IRB#: _____

RENEWAL OR CLOSURE OF APPROVED HUMAN PARTICIPANTS RESEARCH

One you have completed this form, submit it and any needed attachments electronically to sponsoredprograms@meredith.edu.

Instruction Checklist for Submitting

If the research is continuing:

- Include copies of consent documents and all recruitment materials to be used with participants in the upcoming approval period. There is no need to include copies of other approved documents.
- Include documentation of required education for all **new** personnel involved in the research.

1. **Date of Renewal or Closure**:
2. **Approved IRB study #**:
3. **Title of Study**:
4. **Name of Principal Investigator(s)**:
5. **Name of Contact PI**:
    a. **Contact PI Phone #**:
    b. **Contact PI Email**:
6. **Name of Faculty Sponsor (if applicable)**:
    a. **Sponsor Phone #:**
    b. **Sponsor Email:**
7. **Enrollment (for multi-site studies, include only participants covered by this IRB)**
    a. **Total projected participant enrollment as approved by IRB:**
    b. **Total number of participants enrolled to date:**
    c. **Number of participants enrolled since last renewal:**
    d. **Number to be enrolled in upcoming year:**

Answer the following questions based on information since initial approval or last renewal. Only include participants covered by this IRB.

8. **Have any participants withdrawn voluntarily or been withdrawn from the study?**
    ☐ No
    ☐ Yes, Explain:
9. **Have there been unanticipated problems or serious adverse events since the last renewal?**
    ☐ No
    ☐ Yes, Attach copies of all *Adverse Event Reports*
10. **Have there been any findings that alter the risk/benefit ratio or otherwise impact the study?**
    ☐ No
    ☐ Yes, Explain:
11. **Does this study have a Data and Safety Monitoring Plan?**
    ☐ No
    ☐ Yes, Attach copy of Data and Safety Monitoring Plan

12. Are you requesting any modifications at the time of this renewal?

☐ No

☐ Yes, Attach completed *Modification Form*

13. Will you be enrolling, consenting or re-consenting participants in the upcoming approval period?

☐ No

☐ Yes, Attach copies of all consent documents and recruitment materials to be used with participants

Action Requested by Principal Investigator (Choose One)

☐ Renew Approval

- ☐ For continuing enrollment of new participants.
- ☐ Other reason. Specify:

☐ Renew Approval – Enrollment of new participants closed, however:

- ☐ Active interaction/intervention with participants continues.
- ☐ Participants have completed active interaction/intervention, but continue in subsequent monitoring/follow-up.

☐ Close Approval

- ☐ Participant involvement completed - Only data analysis will continue (or study involved only analysis of existing data).
- ☐ Research completed – Identifiable data are stored according to plan already approved by the IRB.
- ☐ Research completed – All data are de-identified and linking lists destroyed.
- ☐ Other reason. Specify:

Signature of Principal Investigator Date

IRB Decision (To be completed by IRB

☐ Approved as Specific Project

- ☐ 45 CFR 46.404, no more than minimal risk to children applies
- ☐ 45 CFR 46.117(c)(1), waiver of requirement of documentation of consent through written signature

☐ Not Approved

IRB approval of this project expires:

Signature of Chair/Vice-Chair, IRB Date