

## DOs & DON'Ts to Reduce IRB Application Turnaround Time

Contact IRB: 915-7482, [irbinfo@olemiss.edu](mailto:irbinfo@olemiss.edu)

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### 1. DO use simple, clear language in your study description.

Write a project description in a style suitable for presentation to a freshman class. IRB members include attorneys, ministers, business men and women, as well as scientists from many fields. If your project description assumes knowledge in your area, some IRB members may not fully understand it. They will then submit questions that you must address *before* they can do the review, and this slows the review process.

### 2. DO provide an outline of procedures.

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.

### 3. DO write your project description in present tense.

Reviewers 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.

### 4. DO start with an IRB-focused outline.

Write your proposal from scratch instead of editing down a grant, thesis, or dissertation proposal. Many project descriptions and protocols can be written in two to four double-spaced pages.

### 5. DO 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.

### 6. DO 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 (data from prior research at UM or from published research helps considerably here), how you intend to address them, if necessary, and how you will train experimenters.

### 7. DO give information on measurement validity.

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.

**8. DO model after accepted applications and use advisors as reviewers.**

Obtain a previously approved application on a similar study and model yours after it. If you are a student, have your advisor review your application. If you are a new faculty member, ask a more senior faculty member to read your application.

**9. DO justify any race and/or gender exclusions from your sample.**

We follow the NIH requirements that no population can be excluded from research without clear justification.

**10. DO submit all scripts 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?" Debriefing scripts that try to educate student subjects about study purposes, scientific methods, and prior research are perceived as beneficial to these students and to the University's mission.

**11. DO proofread 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, for example.

**12. DO call us with questions.**

We can help with such dilemmas as "How do I get started," "Is my project 'research' under IRB," or "Can you help a tight deadline?"

**13. DO submit an application by email and fax the signature sheet for fastest processing.**

**14. DON'T use jargon or complex wording on the consent form.**

One goal of the consent form is to have the subject understand everything that is to happen to him or that she will be asked to do. Provide complete, but simple, descriptions of tasks, the setting, the time required, etc. You must justify omitting description of exactly what the subject will encounter. Target the reading level of your consent form to the subjects. The IRB always questions: "Can *every* subject who might read this consent form be expected to fully understand it?" Consent form language suitable for undergraduates is usually inappropriate for many Lafayette county residents, some of whom may be barely able to read. Wherever possible, substitute simpler words or phrases. Have someone outside your department read your form to see if they understand *every word* in it and *can explain it to you*. [Click [here](#) for examples of ways to simplify consent form language.]

**15. 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!

**16. DON'T submit theses or dissertations before committees accept the proposals.**

**17. DON'T submit applications that do not have all signatures.**

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## *Examples of Ways to Simplify Consent Form Language*

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INSTEAD OF THIS *I am conducting an investigation regarding peer relationships.*

SAY THIS *I am studying how children work and play with each other.*

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INSTEAD OF THIS *The purpose of this study is to compare the physiological responses of CAD patients at intensities based on perceived exertion while exercising on the elliptical crosstrainer and the treadmill.*

SAY THIS *We want to find out if patients with heart problems can benefit more from exercising on a special walking machine than from exercising on a treadmill.*

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INSTEAD OF THIS *Your decision to withdraw will not adversely affect your status at the Clinic or University.*

SAY THIS *Your decision to withdraw will not upset us and will not affect your regular care at the Clinic or anything you do at the University.*