

Common Mistakes with IRB Submissions

Advertisement

Any type of invitation or notice of a research study is considered an advertisement and must contain the following federally required elements:

- PI name and address (email is fine). If it's an email invite, these are probably in the researcher's signature line.
- Purpose of the research (must match the application and any other documents, unless intentional deception exists)
- Benefits to participants, if any (there rarely are any, and if benefits are listed they must be guaranteed)
- Time commitment (this must match what's written in the consent form and application)
- Location (Online? On campus in Vermillion? Sioux Falls?)
- Remember to check for typos and grammatical errors!

Consent Form

- Please use the provided templates on our website as they already contain the federally required elements.
- Which template to use? Only one of the following is required:
 - Cover letter or statement templates are both acceptable for low-risk studies or those that do not need a signature from the participant.
 - Non-medical or medical templates are ideal for studies that do require a signature.
- Time commitment - make sure this matches what is written in the advertisement and application
- Risks – This must match what's listed in the "Risks" section in the application.
- Benefits – Most studies have no direct benefit to the subject so this part usually should start off with "There is no direct benefit in participating, however, we hope that in the future..."
 - Make sure there isn't any mention of compensation or extra credit here. It can be listed in another paragraph since federal regulations prohibit compensation to be listed as a benefit.
- Compensation - If extra credit is offered then there MUST be an alternative way to get the credit without being a research subject. For example, "If you choose not to be in this study, you may obtain extra credit by participating in another study in the SONA system (if applicable) or by asking your professor for other options."
- Confidentiality section – If it is stated here that participation will be anonymous then there shouldn't be any identifying questions on the survey (such as asking for student ID) and there shouldn't be a signature on the consent.
 - If the study involves an interview then participation cannot be anonymous because you will meet the participant in person. For interviews, note if you will be recording participant responses (either audio or video). If you are using audio recordings, we suggest you transcribe and remove any identifying information as soon as possible and then delete the recordings. If that is the plan, please state that here.
 - If you'd like to use participant quotes, you may put in this section that "participant quotes may be used in publication but you will not be identified since there will be no information linking your identity to your responses".
- Suggested wording for focus groups:
 - "The researchers will ask you and the other people in the group to use only first names during the group session. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private."
- If your employment is or might be affiliated with any of the potential subjects, be sure to state you are doing this research as a USD faculty member or student and not through your employment.
- Remember to check for typos and grammatical errors!

Application

- Check to make sure the responses to the section titled "Participant Recruitment" are clear and we have all associated documents/permissions (if needed). **Permissions are one of the most frequently overlooked requirements.**
- The section titled "Participants" should always have an answer to the first question "How many participants do you plan on enrolling?" Even if it is retrospective data analysis, there needs to be an estimate of how many subjects' data will be included.
- "Confidentiality" section:
 - Identifiable study data and documents should be kept in the PI's office or in another secure location on-campus. This data should not leave campus. Once the data is de-identified, the study may be closed.
 - The data retention policy is to keep the data for 3 years after study closure.