the noncompliance from occurring in the future (if possible).

* If applicable please attach any supporting documentation, such as an audit or monitoring report, etc.

E. Have there been similar occurrences? [ ] Yes [ ] No
If yes, please describe.

F. In addition to the IRB, this deviation is being reported to (please note any other on-campus or off-campus authority that should be made aware of this deviation):

SECTION III: INVESTIGATOR ACTION

Please indicate any actions that will be taken as a result of this report:

A. The informed consent process/document will be revised. Please submit an amendment requesting the revisions.

B. The protocol will be revised. Please submit an amendment requesting the revisions.

C. Currently enrolled subjects will be notified. Please attach a copy of the notification.

D. Other corrective and/or preventive action will be taken. Please explain:

E. The event compromised the validity of the data. Please explain:

Statement of Principal Investigator. I have personally reviewed this report and agree with the above assessment.

Signature of Principal Investigator:_____ Date:_____

FOR IRB COMMITTEE USE ONLY

Report reviewed by IRB Chair or designee.

A. Report does **NOT** represent noncompliance. Sign report and return to investigator.

B. Report represents **MINOR** noncompliance. Sign report, return to investigator, and report corrective action to IRB.

C. Report likely represents serious or continuing noncompliance. **Refer to convened IRB**.

Comments/Additional Action:

IRB Chair or designee signature:_____ Date:_____