TWU IRB Reference Sheet for Recruitment and Informed Consent

RECRUITMENT

Recruitment Materials (flyers, email scripts, social media posts, etc.)

- Items that are required:
  - State that research will be conducted
  - State that participation is voluntary
  - If the internet/email is used for participation, include the following statement: "There is a potential risk of loss of confidentiality in all email, downloading, electronic meetings, and internet transactions."

- Items that are NOT required, but recommended:
  - PI's contact information (email is recommended over cell phone #, but both are okay)
  - Location/site of the study
  - Study title
  - Brief description of the study
  - If using a TWU logo, TWU marketing is asking that you use the new logo
  - Main eligibility requirements
  - Benefits for participation
  - Total time commitment

- If your scripts will vary across different platforms (email script, social media post, phone script, etc.), make sure you attach all appropriate scripts. If you are using the same script across all platforms, state so.

- Make sure the information you include is consistent with the information you provide in the application and consent form.

- Remember, it is okay to leave out details that are subject to change (e.g., study or session dates, gift card vendors). It is very possible that your study will not start when you want it to. If you leave out actual dates, you will not need to submit a modification request to change it later. The same thing goes with gift cards. If your study is funded, you may work with ORSP to get gift cards. You may need 40 $5 gift cards, but they do not have 40 from the same vendor. It would be much easier to just state that participants will receive a $5 gift card.

Recruitment Process Tips

- When describing your recruitment process, provide as much detail as possible. Don't just state that you will ask people to participate. Explain when/where/how you will recruit:

    - Will you post flyers in public places? Will you recruit from specific organizations? Will you use email or social media? If so, list the specific platforms (e.g., Facebook, Instagram, Reddit, etc.). Will they be public or private groups? Do you have approval to post your announcement? Say you want to recruit students in your class. How will you do this, exactly?
    - The IRB is looking to see if your recruitment methods are coercive (i.e., persuading or convincing someone to do something using undue influence or other unethical means)

- As part of the recruitment process for some studies, you may need to explain what happens *after* a potential participant shows interest in your study. When they call or email you, what will you say? Most likely, you will provide them with further details of the study, and you might screen them for eligibility. If so, those details need to be included, and you will need to submit those materials (e.g., screening questionnaire, follow-up recruitment email/phone script, etc.)

- Identifying a Target Population vs. Actual Recruitment – You cannot begin actively recruiting participants for your study until you receive IRB approval. That does not mean you cannot identify a target population first. Sometimes, it makes sense to see if your targeted population would even be interested in participating in a survey/interview/intervention, etc. As long as you do not ask individuals to participate in the study, you will be fine.

INFORMED CONSENT

Process for Obtaining Consent

- The consenting process is much more than having a participant sign a consent form. You need to detail:
    - how/when you will give/provide the consent form to the participant (e.g., email, in person, sent home with a child for parents, etc.)
    - how you will explain the study to the participant and give them opportunities to ask questions
    - when/where/how they will sign and return the consent form back to you (e.g., email, in person, mailed, etc.)

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 proceed to the study/survey
    - the PI's contact information should be provided 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 Online 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 that says something to the effect of, "Completion of this survey constitutes your consent to participate in this research study."

- Exempt studies in general do not require complete consent forms (although providing one is nice). If you decide to use one, the IRB suggests that you include the standard elements of a consent form. Those can be found in our *Guide to Writing a Consent Form*.

Common Practices for Obtaining Consent

- If your consent process is done in person, it is standard practice for you to bring 2 copies and have participants sign and initial both copies. They keep one copy and the PI keeps the other.
- 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.

Resources for Consent Form Guidance

- One of the BEST resources that the IRB provides is this *Guide to Writing a Consent Form*. It tells you everything that needs to be included in your consent form.
- While you're at it, here are Sample Consent Forms for Dallas, Denton, & Houston. This is helpful in seeing how the requirements are applied.
- When must written informed consent must be obtained? Click there in case you aren't sure.

Consent Form Tips

Summary and Key Information about the Study

This is a new federal requirement. The TWU IRB is not just making up new rules for fun.

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

For those whose studies were approved prior to the implementation of the new Common Rule, your 'Explanation & Purpose' section already has a lot of these items, and you would simply add a few more statements. Yes, this may seem redundant, but it does not necessarily need to be. You can include general descriptions as *'key information'* but then tell the participants that you will explain them in further detail later on in other sections. For example, you can say, "*The greatest risks in this study are loss of confidentiality and emotional discomfort, but we will discuss them and all other risks later on in this consent form.*"

Possible key information includes, but is *not limited to,* a summary of the items below. Note that not all of these items may be key information for every study.

- 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.

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.
- 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.

Statement on Identifiable Private Information

Another requirement from the new Common Rule is that you must explicitly state how you will handle identifiable private information with regards to future research. For example:

(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).

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."*

*Tip: Yes, these are in quotes here, but remember to remove the quotes in your consent form.

Consent Form Pages & Initials

Adding page numbers to a Header or Footer in Word:

1) Double-click the footer/header.
2) At the top under the Header & Footer Tools **Design** tab, click on the "Page #" and choose "Bold Numbers 1, 2, or 3."

Removing the initials line from the signature page in Word:

1) Click on the **Layouts** tab and click on "Breaks."
2) Add a "Section" or a "Continuous" break on the page before the signature page.
3) Double-click the footer/header of the page with the signature line, and at the top under the **Design** tab, uncheck "Link to previous," and delete the initials line.

Other Helpful Tips

- Be sure to use 2nd person language throughout the consent form
- Make sure all of the information is consistent with the information you provide in the application and recruitment material. (i.e., don't state that the interview will take 30 minutes on the flyer but 1 hour in the consent form.)
- Remember to check your form for spelling and grammatical errors
- Consider your participants when creating your consent form. Use clear and simple language. They might not know all of your technical terms.