

Application for Modification of Approved Human Participants Research

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

This application seeks approval for a modification to a currently approved research protocol.* Any proposed changes to previously approved human participants research must be reviewed and approved by the IRB prior to implementation. This includes modifications to the protocol, inclusion or exclusion criteria, recruitment methods, research personnel, or any new or revised study materials. Note: Substantial revisions may require a revised IRB application.

*Note: Modification approval DOES NOT CHANGE the protocol expiration date.

Instruction Checklist for Submitting

- Provide a concise summary of the requested modification below.
- Attach a revised application, reflecting the changes requested.
- Attach documentation of required training for any personnel **new** to the study.
- Include any **new** or **revised** study materials including consent forms, surveys, advertisements, etc.
- For all changed documents, provide **two copies**. One copy should show the changes highlighted using yellow highlighting or some other obvious method (i.e., track changes) of already approved documents, and one copy should be “clean,” that is, as it will be used in the study. If the measure or form is NEW, only a “clean” copy is necessary.

1. **Date of Modification:**
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. **Description of Changes (bulleted list):**

Signature of Principal Investigator

Date

IRB#: _____

IRB Decision (to be completed by IRB)

- Modification Approved; does NOT change Exempted status; no further review needed unless future protocol changes.
- Modification Approved via Expedited Review.
- Modification Approved via Review by the full IRB at a convened meeting.
- Modification Not Approved

Signature of Chair/Vice-Chair, IRB

Date