Mount Sinai **Grants and Contracts Office**

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

Allison Gottlieb
Rev. 7/15

Table of Contents

I. Overview

These instructions pertain to the process of complying with conflict of interest and suspension and debarment policies for all research projects across the Mount Sinai Health System (MSHS).   Whereas Mount Sinai's Grants and Contracts Office (GCO) services the School, Icahn School of Medicine (ISMMS), the Health System's Offices of Grants and Research Administration (OGARA) service the member hospitals, Mount Sinai Beth Israel (BI), Mount Sinai St. Luke's Roosevelt (SLR) and New York Eye and Ear Infirmary of Mount Sinai (NYEEI).

The 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) submitted to the GCO or OGARA except final reports each 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. GCO/OGARA receives all signed COI and S&D forms. GCO/OGARA cannot review your corresponding sponsored project or research proposal until all investigators have signed the COI / S&D forms in Sinai Central.

Sponsored Project and Research Application Submission
In addition to completing COI and S&D forms on Sinai Central, GCO/OGARA 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.
  - BI OGARA routes scanned in applications by e-mail.
  - NYEEI OGARA uses the IRB Manager software program.
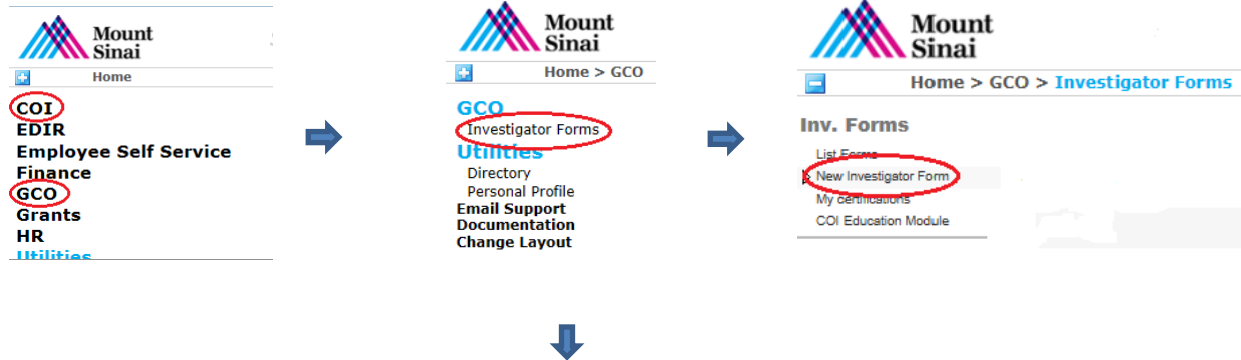 - SLR OGARA uses Novelution Research Management System.

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 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

Edit Investigator Form

Investigator Form

1	Affiliation	[dropdown]
2	Project Title	[text field]
3	ID	IF1778746
4	Status	IN PREPARATION
5	Reminder Date	[date field] * 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	[dropdown]
9	Funding Agency	[dropdown]
10	Funding Agency Type	[dropdown]
11	REF #	
12	Human Subjects	○ Yes ○ No
13	Animal Subjects	○ Yes ○ 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.

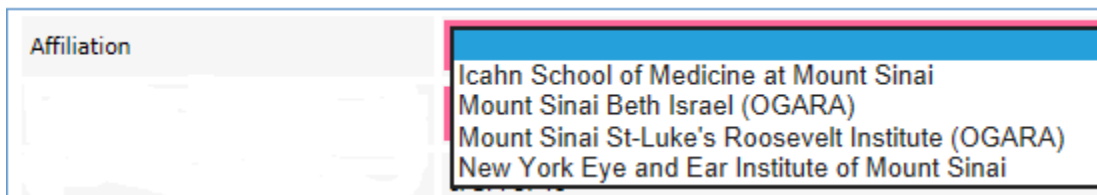**If you are doing human subject research:**
List everyone who meets the Federal definition of an Investigator, that is anyone responsible for the design, conduct or reporting of the project.
AND
List everyone who is involved in the design, conduct or reporting of the human research study. This includes all those listed on the HRP 211 form.
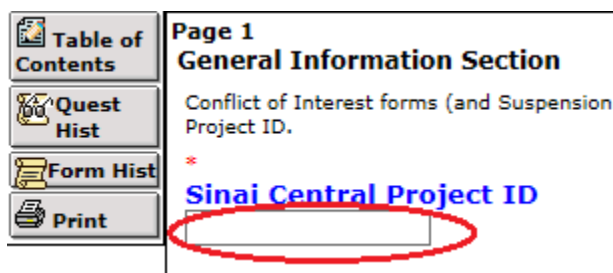
Instructions

1. Affiliation

   Choose the appropriate affiliation of the Principal Investigator. Please note for PIs that have transitioned from Mount Sinai BI, SLR, or NYEEI to the School's Faculty Practice, choose "Icahn School of Medicine at Mount Sinai". If your project includes: 1) investigators from more than one institution in the drop down list (i.e., BI/SLR/NYEEI faculty who have transitioned to Mount Sinai's FPA <u>and</u> BI/SLR/NYEEI faculty who have <u>not</u> yet transitioned to the FPA) and 2) there will be a subaward agreement to transfer funds between the School and one of the Hospitals (BI/SLR/NYEEI), you will need to complete separate IF forms for each.

2. Project Title
   It is recommended that you use the same title as your GCO/OGARA 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 #.

   When submitting to NYEEI OGARA, insert the IF# into the IRB Manager new protocol or annual renewal xforms where prompted.

4. Status
   The status when you begin the form is "IN PREPARATION". In order for the GCO/OGARA 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**

	(Clear value) ☒
🔍 Moise	

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

Proposal Type	
Funding Agency	
Funding Agency Type	
REF #	
Human Subjects	
Animal Subjects	

8. Proposal Type

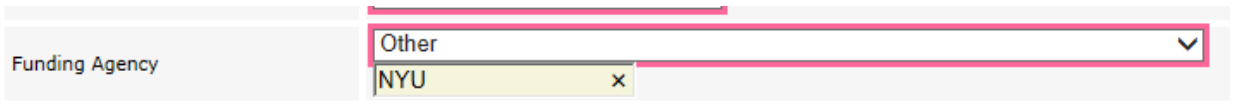| Proposal Type	New or Transfer
	Competitive Continuation
	Non-Competitive Continuation
	No-Cost Extension
	Supplement

   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.
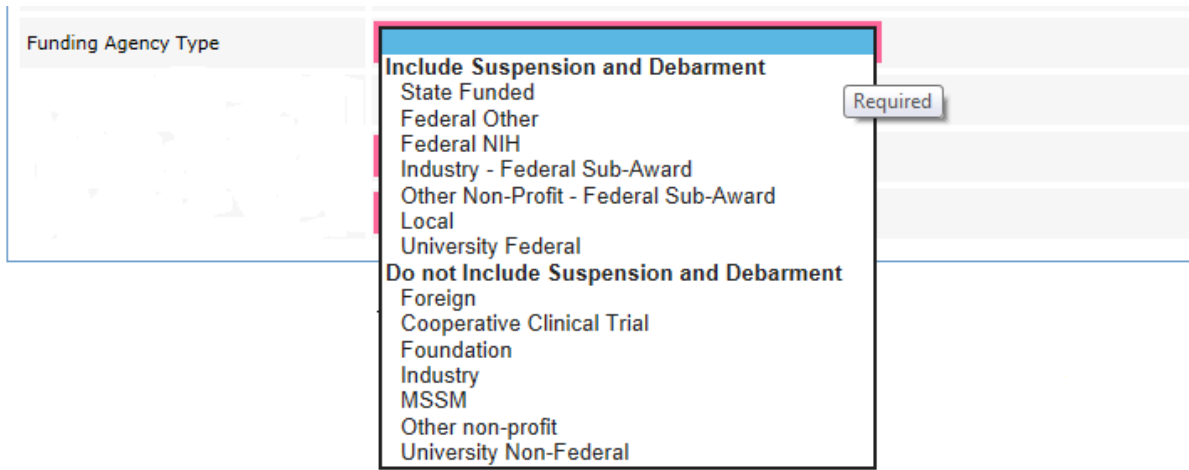
If your project is a subaward and the name of the prime awardee institution (i.e., institution receiving the funds from the funding agency) is not in the drop down list, please select "Other" and then include the prime institution's name in the box provided. For example, if this is a subaward from NYU 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 (not employees of ISMMS). In the case that 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. Click here for the "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.

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   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 and go to pp.3 - 4. 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.

Investigators

Allison Gottlieb **Change**   Role: Principal Investigator

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

Remove

Add an Investigator

Select   Role:

Financial Conflict in Research   Status: NOT STARTED   Fin. Interest?
Suspension and Debarment   Status: UNKNOWN   Issue?
        PPHS Certifications

Add an Investigator

Comments
Add a Comment

Save   **Undo All Changes**

Jean M Stenard **Change**   Role:

Financial Conflict in Research   Status
Suspension and Debarment   Status
        PPHS Certifications

Principal Investigator
Co-investigator
Significant Contributor
Mentor
Non-Key Personnel for PPHS/IRB
Other

Add an Investigator

Comments
Add a Comment

Save   **Undo All Changes**

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/OGARA 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 contact the GCO/OGARA so the GCO/OGARA can 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/OGARA cannot review the sponsored project or research application submission until all investigators have signed the COI/S&D forms in Sinai Central.

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".

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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

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 or 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/OGARA 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/OGARA for assistance. Please reference the IF # in your communication.
Done	All investigators have signed their COI / S&D forms; GCO/OGARA 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.

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.	

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/OGARA 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/OGARA Submission

A. Policy Information - COI / S&D Requirements

If there are new investigators within a current GCO/OGARA 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/OGARA for assistance. For OGARA projects where the COI disclosures were submitted by paper, and therefore there is no Sinai Central IF to add the investigators to, please refer to these instructions and form.

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/OGARA 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/OGARA, IRB and IACUC

1. GCO/OGARA

In the case of new investigator(s) joining the project mid-year, please add the personnel directly to the current IF. GCO/OGARA does not require an additional InfoEd or OGARA project submission within a current budget period. Always include the appropriate personnel in the next annual InfoEd / OGARA 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 / OGARA 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 / OGARA 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

Dept	This office...	Contact Info
GCO / ISMMS	… Answers COI / S&D form questions. … Adds Investigators once the IF is with the GCO and also before it is finalized.	e-mail: grants@mssm.edu Tel# 212.824.8300 Ask to speak with a Grants Coordinator
OGARA/Member Hospitals	… Answers COI/ S&D form questions. … Adds Investigators once the IF is with OGARA and also before it is finalized.	e-mail: OGARA@chpnet.org
IRB/ ISMMS	… Answers study personnel PPHS Certification related questions.	e-mail: IRB@mssm.edu Tel #: 212.824.8200
COI	… Answers COI policy questions.	COI Hotline: 212.241.0845
IT, IT Security	… Deactivates Sinai Central Accounts for users that have more than 1 account.	ITSecurityOperations@mountsinai.org
IT, Development Center	… Fixes technical issues if the form malfunctions.	itdc@mssm.edu

VII. Other Helpful Links

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