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Grants and Contracts (GCO) Application Submission Process: Which Applications and Forms Do I Work on First? Step by Step Instructions for Sponsored Projects

GCO Submission Policy

All sponsored project applications and a subset of ISMMS supported projects are prepared in InfoEd and routed for approval through the department(s) in which there are key personnel <u>each year</u> of the project. Please click <u>here</u> for complete information.

- Step 1: Create the Triggering Event (TE) in <u>eDMS</u>. The project will be given an automatically generated TE #.
 Once you complete the TE, the investigators added receive an email notifying them to answer Conflict of Interest (COI) Research Trigger questions.
 Begin and continue to track whether each investigator has answered these questions.
- **Step 2:** <u>Start</u> your <u>IRB</u> (human subjects) and /or <u>IACUC</u> (vertebrate animals) application, as appropriate. See "GCO's IRB/IACUC Application Submission" section below for more information.
- Step 3: Start your GCO (sponsored project) application in InfoEd so that it is assigned a PD#.
- **Step 4:** <u>Submit</u> your <u>IRB</u> and /or <u>IACUC</u> application, as appropriate to these respective offices. See "GCO's IRB/IACUC Application Submission" section below for more information.
- Step 5: Finalize your Extramural Funding Agency application, if appropriate, and <u>submit</u> 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.
 - Note that GCO will issue you a receipt and review your application 1) after all investigators complete the eDMS COI Research Trigger questions and 2) after checking that you have indeed submitted IRB/IACUC applications, as appropriate. See "GCO's IRB/IACUC Application Submission" section below for more information.
- 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. Effective 1/1/2024, new industry sponsored clinical trials with no competitive review process are no longer submitted to the GCO.
- ♣ 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.

GCO's IRB/IACUC Application Submission Requirement

- For <u>competitive</u> (i.e., new, competitive renewal or resubmission) sponsored projects that are <u>not NIH</u>*, you can submit the compliance application to the appropriate compliance office as part of this process <u>or</u> you can complete the <u>compliance waiver</u> 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.
- For <u>all</u> transfer, non-competitive, and no cost extension projects, check whether you are submitting a compliance application to the PPHS and/or the IACUC every year or every three years.

Use this document alongside GCO's Application Submission <u>Checklist</u> (2 pages) and <u>Instructions</u> for complete information on the submission process.

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

^{*}The compliance waiver form <u>can</u> only be used for these types of applications. 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.