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

Continuing Review Form

I. Protocol Information

SHSU Protocol #: _____ Date of Report: _____

*A. Research Title:

B. Personnel

1. Principal Investigator (PI)

*Name: _____ *University Status/Title: _____

*Department: _____ *College: _____

*Phone Number: _____ *Email Address: _____

Mailing Address: _____

2. Faculty Sponsor - required when PI is a student

Name: _____ University Status/Title: _____

Department: _____ College: _____

Phone Number: _____ Email Address: _____

Mailing Address: _____

3. Co-Investigators and any other Key Research Personnel (Co-PIs)

Name	Department	College	Email Address	University Status/Title

II. Amendments

A. Are you requesting the addition of research personnel?

☐ No (Please list the names of persons no longer associated with this protocol)

Name	Department	College	Email Address	University Status/Title

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☐ Yes (Please list the names of new personnel)

Name	Department	College	Email Address	University Status/Title

B. Have you had any change in funding or sponsorship for this research that has not been reported to the SHSU PHSC? ☐ Yes ☐ No

If yes, please specify: _____

C. Are you requesting any changes to the research protocol? ☐ Yes ☐ No

If yes, please specify: _____

D. Are you requesting any changes to the consent documents? ☐ Yes ☐ No

If yes, please specify and attach the revised consent form:

_____

E. Are you requesting any changes to the HIPAA authorization? ☐ Yes ☐ No

If yes, please specify and attach the revised HIPAA form:

_____

F. Are you requesting any other changes to the research? ☐ Yes ☐ No

If yes, please specify: _____

III. Review Process Determination

☐ The research was originally reviewed and approved by the PHSC under Full Board procedures.

☐ The research was originally reviewed and approved by the PHSC under Expedited procedures

☐ The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions

☐ The research remains active only for long-term follow-up of subjects. (Long-term follow-up refers to collection of data on survival or disease status. It does not include data collection activities such as interviews, clinic visits, lab tests, etc.)

☐ Participants have never been enrolled on this study, and no additional risks have been identified since the last approval.

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IV. Findings from This Research

A. Describe any preliminary results or findings from this research, if available. If the preliminary results are suggestive of one intervention being better or worse than other(s), please discuss when further findings will be available.

B. If there are preliminary results of this study, indicate if there is a change in any of the following:

(1) Risks associated with the research: ☐ Yes ☐ No
(2) Potential for benefit to be gained from the research: ☐ Yes ☐ No
(3) Alternatives to subject participation in the research: ☐ Yes ☐ No
(4) Participant willingness to continue participating in the research: ☐ Yes ☐ No

C. Have the findings been shared with participants? ☐ Yes ☐ No

If yes, please indicate how and when the findings were shared?

V. Participant Enrollment and Demographics

A. AGE RANGE	Total number of participants enrolled since initial (if first year) or last continuing review (most recent year)	Total number of participants enrolled to date (since initial PHSC approval- over all years)	Total number from non-SHSU Sites (if 6+68 is the grant holder or lead institution)
Age: Newborn to 2 Years			
Age: 3 to 6 Years			
Age: 7 to 11 Years			
Age: 12 to 15 Years			
Age: 16 to 17 Years			
Age: 18 to 64 Years			
Age: 65+ Years			
TOTAL			

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B. By population description, indicate the number of participants enrolled:

POPULATION DESCRIPTION	Number enrolled at SHSU since the initial (if first year) or last continuing review (most recent year)	Total number (by category) of participants enrolled since initial PHSC approval (total number of years)
Total		
Special populations		
Mentally Disabled or Mentally Ill		
Decisionally Impaired		
K-12 Students		
SHSU Students		
SHSU Psychology Subject Pool		
Fetuses (prior to delivery)		
Pregnant Women when pregnancy is the primary focus of the research		
Prisoners are *primary* focus of research		
Prisoners are *incidental* (not focus of research)		
SHSU Employees		
Pregnant Women -- Primary (focus of research)		
Pregnant Women -- Secondary (not focus of research)		
Other		

C. By designated demographics, indicate the number of participants enrolled:

DEMOGRAPHIC	Asian or Pacific Islander	Black, not of Hispanic origin	Hispanic	White, not of Hispanic origin	Other or Unknown	Total
Females						
Males						
Unknown						
Total						

D. Informed Consent Process

Are you planning to enroll additional participants? ☐ Yes ☐ No

If yes, please specify: _____

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E. Informed Consent in Other Languages

Have any participants whose primary language is not English been approached to participate and/or be enrolled in the research? ☐ Yes ☐ No

If yes, for these subjects, in which language(s) was the informed consent process conducted? _____

F. Complaints

Have any complaints been received about the research? ☐ Yes ☐ No

If yes, for each complaint describe the substance of the complaint, when it occurred, the complainant's relationship to the study, and how the situation was resolved.

G. Participation Declined

Have any recruited persons (and/or parents, guardians, or legally authorized representatives for the subject) declined to participate in the research after being approached? ☐ Yes ☐ No

If yes, please provide total numbers of persons recruited who were not enrolled: _____

H. Withdrawal

Have any participants dropped out of the research after initial enrollment & participation? ☐ Yes ☐ No

If yes, please provide total number of participants who have dropped out and the reasons, if known.

I. Safety

1. How many study-related serious adverse events (SAE) have occurred for this protocol since its date of approval by the PHSC? _____

Date of Incident	Subject ID #	Description of Incident & Probable Causation	Foreseeability	Resolution

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2. Protocol Violations: Summarize any major protocol violations that have occurred during the past reporting period. (These should already have been reported to the IRB per the SHSU prompt reporting policy)

Date of Incident	Subject ID #	Description of Event	Corrective

INVESTIGATOR'S ASSURANCE

I certify that the information provided in this continuing review form is complete and correct. I understand that as Principal Investigator, I am ultimately responsible for the protection of the rights and welfare of human subjects and the ethical performance of the research. I agree to comply with all applicable SHSU policies and procedures, and applicable federal, state and local laws. I also agree to the following:

(1) The research will only be performed by qualified personnel as specified in the approved research application and/or protocol,
(2) No changes will be made to the research protocol (except when necessary to eliminate apparent immediate hazards to the subject), or the consent process without prior approval by the SHSU PHSC,
(3) Legally effective voluntary informed consent/assent will be obtained from all human subjects, unless this requirement is waived by the SHSU PHSC,
(4) Unanticipated problems involving risks to subjects or others (UPIRSO), serious adverse events, and other reportable events will be reported to the SHSU PHSC in a timely manner.

☐ *I certify that I have completed the required educational program on ethical principles and regulatory requirements in Human Subject Protections.