

Navigating the Approval of Your Research Ethics Protocol

A few observations on things that tend to go wrong during the approval process, focusing mainly on research involving living human subjects

Section B — Summary of Research

11. Rationale

- Describe the purpose and scholarly rationale for the proposed project. State the **research questions** to be examined. The rationale must be CLEAR. Please include references.

11. Rationale

- Do NOT just paste in your doctoral proposal or SSHRC proposal
- There is no reason for this section to be lengthy
- Focus on what they ask for
 - Research questions, why they're important (i.e., why they justify invading people's privacy etc.)
 - REB readers don't need great amounts of detail or theory, just enough background for context and a sense that it's a well-conceived project
 - Don't duplicate what will come in following sections (e.g., methods)

12. Methods

- Please describe all formal and informal procedures to be used. Describe the data to be collected, where and how they will be obtained and how they will be analyzed.

Methods

- Again, keep focused on the questions asked
- The REB is not interested in the parts of your methods that do not require ethics review (e.g., archaeological excavation), so focus on what's relevant
 - Only refer very briefly to recruitment of participants, since that's in section 13 & 15
 - Discuss participant observation, sampling, whether you'll use forms/questionnaires
 - How will you analyze the data? Statistically? Qualitatively? How will you avoid bias?

13. Participants and/or Data

- a) Describe the participants to be recruited or the individuals about whom personally identifiable information will be collected. LIST THE INCLUSION AND EXCLUSION CRITERIA.
 - This is the part that almost no one addresses in their first draft. Simply (and briefly) list what criteria (age, sex, geography, occupation, or whatever) you'll look for to include people in your study, as well as what criteria (e.g., you know them personally, there's a conflict of interest, they're underage) would cause you to exclude them from your study

13. Participants and/or Data

- a) Where the research involves extraction or collection of personally identifiable information, please describe from whom the information will be obtained, what it will include, and how permission to access the data is being sought.
 - Generally this is well done, but note that the focus here is on the kinds of data and how obtained, not on anonymity or confidentiality
 - Go back to this and revise after you've filled out some of the later sections

13. Participants and/or Data

- b) Is there any group or individual-level vulnerability related to the research that needs to be mitigated (for example, difficulties understanding informed consent, history of exploitation by researchers, power differential between the researcher and the potential participant)?
 - Note the focus here is on what the vulnerability is, not how you will deal with that. That comes in section 26

15. Recruitment of Participants

- Where there is recruitment, please describe how, by whom, and from where the participants will be recruited
 - Here they're talking about recruiting participants through flyers, postings on Facebook, "snowball sampling", or making announcements at public meetings, etc.

15. Recruitment of Participants

- Where participant observation is to be used, please explain the form of insertion of the researcher into the research setting (e.g., living in a community, visiting on a bi-weekly basis, attending organized functions)
 - This is pretty straightforward and most applicants for ethics approval answer this well

15. Recruitment of Participants

- If relevant, describe any translation of recruitment materials, how this will occur and whether or not those people responsible for recruitment will speak the language of the participants
- Attach a copy of all posters, advertisements, flyers, letters, e-mail text, or telephone scripts to be used for recruitment

Section C: Risks and Benefits

17. Possible Risks

- Check off whether there are physical, psychological or emotional, social, or legal risks — be realistic
- b) briefly describe each of the risks noted and **OUTLINE THE STEPS THAT WILL BE TAKEN TO MANAGE OR MINIMIZE THEM**
 - Much of the time, the risks will be minimal, but you need to show that you've thought carefully about this

19. Consent Process

- The main things to keep in mind here are:
 - it is the quality, not the form, of the consent that matters (i.e., the participants need to understand what they're consenting to)
 - it needs to be *continuing* consent (i.e., you don't just ask them for consent at the beginning and leave it at that — they should be free to change their minds)

Section E — Confidentiality/Privacy

24. Confidentiality

- Data security measures must be consistent with UT's Data Security Standards for Personally Identifiable and Other Confidential Data in Research. All identifiable electronic data that is being kept outside of a secure server environment **MUST BE ENCRYPTED**
 - It is not enough simply to password-protect
 - Confidentiality is not always necessary, possible or appropriate, so think about this before you check the box saying that your data will be confidential or the participants anonymous — be honest

24. Confidentiality

- “Personally identifiable information” does not just mean names or Social Insurance Numbers etc.
 - If you’re taking photos or videos or recording interviews, participants can be identified by their faces or voices
 - The content of quotes you might make from interviews or conversations could make people identifiable, especially if they’re talking from the position of, for example, a particular role like hospital administrator or officer of an NGO
 - There could be legal requirements for you to report some things
 - Under such circumstances, anonymity may simply be unrealistic, in which case you need to make sure your informants understand that when they consent to their participation (24c – limitations to confidentiality)

25. Data Security, Retention, Access

- a) Describe how data (including written notes, video/audio recordings, artifacts, questionnaires) will be protected during the research and dissemination of results
 - Again, this is relevant to any data that are supposed to be confidential or anonymous. Mention here if that applies to only some of your data while some of it is public and why
 - Otherwise, data must be double-protected (e.g., in locked drawer in a locked room) if it's not encrypted

25. Data Security, Retention, Access

- b) Explain how long data will be retained. Provide details of their final disposal or storage. Provide a justification if you intend to store your data for an indefinite time. If the data may have archival value, discuss how participants will be informed of this possibility during the consent process
 - Note that there is no *a priori* requirement to destroy your data, and there is sometimes good reason to archive it. Just make sure it's justified and included in your consent process

Section F 26. Risk Matrix

- Refer back to the risks you mentioned in Section C
- Make sure you refer both to Group Vulnerability (e.g., children as a group have different vulnerabilities than adults) and Research Risk (risks inherent in the kind of research you're conducting, such as talking to individuals in a public setting where they could be exposed to social risks)

General Comments

- Follow the instructions closely
- Don't pad it with unnecessary detail
- Make it easy for the REB readers to find the information they need
- Focus on the aspects of your research that have ethical implications