AMENDMENT REQUEST FORM

[NOTE: Attach this document to a completed Application]

Changes (check all that apply):

- ☐ A. Protocol (complete Section A)
- ☐ B. Consent Document (complete Section B)
- ☐ C. Principal Investigator (complete Section C, and [if consent document in use] Section B)
- ☐ D. Recruitment Materials (complete Section D)
- ☐ E. Data (complete Section E)
- ☐ F. Other (complete Section F)

Complete only those sections that apply to your amendments/modifications.

Subject Information (complete for Sections A, B, D, E, F – not C)

Total number of subjects enrolled _____

IRB-approved age range of subjects _____

Is the study permanently closed to enrollment? ☐ Yes ☐ No

A. Protocol changes

- Provide a document outlining or highlighting all of the changes requested.
- Provide a clean revised protocol document.
- The IRB protocol number is required on all documents submitted to the IRB.

1. Date when amendment needs to be enacted:
2. This amendment is (check one): ☐ Sponsor generated ☐ Principal investigator generated
3. This amendment involves (check one): ☐ Minimal risk to subjects
   ☐ Greater than minimal risk to subjects
4. Briefly explain what the amendments are, why they are being changed, and how the changes affect the subject benefits and risks.
5. Explain why it is necessary to make these revisions, and how any additional risks to subjects are minimized.
6. Describe how the revisions will affect the risk/benefit ratio for the subject population:

B. Consent Document changes

- Submit 3 copies of the revised form – 2 clean copies and 1 copy with all changes highlighted

1. Date of current approved consent document
2. Date of new, revised consent document
3. Explain why there is a change to the consent document
4. Do the changes affect currently enrolled subjects? ☐ Yes ☐ No
5. Additional explanation:

C. Principal Investigator changes

- Investigator changes require that consent forms be updated. If the study is open to enrollment and a consent document is in use, complete Section B.
- Ask new investigator(s) to read and sign the signature page of the IRB application form.
- A change in principal investigator (PI) will not be approved if the PI has not completed IRB training.

1. Was the use of a consent document waived by the IRB? ☐ Yes ☐ No
2. Changing principal investigator

New Principal Investigator:

Name: _____

Organization: _____

Mailing Address: _____

_____

_____

Phone: _____ Ext: _____

E-Mail: _____

_____

Are you a student? ☐ Yes ☐ No

IRB training completed: ☐ Yes ☐ No (if yes, include documentation)

D. Recruitment forms or procedure changes

☐ New	Submit a clean copy
☐ Revision	Submit a copy with all changes highlighted, and Submit a clean copy

1. Type of Recruitment

☐ Flyer ☐ Poster ☐ Newspaper ☐ Radio ☐ Television

☐ Letter to potential participants ☐ Letter to health care professionals for recruitment purposes

☐ Other. Specify:

2. Indicate site(s) where recruitment material(s) will be posted:
3. For letters to potential participants describe:

   Who will receive these letters?

   How / Why you have access to their information?

4. Recruitment materials must include:

   - The IRB protocol number and a current version date
   - Use of the word “research”
   - Name and address of the local principal investigator
   - Summary of the purpose of the research with a brief list of major eligibility criteria
   - Factual description of the benefits to the participant
   - Financial compensation, if provided, but do not state a dollar amount
   - Location of research and contact information
   - The following statement: “This research has been approved by the Institutional Review Board, under federal regulations, at the Texas Department of State Health Services.”

5. If this is the first submission of recruitment materials for this study, answer the following questions.

Before a potential participant signs a consent document, are there any screening questions that you need to directly ask the individual to determine whether he/she is appropriate for the study? ☐ Yes ☐ No

If Yes, will you record identifiable information about these individuals? ☐ Yes ☐ No

If you record identifiable information, provide a copy of all screening questions.

If you record identifiable information, what will you do with the information for individuals that do not qualify? Choose all that apply:

- ☐ Immediately destroy
- ☐ Store the log until the end of the study, and then destroy
- ☐ Use the information as 'screening failure' data

  Indicate how this information will be used:

  - ☐ Data for local investigator
  - ☐ Provide to someone outside of local investigators, specify who:
- ☐ Request permission from potential participant to maintain the info and contact for future studies
- ☐ Other, specify:

If you record identifiable information, what will you do with the information for individuals who qualify for the study? Choose all that apply:

- ☐ Store until the end of the study, and then destroy
- ☐ Request permission from potential participant to maintain the info and contact for future studies
- ☐ Other, specify:

If you screen potential participants prior to the consent process, provide:

- A procedure for the screening
- A script for the screening, including all questions that will be asked.

E. Data Element criteria changes

☐ Additional Data Records - Attach extra sheets defining the additional records you are requesting and explaining why the additional records are needed.

☐ Additional Data Elements/Fields – Attach extra sheets defining the additional elements/fields you are requesting and explaining why the additional elements/fields are needed.

☐ Additional Years of Data – Specify: _____

F. Other – (Use this section for any issues that do not fall into the above categories or that need additional clarification)

Explain:

G. Name of the person completing this form (printed or typed – no signature required)

Person preparing this form

Date