

Tips for IRB proposals

Most IRB proposals go back to the proposers for informal revision at least once before they are reviewed officially. You may be able to save some time and trouble by considering the following common problems:

In the Initial Review Form:

- 1) First page: Please check all the appropriate boxes so we know what materials to expect in your proposal.
- 2) Section 3: Remember to explain how you'll ensure you get the population you're looking for. If you're only recruiting adults, how will you exclude teenagers, for instance? Estimated population size is the entire group of eligible people; sample size is the number you'll have in your study.
- 3) Section 4: Informed consent. Be sure to attach your informed consent document. In section 4.3, think carefully. People often want to say there are no factors that interfere with free informed consent, when there actually are. If someone with power over the participant knows whether they gave consent, that's a potential interference with their freedom to opt out. Explain how you'll mitigate such issues in section 4.3a.
- 4) Section 6: Study Procedures. Make sure that any research methods you check in 6.1 are included in the methods in 6.3.
- 5) Section 7: Data privacy. Sections 7.1, 7.2, and 7.3 must be consistent. If you say you're not collecting any direct identifiers, then you can't later "de-identify" data, for instance.
- 6) Section 7.2 Remember the possibility of "re-identifying" subjects. For instance, if you collect demographic data, someone might be able to identify the one research subject who is Asian, over 50 years old, and self-employed, even though you haven't used his name. In Section 7.2, it's often necessary to say that you'll exclude categories with fewer than 5 members from your published results, to avoid re-identification of people in smaller groups.
- 7) Section 7.3. When it says you have to provide a building and room number, do so.
- 8) Section 8, Risk-Benefit Analysis. In section 8.2, use your imagination when thinking about whether the information in the study could affect the participants' "reputation or employability". If people have the opportunity to say something critical about their boss, company, or teacher, this could be a problem if that information was leaked. You need to err on the side of caution and then explain how you're mitigating this risk.

Informed Consent Forms:

Refer to the templates provided to be sure that you are including all required elements. Do not say there is no risk; everything entails risk. If the risk is minimal, say that.