NIH’s Guide Notice
NOT-OD-21-073:
Institutional Perspective

June 8, 2021

Moderator:
Kristin West, Director, Research Ethics & Compliance, COGR

Panelists (in order of presentation):

Naomi Schrag, Vice President of Research Compliance, Training and Policy, Columbia University

Lisa Mosley, Executive Director, Yale University

Grace Fisher-Adams, Chief Research Compliance Officer, California Institute of Technology
Presentation Overview

• NIH NOT-OD-21-073, Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components
  • New Biosketch and Other Support format pages
  • Effective Date: May 25, 2020
  • NIH NOT-OD-21-110: New formats are not mandatory until January 25, 2022

• Presentation Focus Areas – Considerations & Tools
  • Summary of Requirements
  • Positively promoting international collaborations in the current environment
  • Consulting
  • Clinical Trials
  • Valuation
  • Gifts
  • Coordinating information from different units; controls
  • Collaborations
  • Training & Communication

C O G R
Council On Governmental Relations
Ironing Things Out

- Many institutions still working on policies and practices.
- Like other requirements, a certain degree of interpretation and institutional decision-making is required for implementation.
- One shot at training!
Positively Promoting International Collaborations

How to foster this:

When headlines look like this:

The New York Times
A Scientist Is Arrested, and Academics Push Back

REUTERS
U.S. doubles down on protecting university research from China
https://www.reuters.com/world/china/us-doubles-down-protecting-university-research-china-2021-03-01/

abc NEWS
Russia tried to hack coronavirus vaccine research, US, UK and Canada say
Consulting

**Requirement:** Sr./Key Personnel must report consulting agreements as "Other Support" if they are "conducting research" as part of the consulting activities.

**Considerations:**

- Treatment of consulting activities that fall within institution’s consulting guidelines (i.e., “one day a week”).
- Pros and cons of reviewing consulting agreements.
  - Institutional review raises complex issues
  - Is it possible to train faculty to review them and certify they meet institutional standards? Does this approach decrease or increase potential for institutional liability?
Consulting: The “Effort Conundrum”

- Under the Uniform Guidance, “effort” is based on Institutional Base Salary (IBS), which does not include external activities by definition and is not based on a particular number of hours per week or other metric. (see COGR’s *Principles for Evaluating Conflict of Commitment Concerns in Academic Research* at 21)

- Uniform Guidance also provides that outside professional activity must be conducted in accordance with institutional policies (Sec. 200.430(c))

- Other Support instructions ask for “actual effort” on consulting that involves the conduct of research, in calendar months.
Where the consulting engagement does not include an effort commitment in calendar months, is it possible to disclose an estimated number of days per year spent on the activity?

“This project is professional activity outside of my institution, as defined in the Uniform Guidance, 2 CFR § 200.430(c), and carried out in accordance with institutional policy on outside activities. I spend approximately _____ days per quarter/year on this outside activity.”
Considerations:

- Are industry-sponsored clinical trials part of “research endeavors” or “clinical activities”?
- What about investigator-initiated clinical trials?
  - How should donated investigational items (drugs, devices) be treated?
Valuation

Requirements:
• In-Kind Other Support includes provision of "high-value" materials that are "not freely available" (e.g., biologics, chemicals, model systems, technology, etc.)
• Time commitment or dollar value of in-kind contributions (or reasonable estimate thereof) must be provided.

Considerations:
• Definition of “high-value.”
• How to value items on which no value can be placed, e.g., human specimens?
• Who will determine values?
Gifts

Requirements: Reporting is not required for training awards, prizes or gifts (i.e., resources provided where there is no expectation of anything, e.g., time services, specific research activities, money, etc. in return).

Considerations:

• Gift v. grants policies.

• Coordination with institutional advancement/development offices.
Inter-Unit Coordination & Controls

Requirements: Institutions must "establish and maintain effective controls (e.g., policies and procedures)" to ensure Sr./Key Personnel fully disclose Other Support to institution as soon as it becomes known.

The Situation “On-the-Ground”:
• Information is housed in different units.
• Units may have different IT systems that don’t communicate.
• All institutions may not have university electronic signature systems.

Considerations:
• How to ensure consistency and alignment of information?
• How to promote cross-communications between units and systems?
• Testing? Validation?
Informing Researchers What to Report

• Penn State University Questionnaire on Other Support & Foreign Component Disclosures

 NIH Questionnaire for PSU Faculty (Other Support Forms and Foreign Component Disclosures):

NIH issued an important notice effective May 25, 2021 (NOT-OD-21-073), updating their expectations for disclosure of Other Support. In addition to disclosing all research activity administered through Penn State, Senior/Key Personnel are also expected to disclose all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at Penn State or received external to Penn State. NIH interprets Other Support to include the following:

- Paid or unpaid appointment(s) at another institution. Please include all research collaboration(s) at another institution that directly benefit the investigator’s research endeavors. Please also include any start-up funds provided by institutions other than PSU (amount currently available).

- Financial support, including, but not limited to, selection to a foreign “talents” or similar-type program, or other foreign or domestic support. This includes research performed outside of a faculty member’s appointment (e.g., a faculty member with a 9-month appointment at Penn State and a two-month appointment at another institution performed during the summer).

- Financial support for laboratory personnel. Please include employees, post-docs, students, and visiting scholars who are paid a salary by their government or home institution. “If the time commitment or dollar value of the in-kind contribution is not readily ascertainable, the recipient must provide reasonable estimates.”

- In-kind contributions, e.g., office/laboratory space, equipment, supplies, and other “high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.).”

- Outside Activities such as consulting where the researcher will be conducting research as part of the consulting activities. Private equity financing (e.g., in support of the SBIR/STTR program) and honoraria in support of an individual’s research endeavors must be included.

- Endowment(s), other PSU Unit/Department support, and retention funds provided in support of an investigator’s research (amount currently available).

- PSU Seed/internal grant (amount currently available).
Collaborations

Requirements: Report as Other Support collaborations with other scientists that directly benefit the reporter's research.

Considerations:
• Thresholds?
• Are all co-authors collaborators?

Tools:
• Caltech chart on collaborations: https://researchcompliance.caltech.edu/documents/19335/Col laboration_Spectrum_General-NIH_ONLY_FINAL.pdf
**Collaboration Spectrum**

<table>
<thead>
<tr>
<th>General Indicators</th>
<th>Report Support</th>
<th>Report Support OR Consider Foreign Component</th>
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<tbody>
<tr>
<td>No shared resources (materials, facilities, equipment, or personnel), no direct or measurable benefit to my research, no collaborative experiments</td>
<td>Co-authorship/Acknowledgement (see below); shared resources, financial or in-kind, including unique or high-value materials, facilities, equipment, or personnel; resources that benefit my research; collaborative experiments.</td>
<td>NIH: Significant element of a project performed outside the US: experiments, human or animal research, extensive data analysis</td>
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<tr>
<th>COLLABORATOR</th>
<th>DOMESTIC OR FOREIGN</th>
<th>DOMESTIC OR FOREIGN</th>
<th>FOREIGN</th>
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## Collaboration Spectrum

### General Indicators
- No shared resources (materials, facilities, equipment, or personnel), no direct or measurable benefit to my research, no collaborative experiments.

### Co-authorship/Acknowledgement
- Significant element of a project performed outside the US: experiments, human or animal research, extensive data analysis.

### Working Together on my Research Project
- My collaborator is outside the US.

### Publishing/Presenting Together

<table>
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<tr>
<th>Statement</th>
<th>Example</th>
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<tbody>
<tr>
<td>Dr. X is a co-author on a paper with me or is acknowledged on a paper where I am an author AND Dr. X contributed to the paper that did not overlap with my research reported in the paper (e.g., we didn’t design or perform experiments, Dr. X didn’t contribute to the data analysis of my data, and Dr. X contributed to the paper that did not benefit my research reported in the paper).</td>
<td>Paper publication example, methodology.</td>
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### Sharing Resources
- I received data, materials, reagents, etc. from my collaborator that led to publishable results or an acknowledgment or authorship in a publication.
- I received materials from my collaborator that were not "unique" or of high value.

### Collaborator DOMESTIC OR FOREIGN DOMESTIC OR FOREIGN FOREIGN
- 1. I had discussions with collaborator at a Conference.
- 2. Open discussions about research on Zoom/phone call.
- 3. I gave a research talk or seminar at another university...

### Scientific Discussions
- 1. I received data, materials, reagents, etc. from my collaborator that led to publishable results or an acknowledgment or authorship in a publication.
- 2. I received materials from my collaborator that were not "unique" or of high value.

### My collaborator
- 1. Received data, materials, reagents, etc. from the collaborator that benefitted my research.
- 2. A publication where I gave co-authorship or acknowledgment to the collaborator.
- 3. My collaborator helped me to perform experiments.
- 4. My collaborator sponsored a postdoc or graduate student in my lab.

### My collaborator’s lab
- 1. Unique materials, reagents, biological lines, etc. were created in a collaborator’s foreign lab and provided to me to work on a federally funded project.
- 2. Experiments were performed in a collaborator’s foreign lab, and data or results were provided to me in support of a federally funded project.
- 3. Human or animal subject studies were performed at a collaborator’s foreign institution in support of a federally funded project.

### University
- 1. I am a visiting scholar, and Dr. X is an experimentalist. We have not started or designed any experiments together.
- 2. Dr. X is a foreign postdoc who left the University 2 years ago to set up a lab outside the US.
- 3. I will publish two papers with him, which include experiments conducted by Dr. X when he was at the University. I will also perform other experiments outside the US, but I will still use some data analysis and writing the paper. The funding agency supported Dr. X when he was in the lab, but he is still offering.
- 4. Dr. X is a long-time collaborator who is a professor outside of the US. We have monthly discussions about our research. I am a visiting scholar, and Dr. X is an experimentalist. I send drafts to my lab at the university to run the experiments. No experiments will be run outside the US.

### University
- 1. Dr. X is my former postdoc. He was not funded by any outside entity while at the University. We finished all experiments on paper, wrote the paper, and submitted it before Dr. X left to set up his lab outside the US. The paper was accepted with only minor edits. Dr. X helped me finish those edits while outside the US.
- 2. Dr. X is a long-time colleague who is a professor outside of the US. We have monthly discussions about our research. I am a visiting scholar, and Dr. X is an experimentalist. We have not started or designed any experiments together.
- 3. Dr. X is my former postdoc who left the University 2 years ago to set up a lab outside the US.
- 4. Dr. X is my former postdoc who left the University 2 years ago to set up a lab outside the US.
- 5. Dr. Y is a professor outside of the US. Dr. Y and I have monthly discussions about our research. I am a visiting scholar, and Dr. Y is an experimentalist. Dr. Y sends drafts to my lab at the university to run the experiments. No experiments will be run outside the US.

### Foreign Lab
- 1. Dr. Y is my former postdoc who left the University 2 years ago to set up a lab outside the US.
- 2. Dr. Z is a long-time colleague who is a professor outside of the US. We have monthly discussions about our research. I am a visiting scholar, and Dr. Z is an experimentalist. Dr. Z offers to set up and perform experiments in his lab in a foreign country.
Training and Communication

• Training for research administrators and faculty
• Keeping up with constantly changing requirements
• The advantage of training – NDAA FY 2021
Tools that Summarize Notice’s Requirements

- University of Florida Table re. Where to Report Items – Other Support, Facilities & Resources, Budget
  - https://research.ufl.edu/dsp/proposals/disclosing-activities-to-nih/other-support-frequently-asked-questions.html

- University of Michigan Table re. Requirement Effective Dates
  - https://orsp.umich.edu/sites/default/files/implementation_of_not_od_21_073_changes_to_biosketch_and_other_support.pdf

- Caltech website
  - https://researchcompliance.caltech.edu/international_collaboration/federal-agency-requirements/nih_compliance
Other Support

Frequently Asked Questions (FAQs):

1. Is “current & pending support” the same as “other support”? Yes, “other support” is sometimes referred to as “current and pending support” or “active and pending support.”

2. What do I do if I am not sure whether to disclose something in my other support? If you are unsure, contact OSP at ospproposals@ufl.edu.

3. If I am submitting a REFM on or after May 30th, do I have to update my other support? Yes, because of the substantial changes and additional information that needs to be included, every key person will need to submit updated other support with their REFM.

4. Who is required to provide other support? All senior/key personnel, NII defines senior/key personnel as all who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Pay close attention to specific solicitation instructions for when others might be required to provide an other support document (i.e. mentor or K award).

5. What should be included in the other support document? All financial and in-kind support for any research that UF key personnel perform whether that is performed as part of their UF appointment, an outside activity, as consulting or as part of any other appointment or access they have.

6. Is other support required at the proposal stage when submitting an application to NIH? It depends. Most research project applications do not require other support at the time of proposal. However, some Funding Opportunity Announcement (FOA) (including R awards) require other support at the time of proposal. If you are unsure, contact OSP at ospproposals@ufl.edu.

Access to but not needed on this project

Access to Core facilities or shared equipment

Budgeted to charge to this project

UF webpage on Disclosing Activities to NIH

NIH webpage on Other Support

NIH FAQs
| **Implementation of NOT-OD-21-073 Changes to Biosketch and Other Support**  
(as of May 18, 2021) |
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<tr>
<td><strong>Biosketch Changes</strong></td>
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<tr>
<td>Use SciENcv to generate Biosketch</td>
</tr>
<tr>
<td>Follow format and provide requested information per NIH guidance in effect prior to release of NOT-OD-21-073</td>
</tr>
<tr>
<td>Follow new format and provide requested information per NIH guidance in NOT-OD-21-073</td>
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<tr>
<td>Add scientific appointments, paid and unpaid</td>
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<tr>
<td>List positions, appointments, honors in reverse chronological order</td>
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<tr>
<td>Highlight research projects within last 3 years in Section A, Personal Statement</td>
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<tr>
<td>D. Research Support “removed”</td>
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<tr>
<td><strong>Other Support Changes</strong></td>
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<td>Disclose all sources of Other Support and related information, including outside activities (e.g. consulting, visiting professorships) if conducting research, In-Kind support, and gifts if donor expects anything in return (e.g. time, services, research).</td>
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<tr>
<td>Use SciENcv to generate Other Support</td>
</tr>
<tr>
<td>Follow new format</td>
</tr>
<tr>
<td>Separate sections for Project/Proposal Support and In-Kind</td>
</tr>
<tr>
<td>Completed Support for the last 3 years</td>
</tr>
<tr>
<td>Submit copies of agreements for investigator’s foreign appointment/employment if listed as Other Support (translated and redacted as necessary)</td>
</tr>
<tr>
<td>When requested, submit copies of agreements for investigator’s foreign appointment/employment if listed as Other Support (translated and redacted as necessary)</td>
</tr>
<tr>
<td>Each senior/key person electronically signs PDF of their Other Support</td>
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<tr>
<td>If Other Support signed, flatten PDF prior to submission</td>
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<tr>
<td>Submit updated Other Support immediately upon learning a source of Other Support for an active NIH grant was not disclosed</td>
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Caltech Website:

https://researchcompliance.caltech.edu/international_collaboration/federal-agency-requirements.nih_compliance

- Caltech Guidance for investigators by agency
- Tools to aid investigators in deciding what, when and where to disclose
- Recent Notices
- Training and FAQ
Below are answers to frequently asked questions. These will be added to as questions are submitted. If you have any other questions, please contact caltechcoi@caltech.edu.

- Disclosure Foreign Engagements and Research Activities
- Biosketch Information

Federal Agency FAQs related to foreign components:

- NIH FAQs on Biosketches
- NIH FAQs on Other Support & Foreign Components
- NSF FAQs on Proposal Preparation & Award Administration
- NSF FAQs on SciENcv
- DOE FAQs on Foreign Government Sponsored Activities
Disclosure Tools for collecting Other Support and Biosketch Information

• Leveraging existing COI systems: Caltech
• Novel systems: Stanford External Activities Questionnaire
  • https://ora.stanford.edu/sites/g/files/sbiybj10141/f/sample_eaq.pdf
Caltech’s Biosketch/Other Support Question

• COI/COC system redesigned to collect information regarding commitments and financial interests on an entity by entity basis
• All commitments disclosed will populate a page that can be shared with grant management personnel (Biosketch Information)
• For each entity, PI’s are asked if the entity provided other support (financial or in-kind). If yes, the information will populate a page that can be shared with grant management personnel (Other Support)
Caltech Biosketch/Other Support:

If there are undisclosed commitments/appointments, researcher is prompted to add to their disclosure.

Researcher Can Add Additional Other Support
Eventually, the Other Support will also include:
- Caltech Grants/Contracts/Gifts
- Visitor/Postdoc Other Support
Stanford’s External Activities Questionnaire (EAQ)

• 7 general questions designed to guide researchers to report details about their outside activities to meet new federal disclosure requirements
• all resources available for their research, no matter who is providing those resources (e.g., awards to perform research outside of Stanford)
• all appointments and affiliations with entities other than Stanford
• all ”in-kind” research support, such as support for visiting researchers, space, equipment, “high-value” research materials (e.g., certain data sets or other materials)

• Connecting the dots:
  • Names (only) of outside entities from COI system are listed in the EAQ
  • Certain responses in EAQ will trigger a new disclosure in COI system
  • PI or Department Administrators can trigger an update of EAQ at any time
1. Do you have any visiting postdoctoral fellows, visiting students, or visiting scholars involved in research in your lab who are paid directly, in full or in part, by any non- Stanford organization, institution, company or government ("Entity")?

Additional Comments:

2. Do you have any Stanford registered postdoctoral fellows or students involved in research for your lab supported in full or in part by any non-Stanford organization, institution, company, or government ("Entity") including fellowships?

Additional Comments:

3. Do you have access to "in-kind" resources in support of your research endeavors that are obtained through a collaboration, appointment, or relationship with an outside institution, organization, company, or other "Entity"?
• Answering “yes” to a question returns names of the active entities in COI system; others entities can be added.

• EAQ collects details that enable administrators and PIs to complete federal forms.