Investigator Form (IF) Instructions
Includes Policy/Procedure Information with Technical Steps

Rev. 6/17
Table of Contents

I. Overview - p. 2
II. Technical Requirements: Access to Sinai Central - p. 2
III. Creating the Investigator Form (IF) - p. 3
   A. Completing Top Section of Form: Required Fields - p. 3
   B. Completing Bottom Section of Form: Adding Project Personnel - p. 7
      2. Technical Steps – Adding and Removing Personnel - p. 7
IV. Tracking the IF Status and Investigator Sign off on COI / S&D Forms - p. 8
   A. Technical Steps – Tracking IF status - p. 8
   B. Status Tables – Helpful Info for PIs and Delegates - p. 10
   C. Problems and Solutions - p. 11
V. Making Study Personnel Changes Within a Current Budget Period on IF Post GCO /HSPO Submission - p. 12
   B. Technical Steps - Adding and Removing Personnel - p. 12
   C. Coordinating Personnel Changes with GCO/HSPO, IRB, and IACUC - p. 12
VI. Contact Information - p. 13
VII. Other Helpful Links - p. 13
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 Grants and Contracts Office (GCO) and Hospital Sponsored Programs Office (HSPO). Individual hospitals within the Mount Sinai Health System administer a small number of sponsored projects through HSPO.

The Principal Investigator (PI) or his/her delegate must create an Investigator Form (IF) on Sinai Central (SC) for every project (e.g., new, yearly renewals, supplement requests, no cost extension applications) except final reports. 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. GCO/HSPO receives all signed COI and S&D forms.

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.

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 SC 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, newly recruited employees may not yet have been added to the SC database. Additional information on accessing and activating SC accounts can be found on the SC site. Departmental administrators typically provide assistance with requesting SC accounts.
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

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<table>
<thead>
<tr>
<th>No.</th>
<th>Field</th>
<th>Value/Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Affiliation</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Project Title</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>ID</td>
<td>IF1778746</td>
</tr>
<tr>
<td>4</td>
<td>Status</td>
<td>IN PREPARATION</td>
</tr>
<tr>
<td>5</td>
<td>Reminder Date</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Coordinator</td>
<td>Allison Gottlieb</td>
</tr>
<tr>
<td>7</td>
<td>Principal Investigator (PI)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Proposal Type</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Funding Agency</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Funding Agency Type</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>REF #</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Human Subjects</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>13</td>
<td>Animal Subjects</td>
<td>☐ Yes ☐ No</td>
</tr>
</tbody>
</table>

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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. This includes all those listed on the HRP 211 form.
Instructions

1. Affiliation
   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. The eForm is located in the Internal Documents tab on InfoEd. Below is the section of the InfoEd eForm where you insert the IF #.

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.

8. Proposal Type

For definitions of the above proposal types, click here.

9. Funding Agency

The choices in the Funding Agency drop down list are agencies that are commons 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.
10. Funding Agency Type

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.

**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 on the HRP 211 form.

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. Click on “Save”. See example on the following page.
Research Coordinator is a common role on COI disclosures for PPHS/IRB purposes. In this case, choose “Non-Key Personnel for PPHS/IRB.” For definitions of “Principal Investigator, Co-Investigator, Significant Contributor, Mentor, and other personnel terms, click here and go to pp.3-5.

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 so 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. 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.

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/HSPO 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.

<table>
<thead>
<tr>
<th>Title</th>
<th>ID</th>
<th>Principal Investigator</th>
<th>GCO Number</th>
<th>Reminder Date</th>
<th>Status</th>
<th>Proposal Type</th>
<th>Affiliation</th>
<th>Funding Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>I really really love Mount Sinai</td>
<td>IF179874</td>
<td>Allison Gottlieb</td>
<td>06/08/15</td>
<td>IN PREPARATION</td>
<td>New or Transfer</td>
<td>Mount Sinai School Of Medicine</td>
<td>Mount Sinai</td>
<td></td>
</tr>
<tr>
<td>today's text</td>
<td>IF1600710</td>
<td>Allison Gottlieb</td>
<td>05/17/14</td>
<td>IN PREPARATION</td>
<td>New or Transfer</td>
<td>Mt Sinai</td>
<td>National Institute Of Mental Health/NIH/PHS</td>
<td>Federal NIH</td>
</tr>
<tr>
<td>text</td>
<td>IF1531286</td>
<td>Allison Gottlieb</td>
<td>05/08/13</td>
<td>IN PREPARATION</td>
<td>New or Transfer</td>
<td>Mt Sinai</td>
<td>Agency For Healthcare Research And Quality/PHS</td>
<td>NIH</td>
</tr>
<tr>
<td>sample</td>
<td>IF1534922</td>
<td>Allison Gottlieb</td>
<td>08/04/15</td>
<td>IN PREPARATION</td>
<td>New or Transfer</td>
<td>Mt Sinai</td>
<td>National Institute Of Mental Health/NIH/PHS</td>
<td>Federal NIH</td>
</tr>
<tr>
<td>I love Mount Sinai</td>
<td>IF1779426</td>
<td>Allison Gottlieb</td>
<td>05/05/15</td>
<td>WITH GCO COORDINATOR</td>
<td>New or Transfer</td>
<td>Mt Sinai</td>
<td>New York State Dept. Of Health</td>
<td>State Funded</td>
</tr>
</tbody>
</table>

**Investigator Form**

- Affiliation: Icahn School of Medicine at Mount Sinai
- Project Title: I really really love Mount Sinai
- ID: IF179874
- Status: IN PREPARATION
- Reminder Date: 06/08/15
- 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
  - Status: SUBMITTED
  - Certification information will be shown after saving the project
  - PP/IS Certification: 11/13/2009

  - **Financial Conflict in Research:** NOT STARTED
  - **Suspension and Debarment:** NOT APPLICABLE

- **Jean M Stein**
  - Role: Co-Investigator
  - PP/IS Certification: PCCI certification 07/17/2014
  - Status: SUBMITTED
  - Certification information will be shown after saving the project
  - **Financial Conflict in Research:** NOT APPLICABLE
  - **Suspension and Debarment:** NOT APPLICABLE

- **PP/IS 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

<table>
<thead>
<tr>
<th>Status</th>
<th>Additional Information</th>
<th>PI or Delegate Can…</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Preparation</td>
<td>User is preparing the IF or not all investigators have signed their COI / S&amp;D forms.</td>
<td>...Continue to add investigators and edit IF.</td>
</tr>
<tr>
<td>With GCO Coordinator</td>
<td>All investigators have signed their COI / S&amp;D forms.</td>
<td>... Neither add investigators nor edit the IF. Contact GCO/HSPO for assistance. Please reference the IF # in GCO communication.</td>
</tr>
<tr>
<td>With Grants Specialist</td>
<td>All investigators have signed their COI / S&amp;D forms.</td>
<td>... Neither add investigators nor edit the IF. Contact GCO/HSPO for assistance. Please reference the IF # in your communication.</td>
</tr>
<tr>
<td>Done</td>
<td>All investigators have signed their COI / S&amp;D forms; GCO/HSPO has completed its review of the IF.</td>
<td>... Add investigators if there are new personnel mid-year.</td>
</tr>
<tr>
<td>Pending GCO Edits</td>
<td>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&amp;D forms.</td>
<td>... Correct information or add Investigators after a form is finalized.</td>
</tr>
<tr>
<td>Pending Edits</td>
<td>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&amp;D forms.</td>
<td>... Correct information or add Investigators after a form is finalized.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Status</th>
<th>Additional Information</th>
<th>PI or Delegate Can…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Started / Draft</td>
<td>Investigator has not started signed the COI / S&amp;D forms.</td>
<td>... Remind investigators to complete form(s).</td>
</tr>
<tr>
<td>In Preparation</td>
<td>Investigator is in the process of completing the COI / S&amp;D forms.</td>
<td>... Remind investigators to complete form(s).</td>
</tr>
<tr>
<td>Submitted</td>
<td>Investigator has signed the COI / S&amp;D forms.</td>
<td></td>
</tr>
</tbody>
</table>
C. Problems and Solutions

1. Problem: Investigator does not receive e-mail informing him/her to sign form(s).
   Solution: Inform him/her to log on to Sinai Central>COI or GCO>Forms I must Complete. In addition, you can send the investigator the COI form instructions and the S&D form instructions.

   You can also ask the IT Help Desk or IT Security to check whether the investigator has more than one Sinai Central account, and whether his/her Active Directory account (username and password) is linked to the correct Sinai Central account.

2. Problem: Coordinator or Investigator does not have a Sinai Central (SC) account.
   Solution: Personnel who create the IF or sign Sinai Central (SC) COI and S&D forms must have a SC 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, newly recruited employees may not yet have been added to the SC database. Additional information on accessing and activating SC accounts can be found on the SC site. Departmental administrators typically provide assistance with requesting SC accounts.

3. Problem: Investigator’s name appears more than once in search results. Which one do I pick?
   Solution: 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 Background Info: 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. Problem: PI or Coordinator can no longer add Investigators.
   Solution: 1) See IF Status Tables – Helpful Info for PIs and Coordinators in section IV.B for instructions. 2) To avoid this issue in the future, also see “Important Note” for information in section III.B on adding investigators at a later date but still prior to GCO/HSP0 submission.

5. Problem: PI/Coordinator and/or Investigator cannot view the Investigator’s IRB/PPHS Certifications.
   Solution: 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 Problem/Solution #3 above for additional instructions. 3) Please contact the IRB with any other questions.
V. 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 investigators to an IACUC protocol with an IACUC approval period, Investigators complete the online form and select the help topic “Ideate/New Personnel Request.” Please contact the IACUC office at iacuc@mssm.edu or 212-241-0153 for information about additional requirements.
VI. Contact Information

<table>
<thead>
<tr>
<th>Dept</th>
<th>This office...</th>
<th>Contact Info</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GCO / ISMMS</strong></td>
<td>... Answers COI / S&amp;D form questions.</td>
<td>e-mail: <a href="mailto:grants@mssm.edu">grants@mssm.edu</a></td>
</tr>
<tr>
<td></td>
<td>... Adds Investigators once the IF is with the GCO and also before it is finalized.</td>
<td>Tel# 212.824.8300</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ask to speak with a Grants Coordinator.</td>
</tr>
<tr>
<td><strong>HSPO</strong></td>
<td>... Answers COI/ S&amp;D form questions.</td>
<td>e-mail: <a href="mailto:OGARA@chpnet.org">OGARA@chpnet.org</a></td>
</tr>
<tr>
<td></td>
<td>... Adds Investigators once the IF is with HSPO and also before it is finalized.</td>
<td></td>
</tr>
<tr>
<td><strong>IRB/ ISMMS</strong></td>
<td>... Answers study personnel PPHS Certification related questions.</td>
<td>e-mail: <a href="mailto:IRB@mssm.edu">IRB@mssm.edu</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tel #: 212.824.8200</td>
</tr>
<tr>
<td><strong>COI</strong></td>
<td>... Answers COI policy questions.</td>
<td>COI Hotline: 212.241.0845</td>
</tr>
<tr>
<td><strong>IT, IT Security</strong></td>
<td>... Deactivates Sinai Central accounts for users that have more than 1 account.</td>
<td><a href="mailto:ITSecurityOperations@mountsinai.org">ITSecurityOperations@mountsinai.org</a></td>
</tr>
<tr>
<td><strong>IT, Development Center</strong></td>
<td>... Fixes technical issues if the form malfunctions.</td>
<td><a href="mailto:itdc@mssm.edu">itdc@mssm.edu</a></td>
</tr>
</tbody>
</table>

VII. Other Helpful Links

Instructions for Completing the COI Form
Instructions for Completing the S&D Form