



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

Final Research Report

I. Protocol Information

SHSU PHSC Protocol #

Date of Report

Project Title

Principal Investigator

Email

Reason for Final Report (check all that apply)

Research was initiated, but no participants were ever enrolled. (Skip to the **Assurance Page**).

Research has been completed, and there will be no further data collection (including long term follow-up) or data analysis for this research (and any thesis defense is completed).

Data collection is complete. The study remains open for data analysis only.

For Sponsored projects, please include the Sponsor's close-out letter when applicable.

The P.I. is terminating the research. (Please specify the reason(s) why research was stopped before meeting approved goals/objectives).

Specify:

The Sponsor is terminating the research. (Include the reason(s) for termination, e.g. interim analysis revealed substantive findings).

Specify:

A. Results or Findings from This Research:

Describe any important results or findings from this research at SHSU and other sites, if appropriate.



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B. Participant Enrollment

Provide the number of participants enrolled (e.g., include all subjects who gave consent to participate, or the total number of records reviewed) by age range. In the first column, enter the total number of SHSU subjects enrolled since initial or last continuing review. In the second column, enter the total number from non-SHSU Sites (if SHSU 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

C. Participant Complaints

Have any subjects made complaints about the research? Yes No

If yes, summarize the following for each complaint including a description of the complaint, the number of times it occurred, and your opinion as to whether it was related to the research, and any actions taken by the investigator in response to the complaints.

D. Declined to Participate:

Have any subjects and/or parents, guardians, or legally authorized representatives declined to participate in the research after being approached? Yes No

If yes, indicate the number of subjects and/or parents, guardians, or legally authorized representatives, the reason(s) they declined to participate.



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E. Participant Withdrawals:

1. Have any participants and/or parents, guardians, or legally authorized representatives withdrawn from the research after initial enrollment and participation? Yes No

2. Have any participants been withdrawn from the research by the Investigator, the study sponsor, or for other administrative reasons? Yes No

If yes to either, please explain; include the total number of participants who have withdrawn or been withdrawn, the reason(s) for their withdrawal, and whether any changes to the research protocol and informed consent process and/or documents were made in response to the withdrawals:

F. Adverse Events or Unanticipated Events or Problems:

Were there any serious and unanticipated adverse events or other unanticipated problems involving risks to participants or others that have occurred involving this research protocol since either the initial review or the last continuing review (whichever is most recent)? Yes No

If yes, Include information regarding the frequency and severity of the events, whether or not they were related to the research (e.g., experimental procedure, whether they resulted in a change in the risk-benefit analysis and change in the research protocol and/or Informed Consent Document.). In addition, include the date of the event, date reported to the IRB, and the outcome.



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G. Assurances

II. INVESTIGATOR'S ASSURANCE FOR FINAL REPORT OF RESEARCH

*I certify that the information provided in this Final Report is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, and the ethical conduct of this research. I confirm that I have complied with applicable SHSU policies and procedures, as well as with applicable federal, state and local laws.