Commitment Transparency

OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION (OPERA)

NIH National Institutes of Health
Office of Extramural Research

Overview

- Background on commitment transparency efforts across the government
- What's **NOT** changing?
- Overview of Updates
    - Biosketch
    - Other Support
- Timeline and Next Steps
- Discussion/Questions

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What is commitment transparency?

Transparency and reporting of *all* **research activities, domestic and foreign**

- Openness and transparency enables productive collaboration and helps ensure appropriate disclosure of potential conflicts of interest and commitment

- Failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments, threatens to distort decisions about the appropriate use of NIH funds

Joint Committee on Research Environments (JCORE)

- In May 2019, the National Science and Technology Council (NSTC) established JCORE to address issues related to research environment safety, integrity, and productivity.

- The JCORE Subcommittee on Research Security brings together agencies from across the government to:

  - Develop guidance for Federal departments and agencies

  - Develop best practices for universities and other research institutions

  - Develop education and outreach materials that highlight examples of risks to research

June 2020 JCORE Guidance

- JCORE Subcommittee on Research Security issued [public guidance](#) on commitment transparency
- Examples of conduct that violate funding agency policies:
  - Failures to disclose:
    - Financial conflicts of interest
    - Conflicts of commitment
    - External employment arrangements
    - Financial support that overlaps with US funding
    - Shadow labs or other parallel research activities
  - Diversion of intellectual property
  - Peer review violations

What about NIH?

- We've had cases covering all these examples!

- At least 201 scientists

- 90+ institutions, many fields of biomedicine, all over US

- Denials despite documentation to the contrary; explanations
  - "I allowed XXX to use my name as PI"
  - "I knew nothing about this grant …"
  - "I didn't actually do the work …"
  - "The affiliations [in published papers] were in error "

Myths re: Financial Conflict of Interest and Foreign Components

Identifying Foreign Components

Key measures for identifying foreign components are as follows:

- Is a portion of the project being conducted outside the US?
  - No – not a foreign component
  - Yes– are the activities being conducted outside of the US significant?
  - Indicators include:
    - Collaborations with investigators at a foreign site anticipated to result in co-authorship;
    - Use of facilities or instrumentation at a foreign site; or
    - Receipt of financial support or resources from a foreign entity.
- Foreign components require NIH *prior* approval

Financial Conflicts of Interest (FCOI)

- Requirements found in 42 CFR Part 50, Subpart F
- Investigators must disclose their significant financial interests to their institution
- This requirement includes financial interests received from a foreign entity
- Separate and distinct from other support and foreign components

So what is changing? Our Approach

- To support the need for full transparency, NIH is clarifying policies and updating forms and instructions
- Utilized JCORE guidance, and collaborated with other research agencies
- Outcomes:
  - Provided details on in-kind contributions, defined "gifts", and outlined the purpose of the biosketch
  - Updated application forms and instructions for   Biosketch and Other Support
  - Updated data format and data collections in collaboration with NSF to reduce applicant and recipient burden

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Biosketch Updates – NIH GPS

- Submission of a biosketch is a longstanding policy

- Biosketch requirements are currently spread out throughout the NIH Grants Policy Statement (GPS)

- NIH will include a new subsection in the GPS 2.3, to consolidate biosketch requirements for easier reference

  - Who submits a biosketch: senior/key personnel

  - When is it submitted: New apps, new senior/key personnel at RPPR, with prior approval requests for change in senior/key personnel

  - How it's used: reviewers utilize the biosketch to ensure that individuals included on the applications are equipped with the skills, knowledge, and resources necessary to carry out the proposed research.

Biosketch Updates – Form and Instructions

- Updated to align with JCORE, minimize duplication of Other Support, and harmonize format with NSF

- Updated title of Section B to capture all scientific appointments

  - Clarify instructions for Section B to request details on *all* positions and scientific appointments, foreign and domestic

- Removed Section D: Research Support, which duplicates information provided in Other Support

  - Removed instructions for Research Support. Note: Scholastic Performance will remain in Section D for fellowship Biosketch. All research support information is now consolidated in the Other Support section of the application.

Biosketch Mock-Up – Non-Fellowship Format Page

CURRENT FORMAT (as of July 2020)

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions and Honors

C. Contributions to Science

D. Additional Information: Research Support and/or Scholastic Performance

Mock-up with Proposed Changes (in red)

DRAFT JULY 2020

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INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions, Scientific Appointments, and Honors

C. Contributions to Science

Biosketch Mock-Up – Fellowship Format Page

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YEAR	COURSE TITLE	GRADE

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DRAFT July 2020

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D. Scholastic Performance

YEAR	COURSE TITLE	GRADE

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Other Support Updates – NIH GPS

- Other support policy language was updated in Dec 2019 to incorporate JCORE guidance and clarify requirement to report all resources in support of all research endeavors

- Additional updates will clarify:

  - **Definition of gift:** Gifts are resources provided where there is no expectation of anything (e.g. time, services, specific research activities, money, etc.) in return.

  - **Expectations for reporting in -kind resources:** in-kind contributions, e.g. office/laboratory space, equipment, supplies, employees, students. If the time commitment or dollar value of the in -kind contribution is not readily ascertainable, the recipient must provide reasonable estimates.

Other Support Updates – Foreign Resources

- IC scientific program and grants management staff will review Other Support information before award to ensure the following:

  - Any foreign resources that meet the definition of a foreign component have received appropriate prior approval

- Institutions are required to submit copies of foreign contracts and awards for all foreign activities and resources that are reported in Other Support. If they are not in English, recipients must provide translated copies.

National Institutes of Health
Office of Extramural Research

Other Support Updates – Format Page

CURRENT FORMAT (as of July 2020)

OMB No. 0925-0001 (Rev. 03/2020 Approved Through 02/28/2023)

For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED

PHS 398 OTHER SUPPORT

Provide active and pending support for all senior/key personnel. Other Support includes all financial resources, whether federal, non-federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

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

For information pertaining to the use of and policy for other support, see NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures. Neither the application under consideration nor the current PHS award for this project should be listed as Other Support.

Effort devoted to projects must be measured using "person months." NIH and other PHS agencies use the concept of "person months" as a metric for determining percent of effort. For more information about calculating person months, see NIH's Frequently Asked Questions on Person Months.

Format

NAME OF INDIVIDUAL
ACTIVE/PENDING

Project Number (Contact Principal Investigator) Source Title of Project *(or Subproject)*	Dates of Approved/Proposed Project Annual Direct Costs	Person Months (Cal/Academic/ Summer)
The major goals of this project are…		

OVERLAP *(summarized for each individual)*

Instructions for Selected Items

Project Number: If applicable, include a code or identifier for the project.

- Current Other Support format page does not collect structured data or allow recipients to provide detail on in-kind contributions

- New format page and detailed instructions document have been developed

Other Support Updates – Format Page

New NIH mock-up with Proposed Changes

For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED

PHS 398 OTHER SUPPORT

Other Support – Projects/Proposals

NAME OF INIVIDUAL:

Commons ID:

1. Title:

   Project Number: Name of PD/PI:

   Major Goals:

   Status of Support: O Active   O Pending   O Completed

   Source:

   Primary Place of Performance

   Approved/Proposed Project Start Date (MM/YYYY):

   Approved/Proposed Project End Date (MM/YYYY):

   Total Award Amount (including Indirect Costs):

   Person-Month(s) (Calendar/Academic/Summer) Per Calendar Year Committed to the Project

Calendar Year (YYYY)	Person Months (##.##)	Calendar Year (YYYY)	Person Months (##.##)
1.		4.	
2.		5.	
3.			

Other Support – In-Kind

\#. Summary of In-Kind Contributions:

Status of Support: O Active   O Pending

Source:

Primary Place of Performance

Approved/Proposed Project Start Date (MM/YYYY):

Approved/Proposed Project End Date (MM/YYYY):

Person-Month(s) (Calendar/Academic/Summer) Per Calendar Year Committed to the Project

Calendar Year (YYYY)	Person Months (##.##)	Calendar Year (YYYY)	Person Months (##.##)
1.		4.	
2.		5.	
3.			

Estimated Dollar Value of In-Kind Contribution: $

OVERLAP (summarized for each individual):

Other Support Updates – Instructions

- Developed new, detailed instructions document to accompany the updated Other Support format page

- Highlights:
  - Includes updated definitions and terms as included in the NIH GPS
  - Provided detailed instructions for how to complete each data element of the form.
  - Added links to GPS for further details.

Estimated Timeline

- Oct/Nov 2020: Guide notice announcing policy, form, and instruction updates

- Jan 2021: Begin requiring use of updated form templates

- Later in 2021/2022: Integrating Other Support templates into ScienCV