



Princeton
Research

> Coffee with ORPA:



Sponsor Requirements Related to
Inappropriate Foreign Influence (aka
Research Data Security)

October 10, 2019

Presenters:

Chi Chung
John Jenkins
Bob Scalese

Office of Research and Project Administration

Princeton > Research

Princeton University Culture

- > "In the Nation's Service and the Service of Humanity"
 - > A University that is more diverse, more international, and values service to others
- > Princeton University Profile 2019-2020
 - > University aim: "...to enroll the most capable students from all parts of the world and to provide them with an educational experience that strengthens their intellects, sharpens their skills, expands their horizons and prepares them for leadership..."
 - > "As a global research university, Princeton seeks to achieve the highest levels of distinction in the discovery and transmission of knowledge and understanding."
 - > Percentage of international students:
 - > Undergraduate: 12%
 - > Graduate: 42%



Office of Research and Project Administration

Princeton > Research

Federal Agency Developments



- > August 2018 letter from NIH Director Francis Collins
 - > Failure on the part of researchers to disclose substantial contributions of resources, including from foreign governments
 - > Diversion of IP to other entities, including pre-publication data
 - > Failure by some peer reviewers to keep information from the process confidential, including disclosure to foreign entities
- > NIH Office of Extramural Research letters to 66 institutions regarding 200 researchers. 16 cases referred to HHS OIG.
 - > Participation in foreign talent programs/affiliations with foreign institutions
 - > Substantial and related foreign grants, "shadow labs"
 - > Foreign patents and startups
- > Investigations have resulted in dismissals of researchers from universities and in some cases federal charges

Office of Research and Project Administration

Princeton > Research

DOE

- > The Department of Energy issued a directive (DOE Order 486.1) dated June 7, 2019, mandating that "federal and contractor personnel *fully disclose and, as necessary, terminate* affiliations with foreign government-supported talent recruitment programs" on new DOE contracts and subcontracts.
 - > **Foreign Government Talent Recruitment Program:** In general, such programs include any foreign-state-sponsored attempt **to acquire U.S. scientific-funded research** or technology **through foreign government-run** or funded recruitment programs that target scientists, engineers, academics, **researchers, and entrepreneurs of all nationalities working or educated in the United States.** These recruitment programs are often part of broader whole-of-government strategies to **reduce costs associated with basic research while focusing investment on military development or dominance in emerging technology sectors.**
- > DOE is expected to issue a separate policy directive to implement the requirement on DOE grants and cooperative agreements.



Office of Research and Project Administration

Princeton > Research

Federal Agency Developments



- July 2019 letter from NSF Director France Cordova
 - Disclosure of current and pending support, appointments, biosketches



- September 2019 proposed rule from Dept. of Education requiring universities to report significantly more foreign gifts and agreements

Office of Research and Project Administration

Princeton > Research

DOD



- FY19 National Defense Authorization Act mandates:
 - Protecting IP and critical technologies
 - Critical technologies list for export controls
 - Limiting foreign access to technologies
 - Prohibit use of Huawei and ZTE equipment on federal projects
 - Prohibit funding for Confucius Institutes
- March 20, 2019 DOD memo outlines disclosure requirements for all key personnel.
 - A list of all current projects the individual is working on in addition to any future support the individual has applied to receive, regardless of the source.
 - Title and objectives of the other research projects.
 - The percentage per year to be devoted to the other projects.
 - The total amount of support the individual is receiving in connection to each of the other research projects or where else if other projects are awarded.
 - Name and address of the agencies and/or other parties supporting the other research projects.
 - Period of performance for the other research projects.

Office of Research and Project Administration

Princeton > Research

Why These Developments Matter

- > Federal Government Sponsors are increasingly concerned with ensuring that the fruits of taxpayer funded research benefit the American people – and conversely, are not used by foreign countries to improve their economic or national security relative to the US.

Office of Research and Project Administration

Princeton > Research

NIH Investigations

- > NIH sent letters to 66 institutions regarding approximately 200 investigators.

MD
Anderson:

Three
researchers
dismissed in
April 2019

Emory
University:

Two
researchers
and four
postdoctoral
fellows
dismissed in
May 2019

Los Alamos:

One
researcher
facing
federal
charges

- > Additional actions by institutions may be likely as investigations proceed

Office of Research and Project Administration

Princeton > Research

NIH Developments – New Notice

- > July 2019 – NIH issued relevant guide notice and FAQs
 - > Notice Number: NOT-OD-19-114 – Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html>)
 - > **Other Support:** 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. *NIH Grants Policy Statement Section 2.5.1*
 - > **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. *NIH Grants Policy Statement Section 16.2 & Section 1.2*
 - > **FCOI:** Investigators must comply with their institutions' FCOI policy and disclose significant financial interests, including financial interests received from a foreign entity. Institutions shall provide FCOI reports to NIH regarding identified FCOI. *NIH Grants Policy Statement Section 4.1.10*

Office of Research and Project Administration

Princeton > Research

NIH – Areas of Overlap



"The intent of this notice is to remind the extramural community about the need to report foreign activities through documentation of other support, foreign components, and financial conflict of interest to **prevent scientific, budgetary, or commitment overlap.**" *Section 2.5.1 of NIH Grants Policy Statement*

- > **Scientific Overlap:** (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.
- > **Budgetary Overlap:** occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source.
- > **Commitment Overlap:** occurs when a person's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application. While information on other support is only requested for Senior/key Personnel (excluding consultants), no individuals on the project may have commitments in excess of 100 percent or 12 person months.

Office of Research and Project Administration

Princeton > Research

NIH - FAQs



- NIH issued several FAQs in conjunction with the July Notice
- July 11, 2019 FAQ - "Outside Activities such as teaching or consulting that may be compensated or uncompensated constitute Other Support if they are in any way related to the investigator's research endeavors or expertise."
- August 6, 2019 - Current FAQ - NIH removed the FAQ in question.

(<https://grants.nih.gov/grants/faq-other-support-foreign-components.htm>)

Office of Research and Project Administration

Princeton > Research

NIH – What counts as Other Support?

- Def. 2.5.1 OS - "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 are not included.**"
- Required for Senior and Key Personnel
- Not Applicable to Other Significant Contributors
- What should be reported: internal competition, donation of lab space or materials, in-kind staff

Office of Research and Project Administration

Princeton > Research

NIH – What is not Other Support?

- What does not have to be reported:
 - Training awards and prizes
- What about gifts and start-ups?
 - Gifts are specifically excluded as OS in the NIH Grants Policy Statement.
 - Start-up funds/retention package was removed from NIH FAQ.
 - But, it depends....



©Ron Leishman - illustrations01.com/9726

NIH – Where and When to Report OS

- Just-in-time
 - Must notify NIH of substantive changes to previously submitted JIT information UP TO THE TIME OF AWARD, including Other Support changes that could lead to budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PD/PI(s) or any Senior/Key Personnel.
 - Other Support versus Research Support
- Annual Research Performance Progress Reports (RPPRs)
 - Changes to Other Support which occur during an active award must be reported annually through the RPPR.
- Sponsored specific forms (i.e. NSF (C&P), DOE, DOD, NASA)

NIH – What to report for each OS entry

OMB No. 0925-0001 (Rev. 11/16 Approved Through 10/31/2018)

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 other support. Information on other support should be provided in the format shown below.

For instructions and information pertaining to the use of and policy for other support, see [Other Support in the Supplemental Instructions, Part III, Policies, Assurances, Definitions, and Other Information](#). Effort devoted to projects must be measured using person months. Indicate calendar, academic, and/or summer months associated with each project.

Format

NAME OF INDIVIDUAL

ACTIVE/PENDING

Project Number (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)		

Office of Research and Project Administration

Princeton > Research

NIH Biosketches – What should be disclosed

- > Senior/Key Personnel must list *all* positions and scientific appointments both *domestic* and *foreign* that are relevant to an application including affiliations with foreign entities or governments.
- > 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).

Office of Research and Project Administration

Princeton > Research

NIH – Foreign Component

› What is a 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.
- › Not dependent on whether the foreign collaborator receives funding from the NIH grant in question.
- › Significant + Outside U.S. = Foreign Component

(NIH Grants Policy Statement Section 16.2)

Office of Research and Project Administration

Princeton › Research

NIH – Foreign Component (cont'd)

- › Examples of grant-related activities that may be significant include:
 - › collaborations with investigators at a foreign site anticipated to result in co-authorship
 - › use of facilities or instrumentation at a foreign site
 - › receipt of financial support or resources from a foreign entity
 - › involvement of human subjects or vertebrate animals at a foreign site
 - › extensive foreign travel for data collection, surveying, sampling, and
 - › any activity that may impact US foreign policy through involvement in affairs of a foreign country.
- › What are activities that are NOT foreign component?
 - › Foreign travel exclusively for consultation
 - › Receiving advice from a foreign investigator on research project
 - › Analysis of data originally gathered abroad
- › Must also report foreign component if you have a subaward with a foreign component

Office of Research and Project Administration

Princeton › Research

NIH – Where to Report Foreign Component

R&R Other Project Information Form

RESEARCH & RELATED Other Project Information OMB Number: 4140-0001
Expiration Date: 10/31/2019

1. Are Human Subjects Involved? Yes No

1.a. If YES to Human Subjects
Is the Project Exempt from Federal regulations? Yes No
If yes, check appropriate exemption number: 1 2 3 4 5 6 7 8
Has the IRB review findings? Yes No
IRB Approval Date:
Human Subject Assurance Number:

2. Are Vertebrate Animals Used? Yes No

2.a. If YES to Vertebrate Animals
Is the IACUC review findings? Yes No
IACUC Approval Date:
Animal Welfare Assurance Number:

3. Is proprietary/privileged information included in the application? Yes No

4. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? Yes No

4.b. if yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? Yes No

4.d. if yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic plus? Yes No

5.a.

6. Does this project involve activities outside of the United States or partnerships with international collaborators? Yes No

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. Project Summary/Abstract

8. Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments

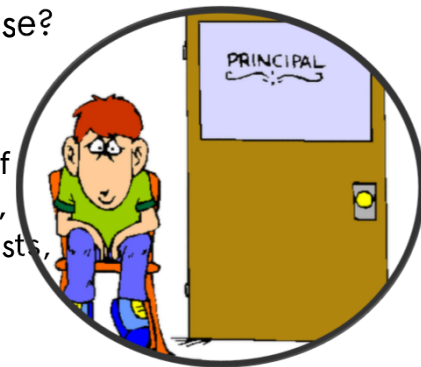
Office of Research and Project Administration

Princeton > Research

NIH – Consequences Failure to Report

> What can happen if your PI fails to disclose?

- > Depending on the severity and duration of noncompliance, NIH may withdraw approval of the Program Director/PI or other researchers, impose specific award conditions, disallow costs, withhold future awards, or suspend or terminate award.
(NIH GPS Section 8.5)



Office of Research and Project Administration

Princeton > Research

NIH - Examples/case studies

- Example 1: PI on NIH grant has appointment and lab at a foreign university. Research being done at foreign lab is unrelated to the PI's NIH project.
 - (a) Does this qualify as a foreign component?
 - (b) Is there a resource that qualifies as Other Support?
 - (c) Should PI report the lab space on the Facilities & Other Resources page?
 - (d) Should PI report the foreign appointment on biosketch?

Office of Research and Project Administration

[Princeton](#) > [Research](#)

Example

- Example 2: Princeton PI on an NIH grant. PI will have visiting post-doctoral fellow from Russian institution who will work in his lab on his NIH grant. Fellow is fully supported by the Russian institution.
 - Does this qualify as a foreign component?
 - What other factors should be considered?

Office of Research and Project Administration

[Princeton](#) > [Research](#)

Conflict of Interest – Platform

- › <https://ria.princeton.edu/conflict-of-interest>
- › Regulations
 - › NIH 42 CFR Part 50 Subpart F – *Promoting Objectivity in Research*
 - › NSF 05-131 Chapter V – *Grantee Standards*
- › Policies
 - › Princeton University COI Policy contained within the Rules and Procedures of the Faculty, Chapter 5, Section I
 - › Conflict of Interest in Research Panel Charter
 - › COI Guidelines on RIA website under COI tab
 - › PHS Funded DOF appointees
 - › NON-PHS funded DOF appointees and all other Faculty, Academic Professionals and Librarians
- › Electronic COI System – Managed by RIA and OIT

Office of Research and Project Administration

Princeton › Research

Conflict of Interest – Forms and Disclosures

- › Annual Disclosure Form – Parts A through I – Changes made to the following sections to address Inappropriate Foreign Influence:
 - › Part A – Work for Outside Organizations
 - › Part B – Management and Fiduciary Responsibility
 - › Part D – Purchasing and Contracts
 - › Part E – Gifts and Solicitations
 - › Part F – Use of Resources including Students, Staff, Equipment or Space
 - › Part G – Significant Financial Interests Relating to your Institutional Responsibilities

Office of Research and Project Administration

Princeton › Research

Conflict of Interest – Forms and Disclosures (con't.)

- › Part A – Work for Outside Organizations
 - › Clarified the term “organizations” and included the term domestic and foreign throughout.
 - › i.e. *The term “organization” includes domestic or foreign governments, and domestic or foreign corporations, universities, professional associations, or institutions.*
 - › Described more examples of what to and not to include while disclosing
 - › i.e. *Please include teaching or administrative activities at any domestic or foreign academic institution other than Princeton.*
 - › Added in the requirement for reporting that a person should disclose their Position/Title in each entity disclosed

Office of Research and Project Administration

Princeton > Research

Conflict of Interest – Forms and Disclosures (con't.)

- › Part B – Management and Fiduciary Responsibility
 - › i.e. *During the last 12 months (i.e., calendar year 2019) have you had a management or other fiduciary role in any domestic or foreign organization other than Princeton.*
 - › Added in the requirement for reporting that a person should disclose their Position/Title in each entity disclosed
- › Part F – Use of Resources including Students, Staff, Equipment or Space
 - › *Engaged visiting scholars/researchers from any domestic or foreign entity (i) that is listed in Part A or B or in which you have an outside financial interest (e.g., external consulting, intellectual property development, start-up company, non-profit, or non-governmental organization) or (ii) that could pose a conflict of time or resources to your institutional responsibilities involving teaching, research or service?*

Office of Research and Project Administration

Princeton > Research

Conflict of Interest – Forms and Disclosures (con't.)

- Part G - Significant Financial Interests Relating to your Institutional Responsibilities
 - *In order to be considered "significant", a financial interest must meet all of the following criteria:*
 1. *It must be held by you, your spouse or dependent children;*
 2. *it must be related to your institutional responsibilities (research, teaching, and/or service); and*
 3. *it must exceed the thresholds described below*

Office of Research and Project Administration

Princeton > Research

Conflict of Interest – Forms and Disclosures (con't.)

- Part G - Significant Financial Interests Relating to your Institutional Responsibilities
 - Clarified the term related
 - *In deciding whether or not a financial interest is related to your institutional responsibilities, you should use common sense and your best judgement to arrive at a good-faith determination. "Related" should be interpreted broadly and includes, but is not limited to, related in subject matter to your University research, teaching or service. By this measure, a financial interest in (including receiving compensation from) any outside organization, domestic or foreign, profit or nonprofit, for work in your area of expertise is related to your institutional responsibilities. On the other hand, a financial interest with a company whose business (e.g., home appliances) is not related to your research (e.g., genetics) does not need to be disclosed. **When in doubt, err on the side of disclosing.***

Office of Research and Project Administration

Princeton > Research

Conflict of Interest – Forms and Disclosures (con't.)

- COI Supplemental Form:
 - Replaces the PHS FCOI Form
 - Form used to report a new SFI by PHS funded individuals with 30 days of acquiring the SFI
 - With the new COI supplemental form
 - Used for all DOF appointees to report new SFIs within 30 days of acquisition
 - Additional section to disclose use of resources including Students, Staff, Equipment or Space
- NIH Travel Disclosure Form:
 - Used to disclose travel over \$5,000 in aggregate for a twelve month period per entity for PHS/NIH funded individuals only

Office of Research and Project Administration

Princeton > Research

Conflict of Interest - Reminders

- 2018 NIH notice reminds PIs to disclose all related significant financial interests to the institution. Includes disclosures of financial interests received from a foreign institution of higher education or the government of another country.
- PIs, Co-PIs, Senior/Key personnel should have an updated COI disclosure form on file at the time of proposal application
- Only PHS-funded individuals are trained in COI
 - PHS –funded PIs, Co-PIs, Senior/Key personnel will have to be trained in FCOI at the time of proposal application

Office of Research and Project Administration

Princeton > Research

How Princeton Has Responded

- › February 2019 and July 2019 letters issued by the Dean for Research (DFR) encouraging the research community to provide complete and accurate information on all sources of support
- › Expanded University Research Board review of proposals involving sensitive countries/activities
- › Corporate gifts undergoing additional vetting
- › Revising COI annual disclosure form to clarify that both foreign and domestic engagement should be disclosed.
- › Inappropriate Foreign Influence Working Group, chaired by the Provost, maintains focus on regulatory and political environment
- › Visitors Working Group, formed by DFR, is drafting guidelines for visitor appointments
- › Evaluating integration/harmonization of University data sets to facilitate compliance with sponsor requirements
- › Monitor new developments in Washington and lobby federal agencies through various channels, including FDP, COGR, AAU, peer institutions, etc.
- › ORPA is providing researchers with guidance (and obtaining feedback) via faculty meetings, on our website, and intends to develop guidance documents
- › Issued "Guiding Principles for Ensuring Research Security from Inappropriate Foreign Influence", Sept 26, 2019 (Dean for Research website)

Office of Research and Project Administration

Princeton > Research

Next Steps for Researchers



- › Review your current federally funded projects. Who is working on that project? Have you disclosed their participation to the sponsor?
- › Be thorough and complete in accounting for all on-going or proposed research projects and all forms of research support, including from foreign sources, in NIH's Other Support (Just-in-Time submission), the NSF's Current and Pending, Progress Reports, and similar documentation submitted to other sponsors.
- › Disclose any changes in support of key personnel in progress reports. Any changes in Other Support must be reported annually through RPPR.
- › Disclose collaboration with foreign & domestic entities in proposals and annual reports (e.g. Collaboration with colleague at a foreign institution to submit a joint application for funding to a foreign entity).
- › Review and update your bio-sketches. Is it current and thorough? Have you disclosed all affiliations (e.g. honorary visiting professorship at foreign institutions, honorary membership at foreign academy of sciences).

Office of Research and Project Administration

Princeton > Research

Next Steps for Researchers (cont'd)

- › Disclose your outside professional activities and financial relationships, whether compensated or not in COI.
- › Discuss any invitation for any academic appointment or position at another domestic or international institution (visiting, honorary, or other) with the appropriate institutional officials prior to accepting the appointment.
- › Disclose foreign component in proposal and contact ORPA to add foreign component on existing award.
- › Ensure proper vetting and screening of visiting researchers. Follow proper appointment process.
- › Disclose involvement in any foreign recruitment or “talent” programs.
- › If you serve on peer review group, keep in mind that information gained through peer review processes – whether reviewing grant applications or publications – is confidential and should never be shared.
- › Lastly, review and ensure answers to yes/no questions are correct.



Office of Research and Project Administration

Princeton > Research

Takeaways

- › We value, are committed to, and encourage international collaboration, welcome foreign students and visitors, and are dedicated to openness in research and academic freedom.
- › We take compliance with federal regulations seriously.
- › We acknowledge current state of inconsistency, lack of clear guidelines, privacy concerns of PIs, and burden of compliance.
- › Encourage disclosure and full transparency.
- › Be consistent in reporting.
- › Review solicitation requirements carefully.
- › Call us if unsure – We want to hear from you!

Office of Research and Project Administration

Princeton > Research