

How to facilitate IRB protocol review

•Follow directions

Signatures: Obtain student signature and two different faculty signatures. These signify that advisor and chair/designated colleague have reviewed and approved of the research as written. Review will not be initiated without these.

Template: Follow the most current protocol template, which forces the investigator to provide required information. Our web site changes frequently so use it; do not use another researcher's form. Retain the outline format for ease of review. Review will not be initiated without this format.

•Protocol

Complete protocol: Submit a complete protocol, including all sections and attachments (all consents/assents, recruiting materials, questionnaires, interview questions, permission letters, etc.).

Background: Provide a scholarly, current review of all pertinent literature and background and explanation of anything needed for the committee to understand your protocol, e.g., if you are using dietary supplements we need to know all about them—studies, risks, benefits; if you are studying Youth Radio, tell us what it is.

Be sure your literature review is related to the human subjects portion of your project. Define all terms and acronyms and avoid use of discipline-specific jargon.

Data analysis: Include methods, not just “the data will be analyzed statistically”. Be sure that the data collected answer the stated research question.

Risks: Be inclusive and specific. Realistically acknowledge possible risks.

Qualifications: Include qualifications to conduct your specific research project, not just “I am a grad student”. Also, be sure you are qualified.

Proofread: While minor errors can be tolerated in the protocol itself, the documents that go out to the public must be perfect.

Consistency: Be sure you are consistent: 20 minutes for the survey in the protocol and 30 minutes in the consent form; changing between calling your activity a survey or interview; different ages of participants in different places will trigger a question from us.

Sample: If you are using a sample protocol to help you with your submission, be sure it is the final, approved version, not an early draft that may have been extensively modified to secure approval.

•Attachments

Consent/assent forms: These need to be complete and concise and at an appropriate level for the intended audience.

Interview/survey questions: We need to see the final version, not a draft or a general idea. For on line surveys, we need to see the print-out for formatting.

Permission letters: Be sure they cover the activities you are going to pursue.

Recruiting materials: Include all scripts, flyers, emails, web postings, etc. in their final form.

● **Follow-through**

Receipt of documents: We acknowledge receipt of all documents. If you haven't heard from us, check.

Address office's/committee's questions: Either incorporate suggested changes or give justification for not doing so.

Timely response: The more quickly you respond to our requests, the faster the process will go.

Approval: If you have not received an approval email, you probably have not been approved.

● **When should you submit?** We receive almost half of our yearly total of protocols in October-December (approximately 225-250). We receive only 15-20 protocols in September.

● **Could this project be modified to be exempt?** Sometimes making a minor change in research design could move a protocol into the "exempt" category, which generally does not require committee review.

● **Does the project need to be this complex?**

● **Your project may not require IRB review**

The following activities may not require IRB review. Please contact the human and animal subjects office to help determine if review is required.

“**Self Improvement**” studies (for example, where someone reviews their own teaching methods with an eye to becoming a better teacher)

Key Informant Interviews where the information presented is about the program and not the individual

Curriculum Development where the curriculum is not being evaluated in the field

Needs Assessments and **Program Evaluation** with the sole intent of sharing the results internally with the agency, organization, etc.

Oral History where the information is merely reported, but not analyzed

Web Design Evaluations, Product Design Assessments

De-Identified Secondary/Existing Data

Classroom projects: If a class project will not be published, it may not need IRB review. If, at a later time, a student wishes to, e.g., use these data in the Student Research Competition or for a thesis, this may be possible.