

# Do I Need to Seek Prior Approval for an NIH Foreign Component?

**Purpose:** This document assists researchers in identifying whether they need to request Prior Approval (permission) from the NIH **to include a foreign collaboration or activity on an NIH funded project**. It is based on the best available guidance from the National Institutes of Health and **is not a substitute for a thorough review of NIH and Harvard policies and guidance**. For questions about international collaborations or activities on a proposal or award from other federal agencies (e.g. NSF, DOD), contact your School's grant submitting office.

**Definition of an NIH Foreign Component:** The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended.

**Values Statement:** Harvard University encourages meaningful collaborations that further our world-class research. We are proud of our domestic and global connections and value openness and inclusivity in research. Full disclosure and transparency of all relationships and resources (including foreign financial support and resources) highlight our values and productivity in service to our mission.

**Investigator Responsibilities:** Researchers must receive Prior Approval for Foreign Components before any work is initiated abroad, including for a Foreign Component added during an active NIH project period. Prior Approval is obtained by indicating the foreign component on the initial application or via a Prior Approval request submitted by your School's grants submitting office.

**Support:** Contact your School's grants submitting office for additional support or to make a Prior Approval request.

## Part 1: Basic Question

Will activities or intellectual contributions in support of my **NIH funded** project be **performed outside the U.S.**? **Yes** **No**

**No**

If you answered "No" to this question, then you likely **do not** have a Foreign Component.

**Yes**

If you answered "**Yes**" to this question, then **go to Part 2, Determine Significance**

## Part 2: Determine Significance

- |  |            |           |
|--|------------|-----------|
| 1. Will the foreign activity or contribution involve human subjects or animals subjects?   | <b>Yes</b> | <b>No</b> |
| 2. Will there be extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities?  | <b>Yes</b> | <b>No</b> |
| 3. Will any activity of the project have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country?  | <b>Yes</b> | <b>No</b> |
| 4. Will the contribution or activity abroad include direct and significant intellectual contributions to design, conduct or analysis of research in pursuit of specific aims included in the NIH proposal or RPPR? | <b>Yes</b> | <b>No</b> |
| 5. Will the contribution or activity abroad be considered fundamental or essential to the completion of the proposed aims/scope of work on a specific NIH funded project?  | <b>Yes</b> | <b>No</b> |

**Yes**

If you answered **Yes** to **any** of the Determine Significance questions, then you **must seek Prior Approval** as an NIH Foreign Component **before your international collaboration or activity begins**. **Next Step:** Contact your School's grant submitting office. Prior Approval requests must be submitted to NIH by an Authorized Organization Representative on your behalf.

**No**

If you answered **No** to all five of the Determine Significance questions, then you likely do not have a foreign component. However, if you anticipate including foreign co-authors on publications that cite your NIH funding, use facilities or instrumentation abroad, or provide funds to or receive funds from an international collaborator, contact your School's grant submitting office to discuss if this constitutes a Foreign Component.

**Unsure?**

If you are still unsure whether an international contribution or activity is significant enough to rise to the level of a NIH Foreign Component, Prior Approval is recommended. Contact your school's grant submitting office.