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Medicine

Office of Sponsored Research Administration (OSRA) Town Hall

Changes to NIH Other Support Document and Biosketch Requirements

Office of Sponsored Research Administration (OSRA)

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Zoom Webinar

- Please utilize the Q&A function to post questions.
- Questions will be answered 1. live at the end of the webinar (time permitting), 2. in writing using the Q&A functionality, or 3. they will be published in FAQs as we clarify answers with the NIH, Cornell's Office of Sponsored Programs (OSP), and our Office of General Counsel.
- NIH guidance continues to change and evolve. Your patience and flexibility are greatly appreciated.



Agenda

- History & Context
- Other Support
- Post-Award Notification
- Biographical Sketch
- Questions



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History & Context



History & Context

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 & Context

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 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 & Stepped Implementation

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





What are the Federal Agency Concerns?

Transparency and disclosure

– **Undue Foreign Influence**

- Undisclosed foreign components in grants
- Undisclosed involvement in Foreign Talent Programs
- Undisclosed foreign appointments and affiliations

– **Conflicts of commitment**

- Overlapping effort and overcommitments (more than 100% effort)

– **Overlapping Science and Resources**

- Undisclosed research resources with a focus on non-US support

– **Diversion of intellectual property/know-how developed with federal funds**

- Unchecked foreign exports

– **NIH Grant Application Confidentiality**

- NIH Review Committee Members sharing proprietary information

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



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What is Undue Foreign Influence?
How does it manifest? How do we codify it? How do we mitigate risk?



Reporting Foreign Financial Conflicts of Interest



Visa applications and renewals denied, foreign nationals stranded.



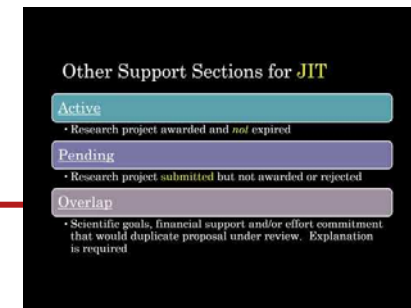
Clarification of Guidelines for what Constitutes a Foreign Grant Component



Changes to NIH Biosketch and Other Support Document Requirements



Higher Education Act Sec-117 Foreign Revenue Reporting



Capturing Foreign Sources of Other Support



Covered Communications Certifications and Assurances



Data Protections



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.



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Cornell'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.



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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 new Other Support Document?

Formatting/Additional Details

- Current and Future Year Effort Commitments
- Project Total Funding
- Primary Place of Performance
- Completed Support for Prior 3 Years

Research Consulting Agreements

- Consulting (aka Advisory) services supporting the conduct of research

Other Financial Resources

- All external financial support from all foreign and domestic entities, that are available to the researcher

In-Kind Resources

- All external non-financial resources from all foreign and domestic entities that are available to the researcher

Investigator Signature

- Investigator's signature required to signify certification of full disclosure under penalty of law

Foreign Agreement Submission to NIH

- Agreements specific to appointments, affiliations, and/or employment with a foreign institution, for resources included in Other Support
-



What must be included in the new 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
 - All financial research resources 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 expected *but not required*.
- Other Support **must** include past 3 years of completed support.
- Other Support **must** include in-kind resources.
- Consulting agreements, when the 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.
- All researchers and administrators **must** notify the assigned Grant & Contract Specialist immediately upon discovering previously undisclosed Other Support.



Consulting Agreements

Investigators and senior/key personnel must include Consulting/Advisory agreement data in the Other Support Document Template as directed by the NIH when:

- The agreement supports the conduct of research

A potential indicator of conduct of research is the intent to co-author a publication

Not conduct of research:

- Expert testimony given in court
- Expert opinion given verbally or in writing
- Expert opinion on research study design



Definition Conduct of Research

Uniform Guidance CFR § 200.87 Research and Development (R&D).

“Research” is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied



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/KP to certify that the information provided is complete and accurate.
- For Other Support submissions that include foreign activities and resources, translated copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution **must** be provided to Cornell and attached to the Other Support Document submitted to NIH.



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OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

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] | |

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

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: _____



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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 Specialist should any undisclosed Other Support information be discovered.



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Biographical Sketch



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 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.



Changes to Biosketch Format

| Section | Existing Format | Updated Format |
|---------|---|--|
| A | Personal Statement | <ul style="list-style-type: none">Personal Statement plus option to include ongoing/completed research projects that highlight this application (3 yrs.) (Section D) |
| B | Position and Honors | <ul style="list-style-type: none">Renamed "Positions, Scientific Appointments and Honors" |
| C | Contributions to Science | <ul style="list-style-type: none">No Change |
| D | Ongoing & Completed Support, Scholastic Performance | <ul style="list-style-type: none">Moved to Section A (non-Fellowship); Scholastic Performance, only for fellowship form |



Changes to Biosketch Format

A. Personal Statement

I am an Associate Professor of Psychology, and my research is focused on neuropsychological changes associated with addiction. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2015-2016, my career was disrupted due to family obligations. However, upon returning to the field, I immediately resumed my research projects and collaborations and successfully competed for NIH support. In summary, I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project.

Ongoing and recently completed projects that I would like to highlight include:

R01 DA942367
Hunt (PI)
09/01/16-08/31/21
Health trajectories and behavioral interventions among older substance abusers

R01 MH922731
Merryle (PI), Role: co-investigator
12/15/17-11/30/22
Physical disability, depression and substance abuse in the elderly



Formerly
included in
Section D



Biographical Sketch

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

| | |
|----------------|---|
| 2021– Present | Associate Professor, Department of Psychology, Washington University, St. Louis, MO |
| 2020 – Present | Adjunct Professor, McGill University Department of Psychology, Montreal, Quebec, Canada |
| 2018 – Present | NIH Risk, Adult Addictions Study Section, members |
| 2015 – 2017 | Consultant, Coastal Psychological Services, San Francisco, CA |
| 2014 – 2021 | Assistant Professor, Department of Psychology, Washington University, St. Louis, MO |
| 2014 – 2015 | NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer |
| 2014 – Present | Board of Advisors, Senior Services of Eastern Missouri |
| 2013 – 2014 | Lecturer, Department of Psychology, Middlebury College, Middlebury, VT |
| 2011 – Present | Associate Editor, Psychology and Aging |
| 2009 – Present | Member, American Geriatrics Society |
| 2009 – Present | Member, Gerontological Society of America |
| 2009 – 2013 | Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD |
| 2006 – Present | Member, American Psychological Association |

Honors

| | |
|------|---|
| 2020 | Award for Best in Interdisciplinary Ethnography, International Ethnographic Society |
| 2019 | Excellence in Teaching, Washington University, St. Louis, MO |
| 2018 | Outstanding Young Faculty Award, Washington University, St. Louis, MO |



| Current Requirements | Effective May 25, 2021 | Effective January 25, 2022 |
|---|---|--|
| <ul style="list-style-type: none">• 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, including affiliations with foreign entities or governments must be disclosed in the Biosketch. | <p>Current requirements, plus:</p> <ul style="list-style-type: none">• Use of the new Other Support Document and Biosketch templates is expected 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 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 Specialist immediately upon discovering previously undisclosed Other Support. | <p>All previous requirements, plus:</p> <ul style="list-style-type: none">• New Other Support Document and Biosketch templates must be used and include PI signature on the Other Support form.• 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/KP. |



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)