IRB Study #: _____

ADVERSE EVENT REPORT FOR APPROVED HUMAN PARTICIPANTS RESEARCH

1. **Title of Study**:
2. **Principal Investigator(s)**:
3. **Name of Contact PI**:

   Contact PI Phone #:

   Contact PI Email:
4. **Name of Faculty Sponsor (if applicable)**:

   Sponsor Phone #:

   Sponsor Email:
5. **Date of Event**:
6. **Place of Event**:
7. **Description of adverse event as determined by Principal Investigator:**

8. **Classification of Event**
   a. Attribution of Event
      - ☐ Not or unlikely related to research procedure
      - ☐ Unknown
      - ☐ Probably or definitely related to research procedure

   b. Severity of Event
      - ☐ Mild
      - ☐ Moderate
      - ☐ Serious
9. **Description of handling/response to event:**

10. **Description of any proposed changes in protocol or consent form due to event:**

11. Who else has been informed about event?

Signature of Individual Reporting Event Date

Signature of Principal Investigator Date

Signature of Faculty Sponsor Date

IRB Use Only

- ☐ Continue study as submitted and approved by IRB; No changes needed
- ☐ Discuss with Principal Investigator
- ☐ Changes recommended in protocol or consent form
- ☐ Place study on hold; Discuss with Principal Investigator
- ☐ Report to Meredith officials; Date:

Signature of Chair/Vice-Chair, IRB Date

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