

Foreign Component Case Studies

Office of Policy for Extramural Research Administration
(OPERA) - Office of Extramural Research (OER)

June 10, 2026

Agenda

01. Background and Policy

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Background and Policy

Background

- The community has raised concerns about conflicting requests from NIH Institutes and Centers related to co-authorship with international collaborators.
- This has resulted in questions regarding whether NIH has changed its definition of a foreign component, and whether a foreign co-author on a publication that cites an NIH grant award automatically results in a foreign component.
- See [NOT-OD-26-084: Reminder Definition of Foreign Components](#)

Policy: International Co-Authorship

- The longstanding definition of a foreign component has not changed (i.e., the performance of any significant scientific element or segment of a project outside of the United States)
- Co-authorships must be reviewed on a project specific basis.
- Recipients should work with their respective administering Institute/Center/Office and if additional support is required, contact the Office of Extramural Research/OPERA.

Reminder of NOFO Requirements

- Recipients must pay close attention to the Notice of Funding Opportunity (NOFO), which outlines whether foreign components are permitted.
- For awards that are issued from NOFOs that do not allow foreign components, publications and other research projects generally should not include foreign co-authors or collaborators.
- When NIH identifies indicators of potential foreign components that have not been disclosed, the funding Institute or Center may request additional information.

Co-Authorship and Other Policies

- How does NIH reconcile concerns regarding foreign co-authorship with NIH policies encouraging public access and scientific collaboration? Does NIH distinguish between data sharing, research collaborations, co-authorship, and foreign components for compliance purposes?
 - The NIH encourages collaboration when scientifically advantageous and allowed by policy, regulation and statute.
 - Foreign collaborations require prior approval because they constitute foreign components – this does NOT mean they are not allowed or are discouraged.
 - The NIH will consider each situation on a case-by-case basis during prior approval to assess if it constitutes a foreign component. Not every instance of co-authorship represent a foreign component, although most do.

Case Studies

Disclaimer: Case studies are provided as examples and are not inclusive of all possible scenarios. Recipients and NIH staff must evaluate individual situations on a project-by-project basis.

Case Study 1

Case Study 1: Scenario

- A graduate student is working on an NIH grant in the United States while they complete their studies.
- At the completion of their graduate program, they accept a position at a foreign institution and leave the United States.
- When a publication resulting from their NIH research activities is published, the individual's current affiliation at the foreign institution is listed in their author information.
- Is this a foreign component?

Case Study 1: Discussion

- Collaboration leading to co-authorship is an indicator that an activity may be significant.
- These determinations must be made on a case-by-case basis.
- In this scenario, none of the published NIH research was conducted outside of the United States. Therefore, there is no foreign component on the project.
- Researchers should use the address where they conducted the research for publications, so that it is clear where the work was conducted.

Case Study 2

Case Study 2: Scenario

- A post-doc works with a PI on an NIH funded grant and all scientific research activities are conducted in the U.S.
- The post-doc takes employment at a university in Canada before the manuscript is published.
- The post-doc is a co-author and is involved in the manuscript editing process while at the Canadian university.
- Is this a foreign component?

Case Study 2: Discussion

- Even though the editing occurred in a foreign country, all the scientific activities were conducted in the United States. This is not a foreign component.
- Community Question: Are institutions expected to end such researcher's access to research data and ability to edit the paper if they leave the U.S. for employment abroad?
 - Institutions must follow their institutional policies, as well as comply with NIH data management and sharing requirements, and specific (programmatic and/or administrative) terms and conditions of award.

Case Study 3

Case Study 3: Scenario

- A PI on an NIH-funded grant awarded to a domestic university has an ongoing collaboration with a researcher at a foreign university.
- They hold regular virtual meetings, and the foreign researcher provides substantive input on the techniques that are used to conduct the NIH funded research.
- No money is paid to the foreign researcher, but they are listed as a co-author on publications arising from the NIH-funded project.
- Is this a foreign component?

Case Study 3: Discussion

- Yes. The foreign researcher routinely collaborated with the NIH-funded PI and provided substantive input on the project, which resulted in co-authorship.
- While no funds were allocated to the foreign activities, a significant scientific element of the project was conducted in a foreign country.
- Therefore, this constitutes a foreign component that must be disclosed.

Case Study 4

Case Study 4: Scenario

- A publication is supported by multiple funding sources (i.e., NIH and non-federal sponsors).
- There is a foreign co-author on the publication that did not contribute to the NIH-funded portion of the work.
- This individual only contributed to the non-federally sponsored portion of the work.
- Is this considered a foreign component?

Case Study 4: Discussion

- No, this scenario does not describe a significant scientific element of the project being conducted outside of the US.
- As a reminder, the Stevens Amendment requires recipients to report the percentage and dollar amount of the total cost of the project or program that will be or was financed by non-governmental sources.
- While this must be reported, it does not signify that it is a foreign component.

Case Study 5

Case Study 5: Scenario

- A researcher is working on a publication related to an NIH funded project that ended in 2015.
- In preparing the publication, a foreign collaborator is contributing some of the theory for the manuscript. This will result in co-authorship.
- None of the research from the NIH-funded project was completed in a foreign country.
- Is this a foreign component?

Case Study 5: Discussion

- The NIH funded project ended over 10 years ago and no element of the project was conducted in a foreign country.
- Therefore, this is not a foreign component.

Case Study 5: Follow-up

- What should recipients do when a potential foreign component is identified after the project period has ended, and all final reports have been submitted?
 - The recipient should notify the funding IC, in writing and document their official file. The NIH IC will document the disclosure.

Case Study 6

Case Study 6: Scenario

- A PI on a NIH grant awarded to a domestic university has a paid consulting agreement with a researcher in a foreign country.
- While in the foreign country, the consultant provides regular input and analysis in support of the NIH project and is listed as a co-author on the resulting publications.
- Is this a foreign component?

Case Study 6: Discussion

- Yes. The consultant conducted a significant scientific element of the project in a foreign country. Therefore, this is a foreign component.

Case Study 7

Case Study 7: Scenario

- A PI on an R35 Outstanding Investigator Award has identified a foreign collaboration that may result in co-authorship.
- R35 awards do not have specific aims.
- How would a researcher gain approval for a foreign collaboration that may result in co-authorship in such cases?

Case Study 7: Discussion

- As outlined in each NIH R35 Notice of Funding Opportunity, new foreign components require prior approval according to existing policies.
- The recipient should contact the funding IC to provide details on the collaboration to determine whether it is a foreign component, and submit a prior approval request, as required.
- If there are still questions, recipients can reach out to OPERALeadership@nih.gov

Case Study 8

Case Study 8: Scenario

- A PI on an NIH grant awarded to a domestic university is conferring with a non-US researcher.
- The non-US researcher did not contribute toward the publication resulting from the research.
- Does the institution need to cite the non-US researcher?
- Is conferring synonymous with collaboration?

Case Study 8: Discussion

- Conferring occasionally does not constitute a collaboration.
- This is not a foreign component and disclosure is not required.

Case Study 9

Case Study 9: Scenario

- A researcher was the PI on an NIH-funded grant that supported a five-year clinical trial. The NIH-funded grant has ended.
- The following year, the researcher uses the data from the previous grant to perform new secondary analysis.
- No NIH is used to pay for the secondary analysis.
- When publishing the secondary analysis, the research cites the original NIH grant because it supported the trial that produced the data.
- Does the Stevens Amendment acknowledgement in the publication also need to include the NIH grant?

Case Study 9: Discussion

- In this case, the NIH grant supported the trial that produced the data and should be cited in the publication.
- However, no NIH funds were used to pay for the secondary analysis being reported in the publication.
- While NIH funds were not used, non-federal funds were used. The non-federal funds must be included in the Stevens Amendment acknowledgement.

Case Study 10

Case Study 10: Scenario

- A researcher conducts a project funded by an NIH grant.
- Later, the researcher uses the data generated by the NIH funded grant as the basis for other projects that are not funded by NIH.
- The non-federally funded projects result in publications.
- Should the NIH grant be cited in the publication? Should the NIH funding be included in the Stevens Amendment acknowledgment?

Case Study 10: Discussion

- The data generated using NIH funds directly benefitted the non-federally funded project. Therefore, the publication must cite the NIH grant.
- Since the published work was not directly funded by NIH, the Stevens Amendment acknowledgement must cite the non-federal funding source(s).

Stevens Amendment

Stevens Amendment (Acknowledging NIH Funding)

- In accordance with the [Stevens Amendment](#), each publication, press release, or other document about research supported by an NIH grant must include:
 - An acknowledgment of NIH grant support clearly stating the percentage and dollar amount of the total costs of the program or project funded with federal money, and the percentage and dollar amount of the total costs of the project or program funded by non-governmental source.

Stevens Amendment – Compliant Example

- Research described in a publication was supported by 4 sources – 2 NIH grants and 2 non-federal awards. Each project received \$1 million in total costs in the timeframe that the published research was conducted.
- Example Acknowledgement:
 - Research reported in the Journal of Health Psychology, March 2026, was supported by 1) the National Institute of Mental Health under grants R01MH123456 and R01MH654321 and 2) the Imaginary University Clinician Scientist award, and an award from the Foundation for Research. A total of \$2 million, or 50 percent of this project was financed with federal funds. A total of \$2 million, or 50 percent of the project was financed with non-governmental funds.

Stevens Amendment - Reminders

- Attributing publications to grants that did not actually support the research does not align with NIH policy and could inadvertently result in compliance actions.
- If the NIH grant only supported a specific part of the published work this should be made clear in the grant citation in the publication and in the [Research Performance Progress Report](#).
- NIH-funded investigators must accurately list their affiliations on publications to reflect where they performed the NIH-funded work rather than using their current address if it is different from the performance site.

Questions?

