

# Sanford Research Pediatric Research COBRE Plan for Ensuring Compliance with NIH Foreign Component Policy

**Purpose:** This plan outlines the steps Sanford Research will implement to ensure compliance with NIH/NIGMS guidance regarding foreign components, specifically the prohibition of foreign components in Pediatric Research COBRE awards and the attribution of publications involving foreign co-authors. Investigators are strongly encouraged to consult with the Office of Grants ([researchgrants@sanfordhealth.org](mailto:researchgrants@sanfordhealth.org)) prior to engaging any foreign entity to ensure compliance.

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## I. Compliance Framework

### A. Administrative policies for attribution of research works to the COBRE

- Publications involving foreign components will *not be attributed* to the COBRE award in RPPRs or MyNCBI
- COBRE grant acknowledgment may only be included when the work aligns with NIH requirements and program restrictions
- Pilot Projects and Core users will be educated on these policies

### B. COBRE Pilot Projects Policy Implementation

Pilot project RFAs will include clear language stating that:

- COBRE-supported projects may not include foreign components, which means no foreign co-authors can be on any publications that cite the COBRE
- COBRE-supported work must not involve directing project resources outside of the United States

#### Ongoing Reinforcement

This guidance will be communicated at multiple timepoints:

- At RFA release
- At time of award
- During Advisory Committee (AC) meetings
- At project closeout (recognizing that publications often occur after the award period)

#### Required Language

The following language will be included in RFA materials and award communications:

COBRE-supported projects must comply with NIH policy prohibiting foreign components. Project activities may not involve performance of work outside of the United States or collaboration with foreign institutions that would constitute a foreign component.

Publications resulting from COBRE-supported work must adhere to these requirements. If a publication includes foreign co-authors or activities that may constitute a foreign component, COBRE funding should not be acknowledged.”

**Definition of 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. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals at a foreign site, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an

impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are:

- collaborations with investigators at a foreign site anticipated to result in co-authorship;
- use of facilities or instrumentation at a foreign site<sup>1</sup>; or
- receipt of financial support or resources from a foreign entity.

Foreign travel for consultation is not considered a foreign component” (see [NIH Policy Statement](#)).

NIH guidance on how to acknowledge NIH support in publications can be found at <https://grants.nih.gov/policy-and-compliance/policy-topics/federal-funding>.

## C. COBRE Core Facilities

### Core-Level Responsibilities

- Provide guidance to users regarding appropriate acknowledgment of COBRE support
- Inform users that publications involving foreign co-authors are not eligible for COBRE attribution
- Communicate expectations at project initiation and project closeout
- Incorporate standardized language into service agreements and user communications

### Required Language

The following standardized language will be incorporated into Core service agreements, project intake/onboarding materials, email communications at project initiation and completion, and on the Core website:

Use of COBRE-supported Core facilities is intended to support research activities that comply with NIH requirements for COBRE awards, including the prohibition of foreign components.

**Definition of 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. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals at a foreign site, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are:

- collaborations with investigators at a foreign site anticipated to result in co-authorship;

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<sup>1</sup> Use of fee-for-service vendors or facilities, including those located outside of the United States, will be evaluated to determine whether the activity constitutes a foreign component under NIH guidance. NIH has clarified that collaborations with investigators at foreign institutions that result in co-authorship constitute a foreign component and are not allowable under IDeA/COBRE awards. Fee-for-service arrangements that do not involve collaboration, co-authorship, or performance of a significant scientific element outside the United States may not constitute a foreign component; however, given current NIH guidance and evolving interpretation, these situations will be reviewed on a case-by-case basis. In all cases, COBRE attribution should only be included where the activity is fully compliant with NIH policy and does not involve a foreign component.

- use of facilities or instrumentation at a foreign site; or
- receipt of financial support or resources from a foreign entity.

Foreign travel for consultation is not considered a foreign component” (see [NIH Policy Statement](#)).

If work performed using Core services contributes to a publication that includes foreign co-authors or involves activities outside of the United States that may constitute a foreign component, the COBRE award should **NOT** be acknowledged in that publication.

Core facilities cannot regulate authorship of its users’ publications; however, it is the responsibility of the user to ensure that acknowledgment of COBRE support is appropriate and compliant with NIH policy.

NIH guidance on how to acknowledge NIH support in publications can be found at <https://grants.nih.gov/policy-and-compliance/policy-topics/federal-funding>.

### **Key Approach**

- Cores cannot regulate authorship decisions of its users
- Instead, they will:
  - Educate users
  - Clarify when COBRE attribution is appropriate

## **II. Ongoing Clarification with NIH**

The PI will continue to engage NIH/NIGMS to seek clarification on:

- Interpretation of foreign co-authorship in relation to foreign components
- Appropriate handling of COBRE Core attribution

This plan will be updated as additional guidance is received.