



**Mount
Sinai**

Grants and Contracts Office

Investigator Form (IF) Instructions

Includes Policy/Procedure Information with Technical Steps

Rev. 7/21

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I. Overview

These instructions pertain to the process of complying with conflict of interest and suspension and debarment policies across the Mount Sinai Health System (MSHS). Completing these forms is part of the process for projects administered by both the Icahn School of Medicine at Mount Sinai (ISMMS) and Hospital Sponsored Programs Office (HSPO). Individual hospitals within the Mount Sinai Health System administer a small number of sponsored projects through HSPO.

For projects administered by Icahn School of Medicine at Mount Sinai, the IF is required for all sponsored project and ISMMS supported (i.e., unfunded research) applications. **Whether a Principal Investigator (PI) is submitting a project to the Grants and Contracts Office (GCO), the Program for the Protection of Human Subjects (PPHS), and/or Institutional Care and Animal Use Committee (IACUC), a corresponding Sinai Central Investigator Form (IF) must also be completed as part of the process.** The PI or his/ her delegate must **create an Investigator Form (IF) on [Sinai Central](#) (SC) for every sponsored project, including supplements, every year of the project.**

The purpose of completing an IF is to generate Conflict of Interest (COI) forms and Suspension and Debarment (S&D) forms associated with the project for the [project personnel](#) to sign. The Conflict of Interest (COI) form is also referred to as “Financial Interest in Research Disclosure (FIRD)” and “Financial Conflict of Interest in Research (FCOIR)” form.

IF Submission and Routing Process

The IF submission and routing process is as follows:

1. PI or delegate (i.e., coordinator) creates IF and adds personnel.
2. Personnel receive e-mail notifying them to sign the COI and S&D forms.
3. Personnel sign forms.
4. It is recommended that the PI or delegate track the COI and S&D form status to make sure personnel sign the forms.
5. ISMMS (i.e., GCO, PPHS, and/or IACUC) / HSPO receive all signed COI and S&D forms.

If a project does need to be submitted to more than one of these office (e.g., PPHS via RUTH and the GCO via InfoEd), only one IF is required. You do not complete an IF for each office.

Sponsored Project and Research Application Submission

In addition to completing COI and S&D forms on Sinai Central, GCO/HSPO must also receive your sponsored project or research application.

For routing sponsored project and research applications:

- GCO uses the InfoEd software program. Click [here](#) for additional information about the GCO process.
- Please contact [HSPO](#) at olga.carr@mountsinai.org for information.

II. Technical Requirements – Access to Sinai Central (SC)

After reviewing [GCO's policy on who must sign COI and S&D forms](#), those personnel who create the IF or sign COI and S&D forms on [Sinai Central](#) must have a Single Sign On (SSO) user name and password. If you are an employee and new to SC, you can activate your account on [Sinai Central](#) by clicking on the “Activate your Account” button once you are on the site. Please note that in some cases, new

employees may not yet have been added. Additional [information on accessing and activating SC accounts](#) can be found on the SC site.

III. Creating and Completing the Investigator Form (IF)

A. Completing Top Section of Form: Required Fields

To create a new IF form, log in to [Sinai Central](#) > GCO or COI > Investigator Forms > New Investigator Form



Investigator Form

1	Affiliation	<input type="text"/>
2	Project Title	<input type="text"/>
3	ID	IF1778746
4	Status	IN PREPARATION
5	Reminder Date	<input type="text"/> * A date by which you want the investigators to complete this form.
6	Coordinator	Allison Gottlieb
7	Principal Investigator (PI)	Allison Gottlieb Change
8	Proposal Type	<input type="text"/>
9	Funding Agency	<input type="text"/>
10	Funding Agency Type	<input type="text"/>
11	REF #	
12	Human Subjects	<input type="radio"/> Yes <input type="radio"/> No
13	Animal Subjects	<input type="radio"/> Yes <input type="radio"/> No

GCO and IRB disclosure requirements differ.

If you are not doing human subject research:

List everyone who meets the Federal definition of an Investigator, that is anyone responsible for the design, conduct or reporting of the project.

If you are doing human subject research:

List everyone who meets the Federal definition of an Investigator, that is anyone responsible for the design, conduct or reporting of the project.

AND

List everyone who is involved in the design, conduct or reporting of the human research study.

Investigator Form continued

14 IDUCC (Institutional Dual use of Concern Committee)

Indicate if your research involves any of the following agents or toxins. An answer for each item is required.

Avian influenza virus (highly pathogenic)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Burkholderia mallei	<input type="checkbox"/> Yes <input type="checkbox"/> No
Foot-and-mouth disease virus	<input type="checkbox"/> Yes <input type="checkbox"/> No
Reconstructed 1918 Influenza virus	<input type="checkbox"/> Yes <input type="checkbox"/> No
Variola major virus	<input type="checkbox"/> Yes <input type="checkbox"/> No
Bacillus anthracis	<input type="checkbox"/> Yes <input type="checkbox"/> No
Burkholderia pseudomallei	<input type="checkbox"/> Yes <input type="checkbox"/> No
Francisella tularensis	<input type="checkbox"/> Yes <input type="checkbox"/> No
Rinderpest virus	<input type="checkbox"/> Yes <input type="checkbox"/> No
Variola minor virus	<input type="checkbox"/> Yes <input type="checkbox"/> No
Botulinum neurotoxin (in any quantity)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Ebola virus	<input type="checkbox"/> Yes <input type="checkbox"/> No
Marburg virus	<input type="checkbox"/> Yes <input type="checkbox"/> No
Toxin-producing strains of Clostridium botulinum	<input type="checkbox"/> Yes <input type="checkbox"/> No
Yersinia pestis	<input type="checkbox"/> Yes <input type="checkbox"/> No

Instructions

1. Affiliation

Affiliation
<input type="checkbox"/> Icahn School of Medicine at Mount Sinai <input type="checkbox"/> Mount Sinai Beth Israel (OGARA) <input type="checkbox"/> Mount Sinai St-Luke's Roosevelt Institute (OGARA) <input type="checkbox"/> New York Eye and Ear Institute of Mount Sinai

Choose the appropriate affiliation of the Principal Investigator. Choose "Icahn School of Medicine at Mount Sinai" for ISMMS GCO administered projects. Choose the appropriate affiliation for HSPO administered projects.

2. Project Title

It is recommended that you use the same title as your GCO/HSPO submission.

3. ID

This field is also referred to as the “IF #”. You must insert (i.e. copy and paste) this IF # from this [Sinai Central form](#) into the [“Eform” in your InfoEd application](#) when submitting to the GCO.

Below is the section of the InfoEd eForm where you insert the IF #.

Conflict of Interest forms (and Suspension & Debarment forms if necessary) are located in [Sinai Central](#). Please complete these components and enter the Project ID.

[Sinai Central Project ID](#)

4. Status

The status when you begin the form is “IN PREPARATION”. In order for the GCO/HSPO to review your application, the status must be “WITH GCO COORDINATOR”. The status will be updated to “WITH GCO COORDINATOR” once all the investigators sign the COI / S&D forms.

5. Reminder Date

You may wish to include today’s date so the investigators are instructed to complete the COI / S&D forms upon your completion of the IF. Do not leave blank.

6. Coordinator

The person completing the IF is called the “Coordinator” and is also referred to as the “Delegate.” The Coordinator can also track whether the investigators have signed the COI / S&D forms and can add investigators at a later date under certain situations if needed.

7. Principal Investigator

The form defaults to the coordinator. When the coordinator and PI are different, click on the “Change” link and enter the PI’s name or life number. Then click on the PI’s name in the search results. See example below.

The PI can also track whether the investigators have signed the COI and S&D forms and can add investigators at a later date if needed.

Coordinator	Allison Gottlieb
Principal Investigator (PI)	Allison Gottlieb Change
Proposal Type	<input type="text" value="Moise"/> (Clear value)
Funding Agency	
Funding Agency Type	
REF #	
Human Subjects	
Animal Subjects	

Name	Title
MOISE, CYNTHIA	ACD
MOISE, DINLEY	513 - Business Associate A
MOISE, FRANCE	725 - Clinical Nurse
MOISE, HEATHER	062 - Billing Coordinator - Accounts Receivable
MOISE, JEAN-PIERRE PLENO	
MOISE, JESSICA	801 - Associate Dean

8. Proposal Type

Proposal Type	<div> <div></div> <div> New or Transfer Competitive Continuation Non-Competitive Continuation No-Cost Extension Supplement </div> </div>
---------------	--

For definitions of the above proposal types, click [here](#). Once a proposal type is selected, a new section on dual use research of concern appears. Please see section 14 below for more information.

9. Funding Agency

The choices in the Funding Agency drop down list are agencies that are common funders of research conducted at Mount Sinai. If the agency you are applying to is not in the drop down list, please select "Other" and include the Agency's name in the box provided.

If your project is a subaward and the name of the prime awardee institution (i.e., institution receiving the funds from the funding agency) is not in the drop down list, please select "Other" and then include the prime institution's name in the box provided. For example, if this is a subaward from NYU on a NIH grant, choose "Other" and type "NYU". See the example below.

Funding Agency	<input type="text" value="Other"/> <div> <input type="text" value="NYU"/> </div>
----------------	--

10. Funding Agency Type

Funding Agency Type

Include Suspension and Debarment

- State Funded
- Federal Other
- Federal NIH
- Industry - Federal Sub-Award
- Other Non-Profit - Federal Sub-Award
- Local
- University Federal

Do not Include Suspension and Debarment

- Foreign
- Cooperative Clinical Trial
- Foundation
- Industry
- Internal (formerly MSSM)
- Other non-profit
- University Non-Federal

In the drop down list, choose an option below the **“Include Suspension and Debarment”** section or below the **“Do not Include Suspension and Debarment”** section. S&D forms are generated for key personnel to sign based on the selection. If this is a subaward, you must find out from your contact at the prime organization where they are applying. For example, if this is a subaward on a NYU grant and the NYU PI is submitting to the NIH, choose “University Federal”. If this is a subaward on a NYU grant and the NYU PI is submitting to the American Heart Association, choose “University Non-Federal”.

11. REF #


This field is not fillable for the user. User leaves this field blank.

12. Human Subjects – Choose Yes or No.

13. Animal Subjects – Choose Yes or No.

14. Institutional Dual Use of Concern Committee

This section appears when a user chooses New or Transfer, Competitive Continuation, or Supplement in the “Proposal Type” section. Indicate if your research involves any of the agents or toxins listed.

NOTE: If there are errors on the form, the field box or boxes will be highlighted in pink  and the IF status will read “In Preparation.” **Investigators will not be able to complete COI/S&D forms if there are IF errors.** Please do complete all the required fields.

B. Completing Bottom Section of Form: Adding Project Personnel

Enter the project personnel who need to complete COI / S&D forms.

1. Policy Information – Who Must Sign COI / S&D forms on Sinai Central?

This section contains policy information regarding which personnel must be included on the IF. **Do not include investigators from other institutions (i.e., subaward personnel). Do not include consultants (i.e., not employees of ISMMS).** If the PI determines that a consultant falls under the definition of Investigator, the consultant should complete a paper COI form. Use the same form link and follow the same process for paper COI submissions in the “Important Note” box below.

Important Note! If Your Project includes a Subaward Institution that ...

1) Does not have a COI policy that complies with Federal regulations AND

2) Agrees to comply under Mount Sinai’s policy

Please provide paper COI forms to the subaward investigators for them to sign and return. Go to [GCO Application Information](#) > Forms and select the appropriate “COI Form for Subawardees Under ISMMS Policy”. Submitting signed paper COI forms to the GCO is also a yearly requirement. Complete information on the GCO policy can be found [here](#).

a. Completing the IF - Personnel Who Must Sign a COI Form

Include everyone who meets the Federal Conflict of Interest definition of an Investigator, defined as any individual responsible for the design, conduct or reporting of the project.

For human subject research projects, also add staff who are involved in the design, conduct or reporting of the human research study. These are the individuals listed in the smartform on the Local Study Team Members tab in RUTH.

b. Completing the IF - Personnel Who Must Sign a S&D Form

A S&D form is required for all key personnel of Federal and State funded projects, even when Mount Sinai is a subaward. **Since key personnel are a subset of individuals who must complete COI forms, you won’t need to add more staff.**

For more guidance about key personnel and who Mount Sinai considers to be an investigator specifically for COI purposes, click [here](#). Reviewing this information can help you select the appropriate individuals to include on the IF.

2. Technical Steps - Adding and Removing Personnel

Adding Personnel

At the bottom of the form, click on “Add an Investigator,” then click on the “Select” link and enter the person’s name or life number. Then click on the person’s name in the search results. Select “Role” from the drop down list.

If the user chose “Yes” to “Human Subjects” in the top portion of the form, this additional question appears. “Is the team member involved in the consent process?” Please select “Yes” or “No.”

Click on “Save.” See example on the following page.

Investigators

Information: Allison Gottlieb **Change** Role: Principal Investigator **Remove**

Financial Conflict in Research Status: NOT STARTED Fin. Interest? Inst. Interest? Submitted: Amended:
Suspension and Debarment Status: UNKNOWN Issue?

PPHS Certifications
GCP MSSM Course 11/23/2009

Add an Investigator

Is the team member involved in the consent process? ☐ Yes ☐ No

Select

Financial Conflict in Research
Suspension and Debarment
PPHS Certifications

Add an Investigator

Comments
Add a Comment

Save **Undo All Changes**

Role:

- Principal Investigator
- Other Investigator - Faculty
- Other investigator - Non Faculty
- Non Key personnel for PPHS - Research Coordinator
- Non Key personnel for PPHS - Research Nurse
- Non Key personnel for PPHS - Student
- Non Key personnel for PPHS - Volunteer
- Mentor - Faculty
- Mentor - Non Faculty

As a reminder, please review the [COI Instructions](#) for information regarding who must complete the COI form and therefore will need to be added to this section of the IF. In addition, review the [PPHS section](#) in this document regarding adding personnel from RUTH.

Once you click on Save and all of the investigators that you added to the IF signed the COI and/or S&D forms, the IF locks and you can no longer add more investigators. See note below for further instructions.



NOTE: If you do not have the complete list of investigators and wish to continue working on the IF at a later time to add them, it is recommended that you partially complete an investigator record. To do so, click on “Add Investigator” and then click on “Save”. You won’t include a person’s name or role. If you do not add a partial record, the IF routes to the GCO/HSPO after the PI and other investigators you have included sign the forms, and you will not be able to edit the IF. You will need to then contact the [GCO/HSPO](#) to add personnel.

And remember to:

Remove the partially completed investigator record by clicking on the “Remove” Icon. The IF is routed to the GCO after 1) It is completed and 2) Investigators sign COI/S&D forms.

Removing Personnel

Click on the “Remove” button in the Investigator row to remove personnel. You won’t be able to change the PI in this section. To change the PI, see the [PI form field instructions](#) in III.A.7.

 Allison Gottlieb **Change** Role: Other Investigator - Faculty 

Undo All Changes


Press the Undo All Changes button to undo all of the changes you have made. However, once you press Save, you will not be able to undo your changes.

 Save 

IV. Tracking Investigator Sign off on COI and S&D Forms

The PI or coordinator can make sure all the investigators sign the COI / S&D forms by tracking their status in the IF. **This is helpful because GCO/HSPD require the form to be complete as part of their review.**


A. Technical Steps - Tracking IF Form Status

To track the form(s), go to: Sinai Central > GCO or COI > Investigator Forms > List Forms > Forms I Manage. Click on  next to “Title”.

Note in the example below that the IF status is “IN PREPARATION”. And, in the “Investigators” section please note the following:


- The PI "SUBMITTED the COI form. The S&D form is NOT APPLICABLE.
- The Coordinator set up a blank record (that is why the name and role is missing) so she can continue to add investigators on the IF.
-

TRACKING IF STATUS

 Sinai C

Home > GCO > **Investigator Forms**


Inv. Forms






 List Forms ☐ Show Canceled Forms ☐

New Investigator Form
My certifications
COI Education Module

Forms I Manage

Showing 1 to 10 of 14
Pages: 1 2 >

Showing 1 to 10 of 14
Pages: 1 2 > Filter: go 

	Title	ID	Principal Investigator	GCO Number	Reminder Date	Status	Proposal Type	Affiliation	Funding Agency	Funding Agency Type
	I really really love Mount Sinai	IF1779874	ALLISON GOTTLIEB		06/08/15	IN PREPARATION	New or Transfer	Mt Sinai	Mount Sinai School Of Medicine	MSSM
	today's test	IF1688710	ALLISON GOTTLIEB		09/17/14	IN PREPARATION	New or Transfer	Mt Sinai		MSSM
	test	IF1531786	ALLISON GOTTLIEB		05/08/13	IN PREPARATION	New or Transfer	Mt Sinai	Agency For Healthcare Research And Quality/DHHS	Federal NIH
	sample	IF1334822	ALLISON GOTTLIEB		08/04/15	IN PREPARATION		Mt Sinai	National Institute Of Mental Health/NIH/DHHS	Federal NIH
	I love Mount Sinai	IF1779426	ALLISON GOTTLIEB		06/05/15	WITH GCO COORDINATOR	New or Transfer	Mt Sinai	New York State Dept. Of Health	State Funded

[View Investigator Form](#)

Investigator Form

Affiliation	Icahn School of Medicine at Mount Sinai
Project Title	I really really love Mount Sinai
ID	IF1779874
Status	IN PREPARATION
Reminder Date	06/08/2015
Coordinator	Allison Gottlieb
Principal Investigator (PI)	Allison Gottlieb
Proposal Type	New or Transfer
Funding Agency	Mount Sinai School Of Medicine

Investigators

Allison Gottlieb	Role: Principal Investigator				
Financial Conflict in Research	Status: SUBMITTED	Fin. Interest? N	Inst. Interest? N	Submitted: 06/08/2015	Amended:
Suspension and Debarment	Status: NOT APPLICABLE	Issue?			
PPHS Certifications					
GCP MSSM Course	11/23/2009				
<input type="text"/>	Role: <input type="text"/>	Certification information will be shown after saving the project			
Financial Conflict in Research	Status: NOT STARTED	Fin. Interest?		Submitted:	Amended:
Suspension and Debarment	Status: NOT APPLICABLE	Issue?			
PPHS Certifications					
Jean M Stenard	Role: Co-investigator	FCOI certification 07/17/2014			
Financial Conflict in Research	Status: SUBMITTED	Fin. Interest? N		Submitted: 06/08/2015	Amended:
Suspension and Debarment	Status: NOT APPLICABLE	Issue?			
PPHS Certifications					



B. Status Tables – Helpful Info for PIs and Delegates

The tables below should help you navigate the IF and determine what steps you may need to take to complete the IF process.

Table 1: IF Status

Status	Additional Information	PI or Delegate Can...
In Preparation	User is preparing the IF <u>or</u> not all investigators have signed their COI / S&D forms.	...Continue to add investigators and edit IF.
With GCO Coordinator	All investigators have signed their COI / S&D forms.	... Neither add investigators nor edit the IF. Contact GCO/HSPQ for assistance. Please reference the IF # in GCO communication.
With Grants Specialist	All investigators have signed their COI / S&D forms.	... Neither add investigators nor edit the IF. Contact GCO/HSPQ for assistance. Please reference the IF # in your communication.

Done	All investigators have signed their COI / S&D forms; GCO/HSPO has completed its review of the IF.	... Add investigators if there are new personnel mid-year.
Pending GCO Edits	The GCO is making GCO-level changes and/or adding investigators to an IF that previously reached the “Done” status. The IF reverts back to “Done” after the changes are saved and/or after the newly added Investigators complete their COI/S&D forms.	... Correct information or add Investigators after a form is finalized.
Pending Edits	The PI/Coordinator is editing the IF and/or adding investigators to an IF that previously reached the “Done” status. The IF reverts back to “Done” after the changes are saved and/or after the newly added Investigators complete their COI/S&D forms.	... Correct information or add Investigators after a form is finalized.
Rejected	The GCO has rejected the form.	... Amend the form by clicking on the “Edit” icon and resubmit.

Table 2: Status of Individual COI / S&D Forms within the IF

Status	Additional Information	PI or Delegate Can...
Not Started / Draft	Investigator has not started signed the COI / S&D forms.	... Remind investigators to complete form(s).
In Preparation	Investigator is in the process of completing the COI / S&D forms.	... Remind investigators to complete form(s).
Submitted	Investigator has signed the COI / S&D forms.	

V. Frequently Asked Questions

1. **I am an Investigator and did not receive an e-mail informing me to sign COI and S&D form(s). Where do I sign the forms?**

Log on to Sinai Central > COI or GCO > Forms I must Complete. Refer to the investigator the [COI form instructions](#) and the [S&D form instructions](#).

If the forms do not appear in Sinai Central > COI or GCO > Forms I must Complete section, please ask the [IT Help Desk](#) or [IT Security](#) to check whether you have more than one Sinai Central account and whether your Active Directory account (username and password) is linked to the correct Sinai Central account.

2. **I am not able to log into Sinai Central (SC) to initiate the Investigator Form (IF). How do I log on?**

All users log onto Sinai Central (SC) by using their Single Sign On (SSO) user name and password. If you are an employee and new to SC, you can activate your account on [Sinai Central](#) by clicking on the “Activate your Account” button once you are on the site. Please note that in some cases, new employees may not yet have been added. Additional [information on accessing and activating SC accounts](#) can be found on the SC site.

3. **I am trying to add an Investigator to the IF and see that his name appears twice. Which one do I pick?**

1) Contact [IT Security](#) (SecAdmin) to deactivate the “non-employee” account.

2) Remove the current listing from the Investigator Form.

3) Re-assign the Investigator to the IF. Make sure that the selection includes the investigator’s department number and title.

Additional Information: When a researcher is hired and needs to submit COI/S&D forms prior to his/her official start date, he/she is issued a Sinai Central extranet (“non-employee”) account. If the researcher’s life number is not entered into the extranet account profile, he/she is automatically issued a second (“employee”) account on or after his/her start date. This results in two accounts.

4. **I am trying to add more investigators to the IF but the form is locked. How do I add more investigators?**

See the “Forms I Manage” screenshot below. If the form status is “With GCO Coordinator” or “With GCO Specialist,” you are no longer able to add more investigators. You will need to contact the [GCO/HSPO](#) for assistance.

Forms I Manage

Showing 1 to 10 of 19
Pages: 1 2 >

Filter:

go

	Title	ID	Principal Investigator	GCO Number	Reminder Date	Status	Proposal Type
	I love Mount Sinai	IF1779426	ALLISON GOTTLIEB		06/05/15	WITH GCO COORDINATOR	New or Transfer

The IF locks when all the investigators on the IF have completed the COI form and the S&D form, if the S&D also required. To avoid this issue in the future, click [here](#) for the instructions on adding investigators later but still prior to ISMMS (i.e., GCO, PPHS, IACUC) / HSPO submission. Also see [IF Status Tables](#) in this manual for complete information on statuses.

5. **The Investigator’s IRB/PPHS Certifications do not appear in Sinai Central. Why can’t I see them?**

1) The Investigator may not have affiliated his/her [CITI Program](#) account with the Icahn School of Medicine at Mount Sinai. Click [here](#) to review IRB’s instructions for affiliating. Go to “What if I have already taken coursework through [www.citiprogram.org](#)” Q&A?

2) The investigator may have more than one Sinai Central account. Please see FAQ #3 above for additional instructions.

3) Please contact [PPHS](#) with any other questions.

6. **I am a new coordinator and would like to access the IFs that the former coordinator prepared. How do I get access?**

Please contact your [designated GCO Specialist, Coordinator, or AOR](#) for assistance. If there are more than five IFs to transfer, please contact sinaicentral@mssm.edu for assistance.

7. **When I set up the IF and add investigators, sometimes they receive a Suspension and Debarment (S&D) form to complete and sometimes they don’t. Why does this happen?**

As per the regulations for Federal, NY State and NY City sponsored projects, all investigators

must disclose information regarding suspension and debarment. See the screenshot below of the “Funding Agency Type” on the IF which are organized into two sections: “Include Suspension and Debarment” and “Do not Include Suspension and Debarment.” Please select the appropriate option in the dropdown menu.

10. Funding Agency Type

Funding Agency Type

Include Suspension and Debarment

- State Funded
- Federal Other
- Federal NIH
- Industry - Federal Sub-Award
- Other Non-Profit - Federal Sub-Award
- Local
- University Federal

Do not Include Suspension and Debarment

- Foreign
- Cooperative Clinical Trial
- Foundation
- Industry
- Internal (formerly MSSM)
- Other non-profit
- University Non-Federal

8. **I need to submit my unfunded research project to the PPHS via RUTH because it’s a human subjects research and to GCO via InfoEd because the GCO must sign a study drug donation agreement. Does this also mean I need to complete two IF forms? One for the PPHS and another for the GCO?**

No, only one IF is required. If for example, you need to submit your project to the PPHS or the IACUC and you also need to submit to the GCO, only one IF is required.

9. **My IACUC approval is for three years. My research project is not receiving any external funding and I don’t need to submit to the GCO. Do I also complete the IF every three years?**

Yes, complete the IF every 3 years.

10. **I am applying for supplemental NIH funding. Do I need to create another IF?**

Yes, please add the PI plus any new investigators when applying for supplemental funding.

11. **I received supplemental funding from the NIH for three years. Do I need to create an IF each year of the supplement?**

It depends. If the NIH issues a separate award notice each year for the supplemental funding, then please also create an IF each year.

If the NIH includes the supplemental funding in the award notice of the overall grant in future years, then do not create a separate IF. Include the investigators for the supplement in the overall IF.

VI. Making Study Personnel Changes Within a Current Budget Period on the IF Post GCO/HSPO Submission

A. Policy Information - COI / S&D Requirements

If there are new investigators within a current GCO/HSPO budget period, please add them to the IF. Only remove project personnel when they are added in error when the IF is still in preparation. If you no longer have access to remove, please contact GCO/HSPO for assistance.

B. Technical Steps – Adding and Removing Personnel

The IF status must read “Done” or “Pending Edits”. For any other IF status, please contact the [GCO/HSPO](#) for assistance. When the IF is in the “Done” status, click on the “Augment” or “Edit” button at the bottom of the form and then [Add and Save the Investigators](#) as described in section III.B.2.

C. Coordinating Study Personnel Changes with GCO/HSPO, IRB and IACUC

1. [GCO/HSPO](#)

In the case of new investigator(s) joining the project mid-year, please add the personnel directly to the current IF. [GCO/HSPO does not require an additional InfoEd or HSPO project submission within a current budget period.](#) Always include the appropriate personnel in the next annual InfoEd /HSPO proposal submission. If this is a sponsored project, refer to the extramural agency’s policies and procedures for more information about required documentation and whether the agency may need to approve the personnel change. If the agency requires approval from an institutional official, please do contact your [designated GCO Grants Specialist](#) / [HSPO](#) who will review the request and obtain signature.

Also in the case of more complicated changes such as the PI and Coordinator leaving Mount Sinai mid-year and adding their replacements, please contact your [designated GCO Grants Specialist](#) / [HSPO](#) who can assist you.

2. [IRB](#)

Click [here](#) for information about IRB’s requirements for study personnel changes within an IRB approval period.

3. [IACUC](#)

To add new personnel to an IACUC protocol within an IACUC approval period, PIs must complete the [online form](#) and select the help topic “eIACUC Training” New Personnel can be added to the protocol and granted access to eIACUC *after* all required training has been completed. Please contact the IACUC office at iacuc@mssm.edu or 212-241-0153 for information about additional requirements.

VII. Contact Information

Dept	This office...	Contact Info
<u>GCO / ISMMS</u> Grants and Contracts Office	... Answers COI / S&D form questions. ... Adds Investigators once the IF is with the GCO and also before it is finalized. ... Can transfer the IF to a new Coordinator.	grants@mssm.edu 212.824.8300 Ask to speak with a Grants Coordinator.
<u>HSPO</u> Hospital Sponsored Programs Office	... Answers COI/ S&D form questions. ... Adds Investigators once the IF is with HSPO and also before it is finalized. ... Can transfer the IF to a new Coordinator.	olga.carr@mountsinai.org
<u>PPHS/ ISMMS</u> Program for the Protection of Human Subjects	... Answers study personnel PPHS Certification related questions.	IRB@mssm.edu Tel #: 212.824.8200
<u>COI</u> Conflicts of Interest Office	... Answers COI policy questions.	COI Hotline for Financial Conflicts of Interest in Research and Confidential Conflicts of Interest: 212.241.0845
Information Technology (IT)		
IT Help Desks	... Assists with account and password issues .	
Most associated research and sponsored projects are submitted to the GCO. Contact the ISMMS help desk. Icahn School of Medicine		ascit@mssm.edu 212.241.7091
If your associated sponsored project is submitted to HSPO, contact one of the Help Desks below for assistance. Mount Sinai Hospital, Mount Sinai Queens		ITHelpDesk@mountsinai.org 212.241.4357
Mount Sinai Beth Israel, Mount Sinai Brooklyn, Mount Sinai St. Luke's, Mount Sinai West		212.523.6486
New York Eye & Ear Infirmary		212.979.4273
IT Security	... Deactivates Sinai Central accounts for users that have more than 1 account.	ITSecurityOperations@mountsinai.org
Sinai Central Support Team	... Fixes technical issues if the form malfunctions.	sinaicentral@mssm.edu

VIII. Other Helpful Links

[Instructions for Completing the COI Form](#)

[Instructions for Completing the S&D Form](#)

In addition to creating the IF to submit COI and S&D forms, you can also use the IF form to review other required certifications for GCO submission. Please see the following document:

[GCO's Application Submission Checklist Instructions](#) > no. 10 and no. 11.

- 10. CITI COI Education Module: Have you checked to make sure all the investigators completed this training?
- 11. Sinai Central Annual COI Forms: Have you checked to make sure all the investigators completed these forms?

VIII. Highlights of Significant Changes to this Document from Previous Versions

Section	Description of Change
7/2021 version	
III. Creating the IF	Removed references to PPHS HRP 211 form and replaced with RUTH. Added function of the “Undo All Changes” button.
9/2020 version	
I. Overview	Updated as per changes in GCO submission process effective for projects 9/23/20 and after.
III. Creating the IF	Added human consent and DURC questions.
V. FAQs	Changed from “Problems and Solutions” to “FAQs”; added new FAQs.
VII. Making Study Personnel Changes Within a Current Budget Period Post GCO / HSPO Submission	Updated IACUC section with eIACUC software.
8/2020 version	
VIII. Highlights of Significant Changes to this Document from Previous Versions	Added new section “Highlights of Significant Changes to this Document from Previous Versions.”
III.B. 2 Creating the IF > Adding Project Personnel	Updated the options available in the “Role” dropdown.
7/2020	
IV.B. 2 Status Tables	Added “Reject” status.