

A “do” and “don’t” list for IRB review preparation

- DO follow directions and fill out forms carefully and correctly. Slavishly copy the format, order, and wording provided in sample protocols and consent forms. Details of document preparation are important because the IRB committee wants to review protocols as efficiently as possible. There are no points for creativity. Uniformity helps reviewers identify problems “at a glance.”
- DON’T imagine that there are short cuts through the bureaucracy.
- DON’T use specialized language, jargon, or terms of art in your protocol; expect that IRB reviewers will be from outside your specialty and discipline.
- DON’T make the committee’s job harder than it needs to be by screwing up the format. Save everyone time and effort by doing it right the first time.
- DO expect human subjects review to be an iterative process. Schedule ample time for resubmitting a protocol revised to the committee’s specifications.
- DO be unfailingly polite to the staff as well as the members and chair of the committee.
- DON’T be afraid to ask questions, especially of the staff member assigned to your case.
- DO use the process of writing the protocol and consent forms to clarify and set down the details of your research procedures. Usually, you submit your materials to IRB after your proposal is funded or approved by your committee. The proposal may have been a bit fuzzy on some procedural points. IRB approval is more likely if your materials show that you have thoroughly thought through what you will do, in what order, to gather and analyze the data.
- DO take seriously IRB concerns for the confidentiality and integrity of the data (Who will have access to the data? How will you preserve data from corruption or tampering?).
- DO take seriously IRB concerns for the dignity and safety of the research subjects (Will you compensate subjects for their time and effort? How will you protect them from potential harms related to participation in your study?).
- DO write consent forms in simple, direct language. Research participants have to be able to understand the research, risks and benefits, and the fact that they may stop at any time.
- DON’T ever misrepresent yourself (including your experience, expertise, or resources) or your research (including proposed methods, questions, or goals). If deception is involved in the research, make that clear to the IRB.
- DON’T try to justify ethically questionable research (failing to obtain informed consent; misrepresenting the research or procedures to subjects; failing to protect subjects from predictable harms) with the alleged importance of the data, “progress of science,” or your own career. These issues are at the heart of research ethics.
- DO realize that IRB committee members are often from medical and “hard” science specialties. They often hold deep disciplinary commitments to positivism, logic, scientific reasoning, and quantitative methods.
- DON’T try to distract or persuade IRB committee members with critical polemic or misguided efforts to question scientific method.
- DO take advantage of the opportunity to translate your own work into a different idiom, if necessary (e.g., hypothesis testing). Seek common ground.
- DO remember: The IRB is there to ensure that research subjects are not exploited as well as to prevent lawsuits against you and the University. Filling out forms and submitting research plans for review serves an important regulatory function but also can help you clarify your project. Keeping that in mind makes the process seem a little less onerous and arbitrary.

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