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 complete the form, a Conflict of Interest (COI) form, and Suspension and Debarment (S&D) form for federal and state sponsored research only are generated for each investigator you included to sign. The investigators receive a notification by email to sign the COI form (and S&D form if applicable.) The IRB and IACUC 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 each investigator has signed their form(s) throughout the submission process.

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

Step 3: Start your GCO (research and/or sponsored project) 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 InfoEd.

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

Step 5: Finalize your Extramural Funding Agency application, if appropriate, and submit 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.

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 I can start at different places in this process? Yes!

For industry sponsored clinical trials, please login to Meditract to submit the clinical trial agreement (CTA) to the Financial Administration of Clinical Trials Services (FACTS) Office for review and negotiation as soon as possible. Ideally, FACTS would like to receive your CTA right after IRB submission. Visit the FACTS site for more information about Meditract.

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 funded 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 form cannot be used for applications in the preceding bullet point. For delayed on-set studies where human subject or animal activities are scheduled to begin after a period of funded protocol development, do not include the waiver form. Do include a memo with your InfoEd application explaining the timeline.

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.