

Frequently Asked Questions (FAQ) of the IRB

What, again, is the I-R-B?

The IRB, or Institutional Review Board, reviews and approves research that involves human participants. It is composed of faculty members who are experienced researchers as well as an outside community member and an administrator. IRB members are nominated and then recruited to the committee by the college's Provost. The full IRB committee meets monthly to review applications involving research with human participants qualifying for full review. The IRB does not meet in January, July or August. Applicants will be notified via email of the results within two weeks of the IRB meeting.

Why does it seem that the IRB at Stockton has become more visible?

The Stockton IRB has a Federal Wide Assurance of Compliance (FWA). The FWA is a contract between Stockton and the federal government allowing research involving human participants to take place. Researchers at Stockton must obtain a FWA number in order to apply for federal grants. This number verifies that the research has been reviewed and approved by a certified IRB. Requirements for FWA certification include increased training and certification for IRB members, increased training for researchers applying for IRB approval, paper and electronic documentation of IRB files, and demonstration of outreach to the community.

I am working on my IRB application and I am wondering why the IRB needs to see a literature review?

While the IRB does not need (or want to read!) a 30 page review of your literature, some recent literature is needed to set the context for the purpose of the research. Remember that IRB members are from many different disciplines. You may think that research on handedness and brain lateralization is important, but some people may not even know what handedness is. For this reason the IRB requires a brief review of current literature.

Why does the IRB need to know how I plan to analyze my data? Is that really their business?

It is within the scope of the IRB to verify that the research is sound and is likely to be productive. If no results can be gleaned from the data, the researcher has wasted the time of the participant and the participant has been "harmed" as a result. To this end, the IRB must have some rough idea of how the data will be analyzed.

What is an Informed Consent Form?

Informed consent is a continual process that reminds the participant of his/her rights and discusses the potential harms and benefits of the research. It also reminds the participant that s/he is free to withdraw at any time, without penalty. An Informed Consent Form (ICF) is the actual document that the participant signs to acknowledge that s/he has been told about these rights and agrees to the research. Typically, two copies of the ICF are signed by the participant. One is returned to the researcher and the other is kept by the participant. In situations where the

researcher does not wish to know the identification of the participant (anonymous research) the researcher may not wish to collect a signature. In that situation a check box can be used along with a statement that indicates, “By checking here you acknowledge your willingness to participate.” Please see the web for examples of ICFs. Research that includes children as participants, will require a legal representative to sign the informed consent and the child to sign the assent form.

Why does the IRB need to know where I keep my data?

This is another requirement of the FWA (see question 2) and Department of Health and Human Services (HHS). Stockton is subject to random inspections to insure that data are being stored properly. In order to facilitate this process, the IRB application must document where the data are being stored behind two sets of lock and key.

What are special populations and why do they need special protection in research?

Special populations include: those under court-ordered guardianship, those with compromised decision-making, those under the age of 18, and prisoners. The first three groups of individuals are unable to consent for themselves so special care must be taken to get consent from their guardians, as well as the participants themselves. Prisoners have a history of being abused in research studies, so they have been added to the category of special populations.

I have taken a research class and I know how to protect human participants. Do I still need to take the training and complete the certification? If so, where is the training? How long will this take? Why is this process so annoying?

Yes, all researchers must comply with the federal requirement to document their knowledge and ability to protect human participants. The certification process can be found on the IRB website. All investigators who participate in data collection and analysis for expedited and full review projects are required to undergo certification via the Collaborative Institutional Training Initiative (CITI) software and can be completed on any computer and at your leisure. You can complete the training in one sitting or several, depending on the amount of time you have. When you are finished, save your certificate and upload it to the IRB application. Your certification is valid for two years and can be used on all your research projects.

I understand exempt activities pose no risk to participants, but what is the difference between expedited and full review, specifically?

This question is tricky to answer without any details of the situation. The rule of thumb is the less risk to participants, the lower the level of review. If your data collection method is anonymous, it will most likely fall under “expedited” review whereas someone collecting the same information but using participant identifiers will need a “full” review. It’s best to check out the guidelines regarding expedited activities on the IRB website and then check with the IRB Chair if you are still not sure.

I am working on a project in the classroom. Should I involve the IRB?

Typically, no. The IRB does not and should not involve itself in normal pedagogical activities. However, there are a few circumstances in which the IRB must be involved with classroom activities: publication, non-course content and student-as-researcher projects. See below.

I have found something really interesting in my class and I want to publish it, do I need IRB approval?

If you plan to publish the results of something that you've used in the classroom, federal guidelines require the project to be reviewed by the institution's IRB BEFORE the data are collected. For example, if you use a pre and post test to determine how much students have learned in your course, and you use this only for your own pedagogical purposes, the IRB does not need to be involved. However, if you'd like to publish these results in an educational journal, then IRB approval is necessary. Very often faculty members think it's pedagogical (so they don't get IRB review) and then find something interesting and are disappointed that they can't publish the findings. Because of this the IRB suggests that anything that *may* be published should pass through the IRB, even if it doesn't result in publication.

I need a quick sample of students and I want to use my large Intro class to collect some data. Do I need IRB approval?

Not if the data will be used solely for your own assessment purposes, that falls under pedagogy. But IRB approval is necessary if data are collected about a topic other than your course content or you want to publish the results. Let's say you are the chair of the Student Services Committee and you want to find out how students feel about the food at Stockton. You want to survey a few classes to find out. This is not pedagogical activity, and therefore students who participate in your survey are acting outside of their role as your student. According to federal guidelines, this is not pedagogical activity and, therefore, must be reviewed by the IRB.

My students are really smart and really careful when they do research as a part of their requirements for my course. Do they need IRB approval?

IRB is required for student projects if the student takes on the role of the researcher and collects data on human participants outside of the classroom. Yes, this is pedagogical activity because the students are using this as a tool to learn interview, survey or other techniques, but there are human participants who are not part of the course. These activities need IRB approval. The IRB at Stockton has streamlined this process so that an instructor who teaches this kind of course every term may have an "open" application on file. Once the preliminary application has been approved by the IRB, the instructor only needs to update the application each term by including the new students' methodologies, CITI training, and Informed Consent Forms. This simplifies the procedure for both the Chair of the IRB and the instructor. Unfortunately the federal guidelines don't make a distinction for smart students, faculty, staff or administrators. All must be approved by the IRB.

I am going to look at some archives and write a paper about the civil war. Do I need to involve the IRB?

Is your archival data public record? If so, you do not need to involve the IRB. Public records are available to everyone, so there is no need to seek IRB approval. If the archive is not public record you may need IRB approval. The IRB would need to know more about the archives and more about the actual data you are collecting. If you are not collecting any identifying information on people, then you definitely don't need IRB review.

I've become really interested in cannibalism and I'd like to write my thesis on this topic. I will look at Lexis-Nexis and use newspaper reports to find out as much as I can about the cannibals. Do I need IRB review and if so, which level of review? Exempt? Expedited? Full?

This sounds like a study of existing documents. You do have human participants, so you do need IRB approval. It would fall under exempt review because Paragraph 46.101(b)4 states that exempt review is required for "the collection or study of existing data, documents, records..." If you plan to get records from the police department to clarify or corroborate your findings you will definitely need IRB approval.

I'm working with a local school to study the importance of physical education in the classroom. If I am working at the school, do I need Stockton's IRB to approve the research?

There are many parts to this question. First, the IRB needs to know more about how you are working with the school. Have they already collected the data? If so, and you are analyzing the data to help them out, does the data have identifying information? If so, you would need IRB approval. It would most likely fall under full review (kids are involved and you know sensitive information about them). If the files do not contain identifiers, then you are using previously collected data and the review category is exempt. On the other hand, if you are going to the school and conducting the research with the teachers, you need full review from the IRB. Why? First, you will likely publish the data. Second, you will need parents to sign Informed Consent Forms and documents permitting the release of information from the school to you. Third, you would want the support of the Stockton IRB in case of any adverse events. If you have IRB approval from Stockton, and you have been following the guidelines for protection of human participants, and, despite all efforts, something unexpected happens to a child, legally, you have done nothing wrong. Without such approvals you may be liable for adverse events. Anything involving children will likely need some level of IRB approval.

I plan to interview participants who have learned English as a second language or who don't speak English at all. Should I be concerned about this?

You are right to be thinking about this, but there are only a couple things you need to do to make sure you are protecting your non-English speaking participants. First, your Informed Consent Form should be in both languages. Also, if you are doing a verbal interview, you'll need a foreign language translator (if you don't speak the language!). Finally, if you will have any written information, a survey, recruitment flyer, etc. they will also need to be reviewed in both English and the foreign language when you submit your IRB application.

I want to tape my participants. Is that ok?

Yes, you may record participants using video or audio equipment. However, this will increase the level of IRB review that you will need – you will need “full” review. Since you will be keeping photos, video or audio of human participants you will need to tell the participants some specific details about how you will use these things, how long you will keep them, how they should contact you if they would like you to stop using them, and where you will keep them stored.

Where should I store my data and for how long?

Typically all data collected from human participants should be stored behind two sets of lock and key (in a password protected computer in a locked office or in a locked file cabinet in a locked office, for example). It is also customary to keep data for up to three years and then discard. You are also required to stop using materials if, at any time, the participant requests that you do so. All of these points should be outlined in the Informed Consent Form.

I've heard that I can offer money to my participants in exchange for their time. Is this true? What else can I offer if I don't have money?

Yes, small amounts of monetary compensation are sometimes utilized to recruit participants for more extensive research projects. Up to \$50 may be appropriate, depending on the amount of time they spend with the researcher. If you are giving money to the participants, it must be given to the treatment and the control groups (if you have control groups) and it must be in exchange for their participation, regardless of whether or not they complete the entire project. Meal tickets, transportation expenses, gift certificates or cards are also appropriate and should be used according to the same standards as cash.

I just received comments from the IRB about my application and the IRB made some suggestions. What does that mean?

The members of the IRB at Stockton take the federal guidelines very seriously. So, there may be some points of your proposal that need clarification before it can be approved. Besides for these mandatory changes, the IRB may see something that you missed and may point that out to you. The suggestion may have nothing to do with protection of human participants, but it may make your research better. These are suggestions and the applicant is not required to change these things. One example may be the wording of a question such as “How old are you?” with answers a) under 18, b) 19-24, c) 25-34, d) 36-44, e) 45 or over. If an IRB member sees that you've missed age “35” s/he may suggest that you fix that. It would certainly help your data analysis down the road, but it has nothing to do with protection of human participants.

I've had a great experience with the IRB and I would like my students who conduct research to see the IRB in action. Can they?

We do permit students (and anyone else who seeks IRB approval) to come to the IRB meeting when their application is being discussed. Please let us know in advance if you are interested.