Evaluating a Foreign Component

of the aims of the NIH funded project

A collaboration with a Foreign Entity should be disclosed as a foreign component when all three criteria are being met:

- □ Portion of project work is being done IN or AT or BY a foreign location
 □ The work abroad is in support of a NIH funded project
 □ The work being done abroad is a SIGNIFICANT segment in direct support of the completion
- Element/segment
 done in, at, or by a
 foreign location

 This is a Foreign
 Component that must be
 disclosed on Federal Grant
 applications or via Prior
 Approval Requests, and
 once approved reported
 via RPPRs

Work aborad is a significant element or segment of the project

Project is funded by the NIH (funds do not have to be spent at foreign site)

The focus of Foreign Component determination is what the foreign collaborator/site contributes towards the completion of proposed the NIH project aims. Do not get hung up on authors listed in publications. A publication does not automatically create a reportable Foreign Component. Likewise, you may have to disclose a Foreign Component even if a publication does not occur.

Foreign Component Decision Tree:

NIH definition: The performance of any <u>significant</u> scientific element or segment of the NIH-supported project outside of the U.S., by the grant recipient or other researcher, <u>whether or not grant funds are expended</u>.

Ask:

Q1. Will a portion of the work be performed outside of the United States?

In no: There is not a Foreign Component on this project to disclose.

If yes, ask:

Q2. Is the work abroad in support of the specific aims of an NIH funded project?

If no: There is not a Foreign Component on this project to disclose.

If yes, ask:

Q3. Are the activities outside of the US considered <u>significant</u> towards the completion of the NIH project aims?

If no: No disclosure required

If yes: **Foreign Component** disclosure required Please work with your Grants Manager and with the Office of Research Administration to make sure the Foreign Component is disclosed on your proposal, RPPR or via a Prior Approval request.

If unsure: Please reach out to the Office of Research Administration to discuss your project and to work through the Determining Significance questions below. For foreign collaborations or foreign site activities whose significance is unclear, you are encouraged to err on the site of disclosure, or you may reach out to your NIH program officer. Please document/confirm any conversation with the NIH in writing.

Questions for discussion: Determining if work done at, in or by a foreign collaborator or site is a <u>SIGNIFICANT</u> element or segment of a project?

Significant is a subjective term. As such, the PI will have to use their best judgement in determining if the work being done at, in or by a foreign site that benefits a federally funded project rises to the level of significant. Some questions that a PI can ask to help make a determination of significant are:

GENERAL QUESTIONS

- 1. Is the work performed in, at or by the foreign site considered to be a substantial, direct, intellectual scientific contribution towards the project?
- 2. Is the foreign site involved in the scientific design, conduct or reporting of any part of the proposed project?
- 3. Would the characteristic of the proposed research fundamentally change if the international component did not occur?
- 4. If the work was not done by the foreign site, could the project be completed as proposed?
- 5. How readily could the work at the foreign site be performed at a different location (domestic or foreign)?

SHOULD BE DISCLOSED AS A FOREIGN COMPONENT

- 6. Does the work at the foreign site involve human or animal subjects? If yes, this should be disclosed as a Foreign Component
- 7. Does the work for the project involve extensive travel by recipient project staff to a foreign site for the purpose of data collection, surveying, sampling, and similar activities? If yes, this should be disclosed as a Foreign Component.
- 8. Does the project involve any activity that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country? If yes, this should be disclosed as a Foreign Component.

MAY NEED TO BE DISCLOSED AS A FOREIGN COMPONENT

- 9. Does the project involve collaborations with investigators at a foreign site anticipated to result in co-authorship? If yes, this MAY indicate a Foreign Component.
- 10. Does the project involve the use of facilities or instrumentation at a foreign site? If yes, this MAY indicate a Foreign Component.
- 11. Are you providing funding to the foreign site via a subaward or consulting arrangement? If yes, this MAY indicate a Foreign Component.
- 12. Does the project involve the receipt of financial support or resources <u>from</u> a foreign entity? If yes, this MAY indicate a Foreign Component.

MAY NOT BE A FOREIGN COMPONENT

- 13. Is the site providing a service or material that you can purchase, develop or acquire elsewhere? If yes, this MAY NOT be a Foreign Component
- 14. Is the Foreign Site a vendor under a vendor agreement or being paid for their materials as a vendor? If yes, this MAY NOT be a Foreign Component

15.	Is the Foreign Site only developing research materials under the direction of the US institution with no independent scientific contribution from the Foreign Site?