**Human and Animal Subjects Research**
**Adverse Event Form**

**This form should be emailed to hasrc@montevallo.edu within 24 hours of an adverse event or effect.**
***Use this form ONLY if the event meets any of the criteria listed below.***

*You are notifying the HASRC of an adverse event or effect that meets a minimum of one of the following criteria: (check all that apply)*

- ☐ Adverse event (any harm and/or damage that a participant experiences either on or off campus)
  - Adverse events can be unexpected OR related to research procedures.
  - Both types should be reported.

- ☐ Information signifies a change to the risks and/or benefits of research
  - Example 1: Researcher notes different and/or additional safety concerns that initially reported or expected
  - New research is published indicating additional or increased potential for harm under similar conditions or variables
- ☐ Breach of confidentiality

- ☐ Change in procedures without prior HASRC review to eliminate harm to participants

- ☐ Complaint of participant when unexpected risks occur

- ☐ Violation of procedures (accidental or unintentional change to HASRC approved procedures) that causes harm or increases potential for harm

- ☐ Unanticipated device effect (unexpected problems associated with equipment)

# Protocol Information

1. **HASRC Protocol Identification**
    - Title of Research
    - Principal Investigator
    - Date of Approval

2. **Principal Investigator(s)**
    - Name
    - Telephone
    - Email

3. **Purpose of Research**

4. **Location of Research**
    - On campus (Include Name of Building and Room Number)
    - Off Campus (Include physical address, building, and room information as applicable)

5. **Adverse Event Information**
    - Description of Event
    - Participant ID #
    - Date of Event
    - Date researcher learned of event
    - Location of Event
    - Identification of problem as potential risk on informed consent document (highlight one)
        - Yes
        - No
    - Outcome as of today's date (highlight one and provide description)
        - Serious but not fatal
        - Death
        - Other (describe)

    - This event has been reported: (highlight all that apply)
        - By principal investigator to HASRC
        - By researcher to principal investigator
        - Other (please explain below)

    - Revision of informed consent form be revised as a result of this event (highlight one)
        - Yes
            - If yes, include revised informed consent document (with revisions highlighted)
        - No
            - If no, provide detailed explanation (ex: risk already included on consent form)

- Have additional participants already signed informed consent documents? (highlight one)
    - Yes
        - If yes, include addendum to informed consent document that participants to will continue in study will sign
    - No

Name of Individual Reporting Event: _____

Signature: _____ Date_____

**HASRC USE ONLY**

_____ _____
Signature of HASRC Chair or Designated Chair Date

Evaluation:

True False The information contained in this report indicates that the event is unexpected considering the participants and nature of the research.

True False The information in this report indicates that participants are at greater risk than previously reported or expected.

Recommendation: (If one of the evaluative statements is true)

_____ The adverse event does not represent an unexpected problem involving risks to participants or others. No further action required by HASRC. PI will include problem in report when filing for continuance.

Recommendation: (If both of the evaluative statements are true)

___ The adverse event indicates or could indicate an unexpected problem involving risk to participants or others. Event will be reviewed by the HASRC and reported to regulatory agencies and institutional officials.