

IRB – Understanding the Full Board Review Process

Dear Principal Investigator,

We have written this letter to introduce you to the full board review process, to make the process more comfortable for you. Proposal writing instructions and cover forms are supplied at this link (<http://www.hrpp.ttu.edu>), so this letter will describe the review meeting itself.

Similar to other levels of human subjects review, your proposal will be assigned a primary reviewer after you submit it. If your study involves a lot of risk for participants, a second reviewer may also be assigned. This reviewer(s) will evaluate your proposal and work with you on making sure it accommodates the federal guidelines for the protection of human subjects. For your convenience, you and your reviewer can email drafts of the proposal back and forth. Typically, you will complete several revisions, answering reviewer questions, clarifying sections, and making changes to language or procedure to follow the federal guidelines.

When your reviewer believes the proposal is ready to be reviewed by the full board, your proposal will be scheduled for one of our monthly full board meetings. Full board meetings take place on the Texas Tech University - Lubbock campus in one of several large conference rooms. You will be sent the room number and a time to attend by email. To save you time, you will be asked to arrive slightly after the meeting begins, because the IRB will take care of some business that you don't need to be present for, such as approving minutes from the last meeting. There may also be researchers presenting on other proposals.

Ideally, all researchers listed on the proposal will attend the meeting, but it is not unusual for only one or two researchers to attend due to conferences, etc.; whoever attends must be able to answer questions about the entire proposal, even if he or she has expertise that only pertains to part of the proposal. If you are the PI supervising a graduate student performing research, you must attend with the graduate student.

Because you have been given a time that is slightly after the meeting begins, the conference room door will be closed when you arrive. Please make yourself comfortable, and the Chair of the IRB, Dr. Rosemary Cogan, will soon open the door and invite you and your co-researchers in. You'll be seated next to her at a table with 12 or more board members. Reviewers are faculty members from all over the university plus community members, to ensure that all viewpoints are considered in human subjects protection. Your reviewer will also be there.

The reviewers will have access to the electronic version of your proposal. Some reviewers will have read every word of the proposal, and others will have skimmed it. Your reviewer will have provided a description of the project and brief history of the review so far to the board.

The reviewers will then ask you questions, about anything from methodology to word choice. Usually, the question and answer period lasts no more than twenty minutes, and sometimes even fifteen. Some questions we ask are just to clarify and only need a simple explanation from you. Some questions we ask you may have already answered for your reviewer. Please don't become frustrated by these questions. It's the IRB's job to ensure that human subjects are protected in your research, and these questions help us determine that they are protected.

Among these questions, reviewers will request changes to the proposal. Typically, these are very small—adding a sentence to the consent form, using a synonym there. Occasionally, they are larger, such as changing an advertising method; usually, your reviewer will have made any large suggestions. It's not unusual for a reviewer to make multiple suggestions and ask you which one would be the best in terms of your project. These suggestions have a collaborative tone, with the shared objective being a successful research project that fulfills federal human subject protection guidelines.

In the past three years, typically researchers in full board meetings are asked to make five to ten changes to their document. You will want to take notes on the reviewers' requested changes, and your reviewer along with Human Research Protection Program (HRPP) staff members will also be taking notes.

After the board has had all of their questions answered, Dr. Cogan will thank you for coming and you and your co-researchers are welcome to leave. The board will then discuss the proposal again privately and vote on what should be done. It is most common for the board to vote that your proposal is approved on the condition that your reviewer ensures that the list of changes has been incorporated. Occasionally, the board might vote that the proposal be revised and returned for additional review.

After the meeting is over, your reviewer or an HRPP staff member will email you with the results of the vote and a copy of the list of changes. You would make the changes and email them to your reviewer at your convenience. Your reviewer will check that they are included and will send you an email announcing your approval and ability to collect data. A formal approval letter from the IRB will arrive in approximately a week.

You may also choose to not make the changes the IRB suggests and abandon the project. It is very rare that a researcher spends time creating a proposal and then cancels it, but it is an option you may take.

We hope that this letter gives you a good mental image of what the full board review process entails. If you have questions about the process, please ask your reviewer or contact one of the HRPP staff members.

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Credit for this letter is given to Dr. Angela Eaton, Professor and IRB Member.