IRB Guidance: Informed Consent

IMPORTANT REQUIREMENT: Consent form templates

Box 2119 • Huntsville, Texas 77341-2119 • 936.294.3061 • Fax 936.294.1056

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 appeTD [(a)-2 ((or)9 [(a)-r)7 (at)-36 (l)6.3(t)-2.5( )-117(j)-4 (u)1..2 oraju

Required Elements of Informed Consent

Regardless of the format of the consent process or 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 prorated 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 item remains active.

- IRB contact information as follows (

Assent for minors

Any research activity that includes minors as participants must also include an assent p Assent.

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-