

ISMMS Workflow Improvements Does My Project Need to be Submitted to the GCO?

Process

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

What is an ISMMS Project?

These are research projects in which the Icahn School of Medicine at Mount Sinai (ISMMS) is not receiving external sponsored project funding to carry out the associated activities.

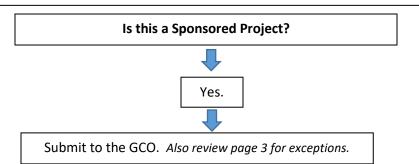
Research is defined as systematic investigation designed to develop or contribute to generalizable knowledge. Activities meet this definition, even when the overall purpose is not primarily research, but may include training, demonstration, or service programs.

What is a Sponsored Project?

A sponsored project is defined as an externally-funded activity in which a formal written agreement (i.e., a grant, contract, or cooperative agreement) is entered into by Mount Sinai and the extramural funding agency generally after a competitive peer review process.

Other types of projects that are submitted to the GCO are industry sponsored projects in which there typically is no competitive peer review process.

Yes. Proceed to page 2 to determine.



ISMMS Projects – Continued from Previous Page

Will your project also be submitted to the PPHS (i.e., human subjects protection committee) or IACUC (i.e., vertebrate animal care and use committee)? No. Yes. Is there a research related agreement that needs to be signed by the Submit to the GCO. GCO? Examples of agreements the GCO signs are data transfer use agreements and study drug donation agreements. For a complete list of agreements the GCO signs, consult the Agreement Navigator. All ISMMS projects that are not submitted to the PPHS or IACUC must be submitted to the GCO via InfoEd. Yes. No. Submit to the GCO. Do not submit to the GCO.

Although the ISMMS project must be submitted to the PPHS and/or IACUC, GCO also needs a corresponding InfoEd record for the agreement it signs.

Sponsored Projects – Exceptions to GCO Submission

1.

Do not submit the project to the GCO if BRANY (Biomedical Research Alliance of New York) serves as the IRB and also negotiates the clinical trial agreement on behalf of Mount Sinai.

2.

Do not submit the project to the GCO if this is a Cooperative Research Group project.

Cooperative research group projects are studies where the overall funding is provided by the NIH either directly or through a subaward and then the Institution is asked to carry out multiple individual clinical studies, which do not have separate applications or budgets. The overall funding continues to go through GCO, but the *individual clinical studies* do not require GCO submissions.