Office of Research and Sponsored Programs
Sam Houston State University
903 Bowers Blvd, PO Box 2448
Huntsville, TX 77341
Phone: 936.294.3621
Fax: 936.294.3622

Amendments Application

AMENDMENTS TO RESEARCH PREVIOUSLY APPROVED BY PHSC

Date Report Completed: **Protocol Number:**

I. Research Protocol Information

1. Research Title:

2. Principal Investigator

Name **University Status/Title**

Department **College**

Phone Number **Email Address**

3. Supervising Faculty - required if PI is a student

Name **University Status/Title**

Department **College**

Phone Number **Email Address**

4. Type of Amendment:

☐	**Protocol Amendment**	**Version #**	**Date**
☐	**Revised Informed Consent Document**	**Version #**	**Date**
☐	**Revised HIPAA Research Authorization**	**Version #**	**Date**
☐	**Change of Data Collection Site(s)**	**Version #**	**Date**
☐	**Research Protocol Title Change**	**Version #**	**Date**
☐	**Investigator Brochure Update**	**Version #**	**Date**
☐	**Principal Investigator Change**	**Version #**	**Date**
☐	**Key Research Personnel Change**	**Version #**	**Date**
☐	**Change in the Funding Source**	**Version #**	**Date**

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5. Describe the proposed amendment(s) and provide the rationale for the amendments.

6. Is this an investigator-initiated amendment? ☐ **Yes** ☐ **No**

7. Is this a sponsor-initiated amendment? ☐ **Yes** ☐ **No**

If yes, provide the name of the sponsor and provide copies of the sponsor amendment.

II. Risk-Benefit Assessment

1. Are the risks to subjects affected (increased, decreased) by the amendment? ☐ **Yes** ☐ **No**

If yes, describe how the amendment will affect the risk -benefit ratio for the subjects.

III. Informed Consent/Assent Process or Document(s) and/or the HIPAA Research Authorization Form

1. Does the proposed amendment affect the informed consent/assent process and/or document(s)? ☐ **Yes** ☐ **No**

2. Does the proposed amendment affect the HIPAA Research Authorization process? ☐ **Yes** ☐ **No**

3. Describe how the process and/or document(s) will be changed. Follow directions for submitting revised informed consent/assent document(s) and/or the HIPAA Research Authorization.

IV. Notification of Subjects

1. Have you ever enrolled any subjects in this research? ☐ **Yes** ☐ **No**

2. Are any subjects actively participating in this research? (If no, go to Question 4.) ☐ **Yes** ☐ **No**

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3. Is it necessary to inform actively participating subjects who have already consented (Please include the revised consent document or addendum or information/letter in this amendment submission)?

Yes (Method to be used)

☐ **Full Revised Informed Consent Document**

☐ **Addendum**

☐ **Information sheet/letter**

No (If no, indicate why not)

4. Is it necessary to notify subjects who have completed their participation in the research? ☐ **Yes** ☐ **No**

If yes, describe how this will be done and submit the documents (if applicable) that will be used.

5. Is it necessary to obtain a revised authorization from subjects who have already signed and authorized the use and disclosure of health information for research? ☐ **Yes** ☐ **No**

If yes, be sure to include the revised authorization document in this amendment.

If no, explain why not: