The Student Researcher and the IRB: Separating Fact from Fiction to get you started

IRB stands for Institutional Review Board; this is the oversight for human subjects protection and approval from the IRB is required when conducting research using human subjects, including their information, biological samples, etc. Not every project needs IRB approval, but be advised that most do (clinical research, survey research, educational research, even chart reviews may need approval).

The most important point to remember is that you cannot make the decision whether or not your research is subject to IRB approval. It is better to submit and have it exempted , meaning they have concluded you are conducting a project that is not human subjects research and is not subject to IRB approval. It is better to be safe than sorry in this matter. Many of your projects will be expedited (given the fast track for approval). Importantly, even if you will be part of an approved project, you will need to be added to the project in order to work with patients or data.

SUMMER RESEARCH students must demonstrate IRB approval for their projects, if appropriate.

Here are a couple of misconceptions and the factual information.

Fiction: As a student, you cannot work on the IRB application form.

FACT: You cannot submit the form for approval, but you can and should help prepare the application. You can complete quite a bit and then have your mentor review and submit the application. To gain access to the system, called SpartaIRB, you must be a registered user. This only occurs by completing the "SpartaIRB New User Request" found on the SpartaIRB Info website:

https://case.edu/research/faculty-staff/education-and-training/spartairb-info.

Once access has been granted, log in at https://spartairb.case.edu with you CWRU ID and password.

SUMMER RESEARCH students must complete the basic CITI training for the conduct of research. You will complete the Social and Behavioral training tract (Group 2). This is one of your payment benchmarks.

Here is the direct link to the page where can start the initial certification. **The ONLY way to enter Case Western Reserve University's CREC Program (and be on the IRB application) is through successful completion of the CITI BASIC course.** http://www.case.edu/research/faculty-staff/education/crec/

Once you are registered, you'll log in and have a personal page where you can start a new project. This opens the electronic application. You have to answer every question in order to move to the next page (somewhat frustrating if you are new and don't know what's coming).

 **Fiction:** Chart reviews don't need IRB approval because of signatures on the patient clinic forms.

FACT: That is not true. You may have to submit an IRB application on the project because you are requesting a waiver of consent to use the chart data. The patient's signature on a SODM form – even if the form states that their data may be used for research purposes – does not replace the IRB approval requirement.

 **Fiction:** It takes forever to get approval.

FACT: Yes, it can take a while, but there are ways to help yourself and help get approval more quickly. Start early; answer the questions completely; use the proper templates for your protocol and informed consent, if needed. Don't be sloppy or evasive in the answers. When the IRB responds and asks for further information, don't ignore them. Maybe you just need to clarify, add details, or a clearer document. There are a number of documents, including Informed Consent, protocol, waiver of HIPAA, copies of surveys/questionnaires, flyers/advertisements, etc. that you may need to submit. Be sure to include everything related to your project.

To help with some of the most common problems that crop up with IRB submission, student protocols will go through a pre-submission review by Dr. Catherine Demko to help identify any common mistakes or omissions in the submission which can prolong the review process. Details can be found here. Please contact Dr. Demko with any questions.

 **FICTION:** It is very confusing to complete and submit the form.

FACT: Like most things, the first or second time you prepare an IRB submission, it can be challenging. The best tips I can give you : 1) Answer all of the questions completely and use minimal scientific jargon. Chances are the person reviewing your protocol will not be a dentist, so be sure to use clear language; 2) Be sure to upload all documents for your project. The protocol template is required for all submissions, but depending on what type of project you will be doing, you may have others like an informed consent, a waiver of HIPAA protections, a questionnaire with cover letter, and others. If it's something that will be seen by your subject cohort, it needs to be included. 3) The SpartaIRB Library contains many documents with instructions and help for your submission. Please take a look and follow directions carefully.

As a member of the CWRU campus, we only deal with the Case IRB.

FACT: Generally that is true, but there are exceptions. The Case IRB will review the majority of submissions from the SODM. But if you are involved in a project that requires access to UH patients, employees, or data, you will need to submit through the UH IRB office. The good news is that you only need approval from one IRB. If you're unsure on which IRB you should use, speak to Dr. Demko.

Fiction: Since I am a student, I do not need any human subjects training.

FACT: You will need to be CITI certified as described above. This is online basic training in human subjects protection, taken at your convenience, but an IRB will not be approved until all members of the study team have been certified

Your mentors will be the best source of advice and help, but don't hesitate to speak with the IRB directly or you can ask Dr. Demko to help get you started.