AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD

Notification of Noncompliance with an Approved Protocol

For help, contact: **THE OFFICE OF RESEARCH COMPLIANCE (ORC)**, 115 Ramsay Hall, Auburn University
Phone: **334-844-5966** e-mail: **IRBAdmin@auburn.edu** Web Address: http://www.auburn.edu/research/vpr/ohs

Revised 2/1/2014 **Submit completed form to IRBsubmit@auburn.edu or 115 Ramsay Hall, Auburn University 36849.**

Form must be populated using Adobe Acrobat / Pro 9 or greater standalone program (do not fill out in browser). Hand written forms will not be accepted.

PI: **Protocol #:**

Title of Study:

Person providing report:

When referring to human subjects research, **noncompliance refers to** acts of commission or omission which result in the conduct of human subjects research that is inconsistent with the requirements established in the federal regulations relating to human subject protections, with Alabama state law, the policies and procedures of the Auburn University IRB, or the specific requirements of the Auburn University IRB or another IRB with the authority and responsibility for overseeing the research.

Noncompliance can take several forms. Examples include, but are not limited to:

- Protocol Exception – the enrollment of a research subject in a protocol that fails to meet the protocol inclusion criteria or did meet the protocol exclusion criteria.
- Protocol Deviation – a departure from the protocol for a research subject once that subject has been enrolled.
- Conducting research activities prior to obtaining IRB approval, or after IRB approval has expired.
- Making changes to the research protocol without submitting a modification form to the IRB.

All incidents of noncompliance must be reported to the IRB. Incidents can be reported by anyone, including the Principal Investigators, members of a research team, or research participants.
NOTE: This form is NOT for adverse events or unanticipated problems involving risks to participants or others.

1. **Describe in detail the nature of the noncompliance, including the date of occurrence.**

2. **Describe the outcome of the noncompliance. The answer should address the following:**
   a. Any outcomes that violated any participants' rights, safety, or welfare.

   b. Any outcomes that affect the integrity of the study.

3. **Explain why or how the noncompliance occurred.**

4. **Explain how future incidents of noncompliance will be prevented.**

5. **Indicate whether or not the Principal Investigator has been informed.**

6. **For funded research, indicate whether or not the Sponsor has been informed. If not, provide a rationale for not reporting.**

_____ _____
Principal Investigator's Signature Date

_____ _____
Other Signature (if report not filed by PI) Date

FOR ORC OFFICE USE ONLY

DATE RECEIVED IN ORC: _____ **by** _____ **DATE OF IRB APPROVAL:** _____ **by** _____

Auburn University's Institutional Review Board Determination
Based on the information provided, the Auburn IRB has determined that the reported incident:

- ☐ DOES NOT constitute noncompliance
- ☐ DOES constitute noncompliance

Reporting of Non Compliance

☐ N/A ☐ OHRP ☐ FDA ☐ Sponsor ☐ Other

Required Action(s):

- ☐ No further action required
- ☐ Protocol revisions and/or additional information required
- ☐ Protocol placed on administrative hold until further review and/or revisions

Comments:

_____ _____
Signature of IRB Chair Date