HENRY J. AUSTIN™
HEALTH CENTER
The center for wellness

MODIFICATION REQUEST FORM

Please use this form to submit your Modification Request. Signature(s) along with any revised or additional project materials, including revised consent forms, information sheets, surveys, questionnaires, etc. should be attached to this completed form.

Protocol IRB#:

Protocol Title:

Principal Investigator:

Phone: **E-mail:**

1. **AMENDMENT DESCRIPTION (Check all categories of proposed changes):**
   - ☐ Funding
   - ☐ Project title
   - ☐ Investigator(s)/Research personnel
     - ☐ Add New (Protecting Human Research Participants Certificates must be attached)
     - ☐ Remove
   - ☐ Advertisement/Recruitment methods
   - ☐ Changes to currently approved research procedures/study design
   - ☐ Subjects/Eligibility criteria *(i.e., change in targeted population or selection criteria)*
   - ☐ Data Collection/Analysis
   - ☐ Consent forms (written, oral, translations, etc.)
   - ☐ Subject population requiring foreign language consent form(s). *Required: submit translated materials*
   - ☐ Study instruments (surveys, questionnaires, interview/focus group guides)
   - ☐ Compensation/Incentives
   - ☐ Addition of research participants (subjects) *Complete section 3*
   - ☐ Change in study status:
     - ☐ Open enrollment ☐ Close enrollment ☐ Temporarily suspended
   - ☐ Fulfillment of previous addition condition *Use Section 2 to describe the condition and how it was fulfilled.*
   - ☐ Other. Please specify:

2. **REVISION/AMENDMENT DESCRIPTION (PLEASE INCLUDE REVISED PROTOCOL)**
   In the space below, please describe in detail what changes you are requesting to your approved protocol. Include a detailed explanation of the reason(s) you are seeking to modify your previously approved research project. In addition, explain how new information from this amendment will be communicated to currently enrolled participants (i.e., will participants be re-consented).

   - Amendment 1
   - Amendment 2
   - Amendment 3

3. RISK ASSESSMENT (Check one)

☐ This revision does not affect risks to participants (expedited review possible).
☐ This revision decreases risk to participants enrolled in the study (expedited review possible).
☐ This revision does not increase risk to participants enrolled in the study (expedited review possible).
☐ This revision adds a newly identified risk or side effect to the protocol/consent form (include specific details in the revision description).
☐ This revision does increase risk to participants enrolled in the study (include specific details in the revision description).

4. SUBJECT RECRUITMENT

☐ Not Applicable
a. Original protocol approved for number of subjects.
b. Previously approved amendments have added number of subjects.
c. Current request is for an additional number of subjects.
d. Total number of subjects for this protocol: (a + b + c)
e. Explain how you determined the number of additional subjects required to complete this study:

5. CONSENT CLARIFICATIONS

For all documents which have been changed by this modification, you must submit 2 versions of each form to distinguish between previously approved information and current requested final changes:

- *Marked* original copy of any new documents with this application documents (noting all changes by **bolding** additions and deletions via strikethrough; or via the track-changes feature in MSWord); Please complete the " additional documentation or attachments form" appended at the end of this form to include a copy of the document**. (Use upload forms function at the bottom of this webpage.)**
- *Unmarked* final copy of any new documents with this application (e.g., consent form, study instrument, advertisement); that may be stamped by the IRB when the amendment is approved. Please complete the " additional documentation or attachments form" appended at the end of this form to include a copy of the document**. (Use upload forms function at the bottom of this webpage.)**

1)

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PI Certification

By signing below, I agree to accept primary responsibility for the scientific and ethical conduct of this project as approved by the IRB. The proposed changes cannot be made until I receive documentation of IRB approval.

Signature of Principal Investigator | Printed Name | Department | Date

FOR STUDENT INVESTIGATORS: A faculty advisor's signature is required.

Faculty Supervisor: By signing below, I certify that I have reviewed this document and approve the proposed changes and continue to approve of the scientific and ethical aspects of the project. I will supervise the above listed student and ensure compliance with human subjects' guidelines.

Signature of Faculty Advisor | Printed Name | Department | Date

MODIFICATION REQUEST FORM

IRB NOTES:

- *Attach any Separate Marked and Unmarked copies of any and all revised or new project materials to this form!* Please complete the " additional documentation or attachments form" appended at the end of this form to include any *Separate Marked and Unmarked copies of any and all revised or new project materials to this form.* **(Use upload forms function at the bottom of this webpage.)**

Format Guideline :

- No ZIP Files
- Add your Title and Protocol Number with "Amendment" to the E-mail Subject Line
- Do NOT send a hardcopy of an E-mailed submission
- If you are a Student Investigator, please copy your Faculty Advisor on this request
- For any listed contact person sending revisions, the Principal Investigator must be copied on this request