



**Mount
Sinai**

Checklist of Required Documentation from Sub-Awardee Institution
When ISMMS is the Prime Institution on a NIH Competitive Application

The ISMMS contact person should complete this section and send this checklist to your contact at the sub-awardee institution.

Project Title: _____

Prime Institution Name: Icahn School of Medicine at Mount Sinai (ISMMS)

ISMMS PI Name: _____ E-Mail Address: _____

ISMMS Contact Person Name: _____ E-Mail Address: _____

Project Period Dates: _____

Funding Opportunity Announcement Link: _____

Yearly Direct Cost Subaward Budget Amount*: _____

Budget Type - *PI/Dept can specify type and format by checking appropriate boxes.*

[] For modular grants, must include these items at a minimum: all key personnel, other direct costs, F&A, and total costs for initial and entire proposed period of support [] Initial and Entire Summary Budgets [] excel [] pdf [] no preference

Deadline for Subawardee to Submit Required Documentation: _____

Is the Subaward PI also a Multiple PI (MPI)? [] Yes [] No

(Recommended deadline to submit documentation to the ISMMS contact person by e-mail is at least 10 business days before NIH deadline.)

Sub-Awardee Institution

The sub-awardee institution should complete this portion of the form and submit the required documents to the ISMMS contact person.

Name of Institution _____

Is your institution participating in FDP Expanded Clearing House Pilot? Click [here](#) to determine. [] Yes [] No

Subaward PI Name: _____ E:Mail Address: _____

Name of Person Completing this Form: _____ E:Mail Address: _____

Required Documents

- [] 1. Signed Statement of Intent to Establish a Consortium Agreement (SOI)
- [] 2. Certification of Compliance with HHS Financial Conflict of Interest (COI) rules and regulations effective 8/24/2012**
- [] 3. Statement of Work (SOW)
- [] 4. Budget
- [] 5. Budget Justification - For modular grants, must include justification for all personnel (e.g., Subaward PI, TBN Post doc, Consultants, Other Significant Contributors). For non-modular grants, must include detailed justification.
- [] 6. Resources and Facilities
- [] 7. Equipment, if applicable
- [] 8. Biosketches for Key Personnel including Other Significant Contributors and Consultants
- [] 9. Letters of Support, if applicable
- [] 10. Planned Enrollment Report*** data for projects with human subjects, if applicable
- [] 11. For Renewal, Resubmission and Revision Applications, Cumulative Inclusion Enrollment Report*** data, if applicable
- [] 12. For institutions not participating in the FDP Expanded Clearing House Pilot, please provide:
Address of Institution (include 9 digit zip code if location is in the USA) _____

Country _____ Duns No. _____ Congressional District: _____

[] 13. Other. Please specify: _____

Additional Information

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

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. ISMMS will also accept a “PHS 398 Face Page” signed by an authorizing official in lieu of a Statement of Intent.

The SOI is the official letter signed by the sub-awardee institution’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 project.**

The actual signing of the subaward agreement by ISMMS and the Subawardee will occur at a later date if the project is funded. This letter does not take the place of the agreement. It is a prerequisite for the submission of the project.

The ISMMS template is available on line [here](#):

Then Go to > Forms > Subaward Statement of Intent Template: ISMMS as the Prime Institution

Many institutions use their own Subaward Statement of Intent form. There is no requirement to use the ISMMS template.

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

Effective 8/24/2012, the NIH issued a revised policy on conflict of interest and mandated that all institutions who receive funds from the NIH either directly or as a subaward must comply with the updated policy. 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. Complete information is located on this NIH site [here](#).

Click [here](#) for the list of COI compliant institutions, entitled “List of Compliant Institutions and Entities” located on the Federal Demonstration Partnership (FDP) website

a. Compliant and on FDP List

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

b. 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-awardee institution must add a certification clause to their Statement of Intent to Establish a Consortium Agreement***, 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.

c. 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-awardee institution must add a certification clause to their Statement of Intent to Establish a Consortium Agreement***, 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. Once signed, please e-mail it back to the ISMMS contact person. One form is required per investigator. The form is located [here](#): *Then go to > Forms > “COI Form for New, Competitive Renewals, and Transfer Applications: For Subawardees Complying with ISMMS Policy”. (Choose the “Non-competitive, no cost extension, and supplement applications” form for the appropriate yearly renewal.)*

d. **Not Compliant**

An institution may not be compliant with COI policy while working on obtaining certification. In this case, the sub-awardee institution must add a certification clause to their Statement of Intent to Establish a Consortium Agreement****, 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 is compliant. **I understand that my institution cannot participate in the project if this requirement is not met.**

3. Statement of Work (SOW)

This is a description of the work the sub-awardee institution will perform. The SOW will be made 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 <http://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-awardee institution’s participation and a general description of the actions to be performed by the site and the expected results.

*Please include facilities and administrative costs on your budget in addition to the direct costs.

**If your institution is listed on this [FDP website](#), ISMMS does not need any further COI certification.

*** For applications with due dates of May 25, 2016 and after, the NIH replaced the “Planned Enrollment Report” form and the “Cumulative Inclusion Enrollment Report” form with the “Inclusion Enrollment” form.

**** As an alternative, the sub-awardee institution can use the ISMMS SOI template located [here](#): *Then go to > Forms > “Subaward Statement of Intent Template: ISMMS as the Prime Institution”*

Other Notes:

The [SF424 Application Guide and the Supplementary Application Instructions](#) includes information on the Planned Enrollment and Cumulative Enrollment forms for projects with human subjects.