**![C:\Users\cad3-admin\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\YRW3XG56\MC900048534[1].wmf]() 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.**

**![C:\Users\cad3-admin\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\X1MOLW6Q\MC900441902[1].wmf]()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 IRIS, you must be a registered user. This only occurs by emailing or phoning the IRB, per the instructions on the webpage.

<https://cwru-iris.case.edu/>

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).

**![C:\Users\cad3-admin\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\X1MOLW6Q\MC900441902[1].wmf]()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 application on the project because you are requesting a waiver of consent to use the chart data. This is something you need to talk to the IRB about.

**![C:\Users\cad3-admin\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\X1MOLW6Q\MC900441902[1].wmf]()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 templates for 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 that you may need to submit. Surveys need to be completed and submitted with the application.

**![C:\Users\cad3-admin\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\X1MOLW6Q\MC900441902[1].wmf]()FICTION:** It is very confusing to complete and submit the form.

**FACT**: the first or second time, it can be challenging. The best tips I can give you : 1) ALWAYS look in the top right corner for the save and continue button – your work will be saved and you can pick up where you left off the next time.; 2) Uploading and attaching documents are 2 different and separate steps; both must be done; 3) even after the submit button, be sure to scroll down on the screen and be sure there isn’t another submit or approve button. Sometimes you think you are done and you are not.

**![C:\Users\cad3-admin\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\X1MOLW6Q\MC900441902[1].wmf]()**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 is about social and behavioral interventions and observational studies. But you may be involved in a project that requires a submission to the UH (University Hospital) IRB. This is true if you intend to survey, interview, collect data from UH employees or patients. Also, any project that is invasive or involves providing a medical or biological intervention will likely require the UH IRB. The good news is, you only need approval from one IRB. If you’re unsure on which IRB you should use, speak to Bridget Patrick (School of Dental Medicine Research Compliance Officer) at 216-368-3948 or bridget.patrick@case.edu or Sue Ambro at the CWRU IRB at 216-368-6993.

**![C:\Users\cad3-admin\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\X1MOLW6Q\MC900441902[1].wmf]() 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. If you deal with patients personally (interviews, for example) or identifiable data, you MUST do this.

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.