

MountGCOApplicationSubmissionProcessforHumanSubjectStudiesSinaiWithout External Funding:Which Applications and Forms Do I Work on First?

GCO Submission Policy

- If the Program for Protection of Human Subjects (PPHS) IRB has provided a three year, expedited approval and there is no external sponsored project funding (e.g., ISMMS, industry clinical trials negotiated by FACTS, and cooperative trial research projects,) GCO submissions are required every three years.
- 4 All other unfunded human subject research projects are submitted to the GCO annually.
- Step 1: Create the Investigator Form (IF) in <u>Sinai Central</u>. The project will be given an automatically generated IF #. Click <u>here</u> for IF instructions.

Remember to include the IF # in the eForm entitled "New/Comp Renew/Resub" or "Non Comp/Supp/NCE" of your InfoEd application. Once you answer the questions on the Investigator Form, a Conflict of Interest (COI) form will be generated for each investigator to sign. The investigators receive a notification by email to sign the COI form.

The IRB and the GCO require the IF # so please do create the Sinai Central Investigator Form (IF) as the first step in this process. Begin and continue to track whether all the investigators have signed the form throughout the submission process.

Step 2: Start your IRB Application.

- **Step 3:** <u>Start</u> your GCO application in <u>InfoEd</u> so that it is assigned a PD#. IRB will reject your IRB application if you have not <u>started</u> your GCO InfoEd application.
 - Click <u>here</u> for the InfoEd Set Up tab Instructions (i.e., the initial technical step in starting your GCO application) for <u>new</u> projects. Click <u>here</u> for instructions for yearly renewals.
 - Click <u>here</u> for instructions on completing other Info Ed tabs.
 - Use GCO's Application Submission <u>Checklist</u> (2 pages) and <u>Instructions</u>. Follow Application Submission Checklist Steps # 1 (InfoEd class required – 1 time only requirement), 2-4, 7-11, 15, and 20 (IRB application required for non exempt projects*) for a successful GCO submission.
- **Step 4:** <u>Submit</u> your IRB application.
- **Step 5:** <u>Submit your InfoEd application</u>. Once the PI approves the application in InfoEd, the InfoEd application is routed to the departments for approval and then to the GCO. Note that GCO will issue you a receipt and review your application 1) after all investigators sign a Conflict of Interest form and 2) after checking that you have indeed submitted an IRB application.

Remember to complete these steps each year of the project.

Have Questions?

<u>Technical Info Ed Support - Research IT</u> I <u>Pre-Award Contacts In Mount Sinai's Depts</u> I <u>Contacts In GCO Assigned to Mount Sinai's Depts</u>

*If you believe your project may fit into a category for exemption from IRB review, please click <u>here</u> for IRB instructions.