

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

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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 <u>letter</u> does not take the place of the <u>agreement</u>. It is a prerequisite for the submission of the project.

The ISMMS template is available on line <u>here</u>:

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 <u>here</u> 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 <u>2</u> actions as follows <u>each year of the project</u>:

#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.)

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.

9. eRA Commons ID for all senior/key personnel including Other Significant Contributors and ConsultantsPlease make sure an eRA Commons ID is included on the biosketch for all senior/key personnel including Other Significant Contributors and Consultants

Beginning with NIH competitive application due dates on or after January 25, 2022, all key personnel must include their eRA Commons ID in the application. NIH is beginning to issue error messages rather than warnings and will reject the NIH application if eRA Commons IDs are missing for key personnel.

Subaward institutions must <u>register their organization in eRA Commons</u> and create their own eRA Commons IDs for their key personnel.

What Are the Options for Obtaining an eRA Commons Username (Commons ID) For a Senior/Key Person Who Isn't Affiliated With a Registered Organization? Please refer to the "Option 1" instructions in this NIH link.

Mount Sinai GCO assumes that academic institutions that routinely submit NIH grants will already be registered. However, there is a concern that these institutions may not have signed up all their key personnel (e.g., consultant on their subaward project) with eRA Commons user names. An additional concern is that institutions that do not regularly submit grants will not register their organization.

<u>Other Notes:</u>

^{*} 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.

^{***} 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"