



# Sam Houston State University

*A Member of The Texas State University System*

## INSTITUTIONAL REVIEW BOARD

### **IRB Guidance: Informed Consent**

#### **IMPORTANT REQUIREMENT: Consent form templates**

When using one of SHSU's consent form templates, always remember to remove any italicized formatting in the final pdf version of the consent form. This formatting only signifies to researchers what project-specific information must be included.

#### **IMPORTANT REQUIREMENT: Final Approved Consent Form Attachment Instructions**

1. Once the IRB has approved your consent form to go out to participants (e.g., all applicable elements included, all grammatical and other errors corrected, etc.), the PI will be instructed—either in a conditional approval or as a Return to PI request—to upload a final pdf copy of the consent form in the application.
2. Approved consent forms will be stamped in Cayuse Human Ethics, and whenever possible, study participants should be provided a copy of the stamped version. The approval stamp appears in the lower right corner of each page, so do not include any information in this section of the footer. In addition, the lower right margin should be at least 1.25" to leave room for the stamp.
3. For online and verbal consent forms, PIs should include a statement that the consent form has been approved by the IRB (e.g., "This study has received approval by the SHSU IRB on [Provide approval date]). The stamped version of the consent form is not required for use for online and verbal consent procedures.
4. After the consent form expires or is superseded, Cayuse Human Ethics will automatically void the consent document. If you need a copy for your records, please print out the consent form before it is voided.
5. Number the pages of every consent document, preferably in a format like "1 of 2," "2 of 2," in the center part of the footer of the document. Additionally, include version dates in the consent form in the following manner:
  - a. Include a version date in the lower left corner of the consent form. Always remember to update the date each time you revise this document.
  - b. **Sample:** *Version Date: 7/25/2023*

### **Informed Consent Guidance Introduction**

1. Informed Consent is a federal requirement intended to provide clear and concise information that a reasonable person would want to decide whether to participate in the research. Information should be written in such a way as to be easily understandable to the participant population included in the research.
2. Unless the IRB approves a waiver of informed consent, no researcher may involve a human subject in research unless he/she has obtained the informed consent of the participant.
3. For more information about these processes (e.g., Waiver of Informed Consent or Documentation), please review [IRB-SOP-023.01](#).

### **The Consent Process and Documentation**

*Sam Houston State University is an Equal Opportunity/Affirmative Action Institution*

The default consent process is for a researcher to have the participant sign a written document called an Informed Consent Form. However, the IRB can approve any number of other consent processes—but **it is the responsibility of the researcher to provide the IRB with an appropriate justification as to why an alternative to the signed consent form is most appropriate for the study that is being reviewed.**

Consent forms must be presented to the IRB in the format in which they will be used. Although not all inclusive, the following are examples of common alternatives to the signed consent form:

*Waiver of signed consent (no signature is obtained)*

- Oral consent
  - May be appropriate for telephone interviews, when there may be literacy issues, or when a signed document is not culturally appropriate.
- Information sheet
  - Largely used for mailed surveys: “By completing and mailing back this survey, you are consenting to participate in the research.”
- “Click here” type of online consent.
  - Research where obtaining a signature is impracticable in an online environment.

*Alteration of the required elements of consent*

- Most appropriate for deception research, where the true purpose or another major element(s) of the research is not revealed until the end of the study.

*Waiver of informed consent (no consent is obtained)*

- Secondary data analysis
  - Unless identifiers are needed in order to meet the aims of the research, non-identifiable data should be used whenever possible.
- Observation of non-focal participants, so long as any data collected about those persons is completely de-identified/in aggregate.
  - NOTE: This does not apply if any form of audio/visual recording is being conducted during observation.

When determining the most appropriate method of obtaining informed consent, consider the following: literacy level of participants/reading level of documents, cultural norms, and/or confidentiality concerns.

### **Documentation of Consent for the Participant**

- Participants should always be offered a copy of the consent document, whether it is in-person, e-mail, online, or a copy of the oral script.
- Participants also need to have access to contact information for the PI and the IRB. In rare events where the IRB determines that having a copy of the consent document in their possession could present a risk to participants (i.e., some international sites), a business card or similar method can be provided to research participants that contains contact information.

## Required Elements of Informed Consent

Regardless of the format of the consent process, consent documents must include the following Required Elements of Informed Consent:

- The study should be clearly identified as a Sam Houston State University research study.
- Title of the study (one that matches the title given in the IRB application)
- Include a description of the purpose of the study.
- Describe what the subject's participation will involve, including the estimated duration/time commitment.
- Any potential risks (and steps the researcher has in place to mitigate those risks) \*\*Risks must match those outlined in the Arrow application. Those risks could include:
  - Sensitive topics, or questions that evoke an emotional response.
  - The risk of a breach of confidentiality.
- Any potential benefits:
  - There are typically no direct benefits to participating in minimal risk research.
- Steps to ensure confidentiality of research records:
  - A statement of who will have access to data, protection and security measures for data such as the use of pseudonyms, data encryption, password protection(s), and secure storage of all data including audio, video, and photos (as applicable).
- If collecting/using private identifiable information or identifiable biospecimens, one of the following statements must be included regarding future research:
  - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- Any compensation:
  - Parking pass, gift cards, extra credit, etc.
  - Ensure that the amount or type of compensation is not coercive.
  - Compensation is not a benefit and should be listed in a separate section of the consent form.
  - Include information about pro-rated compensation and whether or not it will be allowed for those participants only partially completing the study.

- Plan that does not violate the state of Texas' gambling laws
- Whom to contact with questions:
  - PI/researcher(s):
    - Campus contact information (shsu.edu email and/or phone) should be listed for the PI/researcher(s). If a campus phone number is not available, personal numbers can be listed. **\*\*Please consider participant privacy and confidentiality when using a personal cell phone, and that your number will be available to potential participants for as long as that number remains active.**
  - IRB contact information as follows (**note:** the italicized language can be omitted if it is not relevant to the study):
    - **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.

- A statement that participation is voluntary:
  - Participants must have the ability to skip or decline to answer any questions and subjects can withdraw at any time.

### **Other Considerations**

*Write at an eighth-grade level and use lay language*

Write the consent document at the most likely level of understanding of the subject population—in general, an eighth grade reading level. Use everyday vocabulary and simple sentence structure throughout.

#### *Assent for minors*

- Any research activity that includes minors as participants must also include an Assent process.
- Recruitment of minor participants must begin with the parent or guardian.
- Once parent/guardian consent is obtained, minors may be recruited and provide their own assent.
- Assent forms should be written at an age-appropriate level.
- Typically written assent would only be obtained from minors aged 7 and older. Those under age 7 would likely provide oral assent.
- If minors are unable to provide assent, researchers must apply for a waiver of assent and provide a strong justification for the waiver (e.g., lack of understanding due to a disability).

#### *Non-English-speaking participants*

- If the consent document will be presented in a language other than English, translated documents are required to be uploaded to the Cayuse Human Ethics application prior to final IRB approval.

#### *Mandated Reporting Language*

- Required for research taking place in private homes and/or where the Study Design indicates that information that might require reporting could be obtained.

#### *Appropriate Use, Retention, and Storage of Consents*

- When written consent is approved by the IRB, the approved consent form will have an approval date stamped on it.
- Only the most current stamped consent forms should be used; outdated consent forms should not be presented to participants.
- For consent process(es) other than signed consents, the study team should have a process in place for how the researcher(s) will document that each person from whom data was collected provided informed consent through the appropriate approved method.
- Along with other research data, the complete, signed consent forms must be stored and retained on campus for at least 3 years after the completion of the study. These and/or other documentation that consent was appropriately obtained may be requested for review during an audit process.