IRB Request #:

REQUEST FOR REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

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

Date of Application:

Title of Study:

Name of Principal Investigator(s):

Name of Contact Principal Investigator (PI):

Contact PI Phone #:

Contact PI Email:

Name of Faculty Sponsor (if applicable):

Faculty Sponsor Phone #:

Faculty Sponsor Email:

Is this study funded by a grant or contract?

- ◯ No
- ◯ Yes, Provide name of funder:

PI Recommendation (see IRB Manual for guidance)

- ◯ Exempt from further IRB review; Exempt Category Number from manual: Category 1: Normal educational practices
- ◯ Expedited review; Expedited Category Number from manual: Category 1: Clinical studies of drugs and medical devi
- ◯ Full Review

Principal Investigator/Faculty Sponsor: I have reviewed the Meredith College IRB manual and have completed any necessary CITI training. I will personally conduct or supervise this research study. I will ensure this study is performed in compliance with all applicable laws, regulations and policies regarding human participant research. I will obtain IRB approval before making any changes or additions to the project and I will notify the IRB of any changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human participants. I will follow the IRB approved consent process for all participants. I will ensure that all collaborators, students, and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

Signature of Principal Investigator Date

Signature of Faculty Sponsor Date

IRB Request #:

IRB Process (to be completed by IRB)

- ◯ Exempt from further IRB review; Exempt category Number: Category 1: Normal educational practices
- ◯ Expedited review; Expedited Category Number: Category 1: Clinical studies of drugs and medical devices
- ◯ Full Board Review

IRB Decision (to be completed by IRB)

- ◯ Exempted; no further review needed unless protocol changes
- ◯ 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 for documentation of consent through written signature
- ◯ Not Approved

IRB approval of this project expires:

Signature of Chair/Vice-Chair, IRB Date

IRB Request #:

APPLICATION FOR IRB APPROVAL OF HUMAN PARTICIPANTS RESEARCH

1. Is this application for a research project by a member of the Meredith faculty to meet specific learning objectives in a course offered at Meredith College?

   ◯ No

   ◯ Yes (If yes, in lieu of completing the remaining questions, submit a generic explanation of topics and/or methods that students will pursue, with explicit clarification of how the research assignment is relevant to the objectives. Include the course number and title, and indicate how often the course is scheduled.) NOTE: Faculty submitting for such a "blanket" consent must complete CITI training regarding research with human participants prior to IRB approval.

2. Is this a multi-site study (i.e., involves research by organization(s) outside of Meredith College)?

   ◯ No

   ◯ Yes

3. List below all individuals who will have contact with participants or access to identifiable data from participants. NOTE: These individuals must complete CITI training regarding research with human participants prior to IRB project approval.

Attach a separate editable (Microsoft word, Google document, etc.) file containing the answers to the following questions. Pay special attention to any guidance that is underlined.

4. Describe the proposed research, including:

   (a) Study Purpose:

   (b) Study goals, hypotheses, and/or research question(s):

   (c) Population to be studied including number of participants, age range, etc. (Specify if you will recruit individuals from vulnerable populations such as non-English speaking, minors-less than 18 years old, prisoners, women who are pregnant, or individuals whose ability to provide informed consent may be in questions such as those with intellectual disabilities):

   (d) Expected dates for starting and completing study:

5. Describe the research and data collection procedures. Specify if you are you collecting sensitive information (such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc.) and if you plan to obtain a Federal Certificate of Confidentiality for this reason. Attach copies of all surveys, questionnaires, interview questions, or focus groups guides to be used with participants.

6. Describe the process you will use to recruit participants and inform them about their role in the study. Include how you will identify potential participants. If you will give participants gifts, payments, compensation, or reimbursement, please describe. Attach copies of any recruitment materials such as email text, flyers, advertisements, etc.

7. Describe how consent will be obtained and who will obtain the consent. Attach copies of adult (age 18+) consent forms, parental or guardian permission for child/minor (less than 18 years) participation forms, child assent forms (to be completed by minors). NOTE: If you need a waiver of written (signed) consent (such as when gathering consent online as part of a survey), please briefly explain the situation, and describe exactly how your participants will be informed about the study, how you will obtain consent, and what you will provide in writing and/or orally (attach a script) to your participants. If you need to request a waiver of

consent entirely for secondary data analysis or a waiver of elements of consent for other reasons, please complete and attach the *Waiver Addendum Form*.

8. Where, how long, and in what format (i.e., paper, digital, electronic media, video, audio, or photographic) will data be kept? Explain security provisions taken to protect data (i.e., password protection, encryption, etc.).
9. Describe any potential risks to human participants and the steps that will be taken to reduce the risks. Include any risks to the participants' privacy, physical or psychological well-being, social, occupational, financial, or legal status. NOTE: The described risks/harms must be fully disclosed in the consent form, along with a brief description of how those risks are minimized, as relevant, to help reassure participants that the research is safe. If there will be a data and safety monitoring plan, attach a copy.
10. Describe procedures, including confidentiality safeguards, for protecting or minimizing potential risks.
11. What are the anticipated benefits to the participant, if any, as a result of being in the study? What are the anticipated benefits of this research for society, if any? Explain how the benefits outweigh the risks of participation.