Commitment Transparency

NIH OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION



Overview

- Background
 - Why are we focused on commitment transparency and disclosures?
- Required Disclosures
- Overview of Forms Updates
 - Biosketch
 - Other Support
- FAQs
- Resources



BACKGROUND



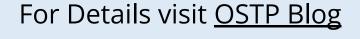
What is commitment transparency?

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

Inter-Agency Areas of Focus

- Some foreign governments are working vigorously to illicitly acquire, and in some cases outright steal, U.S. research and technology
- Key Issues:
 - Conflicts of Interest: An individual, their spouse, or dependent children have a financial interest/relationship which could directly and significantly affect the design, conduct, reporting, or funding of research
 - Conflicts of Commitment: an individual accepts or incurs conflicting obligations between or among multiple employers or entities.
 - Talent Recruitment Programs





NDAA-223

- 2021 National Defense Authorization Act (NDAA), Section 223 Disclosure of Funding Sources in Applications for Federal Research and Development Awards
- Applies to all applicants for research and development awards from Federal Research Agencies
- Requires each covered individual listed in the application to:
 - Disclose the amount, type and source of all current and pending support
 - Certify the disclosure is current, accurate and complete
 - Agree to update such disclosure at the request of the agency prior to award and at any subsequent time the agency determines appropriate



NSPM-33

- National Security Presidential Memorandum (NSPM) on Research Security and Integrity, signed January 14, 2021
- Implementation led by Office of Science and Technology Policy (OSTP)
- Purpose: To strengthen protections of US Government supported Research and Development (R&D) against foreign government interference and exploitation
- Funding agency responsibilities: require participants involved in the R&D enterprise to disclose appropriate information, ensure recipients have policies and processes for research security and integrity, and share information across federal funding institutions



NSPM-33 Disclosure Requirements

- Organizational affiliations and employment.
- Other support, contractual or otherwise, direct and indirect, including current and pending private and public sources of funding or income, both foreign and domestic
- Current or pending participation in, or applications to, programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs
- Positions and appointments, both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional or institutional appointments, whether or not renumeration is received, and whether full-time, part-time or voluntary (including adjunct, visiting or honorary)



SO, WHAT ABOUT NIH?



Issues Seen at NIH

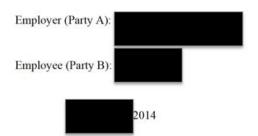
- Failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments and businesses, which threatens to distort decisions about the appropriate use of NIH funds and accurate evaluation of commitment of effort to US-supported research;
- Diversion of proprietary information included in grant applications or produced by NIH- supported biomedical research to other entities, including other countries; and
- Failure by some peer reviewers to keep information in grant applications confidential; including, in some instances, disclosure to foreign entities or other attempts to influence funding decisions.

Undisclosed Employment Agreements

Chinese Academy of Sciences

Employment Contract of "Recruiting Overseas Professionals"





Article 1 Position and Term of Employment

Party A employs Party B as a professor in "Thousand Talents Program" for a period of five years. The employment period is from 2019. Party B shall work full time at Party A premise as a professor effective from the commencement date of this contract.

- 2. Job Objectives during the Employment Period:
 - A. Scientific Research Objectives:
- a. The laboratory in the United States will be gradually moved back to China to rebuild, and the international cutting-edge translational medicine will continue to be carried out.



Undisclosed Employment Agreements

- Time commitment sometimes full-time
- Substantial funding for research (including start-up funds)
- Laboratory, equipment, personnel
- Signing bonus, salary, housing, other benefits
- Deliverables: training personnel, papers, patents/IP
- Creates conflicts of commitment (>100% effort), interest



Institutions say they are unaware

Thousand Talents Program – Dr.

We were unaware of these additional funding sources

Lauer at the NIH. In response to the NIH request we have obtained translations of certain of these applications/contracts

and have now had the opportunity to review these translations. Before we complete our response to the concerns from NIH regarding these sources of funding and your affiliations I would like further clarification from you regarding the following.

A Regarding the Thousand Talents Program. Dr.

when we spoke about these issues you indicated that this was an honor program for distinguished scientists, comparable to an academic title. It is clear from the contract that this program includes provision of space, staff and funds for laboratory research and expected research deliverables from the recipient. Please provide us with a detailed summary of the work that you are conducting using these funds.



New cases continue

- At least 225 scientists (NIH has contacted institutions)
- 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."

Our Approach

- To support the need for full transparency, NIH has updated forms and instructions
- Collaborated with OSTP and with other research agencies to implement NSPM-33 and NDAA 233
- Institutions and researchers need to fully disclose, and institutions must have policies to ensure that they are aware of all research endeavors
- Form updates ensure that NIH is receiving all the information needed to support sound funding decisions



REQUIRED DISCLOSURES



Considerations for Recipients

- When a recipient is determining the likelihood of a compliance risk related to improper influence (foreign or domestic) they should consider and identify relationships, existing and potential, that may impact research integrity, financial conflict of interest, and/or overlap. In evaluating these relationships, institutions should consider the following questions and factors:
- a) Does the relationship affect the integrity of the research by impacting established professional norms and ethical principles in the performance of all activities related to scientific research? In answering this question, institutions should consider the following factors:
 - The "relationship" could be with a collaborator, an outside employer, an external appointment relationship, etc.
 - The "impact" could be real or apparent
 - The "compensation" could be of any type or level; NIH has not established a de minimis level of compensation and considers all types of support, in-kind or otherwise.
- b) Is there potential overlap in any of the following areas?
 - Scientific
 - Budgetary
 - Commitment
- c) Is there a potential Financial Conflict of Interest?

If the answer to any of these questions is "yes," then the relationship is generally reportable. When in doubt, recipients should reach out to NIH early and often.



Type of Activity	Biographical Sketch	Other Support	Post-Award Information Terms & Condition
Professional preparation (e.g., educational degrees)	X		
Organizational Affiliations and Appointments	X		
Academic, professional or institutional appointments,	X		
whether or not remuneration is received, and whether			
full-time, part-time, or voluntary			

Organization affiliations, appointments, and educational information is disclosed in the Biographical sketch. All current appointments must be listed. Historical information is not required.

Type of Activity	Biographical Sketch	Other Support	Annual Project Reports	Post-Award Information Terms & Condition
All projects currently under consideration from whatever source, and		X	X	X
all ongoing projects, irrespective of whether support is provided				
through the proposing organization, another organization or directly				
to the individual, and regardless of whether or not they have				
monetary value (e.g., even if the support received is in-kind such as				
office/laboratory space, equipment, supplies, or employees.)				
Current or pending participation in, or applications to, programs	X			
sponsored by foreign governments, instrumentalities, or entities,	(Appropi	riate		
including foreign government-sponsored talent recruitment	placement	may be		
programs.	contract-dep	endent)		

All current and pending projects, from all sources, must be disclosed. Completed support is not required.



Type of Activity	Biographical Sketch			Post-Award Information Terms & Condition
In-kind contributions not intended for use on the project/proposal being proposed.		X	X	Х

- In-kind contributions **not intended for use on the project/proposal being proposed** in this application must be reported as Other Support.
 - If the time commitment or dollar value is not readily ascertainable, reasonable estimates should be provided.
 - There is no de minimis value. Applicants and recipients may apply a "reasonable standard." Disclosure is not expected for sources with insignificant value or material contribution.
- In-kind contributions **intended for use on the project being proposed** to NIH must be included as part of the Facilities and Other Resources or Equipment section.



Type of Activity	Biographical Sketch			Post-Award Information Terms & Condition
Visiting Scholars in Labs funded by an external entity		Χ		X
Students and postdoctoral researchers funded by an external entity		X	X	X

If a visiting scholar, graduate student, or post-doc is performing research in support of the PD/PI or other senior/key personnel's research, then their support must be disclosed as an in-kind resource.

If the relationship is solely a mentor/mentee arrangement, with no research activities (e.g. associated time commitment), then it is not a resource, and does not need to be reported.



Type of Activity	Biographical Sketch			Post-Award Information Terms & Condition
Consulting that falls outside of an individual's appointment; separate		X	X	X
from institution's agreement.				
Travel supported/paid by an external entity to perform research		X	X	X
activities with an associated time commitment				

Consulting activities that **involve research and fall outside of an individual's appointment**, separate from institution's agreement, must be disclosed as Other Support.



Type of Activity	•			Post-Award Information Terms & Condition
Certification by the individual that the information disclosed is accurate,		X	X	
current, and complete (e.g., signature of the researcher).				

Other Support forms must be signed electronically.

Supporting Documentation (e.g., contracts, grants, other agreements)		Х		
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Supporting documentation, which includes copies of contracts/agreements specific to senior/key-personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support. If the contracts/agreements are not in English, recipients must provide translated copies.



Type of Activity	Biographical	Other	Annual	Post-Award
	Sketch	Support	Project	Information
			Reports	Terms &
				Condition
Significant Financial Interests : Disclosure Not Required in Other				
Support. See NIH FCOI Policy NIH GPS 4.1.10. Disclosures must be				
made in FCOI module.				

Financial Conflicts of Interest (FCOI) are an important part of commitment transparency. NIH has separate regulations and policies for FCOI.

See NIH GPS 4.1.10 and 42 CFR 50, Subpart F



Other Support does not include:

- Training awards
- Prizes
- Gifts
 - Gifts are resources provided where there is no expectation of anything (e.g. time, services, specific research activities, money, etc.) in return. An item or service given with the expectation of an associated time commitment is not a gift and is instead an in-kind contribution and must be reported as Other Support
- Start-up support provided to the individual by the applicant organization
- Consulting activities where the PD/PI or other senior/key personnel is *not conducting* research (e.g. no authorship or co-authorship of publications is anticipated from the activity)



FORM AND INSTRUCTION UPDATES



Form & Instruction Updates

- Updates outlined in <u>NOT-OD-21-073</u> and <u>NOT-OD-21-110</u>.
- Updated forms, instructions, samples and public frequently asked questions are posted for <u>Biosketch</u> and <u>Other Support</u>.
- The updated forms and instructions are required for use in applications and Research Performance Progress Reports (RPPRs) submitted for on or after January 25, 2022.



Biosketch Format Updates

- Section B. 'Positions and Honors' has been renamed, 'Positions, Scientific Appointments and Honors.'
- Applicants and recipients must list all current 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 renumeration is received, and whether full-time, part-time or voluntary (including adjunct, visiting or honorary)
 - Must be listed in *reverse* chronological order
- If all required information is not included, the Biosketch is incomplete

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

Associate Professor, Department of Psychology, Washington University, St. Louis, MO
Adjunct Professor, McGill University Department of Psychology, Montreal, Quebec,
Canada
NIH Risk, Adult Substance Use Disorder Study Section, member
Consultant, Coastal Psychological Services, San Francisco, CA
Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
Board of Advisors, Senior Services of Eastern Missouri
Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
Associate Editor, Psychology and Aging
Member, American Geriatrics Society
Member, Gerontological Society of America
Fellow, Intramural Research Program, National Institute on Drug Abuse, Baltimore, MD
Member, American Psychological Association
Award for Best in Interdisciplinary Ethnography, International Ethnographic Society
Excellence in Teaching, Washington University, St. Louis, MO
Outstanding Young Faculty Award, Washington University, St. Louis, MO

C. Contributions to Science

- 1. My early publications directly addressed the fact that substance use is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging concerns about a substance use disorder. These publications document this emerging concern and guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the behavior, and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for older adults with substance use disorders and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.
 - Gryczynski, J., Shaft, B.M., Merryle, R., & Hunt, M.C. (2013). Community based participatory research with late-life substance use disorder. American Journal of Alcohol and Drug Abuse, 15(3), 222-238.

See full sample <u>here</u>



Biosketch - Requirements

- Section D now *only* includes Scholastic Performance, and is only required for:
 - Applicants for predoctoral and postdoctoral fellowships
 - Applicants for dissertation research grants (e.g. R36)
 - Candidates for research supplements to promote diversity in health-related research from the undergraduate through post-doctoral levels.
- The 5-page limit for Biosketch has not changed

holasti	c Performance	
YEAR	COURSE TITLE	GRADE
	PURDUE UNIVERSITY	
2014	Introductory Biology	A
2014	Introductory Biology Lab	Α
2014	Foundations of Chemical Principles	Α
2014	French and Francophone World	Α
2014	Ethics, Religion, and Culture Today	Α
2015	Organismal and Population Biology	В
2015	Omics	В
2015	First Year Seminar: Nation and Migration	Α
2015	Statistics, Probability, and Reliability	A
2015	Calculus I	В
2015	General Physics I	В
2015	Introductory Chemistry	A
2015	Population & Ecol Genetics	A
2015	Organic Chemistry	В
2016	American Literature	В
2016	6 General Physics II	
2016	g,	
2016	Microbial Pathogenesis and the Immune Response	
2016	Introduction to Cognitive Science	
2016	Self Defense	P
2016	Biological Chemistry	В
2017	Anthropology of Childhood and the Family	A
2017	Disease, Culture, and Society in the Modern World	A
2017	Intro to Psychology	A
2017	Health & Fitness Walking	P
2017	State & Local Govt	Α
2017	Human Genetic20	Α
2017	Senior Project	A
2017	Bioinformatics	В
2018	Cell Biology	A
2018	Quantitative Analysis	В
2018	Quantitative Analysis Lab	Α
2018	Physics in Modern Medicine	Α
2018	Ethical Principles in Law and Economics	В
2018	Bowling	P
2018	Genomics and Svs	A



Other Support Format Updates

Updated form and instructions provide clearer format and data elements, and to align with fed-wide implementation efforts.

PHS OTHER SUPPORT For All Application Types – DO NOT SUBMIT UNLESS REQUESTED

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]	8
5[enter year 5]	

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]	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 Format Updates Cont.

Supporting documentation

- Copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support. If the contracts, grants or other agreements are not in English, recipients must provide translated copies.
- Immediate notification of undisclosed Other Support
 - 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 within 30 days of becoming aware of the non-disclosure.
- PI or other senior/key personnel will electronically sign submissions to certify accuracy of the information provided



COMMON QUESTIONS



Biosketch - Common Questions

- Since research support is no longer in Section D., is that information captured elsewhere in the Biosketch?

 Research support information previously provided in section D is now included in Section A. Personal Statement.
- The Biosketch instructions state that all positions and scientific appointments must be provided. Does this refer to active positions and appointments, or all positions a researcher has ever held? The Biosketch must include all current positions and scientific appointments. The instructions have been updated to reflect this clarification

Biosketch - Common Questions Cont.

- Is the use of SciENcv required? Not at this time.
- Are hyperlinks permitted in the Biosketch? Hyperlinks are not permitted in the Biosketch, and may not be used in citations. Applicants may provide a URL to a full list of their published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography.
- What does NIH consider to be a "scientific appointment"? Applicants and recipients must determine what constitutes a scientific appointment, in accordance with their institutional policies and procedures for tracking and managing outside activities.



Other Support Common Questions

- Does NIH require disclosure of recently completed support? No, NIH
 does not require disclosure of recently completed support in Other Support
 submissions, only current and pending resources.
- Do the forms updates impact the timing of submission (e.g. Just-In-Time, RPPR)? No. The updates to Other Support are to the form and instructions and do not change the process or timing of submission.
- NIH does not allow electronic signatures on attachments in electronic applications. Will electronic signatures be accepted on Other Support submissions? Other Support submissions must be submitted as a flattened PDF, after all signatures are obtained. Recipients and applicants may use the electronic signature software of their choice, and in alignment with their institutional practices. A typed name is not an electronic signature and is not acceptable.



Other Support Common Questions Cont.

- I am key personnel on an NIH grant in the United States. I am collaborating with another scientist in the US, whose experiments have directly benefitted my research. Their experiments were conducted with funds awarded to their institution. Should this be reported as Other Support? Yes. Other Support includes domestic research collaborations that directly benefit the researcher's research endeavors.
- For in-kind resources that do not have any associated effort, can researchers enter zero effort? Yes, for in-kind resources with no associated time commitment, researchers can list zero effort, but must provide the estimated dollar value of the in-kind resource. The effort and dollar value cannot be both be zero.



RESOURCES



Resources Available

- SciENcv
 - Updated <u>SciENcv</u> Biosketch template is available!
 - NIH is collaborating with SciENcv on a template for Other Support
 - Use of SciENcv will NOT be required
- Additional Resources (Continually updated)
 - Other Support Page
 - Forms, Instructions, FAQs and samples
 - Biosketch Page
 - Forms, Instructions, FAQs and samples