AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD

IRB Notification of Event 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: **Has the PI for this project been notified?:** ☐ Yes ☐ No

Please use this form to communicate anything to the IRB that is either an alteration to usual protocol procedures that does not constitute noncompliance, a participant complaint that is not an adverse event or anything else related to recruitment, consent, data collection or management regarding protocol that should be reported to the IRB. Events 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 or for Noncompliance with specific procedures in a protocol. See the forms section of the ORC/IRB website for additional reporting forms.

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

2. Describe the outcome of the event. The answer should address the following:

a. Initial response to participant and who else was informed/involved at the time.
b. Any actions taken by the PI or other research personnel to mitigate the event.
c. Any outcomes that violated any participants' rights, safety, or welfare.
d. Any outcomes that affect the integrity of the study.

4. Discuss how any similar future events will be prevented/handled if this is appropriate.

5. For funded research or research involving other IRBs, indicate whether or not the Sponsor or other IRBs have 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 about the event, the Auburn IRB has determined:

- ☐ The event should be reported on an adverse event form
- ☐ The event should be reported on a Noncompliance form
- ☐ Other

Required Action(s):

- ☐ No further action required
- ☐ The event must be reported to the Full Board IRB for action
- ☐ Protocol revisions and/or additional information required
- ☐ Protocol placed on administrative hold until further review and/or revisions

Comments:

Signature of IRB Chair _____ Date _____