

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?

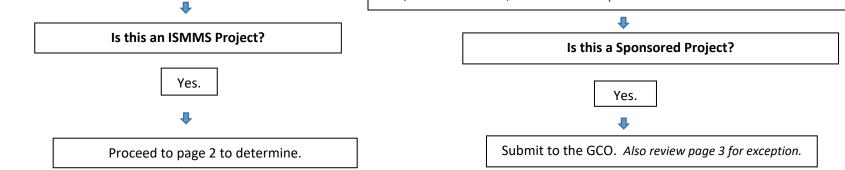
These are research projects in which the Icahn School of Medicine at Mount Sinai (ISMMS) is not receiving external sponsored project funding to carry out the associated activities.

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.

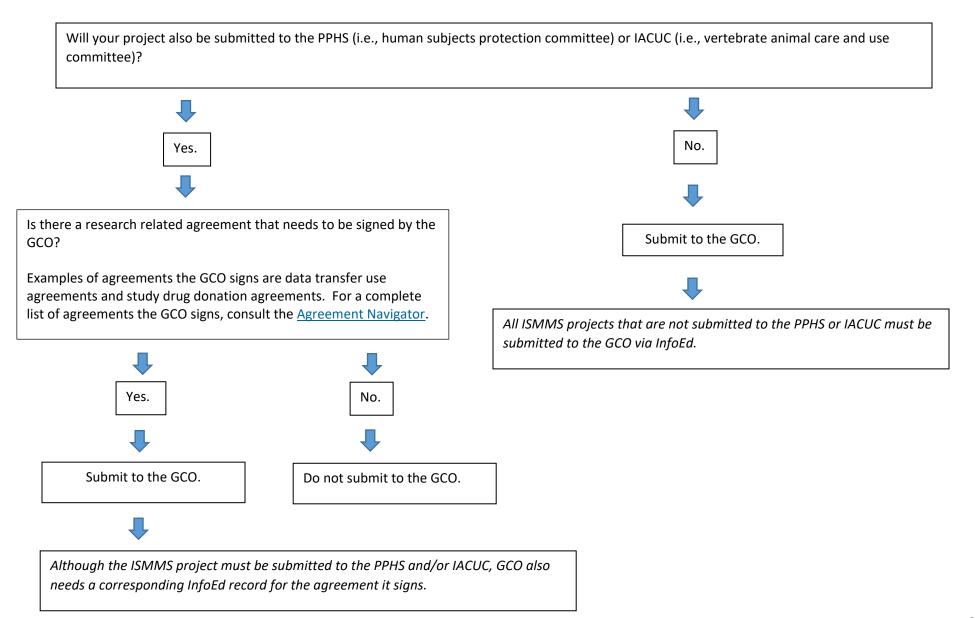
What is a Sponsored Project?

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.

Effective 1/1/2024, <u>new</u> industry sponsored clinical trials and related studies with no competitive review process and for which the agreement is negotiated by FACTS are no longer submitted to the GCO. Ongoing industry sponsored clinical trials and related studies with no competitive review process that have already been <u>submitted</u> to the GCO, please <u>do</u> continue submitting to the GCO through close out. Industry funding where MSIP signs the agreement and <u>all</u> industry funding that is peer reviewed, including but not limited to SBIR/STTR subawards, continues to require GCO submission and review.



ISMMS Projects – Continued from Previous Page



Sponsored Projects – GCO Submission Exception

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.