MEDICAL STUDENT RESEARCH OFFICE

OBTAINING IRB APPROVAL FOR HUMAN SUBJECTS RESEARCH: FREQUENTLY ASKED QUESTIONS

1. DOES MY PROJECT NEED IRB APPROVAL?

All human subjects research requires IRB approval. This includes projects involving direct patient contact, but also many projects that propose the use of human specimens or data, even those that have been previously collected. Because it is often unclear from the project abstracts, all research involving the use of human specimens or data must be discussed with the IRB to make this determination.

2. MY PROJECT IS ALREADY APPROVED BY THE IRB. WHAT DO I NEED TO DO?

Even if you are being added to a previously approved IRB, you must complete the following before you are allowed to participate in the research:
   (1) Complete all required IRB training (box A)
   (2) Submit an amendment/personnel change to be added to the project
   (3) Complete the conflict of interest forms (box B)

Detailed instructions to submit the amendment can be found on the IRB website. http://www.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/researchers-palette/request-to-modify-a-study

NOTE: If you and your mentor agree that you should be designated as a research assistant, which is usually appropriate for summer research, you will not need to submit to the GCO. If you and your mentor decide that your participation is more consistent with the role of co-investigator, you will also need to notify the GCO that you are being added.

A. REQUIRED IRB TRAINING

In order to participate in a new or ongoing project approved by the IRB, you are required to complete basic training in human subjects protection (“CITI” training), data security, and HIPAA for research. Instructions and a link to these courses can be found online.

You do not have to do the modules all in one sitting, but they take some time to complete so it is advisable not to leave this until the last minute.

http://www.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/education

3. HOW DO I SUBMIT A NEW PROJECT TO THE IRB?
You must complete the following **before you are allowed to begin the research:**

1. Complete all required IRB training (box A)
2. Complete the conflict of interest forms (box B)
3. Submit a new proposal to the GCO (box C)
4. Submit a new proposal to the IRB/PPHS
5. Receive documentation of IRB approval


**4. WHAT DO I NEED TO DO AFTER THE SUMMER?**

When your project is completed, your mentor must file a Final Report with the IRB (HRP-212). If you don’t close your study, your mentor may have all of their other studies suspended.

**B. CONFLICT OF INTEREST FORMS**

All members of the research team must complete a financial disclosure form on Sinai Central, a website maintained by the finance office ([https://sinaicentral.mssm.edu/](https://sinaicentral.mssm.edu/)).

- If you are being added to an existing protocol, your mentor will need to add you to the investigator form in Sinai Central. You should then receive an email prompting you to log in and complete the Financial Disclosure form. Complete your annual report first, which will then populate the disclosure form. For projects submitted before the GCO moved to online submission, you may be asked to sign a paper form ("GCO 6") instead.
- If you are submitting a new protocol, you or your mentor will need to start a new investigator form online. Make sure to include ALL members of the research team.

**Login:** Select “Sinai Central Login” ➔ “Login or Password Help” ➔ “I want to log in now.”

If you are unable to log in, please contact the MSRO.

**Complete your annual report:** “COI” ➔ “Annual Report of Outside Relationships”

**Start a new investigator form:** “COI” ➔ “Investigator Forms” ➔ “New Investigator Form” Make a note of the “IF” number, since you will need it later.

**C. GRANTS AND CONTRACTS (GCO)**

In most cases, your mentor should initiate the GCO submission online in InfoEd. If you want to help with this part, you will need InfoEd training in order to gain access. Technical support and course schedules are available by emailing [infoed@mssm.edu](mailto:infoed@mssm.edu) or online at [http://eolas.mssm.edu/e-learn/](http://eolas.mssm.edu/e-learn/)

**5. ADDITIONAL RESOURCES AND HELP**

Staff familiar with the process is available to help you with each of these requirements.

**Office of Clinical Research (OCR):** If you have questions that your mentor isn’t able to answer, the OCR is offering one-on-one assistance. You may sign up for an appointment in the Medical Student Research Office, Annen 13-30.

**IRB** (212) 824-8200; 3 East 101st Street, 1st Floor (between Madison & Fifth)
You should refer to the “frequently asked questions” online before calling the IRB.
http://www.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/faqs

GCO (212) 824-8300; 3 East 101st Street, 1st Floor