YORK COLLEGE
OF PENNSYLVANIA

IRB Guide for Faculty

This document is designed for faculty who are teaching courses that require students to engage in human subject research.

Projects That Require IRB Review

IRB review is required as a preliminary for all research on **human subjects**. Note, however, that projects that count as research from a disciplinary perspective may not count as research from an IRB perspective. Research from an IRB perspective is **systematic** inquiry that seeks to produce **generalizable** knowledge.

To give some examples, surveys that seek to understand general patterns of human behavior (how people respond to stress, the possible correlation between exam performance and certain beliefs or dispositions, etc.) count as human subject research and require IRB review, whereas marketing studies designed solely to determine whether a given product should be introduced in a particular market would not require IRB review, nor would surveys intended solely to determine student satisfaction with current course offerings. However, if a marketing or satisfaction survey seeks to get at general behaviors or preferences beyond their relevance to a particular product or service then it probably would require IRB approval.

Physical interventions, studies of patient care protocols, collection of organic samples from humans, etc. would count as human subject research if they are intended to improve our knowledge of biology, improve care protocols, etc. but would probably not require IRB research if they were intended only for the benefit of the subjects studied. Study of patient records would probably not count as research if its goal was to improve the health of the particular patients studied, but probably would if the goal was to improve procedures for improving the health of patients who suffer from a particular illness.

Historical investigation does not count as research if the goal is to describe the historical specificity of particular events, but would probably count as research if it is designed to contribute to historical generalizations. But only historical research on living persons counts as human subjects research.

When in doubt as to whether a project requires IRB review, feel free to contact the Chair of the IRB for guidance. The IRB process needs to be completed even for projects that count as "exempt" from IRB review. Our goal is to make the process as painless and helpful as possible, while still meeting our obligations to research subjects.

When Do Students Need to Submit Projects for IRB Review?

Any project that meets the above standards of human subject research must go through IRB review. The IRB process isn't just for professional scholars: since its goal is protecting the rights of research subjects, review is required based on the nature of the investigation, not the identity of the investigator.

You might have one student in a class whose work meets this standard, or you might design a course that requires such research of all students. If you supervise student investigation in independent studies, practica, internships, or other types of non-classroom instruction, IRB review may be required.

How to Facilitate a Smooth and Painless IRB Review for Your Students

Faculty who plan to require human subject research of their students, or assign work that might meet these standards, are requested to contact the Chair of the IRB before the semester begins. There are two reasons why the IRB process might interfere with the schedule you set out in your syllabus: the first is time constraints, and the other relates to the content of applications.

If the Board receives a large influx of applications in a short time, it can be hard for us to meet our internal goals for quick review. It therefore helps us to anticipate when to expect an entire class worth of applications. Our goal is to have the same response time for all applications, regardless of how many we receive at a given time; but advance warning makes it easier for us to plan for simultaneous submission of a group of applications.

The most common reasons why student applications get pushed back for revision are lack of detail in the application (we can't approve an application that lacks enough detail for us to know what the investigator plans to do), and because students haven't always learned strategies for assessing or mitigating the risk of harm. Often these problems can be avoided by setting guidelines within an assignment or by educating students on the IRB process and the ethical issues involved.

If you like, we can consult with you on ways to design assignments that will stand a good chance of quick approval. Sometimes subtle changes in an assignment can make review much easier. Clearly your learning goals need to determine how you run your course, but we may be helpful in finding a strategy that meets your goals while also helping us to do our job efficiently, thereby reducing pressure on you and your students.

Periodically we will publish guidance on certain topics, which amount to strategies for developing research plans that will quickly and easily pass IRB review. In addition, the Board can pre-approve elements of projects ahead of time. Then students can simply reference these

elements in their applications and no further review is necessary for that component of the application. Thus, you can plan ahead for a method of recruiting subjects or develop a stock consent form so that students don't have to develop theirs from scratch.

The Application Process for Entire Course Sections

We recommend the following steps if you plan to assign human subject research in your courses.

1. Consult with the IRB Chair ahead of time to develop assignments that will meet your learning goals and proceed through the review process as smoothly as possible.
2. Give the IRB advance notice of your deadlines.
    a. It can be hard for us to keep to our targeted turnaround time when we receive a large number of applications at once, though this is not a problem if we are given sufficient notice and allowed to prepare for it.
    b. Let us know how long you have allotted between application submission and data collection. We cannot promise to meet your deadlines, but we are more likely to do so if we know what they are.
    c. Let us know if you would like us to begin with certain applications that you think may have more problems or require earlier data collection than the rest.
3. **Give us a list of all your students** we will be receiving applications from. Preferably this would be in spreadsheet form. This can help speed the process considerably and allow us to make sure we have not missed any applications.
4. Collect application materials from your students and forward them to us as a group or, if you have stragglers or applications submitted over a period of time, at least in batches.
    a. **Vet the applications** before you submit them to us. The more you can identify potential problems or incomplete applications, the faster turnaround time we can provide.
    b. Make sure your students are able to submit materials electronically. We can scan hard copies if we have to, but sometimes this causes problems, for example when answers to individual questions are long enough as to requiring scrolling within an answer box in our pdf form.
5. Work with your own students. While we work one-on-one with individual researchers, we prefer to deal directly with faculty when they assign human subject research to an entire course. We can provide you with feedback in batches for a group of students, and leave it to you to communicate our comments to your students. You know your students and consequently know better than we do how to explain certain issues to them.
    a. Vet edits to applications just like you did the original drafts.

While we do not require that you follow these steps, if we have to work directly with each of your students it will likely increase the turnaround time for us to do our jobs, and this might not fit with the schedule you originally set. If you only have one or two students in a class who

need to submit IRB applications, we are happy to work directly with them, as we can with students in independent studies, internships, etc.

Generally we will send an official approval memo for an entire class only after all your students' applications have been approved. Until then we will send unofficial OKs for them to proceed with data collection (and the rest of their research). This is for efficiency's sake. When we sent the OK to proceed, this is acknowledgement that their application has been approved. The official memo is a method for documenting approval, not a speech act that grants approval by its very issuance. Sometimes there may be problems with one or two applications, and in such cases we may send an official memo for the bulk of your students, and deal with stragglers individually or collectively in subsequent memos. In such cases the memos will explicitly reference each other so that readers can know when they have the complete set of memos for a particular course.

The Educational Mission of the IRB

Proper methods for conducting human subject research are worthy learning outcomes for many courses and curricula at York College. Students can benefit from engaging in the IRB process, and we encourage research assignments that require students to submit applications to the IRB. However, you may conclude that the learning outcomes for your course do not necessitate your students actually going through with human subject research.

If you do want to require human subject research of your students, you may wish to scaffold the necessary skills over one or more semesters. Members of the Board can consult with you on course design, and we can even attend a class session and provide your students with an inside look at the process of conducting human subject research.

If you choose to require an assignment that necessitates IRB review, you need to build into your course schedule the inherent uncertainty that IRB review entails. Applications aren't always approved on the first draft, and sometimes we cannot meet the quick turnaround times that we aim for. Also, once an application is approved, modifications need to be reviewed by the Board, and this can add precious weeks at the end of the term if, for example, students can't recruit as many subjects as they had anticipated and need to change their recruitment methods. The more you can prepare your students for this uncertainty, the better results you can expect.

If you want to address the IRB process in course units that do not require original research, for example in an introduction to research methods, you are encouraged to use materials from York's IRB. That way, students will be familiar with our forms and processes if and when they need to engage in independent research with human subjects. However, it is important that students understand the purpose and audience of each deliverable you ask of them. If you ask students to use our forms to draft applications for research they will not actually conduct, as assignments that you will grade as part of your course, make it clear to them that ultimately

you are their audience. This can be a useful exercise when you want students to consider the requirements of research projects on a scale or budget that is not available to them.

However, if you want students to actually engage in research, not simply think through the planning process hypothetically, then you are strongly encouraged not to use our forms as graded deliverables for your course. The IRB is the audience for any applications submitted for our review, and our needs (in terms of the amount of detail or background necessary, citation styles, diction, etc.) may well differ from yours. Students can easily be confused when they have to write for different audiences each of whom has distinct expectations and standards; in fact, this is difficult for any writer.

Sometimes learning outcomes in a course may be best served by a series of assignments rather than a single one. For example, you may ask students to develop a research proposal for a project they will not end up pursuing further in the course, and then give them hypothetical data to analyze for a different project. You can also have students practice data collection through interviews, surveys, focus groups, and other methods without requiring that the results be analyzed; this would count as a course exercise rather than research, and therefore not require IRB review.   By breaking up the steps in the research process in this way you can keep tighter control of your course schedule and also avoid the common problem where students have trouble gathering the amount or quality of data that they had hoped for. Sometimes, of course, the complexity and uncertainty of actual research are part of what you want students to learn, and then requiring human subject research can be very beneficial.

Another point to consider: not all data gathering from human subjects counts as research from an IRB perspective. Sometimes it may be beneficial to frame data collection and analysis in ways that allow students to avoid the IRB process entirely. We definitely do not encourage sophistic attempts to avoid IRB review, but you are encouraged to let your learning goals dictate the scope of your assignments such that when human subject research is called for, you allow sufficient time for training of your students and review by the IRB of resulting proposals; but that you consider non-human-subjects-research exercises when these better meet your learning goals.

To be clear: we encourage student applications to the IRB. We also want to help you devise strategies that meet your objectives for your course, whether that involves IRB review or not; and we need to protect our ability to serve the subjects of research regardless of the needs of investigators or faculty.