GCO Application Submission Process:
Which Applications and Forms Do I Work on First?

Step 1: Create the Investigator Form (IF) in Sinai Central. The project will be given an automatically generated IF #. Once you answer the questions on the Investigator Form, then Conflict of Interest (COI) forms, (and Suspension and Debarment forms for federal and state sponsored research only) will be generated for the investigators to sign. The investigators will be notified to sign the form(s) by e-mail.

The IRB, IACUC, and GCO all require the IF # (for IACUC, on unfunded studies only) so please do create the Sinai Central Investigator Form as the first step. Begin and continue to track whether all the investigators have signed the form throughout the submission process.

Step 2: Start your IRB and/or IACUC application, as appropriate. See “important information” section below for GCO’s IRB/IACUC application submission requirements.

Step 3: Start working on your GCO Application in InfoEd so that it is assigned a PD#. If your project involves human subjects, IRB will reject your IRB application if you have not started your GCO InfoEd application.

Step 4: Submit your IRB and/or IACUC application, as appropriate. See “important information” section below for GCO’s IRB/IACUC application submission requirements.

Step 5: Finalize your Extramural Funding Agency application, if appropriate, and your InfoEd application. Once the PI approves the application in InfoEd, the InfoEd application is routed to the departments for approval and then to the GCO. Remember to attach your Extramural Funding Agency application in InfoEd, if appropriate. Note that GCO will issue you a receipt and review your application 1) after all investigators sign the Sinai Central forms and 2) after checking that you have indeed submitted IRB/IACUC applications. See “important information” section below for GCO’s IRB/IACUC submission requirements.

Step 6: Submit your application to the extramural funding agency only after the GCO approves it. Only in the case of InfoEd “System to System” applications (e.g., competitive NIH / other federal grants) or other electronic systems where GCO is the last step, will GCO submit the application for you. Otherwise GCO will return the extramural application to you for mailing or let you know that it is OK to send.

Is there other documentation that can be started at different places in the process? Yes!

- For industry sponsored clinical trials, please submit or have the company submit the Clinical Trial Agreement (CTA) to FACTS@mssm.edu for review and negotiation as soon as possible. Ideally, FACTS would like to receive your CTA right after IRB submission.
- The GCO understands that you may be working on the Extramural Funding Agency application, if applicable, weeks or months before starting the internal submission process.

Important Information on GCO’s IRB/IACUC Application Submission Requirement!
Always submit compliance (IRB/IACUC) applications to the respective offices for internally funded or industry projects (unless it’s a competitive peer reviewed project), non-competitive applications, transfers, and no cost extension projects.

You do not have to submit IRB /IACUC applications if: 1) the funding agency has a two step review process that allows a Just-In-Time (JIT) review by the ISMMS compliance committees at a later date or 2) the Compliance (IRB/IACUC) Application Waiver Form has been included in your InfoEd application. The waiver does not apply to applications in the above paragraph. Also, for delayed on-set studies where human subject or animal activities are scheduled to begin after a period of funded protocol development please just include a memo explaining the timeline rather than the waiver with your InfoEd application.

Use this 1-pager alongside GCO’s Application Submission Checklist (2 pages) and Instructions for complete information on the submission process.

Remember to complete the steps above each year of the project.