

Research Integrity & Undue Foreign Influence

Basic Guidance for Researchers: Cataloging and Reporting International Collaborations

In an increasingly global society, international projects and collaborations are essential to continue the advancement of science and technology and address challenges we all face. Understanding that international collaboration should and must occur, the key is to ensure that those collaborations are transparent – meaning disclosed to, and where necessary, approved by, employers and federal agencies or other organizations who may be supporting the researcher or his/her home institution.

Below are some basic principles researchers can apply to understand how funding agencies define the types of collaborations that may need to be disclosed, when they need to be disclosed, and to whom they need to be disclosed. The principles set forth below are based on NIH guidelines. Other agencies may have additional or different requirements. As a result, researchers should always:

1. consult with research integrity personnel at their home institutions in order to understand any special disclosure requirements that may apply to their award portfolio and
2. carefully review both federal and internal disclosure guidelines.

When disclosing foreign activities/relationships, err on the side of being over-inclusive – at least with your home institution. Having the foreign affiliation is often not an issue – failing to disclose it is. If you've failed to disclose a foreign component or foreign affiliation involving an active award, keep in mind that disclosure errors do not improve or go away with time. Contact your institution or personal counsel to determine whether a corrective disclosure may be necessary and how best to make one.

Key Concept #1 - Foreign Component

- **Definition:** The performance of any significant scientific element or segment of a NIH-supported project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, and whether or not NIH grant funds are expended to perform the overseas elements/services.
- **Examples include:**
 - Collaborations with investigators at a foreign site anticipated to result in co-authorship
 - Use of facilities or instrumentation at a foreign site
 - Receipt of financial support or resources from a foreign entity
 - Involvement of human subjects or vertebrate animals at a foreign site
 - Extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities
 - Activity that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country
- **How to disclose:**
 - Foreign components require **prior approval from NIH**
 - Approval can be obtained using a “Foreign Justification” form
 - Progress Reports/RPPRs contain a “Foreign Component” section
 - Depending on the nature of the foreign component, it may need to be listed in “Facilities and Other Resources,” “Participants” or “Senior/Key Personnel,” or “Other Support” sections of various grant documentation

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➤ Key Concept #2 - Other Support

- **Definition:** All resources made available to the researcher or senior key personnel in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value, regardless of whether they are based at the institution the researcher identifies for the current grant, and regardless of whether the support relates to the award for which the researcher is submitting an application, JIT or RPPR. Other Support excludes training awards, prizes, gifts or start-up support from a researcher's U.S. based home institution.
- **Examples of Other Support to be disclosed include:**
 - **Financial support**, like foreign grants, cooperative agreements, contracts, and financial support for researchers or the purchase of equipment
 - **In-kind support**, like office/laboratory space, supplies, free labor
 - **Positions** including certain adjunct/visiting/honorary appointments, selection to foreign talent programs
 - Other foreign resources, like those that support the research but otherwise do not constitute a foreign component because the work is being performed in the U.S.
- **How to disclose:**
 - Biosketch, JIT, and/or RPPR; must be updated whenever an updated Other Support or Current/Pending Support page is due

➤ Key Concept #3 - Financial Conflict of Interest (FCOI)

- **Definition:** A FCOI exists when the recipient institution's designated official reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. Keep in mind that this determination is made by the institution, not by you. You must report any significant financial interest – your role is not to determine on your own whether you believe the interest poses a conflict.
- **Examples of financial interests that may create a FCOI include :**
 - Consulting fees honoraria, paid authorship, equity interests (e.g., stock, stock options), intellectual property rights and interests, and reimbursed or sponsored travel
 - Reimbursed/sponsored travel is often overlooked; it applies to travel sponsored by domestic or foreign corporations, a foreign government, foreign universities, and foreign research institutes
- **How to disclose:** Your home institution is required to have a financial conflict of interest review process. If your home institution believes there is a FCOI that requires management, it must work with you to implement a management plan and they will report the plan to the relevant funding agency. Keep in mind that some institutions prohibit specific types of FCOIs, even in situations where a funding agency might permit the arrangement.