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Guidance for Collaborative International Research Award Applications

Introduction

This guidance document outlines the administrative, application preparation and submission requirements for NIH grant applications proposing a Collaborative International Research Award involving a foreign collaboration that meets the definition of a subrecipient. Its purpose is to assist ISMMS investigators and administrators in determining whether this award structure is appropriate, understanding the roles and responsibilities of domestic and foreign participating institutions, and ensuring that all required registrations, system access, application components, and compliance elements are in place prior to submission.

The document provides a detailed overview of key pre-application considerations, including relationship determinations, required registrations and assurances for foreign collaborators, assignment of application preparation responsibilities in ASSIST, and coordination with the ISMMS Grants and Contracts Office (GCO). It also highlights award-specific application components and documentation requirements unique to the Parent PF5 funding opportunity. A resource section with relevant links is included to support compliance with NIH policies, systems, and instructions.

Determination and Process Steps

1. Determine if the foreign collaboration qualifies as a Subrecipient relationship - see [GCO Determination Checklist](#).
 - a. If yes, the Collaborative International Research Award structure is appropriate for the application.
 - b. If the foreign collaboration fits one of the other relationship types (Consultant or Vendor), DO NOT use the Collaborative International Research Award NOFO. The application can be submitted using a standard NOFO. Consult [GCO](#) if unsure.
2. Determine if each foreign collaborator has all of the required registrations and system accounts, and is aware of and willing to accept applicable NIH rules and regulations.
 - a. Have a [SAM.gov](#) Unique Entity ID (UEI) number and be willing to complete a full SAM.gov registration (if not already fully registered)
 - i. Prior to award, full SAM.gov registration is required; however, only having the UEI number is sufficient for the application.
 - ii. [NATO Commercial and Government Entity \(NCAGE\) Code](#) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
 - b. Registered in [eRA Commons](#) and have appropriate [Commons accounts/roles](#)

- i. Key Personnel must have an eRA Commons ID. Person serving as the PI Project Lead must have the PD/PI role.
 - ii. At least one person must have a Signing Official (SO) role
 1. If the Project Lead will serve as both the PD/PI and SO, they will need TWO separate eRA Commons accounts for each role.
 - iii. Key Personnel must complete their [eRA Commons Personal Profile](#), and link their [ORCID ID](#) to their Commons Profile. If they do not have an ORCID, they must register to create one.
 - iv. Key Personnel must register in [MyNCBI](#) using their eRA Commons login credentials, and use [SciENcv](#) to create a Common Form Biosketch.
 - c. Have applicable compliance registrations based on their scope of work:
 - i. [Vertebrate Animals](#) – Office of Laboratory Animal Welfare (OLAW) [Number](#)
 - ii. [Human Subjects](#) – Federal Wide Assurance (FWA) [Number](#)
 - d. Have an FCOI Policy that complies with [NIH requirements](#) and [42 CFR Part 50, Subpart F](#). Foreign collaborator will not be able to rely on ISMMS for FCOI review.
 - e. Comply with the applicable requirements of [NIH Grants Policy Statement Section 16](#), especially section 16.8, and be willing to enter into a Written Agreement with ISMMS, as required by Section 16.8.7. A draft of Mount Sinai’s Collaboration Agreement can be provided to the foreign collaborator for their reference.
 - f. Registered in [Grants.gov](#) (by JIT)
3. Determine who at ISMMS will be responsible for initiating and primarily entering the information in ASSIST. This person should initiate the application and create the skeleton of the application by adding the required components – Research Project Component and International Project Component(s) (one for each foreign collaborative sites).
 - a. Except in very limited circumstances, the Foreign Collaborator Project Lead should NOT be included on the Overall component as an MPI.
4. The responsible person should collect a list of the eRA Commons IDs, names and roles of all personnel who will need to have access to complete the application in ASSIST, including the Foreign Collaborator’s Signing Official and any other administrative support staff assisting with the application. Also refer to GCO’s [NIH ASSIST](#) checklist for other administrative, technical, and budget instructions.
5. Send the list to the ISMMS GCO AOR. The GCO AOR will grant the access rights requested, and provide the application initiator with the access maintainer role so that this person can provision any further access rights as needed, without GCO involvement.
6. An InfoEd record, setup as Non-S2S with budget, and related eDMS Triggering Event must be submitted and received by GCO no later than 5 business days prior to the application deadline, but preferably sooner. DO NOT include any foreign collaborator details or budgetary information.

7. The Foreign Collaborator’s institution will be responsible for entering the application details and attachments within their designated International Project Component. The [SF424 Application Instructions](#) provide guidance on how to complete each section. The GCO Grants Specialist will assist with clearing any identified errors, but will not provide full review of the International Project Component.

8. Unique sections

- a. Overall Component – Research Strategy: Approach Section – must include a clearly identified **Dispute Resolution Plan**
 - i. Suggested text: If a potential conflict develops, the domestic Research Project PI and the International Research Project Lead shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the disagreement will be referred to an arbitration committee consisting of members appointed by NIH. If the dispute cannot be resolved by the committee, any scientific or programmatic disputes will be escalated to NIH Program Officers for adjudication; any financial, administrative, NIH policy, regulation, or other related matters, will be escalated to the NIH Grants Management Specialist for adjudication. The Research Project PI and International Project Lead agree that any decisions made will be final and binding.
- b. International Project Component – **Letter of Support** from Foreign Collaborator Institutional Official (AOR)
 - i. Person signing the letter must have a Signing Official role in Commons.
 - ii. Suggested text: As an AOR for {Organization Name}, I understand that, should the application be selected for funding, my organization will fill the role as a recipient organization for the disaggregated award, and therefore will have all the necessary registrations listed in the Required Registrations – Applicant Organization section of this NOFO.

The appropriate programmatic and administrative personnel involved in this application are aware of all applicable NIH rules and regulations, as stipulated in the NIH Grants Policy Statement Section 16. The organization will establish the necessary Written Agreement with the domestic applicant, consistent with the requirements of this section.

- c. The following table provides a snapshot of some of the unique PF5 ([PA-26-002](#)) section instructions for quick reference. **YOU MUST STILL READ THE FULL NOFO AND BE SURE TO FOLLOW ALL NOFO INSTRUCTIONS.**

P5 Sections Quick Reference Table

YOU MUST STILL READ THE FULL NOFO AND BE SURE TO FOLLOW ALL NOFO INSTRUCTIONS.

Application Sections	Overall	Domestic Research Project	International Research Project
Performance Site	Only enter primary applicant	Enter performance sites specific to domestic component. Do not enter International Component Site(s) information.	Enter performance sites specific to international component.
Other Project Information - Activities outside of the US or Partnerships with international collaborators; Foreign	Field 6 is Yes. Field 12, upload Foreign Justification. Identify each foreign component, and specify whether it is monetary (i.e., an International Project), or non-monetary. For each component, describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting.	Field 6 is only Yes if the Research Project proposes a foreign component that is distinct from the International Project Component(s). If no other foreign components, check No. Only include a Foreign Justification attachment if Field 6 is Yes.	Field 6 is Yes, identify the country for this International Project only. Field 12, Foreign Justification attachment, describe the special resources or characteristics of the international research project, including reasons why the foreign location is more appropriate than a domestic setting.
Project Narrative	Attach in the Overall, describing the project's relevance to public health.	Do not include a Narrative attachment. The one attached in Overall will apply to the domestic project.	Include a Narrative. Focus on relevance of the research conducted within the international project to public health.
Specific Aims	The Specific Aims of the Overall component should encompass the international collaborative project as a whole , including activities anticipated for both domestic and international performance sites .	List the broad, long-range objectives and goals of the proposed Research Project .	List the long-range objectives and goals of the proposed International Project .
Research Strategy	Provide a general description of the overall project, with sufficient details for reviewers to understand the purpose and general approach taken by the research team. Applicant may refer to the Research Strategy of the Research Project component for technical details and specific experimental approaches. Significance: identify relevance of the overall project to both US and global audiences. Approach: the rationale and implementation of an international collaborative approach should be explained. This section must include a clearly labeled dispute resolution plan. 12 Page Limit	The scope of the Research Project will include both domestic and international efforts . The Research Strategy should provide a comprehensive description of the research proposed, regardless of performance location. Identify the site(s) performing the proposed activities and clearly articulate how these activities come together to address the proposed hypothesis. 12 page limit	Significance: describe significance of the contribution of the foreign organization to the overall collaborative team effort. Approach: address how the foreign organization will address the scope of work in the component's Specific Aims. Articulate how experimental and technical approaches undertaken by the foreign organization will integrate with the overall goals of the project. 6 page limit
Letters of Support	Do not submit duplicate letters that have been provided in other components.	Only letters applicable to the Research Project should be included.	A Letter of Support MUST be provided from an ADR of the foreign organization. The person signing must have an ADR/SD role in Commons.
Consortium/ Contractual Arrangements	Do not include the International Component as a Consortium.	Do not include the International Component as a Consortium. Only describe domestic subrecipients.	There should be none under the International Project component.
Personnel - Multiple PD/PI	Only include the Domestic applicant PD/PI, unless the International Project Lead meets qualifications for Multi-PD/PI. Otherwise, they should be considered a Project Lead/Co-Investigator for the International Component activities only.	Only include Domestic PD/PI and any other domestic personnel	International Project PI should be entered with role "Other", Project Lead, unless they are serving as MPI. If MPI, choose PD/PI role.
Other Plan(s)	Must attach a Data Management and Sharing Plan. Must address the data management and sharing needs of the project overall, as well as the roles and responsibilities for the applicant organization and all components . During the Just-in-Time process, DMS Plans for the disaggregated foreign awards may be requested.	Do not attach a DMSP . The Data Management and Sharing (DMS) Plan must be provided in the Overall component.	Do not attach a DMSP . The Data Management and Sharing (DMS) Plan must be provided in the Overall component. Foreign site should be made aware they may need to provide a DMSP at JIT.

Resources

GCO

- [Subawardee, Consultant and Vendor Determination Checklist](#)
- [NIH ASSIST Checklist](#)
- NIH Collaborative International Research Project (Parent PF5 Clinical Trial Optional) Apr 15, 2026 GCO Grants Forum [Presentation](#) (40 minutes) | [Slide Set](#)

Federal-Wide

- [Federal Wide Assurance \(FWA\)](#) – Human Subjects compliance registration (if applicable)
- FCOI Policy: Comply with [NIH requirements](#) and [42 CFR Part 50, Subpart F](#)
- [Grants.gov Registration](#)
- [NATO Commercial and Government Entity \(NCAGE\) Code](#) – Required for foreign institutions
- [ORCID ID](#) – Required for Key Personnel
- [System for Award Management \(SAM.gov\)](#) – Required for foreign institutions
- [Science Experts Network Curriculum Vitae \(SciENcv\)](#) – Required for Senior/Key Personnel
- [Office of Laboratory Animal Welfare \(OLAW\)](#) – Vertebrate Animals compliance registration (if applicable)

NIH

- [NIH Collaborative International Research Project NOFO](#) (Parent PF5 Clinical Trial Optional) (PA-26-002)
- [NIH's Collaborative International Research Projects \(PF5\) Video Overview](#) (6 minutes)
- [eRA Commons Registration](#) - Institutional Registration
- [eRA Commons User Accounts](#) - User account creation and role management
- [eRA Commons Personal Profile](#) - Completion and maintenance for Senior/Key Personnel
- [NIH Grants Policy Statement Section 16](#) - Grants to Foreign Organizations, International Organizations, Domestic Grants with Foreign Components and Collaborative International Research Awards
- [MyNCBI](#) - Required for Senior/Key Biosketch and Current and Pending (Other) Support generation and integration with SciENcv