PROTECTION OF HUMAN SUBJECTS

INSTRUCTION FOR COMPLETING THE SHSU RESEARCH KEY INFORMATION AND DETAILED CONSENT FORMS

Informed consent must begin with a concise and focused presentation of the KEY INFORMATION that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

1. This document identifies the information that should be communicated to potential participants in the Key Information Consent Form and in the Detailed Consent Form.

2. The bold headings should not be changed.

3. Appropriate text is given in standard font.

4. Type your information in the area enclosed in parenthesis with italics font.

5. You may add additional information as needed.

6. After you complete the form and it has been approved by the IRB, print out the approved form and use it in your study. Do not substitute another form for the one that is approved.

7. Be sure to save a copy of this form to your computer.

8. Upload the form into your application.

9. **When you complete your consent form or cover letter, please delete these instructions before uploading file into your IRB application.**

Sam Houston State University
Consent for Participation in Research

KEY INFORMATION FOR *(Title of Research)*

You are being asked to be a participant in a research study about *(add a brief description of the study).* You have been asked to participate in the research because *(explain how subject was identified)* and may be eligible to participate.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

*(**Briefly** describe the purpose of the study and the procedures to be followed in **lay terms**.)*

By doing this study, we hope to learn *(complete_____)*. Your participation in this research will last about *(state in hours, days, months, years).*

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

(State the most important reason(s) {i.e. potential benefit(s)} a person may want to volunteer to participate in this study?)

For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
(State the most important reason(s)/risk(s) why a participant may NOT want to volunteer for this study considering the participant's perspective.)

For a complete description of risks, refer to the Detailed Consent. *(If applicable, discuss alternative treatments/procedures that might be advantageous to the subject.)*

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer. *(Add the following for student volunteers:* As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s). *)*

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of this study is *(Principal Investigator, PI)* of the Sam Houston State University Department of *(list department)*. *(Add the following if the PI is a student:* who is working under the supervision of *{Faculty Sponsor}*.If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: *(PI and Faculty Sponsor contact information)*. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Office of Research and Sponsored Programs – Sharla Miles at 936-294-4875 or e-mail ORSP at sharla_miles@shsu.edu.

Sam Houston State University

Consent for Participation in Research

DETAILED CONSENT *(Title of Research)*

Why am I being asked?

You are being asked to be a participant in a research study about *(add a brief description of the study)* conducted by *(add name of investigator or student/faculty; investigator's department and/or college)* at Sam Houston State University and insert names of any other cooperating institutions. I am conducting this research under the direction of [*Faculty Advisor Full Name*]. You have been asked to participate in the research because *(explain how subject was identified)* and may be eligible to participate. We ask that you read this form and ask any questions you may have before agreeing to be in the research.

Your participation in this research is voluntary. Your decision whether or not to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Why is this research being done?

(Using lay language include a short summary of the research purpose, procedures involved, the risks, benefits, and alternatives, if any.)

What is the purpose of this research?

The purpose of this research is:

(Explain research question and purpose in lay language.)

What procedures are involved?

If you agree to be in this research, we would ask you to do the following things:

(Describe the procedures chronologically using simple language, short sentences and short paragraphs. The use of subheadings helps to organize this section and increases readability. Medical and scientific terms should be defined and explained. Identify any procedures that are experimental.)

(Specify the participant's assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of the procedures to be done, etc.)

(If there are calendars, flowcharts, tables or pictures, that would help explain the procedures, note what they are and attach them.)

Approximately *(add number of subjects)* may be involved in this research at Sam Houston State University. *(If a multicenter research, add the total number of subjects anticipated and projected number of research sites.)*

If you are collecting data that is protected by FERPA, you are required to include this information:

• Clarification of the specific records that will be disclosed to the researchers
• The purpose of the data disclosure
• The people or organizations that will have access to the student data

What are the potential risks and discomforts?

(If the research has potential risks for participants, address them below.)

(Explain the risks, discomforts and inconveniences including the likelihood, severity, and reversibility, if applicable, of each risk.)

(If there are significant physical or psychological risks to participation, the subject should be told under what conditions the researcher would stop the research itself or stop the subject's participation in the research.)

(If there is a potential for a participant to be participating in more than one research protocol at the same time, add a statement that the participant should inform the researcher if they are currently participating in a research protocol.)

Are there benefits to taking part in the research?

(Include a statement describing any benefits to the participant or others (science or society) that may be reasonably expected from the research. If there are no direct benefits to participant, state that here. Payment for participation is not, in and of itself, a direct benefit of the research.)

What other options are there?

(Describe the appropriate alternative procedures or courses of treatment that might be advantageous to the participant. If there are no alternatives, as is the case in some survey research, this item need not be included on the form; however, the reason for not including this item should be explained in the research protocol itself.)

What about privacy and confidentiality?

(Suggested text) The only people who will know that you are a research participant are members of the research team. No information about you, or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the SHSU Protection of Human Subjects monitors the research or consent process); or
- if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for educational purposes, your identity will be protected or disguised.
Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law.

(If information will be released to any other party for any reason, state the person/agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure.)

(If activities are to be audio- or videotaped, describe the subject's right to review/edit the tapes, who will have access, if they will be used for educational purpose, and when they will be erased.)

(Describe the subject's right to review/edit the tapes, who will have access, and when they will be erased. Describe how personal identities will be shielded, disguised, etc.)

(Give a brief description of how personal information, research data, and related records will be coded, stored, etc. to prevent access by unauthorized personnel.)

(Explain how specific consent will be solicited, if any other uses are contemplated.)

(If applicable, explain when individual responses to survey questionnaires will be destroyed, following analyses of the data.)

What if I am injured as a result of my participation?

In the event of injury related to this research study, you should contact your physician or the University Health Center. However, you or your third party payer, if any, will be responsible for payment of this treatment. There is no compensation and/or payment for medical treatment from Sam Houston State University for any injury you have from participating in this research, except as may by required of the University by law. If you feel you have been injured, you may contact the researcher, *(add name)* at *(add phone number).*

What are the costs for participating in this research?

(Include an explanation of additional research costs for which the subject will be responsible.)

Will I be reimbursed for any of my expenses or paid for my participation in this research?

(State whether the subject will be paid or offered other gifts (e.g., free care). If not, state this clearly.)

(If the subject will receive payment, describe remuneration amount, when payment is scheduled and proration schedule should the subject decide to withdraw or is withdrawn by the investigator.)

(If the subject will be reimbursed for expenses such as parking, bus/taxi, baby-sitter, travel companion/assistant, etc., list payment rates.)

Can I withdraw or be removed from the study?

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

(If appropriate, describe the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.)

(If applicable, explain the consequences of a subject's decision to withdraw from the research and state whether withdrawal must be gradual, for reasons of safety.)

(Be sure that this aspect of terminating participation at the request of the PI is also noted in the section on Payment for Participation, and that the information in both sections is consistent.)

Who should I contact if I have questions?

The researchers conducting this study are *(add name(s)).* You may ask any questions you have now. If you have questions later, you may contact the researchers at: Phone: *(add phone number(s)).*

(If the researcher is a student, include the adviser's name and telephone number.)

What are my rights as a research subject?

If you feel you have not been treated according to the descriptions in this form, or you have any questions about your rights as a research participant, you may call the Office of Research and Sponsored Programs – Sharla Miles at 936-294-4875 or e-mail ORSP at sharla_miles@shsu.edu.

You may choose not to participate or to stop your participation in this research at any time. Your decision whether or not to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(If you are a student, this will not affect your class standing or grades at SHSU. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected.)

(If you are a staff person at SHSU, your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at SHSU.)

You (*will or will not)* be offered or receive any special consideration if you participate in this research.

Agreement to Participate

I have read (*or someone has read to me)* the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research.

Consent: I have read and understand the above information, and I willingly consent to participate in this study. I understand that if I should have any questions about my rights as a research subject, I can contact *PI's name* at *PI's contact phone* or by email at *PI's email address*. I have received a copy of this consent form.

Your name (printed):_____

Signature: _____ Date: _____