**IRB Proposal Tips**

All researchers who use human participants must complete research ethics training and provide documentation of completion with their requests for review. *Access to the training materials can be requested here:* [*https://forms.office.com/Pages/ResponsePage.aspx?id=B0hl-YTnSUy0iCRpmvdAXa0pmh9QumNJuiQy3fSHJJNUNzFTSlA3N0U4T1JPMTgzRjQ4OEpDUTQ5MS4u*](https://forms.office.com/Pages/ResponsePage.aspx?id=B0hl-YTnSUy0iCRpmvdAXa0pmh9QumNJuiQy3fSHJJNUNzFTSlA3N0U4T1JPMTgzRjQ4OEpDUTQ5MS4u).

**The minimum passing score is 80%. A link to the certificate of completion will be provided within 48 hours of passing the quiz.**

Submit a copy of your completion certificate with your proposal unless it is already on file with the IRB committee. **Training approval is valid for three years.**

1. Decide what type of proposal you should submit:
	1. **Exempt**

***Screened for Exempt*** proposals are reviewed by two IRB members, sometimes in consultation with others. A research activity may be declared exempt if it is considered low-risk and the only involvement of human subjects will be in the categories outlined in [**45 CFR 46.101(b)**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101(b)). Briefly described, these categories are:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices**.**
2. Research using anonymous or no-risk tests, surveys, interviews, or observations.
3. Most research involving public officials.
4. Research involving the collection or study of existing data if it is publicly available, or if subjects cannot be identified.
5. Research examining public benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies.

**Although subject consent is always needed, signed consent forms are typically not recommended if they are the only identifying variables in an otherwise anonymous project.**

Most exempt level reviews are completed within two weeks after being received by the IRB chair.\*

* 1. **Expedited**

Projects not eligible for an exempt review may be eligible for an expedited review. "Expedited" proposals are reviewed by the IRB chair and two or more experienced reviewers.

In general, research may qualify for expedited review if it is judged to involve only minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate informed consent procedures. For example, the collection of physical data through non-invasive procedures is eligible for an expedited review, including:

* Height and weight
* ECG, MRI, Ultrasound
* Moderate exercise
* Blood or other bodily fluid

Most expedited reviews are completed within approximately three weeks after being received by the IRB chair.\*

* 1. **Full**
* A full board review is required for research that is not eligible for exempt or expedited review. In short, research that is judged to involve more than minimal risk, or involves protected populations such as children, prisoners, or individuals with disabilities, must undergo a full board review. Individuals intending to conduct research that requires a full board review should allow ample time to complete the review process.

The following categories of research require full IRB approval:

1. Projects for which the level of risk is determined by the IRB Chair to be greater than minimal.
2. Projects involving the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
3. Projects involving sensitive or protected populations (such as children (outside of a traditional classroom setting), cognitively disabled individuals or prisoners).
4. Projects that plan to use procedures which are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

Most full reviews are completed within approximately four weeks after being received by the IRB chair.\*

1. You may obtain the necessary form from your faculty advisor.
2. Carefully consider the title of your proposal/project. It should reference your research question. The title should be consistent on all documents submitted.
3. **If you are a student, your submission will go to your faculty advisor for approval BEFORE it goes the committee for review.**
4. Write a clear and concise **Informed Consent** (see template).
5. What you are studying
6. Who – Why they were selected
7. Time commitments of participants
8. Risks and Benefits to participants
9. Electronic studies, such as surveys, also require an informed consent – You can use a statement such as, “By clicking **Start Survey**, you agree to…”
10. If your study includes minors (under 18 years old), you may also want to include an **Assent Form**. While parents/guardians must sign the **Informed Consent Form**, minor participants should understand the research and sign an **Assent Form. Use your best judgement on whether young participants can understand an assent form or if it is necessary. The IRB Committee may ask for one during the review process.**
11. **DON'T use jargon or complex wording on the Informed Consent. Be sure your audience can read and understand the Consent. Target the reading level of your consent form to the subjects. Also consider the culture of the subjects.**
12. One goal of the consent form is to have the subject understand everything that he/she will be asked to do, and how much time and what type of energy, effort will be required. Provide complete, but simple, descriptions of tasks, the setting, the time required, etc. You must justify omitting a description of exactly what the subject will encounter. The IRB always questions: *“Can every subject who might read this consent form be expected to fully understand it?”* Wherever possible, substitute simpler words or phrases. Have someone outside your department or field read your form to see if he/she understands every word in it and can explain it to you. It is your job to make sure your subjects understand. **If you are recruiting participants who may not be able to read and understand the Informed Consent independently, you will need to explain it to them. Always allow time for questions.**
13. If doing a survey, include it with the proposal (even electronic surveys).
14. Include interview question guides (if interviewing).
15. Include an observation field note guide if using observation as a manner of collecting data.
16. Include any other documents participants receive or see.
17. Provide an outline of your procedure.
18. Include your abstract, methodology, methods of data collection and how data is securely stored.
19. If you have multiple measures with multiple phases or interventions, a simple outline of procedures will save IRB members review time and can help them understand exactly what happens to the subject at each step of the study.
20. **Write your project description in future tense. (ex. “I will administer surveys….”)**
Reviewers and/or auditors cannot tell whether studies or some parts of studies, such as pilot research, have already been done when descriptions are entirely in the past tense. Of course, any previous pilot work should be written in past tense. (Note: Even pilot studies require IRB approval.)
21. **When you begin working on your proposal, start with an IRB-focused outline\*. (This outline is a working outline for you. Do not turn this in with your proposal.)**
Write your proposal from scratch instead of editing down a grant, thesis, or class paper. Many project descriptions and protocols can be written in two to four double-spaced pages. *\*Students may be given an outline in class. This is up to the faculty research supervisor. Even if students are provided an outline, the IRB forms must be used when applying for approval.*
22. **Be aware that IRB uses a cost-benefit approach.**
Not only does the IRB try to protect subjects, it also weighs the predicted benefit of a study against the risks. An IRB in a medical institution will approve protocols that anticipate some deaths from the research — if the benefits are great enough. At the other extreme, a protocol written with no apparent benefit to subjects, to others, or to science could be rejected, even if the only costs were a half-hour of undergraduates’ time in filling out a survey. A clear statement of why your research is important, how it fills a need, how it addresses limitations of previous research, and how it may directly or indirectly benefit the subjects or others will add points to the IRB's “benefits” column and make risks more acceptable.
23. **Show your awareness of your study's risks.**
Not all risks need to be listed on the consent form, but all risks should be clearly articulated on the study description. Do not be “defensive” about risks. Instead, show the IRB you are fully aware of all possible risks by listing them and then by commenting on how significant they might be, how frequently they occur in this type of research. Note: There is always a risk of inconvenience. Be sure to mention this in the Informed Consent.
24. **Validity of measures** **used** is an important factor the IRB routinely considers**. A measure of unknown validity can severely or completely compromise a study's value and shift the risk/benefit ratio from acceptable to unacceptable.** Briefly mention the validity of measurement procedures, either by citing literature and validity and reliability coefficients, or by simply mentioning that they are standard measures for the field and appear in published, peer-reviewed literature, if that is the case.
25. **Submit recruiting scripts/flyers with the proposal.**
The best way to help the IRB understand risks and how you will handle them is to provide verbatim scripts of what you will tell subjects in a telephone recruitment call, in task instructions, and in debriefings. IRB reviewers ask the question: *“What information are the subjects getting (or not getting) that would help them decide to participate (or not) or to continue to participate, and is this information being given as soon as possible?”*
26. **DON'T confuse anonymous with confidential.**
Anonymous means you cannot identify even one subject by the materials that you collect. Watch out for demographics here! Confidential means you, the researcher, could identify the subjects in some way, but you will keep data and any identifying information secured so that only the researcher(s) have access to it.
27. **PROOFREAD YOUR PROPOSAL very carefully to ensure accuracy and consistency throughout the application.**
We've seen applications that list conflicting numbers of subjects, ages of subjects, and numbers of sessions. We have also seen applications with numerous typographical and grammatical errors**. If a proposal contains multiple errors, we will return it to you and ask you to correct the errors before it is sent out to reviewers. This significantly slows down the review process.**
28. **Contact Dr. Joanne Fish, IRB Chair, with questions. Dr. Fish can be reached at:** **jfish@fontbonne.edu** **or 314-719-8098. (Email is the preferred mode of contact.)**
Dr. Fish can help with such dilemmas as “How do I get started,” “Is my project ‘research’ under IRB,” or “Can you help a tight deadline?”
29. Time frame for the review process:

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| **Type of Proposal** | **Number of Reviewers** | **Time Frame\*** |
| Exempt | Two | 2 weeks |
| Expedited | Three | 2-3 weeks |
| Full  | Four | 4 weeks |
| **\*Note: The review time frames may be longer during off-times, such as over winter break and summer months.** |

1. All applications must be submitted through the appropriate link in GriffinShare (<https://griffinshare.fontbonne.edu/irb>).