TEXAS WOMAN'S UNIVERSITY

Denton & Dallas Institutional Review Boards (IRBs)

Workshop Session III – Informed Consent Process

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Informed Consent

What is Informed Consent?

Informed consent is the process of telling potential research participants about the key elements of a research study and what their participation will involve. The informed consent process is one of the central components of the ethical conduct of research with human subjects.

When are you required to obtain written informed consent?

Guide to Writing a Consent Form

This Guide to Writing a Consent Form provides the minimum standards for preparation of the written consent form.

New consent form requirements went into effect on January 21, 2019. Most notable requirements are:

- Key Information Summary
- Identifiable Private Information in future research

Informed Consent Process

The process for obtaining consent is much more than just having the participant sign a consent form. You must provide sufficient details about how/when/where you will obtain informed consent.

- **How** – Will you do this face-to-face? Will you mail or email consent forms to potential participants? Will participants be allowed appropriate time to read and make their decision? How will they get the forms back to you? How will they contact you with questions? How will they receive a copy of their consent form?

Informed Consent Process

- **When** – Will they need to decide right then and there? Can they take the consent form home to read over and decide later? Will they have access to the consent form prior to the initial meeting time, and if so, is that when they sign the consent form?

- **Where** – Will consent be obtained online? Will you have participants sign the consent form in person at the site of the initial meeting? Will they scan and email their signed consent forms? Will they return consent forms to a school official?

Obtaining Consent in an Online Study

- Even if your study is conducted online, you still need to outline a consenting process in your application. This usually consists of:
  - the participant being asked to read the study summary or consent document that is provided before they get to the study/survey
  - the PI's contact information included in case there are any questions about the study
  - a statement asking the participant to indicate their consent by clicking 'agree' to continue on to the survey or to close the browser/click 'disagree' or to decline participation

Obtaining Consent in an Exempt Study

- If your study is an Exempt study that involves a simple survey, you are not required to provide a complete consent form but you need to include a statement at the top of the form before the beginning of the survey such as, *"Completion of this survey constitutes your consent to participate in this research study."*
- Not all Exempt studies require complete consent forms (although providing one is nice). If you use one, make sure to include the standard elements of a consent form found in the *Guide to Writing a Consent Form*.

Consent vs. Assent

CONSENT

- Obtained from adult participants
- In the state of Texas, the legal age of consent is 18. You may need to check the laws in other states or countries.
- If the participants are minors, consent must be obtained from a parent or legal guardian of the minor.

ASSENT

- Obtained from minors or adults who cannot provide consent for themselves.
- Adequate provisions must be made for attaining the assent of minors when the minors are capable of providing assent
- Although written assent is not required, it is good practice. Verbal assent is always required.

Consent Form Tips

SUMMARY AND KEY INFORMATION ABOUT THE STUDY

The purpose of this section is to provide enough key information so that the potential participant has enough information up front that they can decide whether or not they want to participate.

This includes, but is *not limited to* a summary of the items below.

- a statement that the study being conducted is for research (required),
- the purpose of the research (required),
- main study procedures or activities required of the subjects (required), total time commitment,
- major risks associated with participation in the study,
- significant inclusion or exclusion criteria for participation,
- setting of study,
- benefits of the study, or
- any other study-specific key information.

Consent Form Tips

PROCEDURES

- Include detailed information on what you are asking the participant to do in your study or what you will do to/with them.
- Break down the time commitment into clear sessions or tables, if appropriate.
- Detail when and where all research activity will occur.
- Use simple language. Be mindful of your participants. They may not understand technical terms that you are used to.

Consent Form Tips

POTENTIAL RISKS

- Include ALL the risks of the study. Make sure the steps to minimize each risk match the steps you describe in the application.
- Please do not state that there are minimal risks; that is a subjective assessment. Let the participants decide if they find the risks minimal.
- Make sure the steps to minimize each risk makes sense. Giving a gift card doesn't minimize the loss of time. It's a nice benefit, but it does not shorten the time commitment.
- Please separate all risks so that it is easy for the participants (and the IRB) to read and understand.

Consent Form Tips

IDENTIFIABLE PRIVATE INFORMATION

You must explicitly state how you will handle identifiable private information with regards to future research. Use the statement that applies to your study:

(1) The researchers will remove all of your personal or identifiable information (e.g. your name, date of birth, contact information) from the audio recordings and/or any study information. After all identifiable information is removed, your audio recordings and/or any personal information collected for this study may be used for future research or be given to another researcher for future research without additional informed consent.

If you would like to participate in the current study but not allow your de-identified data to be used for future research, please initial here _____.

OR

(2) Your audio recording and/or any personal information collected for this study will not be used or distributed for future research even after the researchers remove your personal or identifiable information (e.g. your name, date of birth, contact information).

Consent Form Tips

REQUIRED STATEMENTS

The IRB requires several statements to be included in every consent form:

- A statement that participation is voluntary
- LoC statement: *"Confidentiality will be protected to the extent that is allowed by law."*
- Internet/Email statement: *"There is a potential risk of loss of confidentiality in all email, downloading, and internet transactions."*
- TWU Disclaimer – *"The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research."*

*Remember to remove the quotes when you include this in your consent form.

Common Practices for Obtaining Informed Consent

- When obtaining written consent in person, it is common practice to have the participant sign 2 copies of the consent form. They would keep one copy, and the PI keeps the other copy.

- If you are obtaining written consent, but cannot collect the consent form in person, the participant can sign, scan, and email the consent form back to the PI. Digital signatures (e.g., DocuSign, electronic stamps, e-signatures) are acceptable as well.

- Signed consent forms should be stored in a secure location separated from the study data.

Other Consent Form Tips

- Remember to use simple language.
- Use 2nd person language. Speak *to* the participants, not *about* them.
- Make sure all information in the consent form is consistent with the information you provide in the application and other documents.
- Be sure to spell-check and grammar-check.

Sample Consent Forms

From the IRB Website

- Sample Consent Form – Dallas
- Sample Consent Form – Denton
- Sample Consent Form – Houston

- Sample Consent Form(Health Sciences)
- Sample Assent Form (Health Sciences)
- Sample Online Consent Form

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Thank you!!

Office of Research & Sponsored Programs
Institutional Review Board (IRB)

https://twu.edu/institutional-review-board-irb/