Oakland University - Reference Guide for Creating/ Submitting Your Initial IRB Application

Work with your mentor to create and review your IRB documentation prior to submission. One of the Medical Education Directors will review your entire IRB package prior to obtaining signatures.

YOU MUST HAVE A CAPSTONE PROJECT PROPOSAL APPROVED BY THE CAPSTONE COURSE DIRECTORS (DRS. BAXA & SAWARYNSKI) PRIOR TO SUBMITTING YOUR IRB.

(1) After logging in to IRBNet (see registration instructions if you have not set up your IRBNet account), click on *Create New Project* on the left hand navigation bar.

(2) Enter your study information (title, etc.) in the project information box (**Note, your title can be edited at a later date!)

(3) Click on *Forms and Tools* on the left hand navigation bar to download the appropriate forms for your project.

(4) ALL projects will need the following forms:
   a. Application – Exempt, Expedited, or Full Board Review (Check with your faculty mentor or Capstone Director if you are not sure which form to use)
   b. CITI training completion documents for all key personnel (**Note, these can be uploaded to the IRBnet user profiles – see registration instructions)
   c. Conflict of Interest Disclosure (COID) forms (one for each person listed as key personnel)
   d. Data collection tool or list of variables

(5) MOST projects will need the following:
   a. Information sheet or consent form(s)
   b. Appendices and/ or waivers (if applicable – refer to your IRB application and/ or mentor and director to determine if you need additional appendices or waivers)

(6) Send your completed IRB and accompanying documentation (informed consent, appendices, etc) to your mentor for review and comment. Send final documents to the appropriate Medical Education Director (see below) for final revisions and to facilitate the signature process (every application requires signatures from the Department Chair, Dr. Venuti. If you as the student are the PI, it will require faculty adviser, department chair, and dean signatures).

(7) When you've completed the required documentation and have obtained appropriate signatures, upload all applications and forms to your project under *designer.*

(8) Once all forms are uploaded, click *share this project* and search for your mentor and all key personnel on IRBnet. Share your IRB Package with EACH person. (To do this, all must be registered and have their CITI documentation uploaded. See registration instructions). **Note – if you have Beaumont physicians on your Oakland University IRB, they do not have to register in IRBnet unless they are co-investigators. You WILL need to obtain their CITI training documents to add to your IRBnet package if they are not on IRBnet.

(9) After you've shared your IRB Package with each member on your team, you will need to link their CITI documents to your project. In the *designer* screen, after you've uploaded your required documentation, click the link on the bottom of the screen that says "link CITI training credentials." Click on the name of all of the people involved in your study.

(10) After all documents are uploaded in to your IRB package, the PI must sign the package. Click on "Sign this package" on the left-hand navigation. If the student is the PI, both the PI and the faculty adviser/ mentor must electronically sign the package.

(11) To submit your package, go to *my project (left hand side)* and click on *Submit (left hand side).*

Medical Education Directors

Director of Education Training – Rose Wedemeyer, PhD – ragutier@oakland.edu (school/ education projects)
Director of Research Training – Tracy Wunderlich, MA – wunderli@oakland.edu (clinical projects)
Director of Service Learning – Jean Szura, PhD – mick@oakland.edu (community based projects)