

IRB Red Flags: Common Risks and Solutions

We see a lot of projects that become delayed because of problems that are easily solved. Here is a list of some of the “red flags” that might mean the difference between a “conditional memo” and the coveted “approval memo”:

- Use the terms “confidentiality” and “anonymity” correctly
 - *Anonymous* means that there is no way for the researcher to connect survey responses or data to specific individuals, even if they wanted to.
 - *Confidential* means that the researcher may have private information and/or data about specific individuals on record, but this information will be kept secret and not disclosed to anyone else.
- Avoid technical or scientific jargon
 - Aim for communicating at a 7th-8th grade reading level, both in your application and your appendices. You want non-scientists and those unfamiliar with your field to be able to understand the application.
- Informed Consent
 - Even anonymous studies need consent processes.
 - Remember to include contact information for the researcher and PSU’s HSRRC, a statement that participation is voluntary, mention of all risks and safeguards, and details about what participation will involve (length of time for a survey or interview, whether the interview is recorded, etc.).
- Can’t guarantee confidentiality in a small sample
 - If you are using a small sample size, there is a risk that characteristics of an individual story could lead to identification of a subject in materials published or shared from your study. State this risk in the informed consent document. You can use language such as “This research is a chance to tell your story, and every attempt will be made to keep your identity confidential. However, your story could be identified and your confidentiality cannot be guaranteed.”
- Can’t guarantee confidentiality in a focus group
 - If you are using a focus group in your research, you cannot guarantee confidentiality since other participants could disclose private information to people outside of the group. You can just mention that this is a risk and ask participants to respect each other’s privacy by not talking about who attended the group or what was said.
- Extra credit options for student subjects
 - If you are using students as your research subjects, and you want to offer extra credit to those who participate in the research, an alternative extra credit assignment must be offered to non-research participants. The alternative should be equivalent in duration and difficulty to participation in the research. Just explain that an alternative will be offered and what that extra credit assignment will be.

- Vulnerable populations & sensitive topics
 - The federal government requires special safeguards to protect groups that may be especially vulnerable to the risks inherent in research. These groups include:
 - Prisoners
 - Children
 - Pregnant women
 - Individuals with diminished cognitive capacity
 - In addition, research that deals with sensitive topics such as drug abuse, crime, sexual issues, violence, abuse, mental health issues, or illness most likely require additional information and safeguards.
 - These research projects will probably take longer to review (up to 6 weeks), so be sure to submit your application early. It helps to include information about the researcher's experience working with the topic or subject population, as well as details about what special precautions will be taken to keep subjects as safe as possible.
- Records and Distribution
 - Mention how you will keep your records safe—most likely that means storing them in a locked office on the PSU campus, on a password-protected computer, and backed-up on the secure PSU server.
 - Mention how long you will keep the records before they are destroyed (usually a minimum of 3 years).
- Partial or Sloppy Applications
 - Remember to submit the Investigator's Assurance cover sheet, signed by the principal investigator as well as the appropriate department head and/or advisor.
 - Remember to complete all narrative elements of the application.
 - Remember to proofread your application and include page numbers.
- Missing Appendices
 - Remember to include copies of all the documents you will use during your research. That may include:
 - Recruitment forms, letters, emails, posters, or verbal scripts
 - Informed consent forms for all participants
 - Sample assessment instruments (surveys, interview questions, etc.)
 - Documentation showing that any other involved institutions have agreed to the research (schools, corporations, non-profit agencies, etc.)