Principal Investigator:

IREC Study Number:

Document Date:       [to be assigned by IRB]

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 participants that fails to comply with research regulations, or institutional policies governing human participants research or the requirements or determinations of the IREC Committee. Examples include, but are not limited to, failure to obtain IREC approval, inadequate supervision, failure to follow recommendations made by IREC, failure to report unanticipated problems or protocol changes, etc. This is different from a protocol deviation,which is an alteration/modification to the IREC-approved ***protocol*** that is not approved by IREC prior to its initiation or implementation. If you need to report a ***major*** protocol deviation, please use the Prompt Reporting Form.

# Additional Requirements

1. If this report applies to multiple studies, complete a form for each study.
2. Attach any supporting documentation to the report.

## Section I: Investigator Information

**Principal Investigator:**

Name: Click here to enter text.

Department:      Phone:       E-Mail:

**Additional Study Contact**:

Name:       Phone:       E-Mail:

Project Title:

Sponsor/Funding Agency:       Sponsor Number:

## Section II: Study Information

This study is:

Open to enrollment

Closed to enrollment

Number of active participants: Click here to enter text.

## Section III: Noncompliance Information

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

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

1. 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).

\* Please attach any supporting documentation, such as an audit or monitoring report, etc.

## Section IV: Investigator Action

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

1. The informed consent process/document will be revised. Please submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first), please explain:

The informed consent document will **NOT** be revised. Please explain:

1. The protocol will be revised. Please submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first), please explain:

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

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

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

Recorded in the Minutes of:

## Section VI: Investigator Statement of Compliance

By submitting this form, the Principal Investigator assures that all information provided is accurate. He/she assures that procedures performed under this project will be conducted in strict accordance with federal regulations and Indiana University policies and procedures that govern research involving human subjects. He/she acknowledges that he/she has the resources required to conduct research in a way that will protect the rights and welfare of participants, and that he/she will employ sound study design which minimizes risks to participants. He/she agrees to submit *any* change to the project (e.g. change in principal investigator, research methodology, participant recruitment procedures, etc.) to the Board in the form of an amendment for IREC approval prior to implementation.

## Section V: IREC Approval

This report and the actions described herein has been accepted by IREC, which has determined that the study continues to meet the criteria for approval IREC has determined that the information provided in this report represents:

Serious Noncompliance

Continuing Noncompliance

Serious and Continuing Noncompliance

NEITHER Serious nor Continuing Noncompliance

Authorized IREC Signature: IREC Approval Date:

Name of IREC Member:

*For IREC Human Participants Office use only.*

Recorded in the Minutes of: