



## Amendment Request

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IRB# \_\_\_\_\_ Principal Investigator/Data Requestor: \_\_\_\_\_

Study/Project Title: \_\_\_\_\_

### Instructions:

- A. Complete only those sections that apply to your amendments/modifications.
- B. Submit this document with a completed [Application form](#)

### Changes (check all that apply):

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

### 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

### Section A. Protocol Changes

#### Instructions:

- A. Provide a document outlining or highlighting all of the changes requested.
- B. Provide a clean revised protocol document.
- C. The IRB number, assigned by the DSHS IRB, 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:  
\_\_\_\_\_

### Section B. Consent Document Changes

#### Instructions:

- A. Submit 2 copies of the revised document – 1 clean copy 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:  
\_\_\_\_\_

### Section C. Principal Investigator Changes



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**Instructions:**

- A. 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 also.
- B. Ask new investigator(s) to read and sign the signature page of the IRB application form.
- C. A change in principal investigator (PI) will not be approved if the PI has not completed a human research subject protection course.
  - 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

Human Research Subject Protection course completed: Yes  No  (if yes, include documentation)

**Section D. Recruitment Forms or Procedure Changes**

**Instructions:**

- A. New: Submit 1 clean copy
- B. Revision: Submit 2 copies of the revised form – 1 clean copy and 1 copy with all changes highlighted
- C. 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.”

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. 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 ask directly the

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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? 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:

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

a. A procedure for the screening

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

### Section 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 what years and explain why they are needed:

### Section F. Other

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

Explain:

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

Person preparing this form

Date