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Documentation and Instructions for Sponsored Projects with Subawards When ISMMS is the Prime Institution

Introduction

The purpose of this memo is to inform you of the required documentation you will need from the sub-recipient and the pertinent extramural and internal policies and procedures when the Icahn School of Medicine at Mount Sinai (ISMMS) is the prime institution submitting a sponsored project application. It also includes information specific to NIH competitive applications. The terms “sub-award” and “sub-recipient” are used interchangeably. The memorandum is organized in the following sections:

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Sections highlighted in blue are instructions on placement of information and documentation in InfoEd.

Any document that is for GCO use only and not submitted to the extramural funding agency, upload in InfoEd in the “Internal Documents” tab. All other documents, place in the appropriate InfoEd section.

Please contact your assigned GCO Grants Specialist for any questions you may have. For a listing, please click [here](#):

I. List of Required Documentation

A. All Application Types (i.e., Competitive, Non-Competitive, No Cost Extensions)

The following documents are required for all sponsored project submissions with a subaward or subawards except when submitting final report applications:

1. [Signed Statement of Intent \(SOI\) to Establish a Consortium Agreement](#)
2. [Statement of Work \(SOW\) or Confirmation of No Change](#)
 - Competitive Applications: Include a SOW.
 - Non-Competitive and No Cost Extension Applications: Include a SOW or confirmation statement from the ISMMS PI that there is no change.

The following document may be required from the sub-awardee except when submitting final report applications:

3. [Certification of Compliance with HHS Federal Conflict of Interest \(COI\) rules and regulations effective 8/24/2012](#)
Many federal agencies including the National Institutes of Health (NIH) and nonprofit agencies such as the American Cancer Society (ACS) do require compliance with COI certification. Click [here](#) for a “List of Agencies using the PHS FCOI Regulations” on the Federal Demonstration Partnership (FDP) website.
4. [Other Documentation Required by Funding Agency](#)

Also, please review these sections: 15. [Data Entry on InfoEd Budget and Personnel Tabs](#) and [16. Subawards on Subawards](#).

B. Competitive (i.e., New, Resubmission, and Competitive Renewal) and Non-Competitive Applications

In addition to # 1 - 4 above, the following document is required from the sub-recipient for competitive and non-competitive sponsored applications in which funding is requested:

5. [Budget](#)

C. Competitive Applications

In addition to # 1 - 5 above, the following document is required from the sub-recipient for competitive applications:

6. [Budget Justification](#)

D. NIH Competitive Applications (e.g., New R01, Competitive Renewal P30)

In addition to # 1 - 6 above, the following documents are required from the sub-recipient for all NIH competitive applications:

7. [Performance Site Information](#)
Institution Name, Address, Country, DUNS #, Congress District
8. [Resources and Facilities page](#)
9. [Biosketches](#) for Key Personnel including Other Significant Contributors and Consultants
10. [Letters of Support](#)
11. [Single IRB \(sIRB\) Reliance Statement](#), if applicable
12. [Inclusion Enrollment Report Data](#), if applicable
13. [Multiple PD/PI Leadership Plan](#), if applicable
14. [Consortium/Contractual Arrangements](#)

II. Checklist: Subaward Documentation on a NIH Competitive Application

The checklist is a tool designed to help the PI and his/her research team gather the required information and documents for competitive applications as well as to provide the subawardee team basic administrative information they will need such as the project period dates, the subaward budget amount, funding opportunity #, and your deadline for submission of materials. The checklist includes additional instructions on the Statement of Intent (SOI) to Establish a Consortium Agreement, Statement of Work (SOW), and Federal COI policy. It is a duplication of instructions covered in this memo for the subawardee team.

The checklist entitled “NIH Competitive Subaward Checklist: ISMMS as the Prime Institution” can be downloaded [here](#).

To use, complete the appropriate sections of the checklist and forward it to your contact at the sub-recipient.

We recommend that you receive all the required documentation (#1-13 in Section I above) in FINAL form from the subawardee at least 10 business days before the NIH deadline. Your application is due to the GCO in COMPLETE and FINAL form, including completed and signed Conflict of Interest and Suspension and Debarment forms as appropriate, at 11am 5 business days before the NIH deadline. That gives you 5 business days to review, enter, upload the information as well as process your InfoEd application through your department and any other departments where there are key personnel.

The checklist is not a required document. You do not need to upload it in your InfoEd application.

III. Additional Instructions

A. All Application Types (i.e., Competitive, Non-Competitive, No Cost Extensions)

1. Signed Statement of Intent (SOI) to Establish a Consortium Agreement

a. Other commonly used terms

This document is also commonly referred to as “Subcontracting Letter of Agreement,” “Consortium Letter of Intent,” and “Letter of Commitment or Intent Signed by the Consortium Participant” among other variations.

b. Purpose of Letter

The SOI is the official letter signed by the sub-recipient’s Authorizing Organization Official (AOR) attesting that his/her institution is aware of all applicable Federal regulations and policies and will establish a subaward agreement. **ISMMS cannot submit the sponsored project application to the extramural funding agency without the SOI. Failure to obtain a signed SOI will result in the subawardee being removed from the application.**

Also, please note that the actual signing of the subaward agreement by ISMMS and the sub-recipient will occur at a later date if the project is funded. This letter does not take the place of the agreement. The SOI is a prerequisite for the submission of the application.

c. Template Form

Click [here](#) for a template. Many institutions use their own Subaward Statement of Intent form. There is no requirement to use the ISMMS template.

Also please note that this template is only used for NIH sponsored projects and other HHS agencies, such as AHRQ, CDC, FDA, HRSA, SAMHSA, which are listed on the Federal Demonstration Partnership (FDP) website and abide by the Federal COI policy revised 8/24/12. For information about other Federal and non-Federal agencies that abide by this policy, please visit [this site](#) and click on document entitled “List of Agencies using the PHS FCOI Regulations.”

Please contact me (e-mail: allison.gottlieb@mssm.edu; telephone: 212.731.7089) if the sub-recipient you are working with needs assistance in preparing a SOI template for a different extramural agency other than the ones noted above.

d. PHS 398 Face Page Option

GCO accepts the PHS 398 face page in place of the statement of intent since it includes the required language and signature.

e. Institutional Addressee and Signatory

SOI letters and templates from other institutions may require the name of your authorizing organization official (AOR). If so, please have them address the SOI to your designated ISMMS AOR. A listing of ISMMS AORs by department is available [here](#).

The subawardee AOR must sign the SOI.

Please include the signed SOI in your InfoEd application > Internal Documents tab. Choose the “Subaward Statement of Intent to Establish a Consortium Agreement” category.

2. Statement of Work (SOW) or Confirmation of No Change

For competitive applications, include a SOW. For non-competitive and no cost extension applications, include a SOW or confirmation from the ISMMS PI that there is no change. The confirmation document can be a memo from the PI stating, “I confirm there is no change to the Statement of Work.”

A Statement of Work is a description of the work the sub-recipient will perform. The SOW will be part of the legally binding subaward agreement if the project is funded. Also, if funded, please note that the SOW should be 4,000 characters or less and include information that may be made publicly available to comply with Federal Funding Accountability and Transparency Act (FFATA) requirements since it will be used to populate the “Sub-Award Description” section of usaspending.gov. There is no template since it is project specific. The document at a minimum should include the objective or purpose of the sub-recipient’s participation and a general description of the actions to be performed by the site and the expected results.

Please include the SOW or confirmation in your InfoEd application > Internal Documents tab. Choose the “Subaward Statement of Work” category.

3. Certification of Compliance with HHS Financial Conflict of Interest (COI) Rules and Regulations Effective 8/24/2012

The National Institutes of Health (NIH), Centers for Disease Control (CDC), Agency for Healthcare Research and Quality (AHRQ), Health Resources and Services Administration (HRSA), other government agencies, in addition to the American Cancer Society (ACS), American Heart Association (AHA), Patient-Centered Outcomes Research Institute (PCORI), as well as other nonprofit agencies do require compliance with COI certification. Click [here](#) for a “List of Compliant Institutions and Entities” on the Federal Demonstration Partnership (FDP) website.

a. NIH Policy

The NIH issued a revised conflict of interest policy and mandated compliance from all institutions who receive funds from the NIH either directly or as a subaward. The revised regulations were designed to promote greater objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from an investigator’s financial conflicts of interest. Policy information is located on the [NIH COI website](#).

b. Compliant Institutions: Check to Ensure Sub-recipient’s COI Compliance in Advance of the NIH Deadline

Many, if not most of the institutions, we work with, such as other academic medical centers, are compliant with the regulations but some smaller sites and international sites that don’t receive funding from the NIH might not be.

Check as soon as possible the list of compliant institutions entitled “List of Compliant Institutions and Entities” located on the [Federal Demonstration Partnership \(FDP\)](#).

In the cases numbered “ii – iv” below, the sub-recipient will need to submit an additional certifying statement or add the appropriate certification statement in the Statement of Intent to Establish a Consortium Agreement (SOI). The institution can also use the [ISMMS SOI template](#), which includes the COI language.

i. Compliant and on FDP List

If the institution is compliant and also listed on the FDP list, there is no further action necessary.

ii. Compliant and not on FDP List

If the institution is compliant and not listed on the FDP list, the Subawardee AOR must certify that his/her institution is compliant with the COI regulations. The sub-recipient must submit an additional certifying statement or add a certification clause to the SOI, as follows:

“My institution is compliant with HHS Financial Conflict of Interest (COI) Requirements 42 CFR Part 50, Subpart F, entitled “Responsibility of Applicants for Promoting Objectivity in Research” effective 8/24/12.”

iii. Compliant under ISMMS Policy

Institutions that are not compliant may choose to become compliant under ISMMS Policy. They will need to take 2 actions as follows each year of the project:

#1: The sub-recipient must submit an additional certifying statement or add a certification clause to the SOI, as follows:

“My institution agrees to comply with HHS Financial Conflict of Interest (COI) Requirements 42 CFR Part 50, Subpart F, entitled “Responsibility of Applicants for Promoting Objectivity in Research” effective 8/24/12 under ISMMS COI policy. Each investigator, defined as a person responsible for the design, conduct or reporting of research regardless of title or position, shall complete the education presentation and disclosure form. Any potential conflicts shall be managed through a plan formulated by ISMMS.”

#2: Each investigator (see definition in #1 above) must complete the education presentation and disclosure form. Both of these items are included on one form. Click [here](#) for the “COI Form for Subawardees Under ISMMS Policy – New, Competitive, Renewals, and Transfer Applications. For the COI form for non-competitive applications, no cost extensions, supplements or to report new financial interests or a new investigator, click [here](#).

Please upload the signed COI form(s) (one form per investigator) in your InfoEd application > Internal Documents tab. Choose the “Subaward COI Information” category.

iv. **Not Compliant**

An institution may not be compliant with HHS COI policy while also working on obtaining certification. In this case, the sub-recipient must submit an additional certifying statement or add a certification clause to the SOI, as follows:

“My institution is not compliant with HHS Financial Conflict of Interest (COI) Requirements 42 CFR Part 50, Subpart F, entitled “Responsibility of Applicants for Promoting Objectivity in Research” effective 8/24/12. I will inform the ISMMS Authorizing Organization Representative immediately in writing by email at grants@mssm.edu when my institution becomes compliant. **I understand that my institution cannot participate in the project if this requirement is not met.**”

4. Other Documentation Required by Funding Agency

Refer to the extramural funding agency application instructions for any documents or information that the agency requires from the sub-awardee. You will need to submit those documents to the GCO as well.

B. Competitive and Non-Competitive Applications

In addition to #1 - 4 above, the following document is required from the sub-recipient for all competitive and non-competitive sponsored applications in which funding is requested:

5. Budget

GCO requires, at a minimum, as much budget information and documentation as the extramural funding agency requests.

a. Competitive Applications

See note above for requirements. For NIH non-modular grants (e.g., new R01 where direct costs per year are greater than \$250,000), an initial budget from the subaward is required. If the budget differs each year, also please provide the entire proposed period of support budget. In the case of NIH modular grants, at a minimum, the subaward budget must include all key personnel, other direct costs, F&A, and total costs for the initial and entire proposed period of support.

b. Non-Competitive Applications

The GCO requires the budget for the upcoming budget period only. If this was originally a NIH modular grant, you will need a budget that at a minimum includes all key personnel, other direct costs, F&A, and total costs.

c. No Cost Extensions

Only in the case where the funding agency requires a budget, does the GCO also require the budget. Please consult the extramural funding agency instructions for additional information. Since the NIH does not require a budget for the first no cost extension period requested prior to the project period end date, GCO does not require the budget either. However, do consult with your department for other requirements. It is good business practice, for example to request a budget for an NIH no cost extension, if there are key personnel from the sub-recipient designated on the notice of award to confirm that effort will not be reduced by 25% or more.

a. – c. *above*:

For S2S submissions, please upload the budget(s) InfoEd > Internal Documents tab. Choose the “Subaward Budget” category.

For non-S2S submissions when the budget is part the funding agency application (e.g., new private foundation grant application that has a budget form, upload it in InfoEd > Research or Program Plan tab for new projects and the InfoEd > Progress Report tab for all others. You don't need to separate it from the rest of the documents that you upload in these tabs.

For non-S2S submissions when the budget is not part the funding agency application forms (e.g., NIH R21 non-competitive continuation, upload it in InfoEd > Internal Documents tab.

C. Competitive Applications (i.e., New, Resubmission, Competitive Renewal)

In addition to # 1 -5 above, the following document is required from the sub-recipient for competitive applications:

6. Budget Justification

For NIH modular grants, provide a budget narrative for all personnel (e.g., subaward PI, TBN post doc) including consultants and other significant contributors. For NIH non-modular grants, provide a detailed budget justification. Please refer to the agency instructions for all other applications.

For S2S submissions (e.g. NIH new R01), upload in InfoEd Budget>Budget Items>Subcontractors> Detailed Budgeting > Justifications.

For non-S2S submissions, if the budget is part of the documents requested by the funding agency, upload into the “Research or Program Plan” tab for new projects and the “Progress Report” tab for all others. You don’t need to separate the justification from the rest of the documents that you upload in these tabs.

NIH Competitive Applications: Additional Documentation

Numbers 7 - 14 below are additional instructions for NIH competitive applications.

7. Performance Site Information

As per the NIH instructions, the Institution’s name, address including the 9 digit zip code, country, and congressional district number are required. This information may be pre-populated in InfoEd so you may wish to check this tab once you set up the subaward. Also, some subawardee institutions are participating in a Federal Demonstration Partnership (FDP) pilot program whose goal is to reduce the administrative burden associated with subawards. If the institution is included on this [FDP Expanded Clearinghouse list](#), you will find the required administrative information for the performance site tab, and therefore will not need to request it. Finally, if you use GCO’s [NIH Competitive Application Subawardee Checklist](#), the contact person at the sub-award institution submits this information to you on the form but can opt out completing this section if the institution is on the FDP Expanded Clearinghouse list. The GCO checklist also includes the DUNS number (optional in NIH application for secondary sites) because InfoEd requires this unique identifier for all subawards.

Data enter this information on InfoEd > Performance Sites tab.

8. Resources and Facilities page

As per the NIH instructions, “If there are multiple performance sites, describe the resources available at each site.” Obtain an additional Equipment statement, if applicable. “List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.”

Upload the Resources and Facilities page in InfoEd > Resources tab.

9. Biosketches for Key Personnel including Other Significant Contributors and Consultants

Upload the Biosketches into the “CV” sections in InfoEd > Personnel tab.

10. Letters of Support

As per the NIH instructions, “Obtain appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters should stipulate expectations for co-authorship, and whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.”

Upload these letters in InfoEd > PHS398_Research Plan > Letters of Support section.

11. Single IRB (sIRB) Reliance Statement, if applicable

If the use of a sIRB is required for your research, and the sub-recipient is a named site, approval of the sIRB is required at the time of application. Examples of acceptable supporting documentation are as follows:

- The named site can include an additional certification statement in their Statement of Intent to Establish a Consortium Agreement (SOI),
- A link to the institution’s posted policy,
- A separate approval letter/memo/email signed by a business official

Please refer to the [GCO SOP on sIRBs](#) for complete information.

Please include the approval in your InfoEd application > Internal Documents tab.

12. Inclusion Enrollment Report Data for Projects with Human Subjects, if applicable

If the Inclusion Enrollment Report (IER) form is required for your research, please obtain the data from the subaward site so you can add it to the form.

Data enter this information in InfoEd > Human Subjects/CT > Study Record > Inclusion Enrollment Report.

13. Multiple PI (MPI) Plan, if applicable

If this is a multiple PI grant and the Subaward PI is one of the MPIs, you must include the required plan in your NIH application. The GCO template, which includes additional language for grants with PIs at subaward sites, can be downloaded [here](#).

Upload this section in InfoEd > PHS398_ResearchPlan > Multiple PI Leadership Plan.

14. Consortium/Contractual Arrangements

In this section of the application as per the NIH instructions, “Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.”

The GCO recommends including the following information:

- For programmatic arrangements, adapt language that the subaward already provided in the SOW.
- For fiscal arrangements, state: “We will establish a standard subaward agreement which will allow ISMMS to issue payments to the site.”
- For administrative arrangements, explain how the teams collaborate and communicate (e.g., weekly/monthly/yearly in person meetings and/or teleconferences.)

Upload this section in InfoEd > PHS398_ResearchPlan > Consortium/Contractual Agreements.

15. Data Entry on InfoEd Budget and Personnel tabs

Enter the budget in InfoEd > Budget > Subcontract tab and the personnel in InfoEd > Personnel tab.

Click [here](#) for further InfoEd technical step by step instructions.

You can data enter the subaward budget and personnel in its entirety or follow the shortcut instructions in the following table.

Data Entry on InfoEd Budget and Personnel tabs*				
#	Technical System Type / Funding Agency Budget Type	Examples	Budget Tab Instructions	Personnel Tab Instructions
1	S2S / Federal Detailed	<ul style="list-style-type: none"> ♦NIH New non-modular R01 (> \$250,000 DC per yr) ♦NIH U01 Resubmission ♦DOD Competitive Renewal 	Enter the following budget information: 1. All budget information as per detailed and summary budgets.	Enter the names of the following personnel: 1. All
2	S2S / Federal Modular	<ul style="list-style-type: none"> ♦NIH New modular R01 (> \$250,000 DC per year) ♦NIH R21 Resubmission 	1. Each key personnel (KP) with % effort (no \$s) 2. <u>Cumulative</u> Direct Cost (DC) only; NO itemized costs 3. Facilities and Administrative Costs (F&A)	1. KP; do not enter non-KP staff (e.g., research coordinator)
3	<u>Non-S2S/</u> All	<ul style="list-style-type: none"> ♦NIH Non-Competitive RPPR SNAPs (e.g., R01s, R21s) ♦NIH RPPR Non-SNAP (e.g., P50, 	1. Subaward PI only with % effort (no \$s) 2. <u>Cumulative</u> DC only; NO	1. Subaward PI only; do not enter other staff (e.g.,

	U19) ♦NIH ASSIST New P01 grant ♦New Foundation grant ♦Non-Competitive Foundation Grant	itemized costs 3. Facilities and Administrative Costs (F&A) 4. Upcoming year’s budget only	co- investigator, research coordinator)
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The Technical System Type in the table refers to the two InfoEd submission types: 1. System to System (S2S); 2. Non System to System (nonS2S).

For S2Ss, InfoEd is used to submit NIH and other federal sponsored projects to these agencies directly. You don’t need to complete a separate agency application. For #s 1 and 2 in the above table, you need to enter more details because InfoEd exports this information into the SF 424 agency forms which are submitted to the extramural funding agency. The agency requires this information on their forms.

For NonS2Ss, InfoEd is used internally at ISMMS only. For # 3 in the above table when you are not using InfoEd to submit your project to the extramural funding agency, less information is needed on the InfoEd budget and personnel tabs.

16. Subawards on Subawards

The GCO discourages the use of subawards on subawards, which is defined as the process of a sub-recipient issuing a subaward to a third tier institution. Subawards on subawards will add unnecessary bureaucratic burdens and delays to your project. They also put Mount Sinai at risk for late filing of reports. The GCO understands that the desire to use subawards on subawards is often driven by scientific reporting lines. These scientific reporting lines can be preserved without adding extraneous institutional financial and administrative reporting lines. The direct subaward arrangement expedites both the research project as well as the receipt of funds. Please contact your designated [Grants Specialist](#) if you have any questions.

17. NIH Application Instruction Guide

Refer to [SF424 Application Guide](#) for complete information on the NIH sections included above.

IV. Significant Changes to this Document from Prior Versions

<u>Date</u>	<u>Description</u>
3/21/18	Added sIRB Reliance Statement, if applicable, in Section III.11.
3/21/18	Updated the Inclusion Enrollment Report data requirement, if applicable, in Section III.12.
4/11/16	Added FFATA requirement in Statement of Work in Section III.A.2
4/11/16	Added information about subaward institutions participating in FDP Expanded Clearinghouse pilot project In Performance site section in Section III.C.7
4/11/16	Added information about “PHS 398 Inclusion Enrollment” form for applications with dues dates 5/25/16 and later in Section III.C. 11 and 12.
1r2/22/15	Moved “3. Certification of Compliance with HHS Policy” from the “NIH Competitive Applications” section to the “All Application Types” section.

12/22/15	Added the option to include a signed PHS 398 Face Page in lieu of SOI in Section III, "1. Statement of Intent (SOI)".
12/22/15	Added the clarifying statement that documentation is a yearly requirement in Section III, "3. Certification of Compliance with HHS Policy".
12/22/15	Updated the link to GCO's most updated policy document in Section III, "13. Multiple PI/PI Leadership Plan".
12/22/15	Added "Subawards on Subawards" to Section III.

* For NIH Diversity Supplements, always data enter the Subaward PI and the diversity candidate in InfoEd Personnel and Budget tabs.