Office of Sponsored Programs (OSP) Roundtable

Changes to NIH Biosketch and Other Support Document Requirements

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Agenda

- Background & History

- Other Support Document

- Post-Award Notification Requirement

- Biographical Sketch

- Questions

Background & History

What are the Federal Government concerns?

- Failure to disclose
  - Financial conflicts of interest
  - Conflicts of commitment
  - External employment arrangements
  - Financial support that overlaps with U.S. funding
  - Shadow laboratories or other parallel research activities
  - Diversion of intellectual property
  - Peer review violations

The FBI has more 1000 investigations into China's actual and attempted theft of American technology.

What are the Higher Ed concerns?

- Chilling effect on international collaboration
- How to discern the good collaborations from the more concerning ones
- Climate of fear and suspicion
- Negative impacts on foreign students and researchers
- Administrative burden
- Lack of clarity in regulations and lack of harmonization across agencies
- Continually evolving guidance

Perspective: The NIH incidents we have seen so far involve 87 institutions with confirmed violations of NIH rules by over 150 scientists. NIH funds scientists across the country and even across the globe. Each year, NIH awards more than 60,000 research and training grants. These support approximately 300,000 researchers.

Cornell University's Commitment to Global Engagement

- "An institution where any person can find instruction in any study."
  - Diverse community of students, researchers, and faculty representing over 90 countries.
  - Strong commitment to global engagement, an appreciation of intercultural differences, and a spirit of collaboration for mutual benefit.

- May 2019, Academic Integrity and Undue Foreign Influence: Guidelines
  - Reaffirmed Cornell's commitment to international partnerships and activities
  - Summarized best practices and resources available to support Cornell researchers

- OSP Roundtables, Disclosing Foreign Relationships and Activities
  - November 2019 Recording
  - September 2020 Recording

History

August 2018
Letter from NIH Director Dr. Francis Collins

- Some researchers failing to disclose contributions to their research
- Diversion of IP to other entities, including pre-publication data
- Some peer reviewers failing to keep information from the process confidential

Early 2019
NIH Office of Extramural Research Letters ("Lauer Letters")

- Focused on undisclosed participation in foreign talent programs, affiliations with foreign institutions, substantial and related foreign grants, "shadow labs", and foreign patents and startups
- Investigations continue today

History

July 2019
NIH Policy Notice NOT-OD-19-114 & FAQs

- **Other Support** – _All_ financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of _all_ of an individual's research endeavors.

- **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_. (Foreign subawards are defined as foreign components per NIH.)

- **FCOI** – Investigators must comply with their institutions' FCOI policy and disclose significant financial interests, including financial interests received from a foreign entity.

New Requirements!

March 2021
NIH Policy Notice **NOT-OD-21-073**

April 2021
NIH Policy Notice **NOT-OD-21-110**

- Implements several significant changes to the Other Support Document, including related required post-award notifications, and the Biographical Sketch.
- Introduces new Biosketch and Other Support Document formats.
- Expands scope of required documentation.

May 25, 2021
Partial Implementation

January 25, 2022
Full Implementation

Office of Sponsored Programs (OSP) Roundtable

Other Support Document

What does the NIH use the Other Support Document to assess?

- All resources made available to an investigator, including any foreign activities, are considered prior to making an award

- Possible scientific and/or budgetary overlap

- Sufficient levels of effort are committed to the project

- Researcher time commitment and the potential for overlap or over-commitment (i.e. effort greater than 100%)

- Funds necessary to the approved project are included in the grant award

What must be included in the Other Support Document?

- Financial Support
  - Sponsored awards that support an investigator's research efforts, held at Cornell, at another institution/entity, or as an individual
  - Start-up packages from entities other than Cornell
  - Institutional awards at Cornell or other institutions that are separately budgeted and accounted for.

- In-kind Resources
  - In-kind contributions, e.g. office/laboratory space, equipment, supplies, support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.), employees or students supported by an outside source.
  - If the time commitment or dollar value of the in-kind contribution is not readily ascertainable, the recipient must provide reasonable estimates.

What *does not* need be included?

- Cornell start-up packages, gifts, or endowed chairs
- NIH training grants
- Non-financial resources that are available to the Cornell community at large, such as core facilities or shared equipment or other non-financial resources at Cornell not supported by an outside source

New requirements effective May 25, 2021…

- Use of the new Other Support Document template is encouraged *but not required*.

- Consulting agreements, when the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities must be included in Other Support. Non-research consulting agreements do not need to be included.

- Translated copies of foreign employment/appointment agreements and any agreements for foreign support listed on the Other Support Document **must** be available if requested by Cornell or NIH.

- Other Support **must** include past 3 years of completed support.

- All researchers and administrators **must** notify the assigned Grant & Contract Officer immediately upon discovering previously undisclosed Other Support.

New Requirements Effective January 25, 2022…

- New Other Support Document templates **must** be used.

- Financial and in-kind support is now in two separate sections

- Other Support documents must be signed by the PI/PD/KP to certify that the information provided is complete and accurate

- Translated copies of foreign employment/appointment agreements and any agreements for foreign support listed on the Other Support Document **must** be provided to Cornell and attached to the Other Support Document submitted to NIH.

**For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED
PHS 398 OTHER SUPPORT**

*There is no "form page" for reporting Other Support. Information on Other Support should be
provided in the format shown below.*

*Name of Individual:
Commons ID:

Other Support – Project/Proposal

*Title:

Major Goals:

*Status of Support:

Project Number:

Name of PD/PI:

*Source of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date: (MM/YYYY) (if available):

* Total Award Amount (including Indirect Costs):

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1.___[enter year 1]	
2.___[enter year 2]	
3.___[enter year 3]	
4.___[enter year 4]	
5.___[enter year 5]	

Name of Individual:
Commons ID:

IN-KIND

*Summary of In-Kind Contribution:

*Status of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date (MM/YYYY) (if available):

*Person Months (Calendar/Academic/Summer) per budget period

Year (YYYY)	Person Months (##.##)
1.___[enter year 1]	
2.___[enter year 2]	
3.___[enter year 3]	
4.___[enter year 4]	
5.___[enter year 5]	

*Estimated Dollar Value of In-Kind Information:

*Overlap (summarized for each individual):

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

*Signature: _____

Date: _____

Other Support
Post-Award Notification Requirement

Post-Award Notification Requirement

- When a recipient organization discovers that a PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information outside of Just-in-Time or the RPPR, as applicable, the recipient must submit updated Other Support to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.

- PIs and campus research administrators are expected to reach out to their assigned Grant & Contract Officer should any undisclosed Other Support information be discovered.

Biographical Sketch

What must be included in the Biosketch?

- Any position or scientific appointment held by investigators that is relevant to the application

- Includes domestic or foreign, paid or unpaid, or full/part-time/voluntary.

- Titled academic, professional, or institutional appointments, including adjunct, visiting, or honorary must be disclosed.

- Outside activities that are not research related (e.g. serving on a science advisory board for a start-up company where the investigator will not perform research) do not need to be included in the disclosure, *but may still require disclosure to Cornell in the annual financial conflict of interest (fCOI) disclosure*.

Effective January 25, 2022

- ## Section A, Personal Statement
  - All applicants may now include details on ongoing and completed research projects from the past three years that they want to draw attention to (previously known as Research Support).

- ## Section B, Positions, *Scientific Appointments*, Honors
  - This section has been expanded to require disclosure of all positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

- ## Section D, Research Support and/or Scholastic Performance
  - This section has been removed for non-fellowship applications and RPPRs.
  - Section D is solely present on the fellowship version of the Biosketch, and no longer includes research support, only Scholastic Performance.

Current Requirements	Effective May 25, 2021	Effective January 25, 2022
• All senior and key personnel **must** report all support related to their research activities - whether funded or in-kind, domestic or foreign, held at Cornell or another institution or privately – in the Other Support Document provided with a JIT or RPPR submission. • All positions and scientific appointments – whether paid or unpaid, domestic and foreign – that are relevant to an application including affiliations with foreign entities or governments **must** be disclosed in the Biosketch.	Current requirements, **plus**: • Use of the new Other Support Document and Biosketch templates is encouraged but not required. • Translated copies of foreign employment/appointment agreements and any agreements for foreign support listed on the Other Support Document **must** be available if requested by Cornell or NIH. • Consulting agreements, when the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities must be included in Other Support. • Other Support **must** include past 3 years of completed support. • All researchers and administrators **must** notify the assigned Grant & Contract Officer immediately upon discovering previously undisclosed Other Support.	All previous requirements, **plus**: • New Other Support Document and Biosketch templates **must** be used. • Translated copies of foreign employment/appointment agreements and any agreements for foreign support listed on the Other Support Document **must** be provided to Cornell and attached to the Other Support Document submitted to NIH. • All Other Support Documents **must** be signed by PI/PD/KP.

Office of Sponsored Programs (OSP) Roundtable

Questions

NIH Resources

- [Biosketch Format Pages, Instructions and Samples](#)
- [Other Support Format Pages, Instructions and Samples](#)
- [FAQs](#)
- [NOT-OD-19-114](#), Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components (July 2019)
- [NOT-OD-21-073](#), Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021 (March 2021)
- [NOT-OD-21-110](#), Implementation of Changes to the Biographical Sketch and Other Support Format Page (April 2021)

Cornell Resources

- Foreign Collaborations and Support
- Disclosing International Partnerships to Cornell and External Sponsors
- NIH: Disclosing Other Support and Foreign Components
- NSF: Disclosing Current & Pending Support, Biographical Sketches, and International Partnerships
- NASA: Affiliations with China and Disclosing Current & Pending Support