



Advice for Student Investigators

The IRB holds everyone pursuing human subject research to the same standards, because our charge is to protect the rights and welfare of subjects. Student investigators are not treated differently than “professionals” in their fields. Once you engage in human subject research you are a professional, and you are expected to act like one. The following advice is targeted specifically at investigators who are still learning how to practice their craft, so students are the primary audience of this document, but everything here applies to all investigators equally.

Only submit complete applications. Make sure you have all your subsidiary documents (consent forms, interview protocols, surveys, etc.) finished and collected before you submit your application. Incomplete applications will not be processed, and submitting materials piecemeal just slows the review process. If possible, save all your materials in a single pdf document; if you don’t know how to do that, include them all in the same email.

Also be aware that issues may be caught in re-readings of your application that were missed the first time. Thus, if you send in an initial application and receive feedback that requires clarification on your part followed by a second reading by us, we may comment on things in the second version that we overlooked initially even though they were in your initial application.

Submit all materials electronically. Occasionally students have trouble with the IRB application form. Make sure you save the pdf form to your computer before you begin completing it, and then use a version of Adobe Acrobat to answer the questions. Other software programs, such as Preview for Apple computers, may result in text that you have entered not displaying. We store all our records electronically, so we really do need all materials in machine-readable formats. In fact, we accept only Word or PDF formats. If you absolutely cannot fix problems you are having with our forms, you can scan a printed copy and then save as it in pdf format. In the worst case, we can scan hard copies for you. Also, be aware that hard copies tend to get misplaced in ways that electronic copies don’t, and they tend to be the last applications read. It’s better to ask for help in completing our form than to make us scan a hard copy for you.

Audience and the rhetorical situation. Your IRB application isn’t a course document, even if it is being submitted for research that is conducted for a course. The audience for your application is the IRB. We don’t know what went on in your course and we may not be specialists in the topic you’re studying. However, we do understand how research gets conducted, and all Board members have at least some background in statistics, experimental design, etc. Don’t condescend to us, but **explain things**. The most common reason that we send back students’ IRB applications for further work (besides being incomplete) is that they often do not give us enough information to know what the student intends to do.

Make sure you tell us everything we need to know. The questions asked on the application are designed to serve as prompts, to give you an idea of the things that need to be addressed. A satisfactory application is not just one that has something written in every field. Your application needs to tell us a story, namely, what you intend to do and why you intend to do it. If there are things we need to know, find a way to get them into your application. So the prompts in individual questions should give you a good starting point, but once you've produced a draft of your application, read through it to make sure you've said everything you need to say. Also, think about the order in which you say things. The form allows for somewhat repetitious presentation of material. Some repetition is alright, maybe good, but too often students who are still learning to be researchers repeat the same sentence or two over and over throughout the application. If you find yourself doing this, it probably indicates that you're misunderstanding the questions. They really do ask about different facets of your research, and should elicit different types of information. The question about the purpose of your study is a good place to provide a nice overview of what you intend to do and why.

Understand what we're looking for. The IRB is concerned with the protection of human research subjects. It's not our job to weigh in on whether your research is valuable (except to the extent that we have to balance it against risk to participants), whether your methods will yield reliable results, or whether we like what you're doing – and in fact it would be improper for us to consider these issues in evaluating your application. (That said, we are human, and occasionally we may make a passing comment about matters that do not enter into our deliberations.) We need to have some context for what you're doing, and that's why we ask about the purpose of your study. The best applications are the ones that address the issues we need to see addressed, and don't focus on details that may be of interest to your instructor, but don't relate to human subject protections.

Think the details through ahead of time. As a rule, the IRB application will contain complete protocols for how research will be conducted: knowing what questions you will ask in interviews or surveys often is very important for our being able to understand the reputational or informational risks your research might pose for subjects. Likewise the actual clinical procedures you will perform affect the physical harm subjects may suffer. Don't wait to work out these details until you are ready to collect data: you need to work this out ahead of time in order to get approval from the IRB. Knowing what details to include will help you get your application approved more quickly.

When to submit a modification. Once your application has been approved, you are expected to stick to every detail of what you said you would do. If you find that you need to make a change in your procedures, you need to submit a modification to your original application, and until that is approved you should not continue data collection. (There are exceptions for immediate risks of harm that occur in clinical settings, but York students will almost never have to deal with those situations.) Therefore it is in your best interest to anticipate problems so that you don't need to seek approval for modifications.

However, if you need to modify your original application, you have to do so. The twin requirements of needing to provide detail in your application, and needing to follow through on those details, mean that you need to anticipate potential problems when you are first designing your research. What will you do if you have trouble recruiting subjects? What if a subject suffers a medical emergency during moderate exercise, or suffers from an allergy that you did not screen for? You need to think not just about what you want to happen, but also about what might happen.

Don't get personal. Personal reasons don't count as reasons from an IRB perspective: the IRB application is not the place to provide personal reflections such as why you find a topic interesting or what you want to gain personally from engaging in a particular research program. In contrast, reasons that should be given on an IRB application may include: that there are gaps or inadequacies in the existing literature on the topic; because previous work needs to be validated or reproduced; because results need to be checked with different populations. The importance of a problem can also be relevant to why a particular research program is needed: illnesses or disorders that affect large populations, or which are particularly debilitating, tend to get more extensive study than some others, and there is justification for this. Consequently, the extent or significance of a problem may contribute to the need to study it, and thus can reasonably be addressed in an IRB application, though this is never a sufficient reason to pursue a problem.

Don't overstate the positives. The application asks you to balance the benefits of your research with the risks it poses. This question is important, and please take it seriously. Most research chips away at what we know about the world, and studies that are truly transformative are generally hard to pull off and highly complex. Often students will leap quickly from the importance of the topic to grand claims about the value of their work. Don't do that. If you have a small subject pool and develop the questions you intend to pursue rather quickly, the chances are that your results will be hard to generalize. That's fine, that's how research gets done. Just don't make claims for your study that exceed what you can actually learn from it. And similarly don't underestimate the risks your research involves. Much student research involves a balancing between small quantities: marginal increases in our knowledge of the world against small risks as a result of your seeking answers to questions. The more you appreciate this, and can express it clearly, the better your chances of having your application approved.

On a related note, sometimes students emphasize the personal value to subjects of engaging in research. Only say that your subjects will benefit from your intervention (or survey, etc.) if they really will. Some research is directly worthwhile to subjects, but other research may be of value to society at large, by increasing our understanding of the natural or social world, but doesn't directly benefit subjects. Again, you will do well to think critically about the claims you make and ensure that you adequately balance potential benefits and harms.

Subject protections. The IRB is charged with understanding the harms that your subjects may suffer, and the risks of harm even if no harm results. After identifying these, we look to see how well you protect your subjects. Protections need not be absolute: we don't expect that there will be no risk of harm, just that harms and risks are adequately identified and accounted for. The greater the harms and risks your study may subject your subjects to, the greater need for corresponding protections. It is absolutely essential that you understand these issues, or else your application will probably not be approved.

Things to consider. There are some issues that all or at least most investigators will have to consider as they design human subject research.

Age. Anyone under 18 years of age (and in some cases 21 years) is legally a minor. As a rule, minors cannot consent legally to serve as research subjects and a parental waiver is necessary. In most cases, therefore, it is best to screen out minors and not use them as subjects. For some research, however, the use of minors (or other special populations) as subjects is essential. In that case you need to attend especially carefully to the issues that your subject population requires.

Opportunity cost. Whenever we have choices, accepting one option may mean that we have to do without the alternatives. This means that the cost of foregone actions needs to be taken into account when considering the harms to research subjects. An afternoon spent in your lab means less time for student subjects to study or relax by watching television. Even the five or ten minutes students take in a class filling out a survey form is five or ten minutes they don't have to learn the material they enrolled in the course for. You always need to be aware of the opportunity cost that participation in your study entails for your research subjects. Identify these accurately in your application, and include estimates of the time your study will take in any informed consent documents you write.

Informed consent. An essential aspect of human subject research is the belief that persons have the right to choose freely whether or not to participate in a particular research program. This means two things: that they understand what they are being asked to do, along with the harms and risks that participation might entail; and that they be able to decide whether or not to participate free of coercion. This choice needs to be documented in something called an "informed consent form," but more importantly, investigators need to ensure that potential subjects actually are able to base their consent on a reasonable understanding of what they are consenting to. The goal of the informed consent process is the not getting the form completed, but rather the communication and assent that the form documents.

Thus, things that are sure to get an application rejected include: not taking proper account of the age of potential subjects, not identifying and communicating the opportunity costs of participation in addition to other harms and risks, not including an informed consent form with your application (or an argument why the form is not necessary), and not having adequate procedures in place for ensuring that consent is in fact informed and free of coercion.

Don't avoid a topic because of the IRB. This is so important it occupies a privileged position in this document: it's the last topic we mention and the culmination of what we've already said. Dealing with the IRB takes time, and seems overly bureaucratic. We in the IRB don't want to make the process so onerous that we drive investigators to change the research they're doing, to take on a project that's easy to get approved instead of one that is more worthwhile to pursue. Research on special populations such as children or the indigent is important, and the protections designed to safeguard the rights of the people you want to help through your research shouldn't get in the way of doing this kind of research. Similarly, surveys about people's favorite color or favorite ice cream are easy to get approved, but may not be of much value. But studies of sexual issues or drug use can actually improve society, and should be encouraged when done responsibly. We'd much rather work with you to develop studies that are harder to plan, but more valuable to pursue; and we hope that you're willing to put the time and effort into developing projects that matter.

A Brief Glossary. The following terms are used throughout the IRB's documentation and forms, and it may be worthwhile to explain or define them here.

IRB = Institutional Review Board. This term is used both to refer to a process for review and oversight of human subject research at an institution, and also to the collection of people who oversee this process. Sometimes the latter is referred to as the "Board."

PI = Primary Investigator. The lead researcher for a given project. One person (or occasionally several) is typically designated a primary investigator for any research project. Primary Investigators have additional responsibilities not shared by other members of a research team.

Version 4-17-15