Mount Sinai

rev. 1/2020

Grants and Contracts (GCO) Application Submission Process: Which Applications and Forms Do I Work on First?

GCO Submission Policy

Most research and sponsored project applications are prepared in InfoEd and routed for approval through the department(s) in which there are key personnel each year of the project. There are very limited exceptions.

- **Exception to InfoEd Submission – BRANY Projects**
  Do not submit the project to the GCO if BRANY serves as the IRB and also negotiates the clinical trial agreement on behalf of Mount Sinai.
- **Exception to Yearly Submission – Expedited IRB Projects Without External Sponsored Project Funding**
  If the Program for the Protection of Human Subjects (PPHS) 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 also only then required every three years.

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. Note: See the GCO Submission Policy above and the "Important Information" section below for more information.

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. Same note as in Step 2.

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.**

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, single project NIH and 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 submission 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!

- For competitive (i.e., new, competitive renewal or resubmission) sponsored projects that are not NIH*, you can submit the compliance application to the appropriate compliance office as part of this process or you can complete the compliance waiver and attach it in the Internal Documents tab of your InfoEd proposal. You will then submit the IRB/IACUC application to the respective office once you find out the funding agency intends to fund the project.

- For NIH sponsored competitive projects, or if 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, you can submit the compliance application to the appropriate compliance office as part of this process or submit later. A compliance waiver is not needed with your GCO application. For NIH applications, you will then submit the IRB/IACUC application to the respective office once you find out whether your application is in the fundable scoring range. For all others, you will submit once you find out the funding agency intends to fund the project.

**The waiver form can only be used for applications described in this bullet point. It cannot be used, for example, for unfunded studies or for PIs transferring sponsored projects to Mount Sinai. 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 document 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.