Tips 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 a personal 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.

- Upload the material in the format in which you will post. For example, if you use Instagram, upload the image that you intend to post to Instagram. The Instagram post would be different from an email script, so if you use Instagram and email, upload both.

- 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? Say you want to recruit students in your class. How will you do this, exactly?
    - Will you use email or social media? If you do use social media, 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?
    - 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., in person, electronically, via mail, etc.)

Even if your study is conducted online, you still need to outline a consenting process in your application.

- Describe how the participant will be asked to read the study summary or consent document that is provided before they proceed to the study/survey.
- Include the PI's contact information in case there are any questions about the study.
- Consider whether you need to obtain documented consent (digital signature) or if clicking a button to agree will work. If the study has more than minimal risk, documented consent may be required.

If your study is an Exempt study that involves a simple survey with minimal risks, 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."* You would also provide buttons for participants to agree or decline to participate.

Common Practices for Obtaining Consent

- If your consent process is done in person, it is recommended 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/documented consent (more than just clicking to agree), but cannot collect the consent form in person, you can use electronic consent (e.g., Adobe, Google Forms, or DocuSign) to obtain documented signatures. This can be capturing an actual signature or having the participant type their name to document their consent.
- For electronic consent forms, be sure to give the participants an option to print or have a copy emailed to them.
- Signed consent forms should be stored in a secure location separated from study data.

Resources for Consent Form Guidance

- Check out our Informed Consent Guidance page. You'll find guides and samples that you can use as templates. Just be sure to tailor the sample to fit your study.
- When must written informed consent must be obtained? Click there in case you aren't sure.
- 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.

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 can decide after reading this section whether or not they want to participate.

This may seem redundant, especially if you have a short consent form, 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

Per federal requirements, you must explicitly state how you will handle identifiable private information with regards to future research. If you collect any identifiable data in your study, you must include EITHER of the two statements in your consent form, depending on what you intend to do with that data in regards to future research.

(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 indicates that the study is research.
- 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.*

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. You are speaking to the participants with the consent form, not about them.
- Make sure all of the information is consistent with the information you provide in the application and recruitment material.
- Remember to check your consent 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. If you cannot simply the terms, define them in simple language.
- When using acronyms, spell them out during the first use.
- Make sure the consent form is clear and easy to read. Divide the consent form into sections with clear subheadings. It's okay to have multiple paragraphs.
- Be direct and concise. You must include all of the study information, but try not to get too wordy or too fancy.