

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

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September 4, 2019

MEMORANDUM

TO:

FROM:

Faculty & Staff Laurie E. Locascio Vice President for Research

SUBJECT: International Research Collaborations

On May 30th, President Loh sent a <u>letter</u> to the campus community expressing the University of Maryland's ongoing commitment to supporting our international faculty and global collaborations. International students, faculty, visiting scholars, and research partners are woven into the fabric of the University and are integral to our success in carrying out our mission as a top tier institution of higher learning - promoting the open sharing of knowledge and fundamental research. As a university, we are entrusted to carry out this mission, and while doing so, we must be vigilant in abiding by U.S. policies, guidelines and regulation to protect the U.S. interests and the intellectual property that is created here. To retain public trust, we must continue to be open and transparent in our work and responsibly report potential financial conflicts of interest, conflicts of commitment, and foreign relationships of researchers. Many of the U.S. policies and regulations regarding international relationships are complex and changing and there is limited guidance from the funding agencies in many cases.

The Division of Research has compiled this Frequently Asked Questions (FAQ) document to help Maryland researchers understand and navigate the requirements. We will also be uploading this document to our web page at: <u>https://research.umd.edu/memos-and-guidance</u> and updating it as appropriate.

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1. What are the main concerns of the U.S. Government and funding agencies?

[LAST UPDATE: 8/1/2019]

The U.S. Government's main concerns include but are not limited to:

- Undisclosed financial conflicts of interest;
- Infringement on academic freedom;
- Undisclosed or unmanaged conflicts of commitment;
- Undisclosed foreign collaborations (funded and unfunded);
- Participation in foreign "talent programs";
- Diversion of intellectual property to others, including foreign entities;
- Unauthorized disclosures of confidential proposal information by reviewers who share the information with others, including foreign entities, or otherwise attempt to influence decisions;
- Unauthorized transfers of confidential data;
- Non-compliance with export-control laws and regulations.

2. What results from enforcement activities have been reported in the United States?

[LAST UPDATE: 8/1/2019]

Among the prohibited activities that agencies have discovered through enforcement activities are the following:

- Undisclosed foreign collaborators;
- Investigators receiving duplicate income for the same effort;
- Undisclosed foreign talent program contracts requiring investigators funded by U.S. grants to abide by terms and conditions of foreign entities (such as requirement to include specific foreign authors on publications);
- Labs duplicating US-funded labs in other countries and inappropriate sharing of information (aka "shadow labs");
- Confidential proposal information used by others without citation;
- Unauthorized data transfers.

3. Have enforcement activities uncovered deliberate non-disclosures of foreign affiliations?

[LAST UPDATE: 8/22/2019]

Yes. The NIH has undertaken one of the most extensive efforts by a federal sponsor aimed at stemming non-disclosure violations by its supported researchers. This effort was initiated after the Department of Health and Human Services Office of the Inspector General informed NIH that a Federal Bureau of Investigation (FBI) probe uncovered unauthorized proposal sharing between an NIH reviewer and outside individuals, including researchers in other countries. The initial probe and related NIH review resulted in firings of undisclosed individuals across institutions and the repayment of grant funds. Recently, NIH sent 180 letters to more than 60 U.S. institutions where scientists are suspected of violating disclosure rules related to sources of

funding and outside employment. On August 20, 2018, NIH sent a letter to the research community broadly stating the responsibilities to comply with NIH policies and US regulation and to responsibly disclose all foreign collaborations and relationships. To our knowledge, NSF has not sent a broad inquiry letter as NIH did, but we have heard reports that NSF is conducting investigations on grant recipients with undisclosed "talent program" contracts and/or foreign labs designed to duplicate their US lab ("shadow lab"). NSF has also issued a "Dear Colleague Letter" this July addressing the concerns and suggesting that additional changes may be implemented in the near future:

https://www.nsf.gov/pubs/2019/nsf19200/research_protection.jsp

This August, the US Department of Justice released information about a University of Kansas faculty member indictment under the charge of fraud for Failing to Disclose Conflict of Interest with Chinese University:

https://www.justice.gov/opa/pr/university-kansas-researcher-indicted-fraud-failing-discloseconflict-interest-chinese

An article about NIH investigations can be found at: <u>https://www.sciencemag.org/news/2019/06/nih-probe-foreign-ties-has-led-undisclosed-firings-and-refunds-institutions</u>

4. How is the U.S. Government targeting cases for investigation?

[LAST UPDATE: 8/1/2019]

It depends on the funding agency. The NIH has publicly disclosed that they are reviewing publications for additional collaborators or funding sources and then cross-referencing that information with what was disclosed in the NIH proposal. This information is then used for additional inquiries. NIH is not discouraging foreign collaborators or other sources of funding, but the Principal Investigator must be transparent with all required information at the time of the proposal. There are also reports of examples where the FBI is reporting information on participation in foreign talent programs to the funding agencies.

5. Are NIH and NSF the only federal agencies who have expressed concern about potential foreign influence on research integrity?

[LAST UPDATE: 8/1/2019]

No, this matter is of concern to the research agencies more broadly. The Departments of Defense and Energy, and NASA, have also issued statements regarding this issue. Given the current U.S. Government focus on this issue, we anticipate similar guidance, statements, or requirements will be forthcoming from other funding agencies.

• The National Defense Authorization Act, signed in August 2018, included <u>Sec. 1286</u>, which stated that "The Secretary of Defense shall, in consultation with other appropriate government organizations, establish an initiative to work with academic institutions who perform defense research and engineering activities . . . to limit undue influence,

including through foreign talent programs, by countries to exploit United States Technology ... "This Act also restricts restricted universities that host Confucius Institutes from receiving DOD funding for Chinese language instruction.

On March 20, 2019 the Department of Defense issued a <u>memo</u> explicitly outlining disclosure requirements for all key personnel listed on research and research-related educational activities supported by DoD grants and contracts.

- The Department of Energy issued a <u>directive</u> 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. DOE is expected to issue a separate policy directive to implement the requirement on DOE grants and cooperative agreements.
- NASA has long-standing restrictions on using NASA funds to enter into agreements "to participate, collaborate, or coordinate bilaterally in any way with China or any Chinese-owned company, at the prime recipient level or at any subrecipient level, whether the bilateral involvement is funded or performed under a no-exchange of funds arrangement."

6. What is a financial conflict of interest as it relates to research?

[LAST UPDATE: 8/1/2019]

Federal sponsors include descriptions of financial conflict of interests in their policy manuals. We have cited the National Institutes of Health (NIH) and the National Science Foundation (NSF) references below:

The NIH Policy Manual defines a financial conflict of interest as follows: "A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Researcher's Significant Financial Interest is related to a funded research project and could directly and significantly affect the design, conduct or reporting of the research. Typical examples include owning stock or receiving gifts from a company where the share price could be influenced by the research findings."

https://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3180

The NSF's Proposal and Award Policies and Procedures Guide (PAPPG) addresses grantee conflict of interest in detail, noting that, "NSF requires each grantee organization employing more than fifty persons to maintain an appropriate written and enforced policy on conflicts of interest and that all conflicts of interest for each award be managed, reduced or eliminated prior to the expenditure of the award funds... An organizational conflict of interest policy should require that each investigator disclose to a responsible representative of the organization all significant financial interests of the investigator (including those of the investigator's spouse and dependent children): (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial

interests would reasonably appear to be affected by such activities. The term "investigator" means the PI/PD, co-PI/co-PDs, and any other person identified on the proposed project who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF. The term "significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights)." ... An organizational policy must designate one or more persons to review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the organization to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities."

See the full NSF COI policy at: <u>https://www.nsf.gov/pubs/policydocs/pappg19_1/pappg_9.jsp</u>

See the University policy on conflict of interest at: https://president.umd.edu/sites/president.umd.edu/files/documents/policies/II-310A.pdf

7. What is a conflict of commitment?

[LAST UPDATE: 8/1/2019]

A conflict of commitment exists when a non-University of Maryland obligation prevents an individual from spending the time required for his/her full-time commitment to the University. Examples include:

- Membership by an individual on corporate boards or scientific advisory committees that could divert them from their University job to the extent that the employee's obligations to the University are not met;
- Employment by another entity or consulting work that is intended to be part-time, but that interferes with full-time duties at the University.

See the University policy on conflict of commitment at: <u>https://president.umd.edu/sites/president.umd.edu/files/documents/policies/II-310A.pdf</u>

8. Do I need to report outside professional activities or research collaborations to funding agencies, and when?

[LAST UPDATE: 8/1/2019]

Yes, you must report outside professional activities and research collaborations to certain funding agencies. NIH, NSF, and other sponsors require that these activities be disclosed in proposals for funding. NIH uses the term "Other Support" while NSF, and other federal sponsors and funding entities, use the term "Current and Pending Support" to request the

submission of information for key personnel's active and pending review or awarded research funding. This information is submitted at the time of proposal. The format varies by sponsor.

Additional guidance on NSF and NIH specific reporting requirements can be found in Exhibit 1.

9. Do unfunded collaborations have to be reported?

[LAST UPDATE: 8/1/2019]

Yes, reportable collaborations include unfunded activities, even if not directly related to the grant.

NSF requires that "...any substantial collaboration with individuals not included in the budget should be described in the Facilities, Equipment and Other Resources section of the proposal (see Chapter II.C.2.i) and documented in a letter of collaboration from each collaborator. Such letters should be provided in the supplementary documentation section of the FastLane Proposal Preparation Module and follow the format instructions specified in Chapter II.C.2.j. Collaborative activities that are identified in the budget should follow the instructions in Chapter II.D.3."

Foreign collaborations involving NIH funding have always required prior approval. Recent congressional concern over the U.S. losing intellectual property to foreign countries has led to a reminder announcement in May, close review of publications cited in Research Performance Review Reports to confirm compliance, and a special announcement by NIH Director Collins. The latest NIH announcement reiterates that the policy applies to foreign conduct of any of the work scope, inclusive of subawards, regardless of the source of funding. A "foreign component" is defined as 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*. Based on program officer reviews recently received, such involvement includes unfunded collaborations with a foreign entity or a foreign person, including visiting scholars, graduate students, and fellows funded by their home country, exchanging material and/or data, or other use of foreign resources.

10. Where is this requirement stated in the NSF/NIH proposal guides?

[LAST UPDATE: 8/1/2019]

The NSF guidance is included here: https://www.nsf.gov/pubs/policydocs/pappg19_1/pappg_2.jsp#IIC2div

The NIH application guidance is here: https://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch16.htm#_Toc271265275

11. When do outside professional activities have to be reported to UMD?

[LAST UPDATE: 8/1/2019]

The University of Maryland Policy on Conflict of Interest and Conflict of Commitment requires faculty and exempt staff to report significant outside professional activities to their unit head as soon as possible and also to submit an annual report on outside professional activities (see below). Consistent with University of Maryland's Conflict of Interest/Conflict of Commitment Policy, outside professional activities are generally permitted as long as they do not result in a potential conflict of interest or a conflict of commitment. The responsibility for managing potential conflicts of interest or commitment begins with the faculty and staff members involved, who must disclose certain relationships or activities. Further action is required only in cases where a conflict (real, potential, or apparent) is identified by the unit head or the employee involved. In many cases, disclosing and managing a conflict of interest is simple and straightforward. The Conflict of Interest committee and staff work directly with the researchers to work to implement a management plan. More information can be found at: https://research.umd.edu/coi

The annual UMD OPA reporting tool is currently housed in the ARES website here: <u>https://ares.umd.edu/home/</u>

12. What are department chair/unit head responsibilities associated with reviewing OPA disclosures?

[LAST UPDATE: 8/1/2019]

Under the <u>University of Maryland Policy on Conflict of Interest and Conflict of Commitment</u>, it is a responsibility of department chairs and other unit heads to ensure that members of their unit are familiar with University policies and procedures relating to outside professional activities, conflicts of interest, and conflicts of commitment. The unit head is responsible for monitoring the level of outside activity for appropriateness relative to the mission of the unit and must be knowledgeable concerning the kinds of activities that may lead to conflicts and, in consultation with the Dean's office and the President's Advisory Committee on Conflict of Interest where appropriate, advises faculty, staff, and other employees so that they may avoid or manage conflicts of interest and commitment or situations that may adversely affect the researcher and/or University.

The unit head maintains a special overview of outside professional activities in which senior and junior faculty and students in the department are associated together and makes clear to all parties the necessity to safeguard the academic relationship. The researcher and the unit head are responsible for initiating a Conflict of Interest disclosure when appropriate.

13. What are the concerns with "foreign talent programs"?

[LAST UPDATE: 8/1/2019]

Federal sponsors have become particularly concerned about participation in "foreign talent programs". While there is no agreed-upon government definition, these are generally any attempts, sponsored by a foreign government, to acquire U.S.-funded scientific research through recruitment programs that target scientists, engineers, academics, researchers, and entrepreneurs of all nationalities working or studying in the United States. The U.S. Government is especially concerned about the active recruitment of foreign scholars into "foreign talent (recruitment) programs" by foreign governments, and their apparent attempts to influence foreign nationals to misappropriate federally-funded research results and intellectual property from U.S. institutions of higher education. The FBI has warned that these recruitment programs may require U.S. researchers to sign contracts that limit who they can hire in their U.S. laboratory, require them to higher and mentor students from a specified country, require the investigator to spend time at the foreign institution, and to name the foreign institution as a primary contributor. Please note that University personnel are not authorized to sign contracts relating to University work or University resources without a written delegation of signature authority. If you are presented with a contract, please route it to the University Office of Research Administration or send it to the Office of General Counsel.

While participation in foreign talent programs is not banned, any support from such a program must be disclosed both to the University and to the U.S. government during the proposal process, when required by the funding agency (see sections above on current NIH/NSF requirements). Depending on the sponsor and proposed research, Key Personnel may be advised (or required) to terminate their affiliation with the foreign talent program in order to receive an award.

As a result of these concerns, sponsors may implement additional conditions or restrictions on participation in foreign talent programs. For example:

- NSF and NIH have suspended and terminated grants where the PI did not disclose talent program participation.
- Funding agencies may require a copy of the talent program contracts prior to making an award or releasing a funding increment.
- Specific talent program contractual requirements, as identified above, may deem the PI ineligible to receive U.S. Government funding.
- DOD has suggested that policy changes may be forthcoming, which will prevent foreign talent program participants from obtaining or otherwise working under DOD funding.

14. How do I protect unpublished research data or unprotected IP?

[LAST UPDATE: 8/1/2019]

The following are suggestions that a researcher may consider if they have sensitive research data that requires additional protections:

- Work with the University Office of Research Administration or Office of General Counsel to establish non-disclosure agreements with researchers and strict protocols on how researchers may handle data.
- Limit datasets and analysis to a need-to-know basis for all lab personnel.
- Utilize secure data storage systems that limit who has download rights and logs all downloading of files.
- Disclose inventions to UM Ventures College Park (formerly Office of Technology Commercialization) as soon as possible.
- Follow agency guidance for reviewers. NIH <u>protects the integrity and confidentiality</u> of Peer Review for reviewers and applicants and has <u>consequences for the breach</u> of review integrity as does <u>NSF</u>.
- Follow guidelines for ethical Peer Review of journal articles. Guidelines can be found here: <u>COPE Ethical Guidelines for Peer Reviewers</u> and <u>What is Peer Review</u>? on Elsevier's website. Additionally, Elsevier has a <u>Researcher Academy</u> with learning modules covering topics such as ethics responsibilities for peer review, diversity in peer review, and transparency in peer review.

15. What should I do if a law enforcement agent makes contact with me?

[LAST UPDATE: 8/1/2019]

The University of Maryland Police Department has established a protocol with the FBI and other agencies asking that agents first contact the Police Department and make a request to schedule a meeting. The Police Chief will then contact the appropriate individuals, including the PI, Dean, Department Head, and Office of General Counsel to decide on a response and whether to include a University of Maryland attorney in the meeting. Although this protocol has been established, there is nothing that prevents an agent from coming to the university unannounced and asking questions of researchers.

If you are visited by a federal law enforcement agent, it is important to verify the agent's credentials. Most agents will show you their official ID badges, but you should ask if that is not presented. It is a good idea to write down the name, agency, and contact information for future reference or ask for a business card. After you verify the agent's identity, we recommend that you contact the University of Maryland Police Department (Chief David Mitchell: 301-405-5726) or the Office of General Counsel (301-405-4945) prior to engaging in a meeting. If you are busy at the time of inquiry, you can request that the agent make these contacts and set up a meeting at a future time. We also recommend that you notify your unit head and/or next-level supervisor as soon as possible.

16. Am I required to meet with a law enforcement agent if they show up and request a meeting with me?

[LAST UPDATE: 8/1/2019]

If the agent presents a warrant, subpoena, court order, national security letter or other legal document requiring immediate participation, please refer to the next question, Question 17.

You have the right to decline or delay participation and ask that the agent contact the University of Maryland Police Department (Chief David Mitchell: 301-405-5726) or the Office of General Counsel (301-405-4945) to schedule a visit at a time when a University representative can be present. The Office of General Counsel represents the University, including all faculty and staff acting within the scope of their employment. Faculty and staff also may consider obtaining personal legal representation if there are any concerns or uncertainties.

If you choose to proceed with the meeting, **you must not provide names and nationalities or any other personally identifiable information including addresses and phone numbers for students, faculty, or staff**. To do so could violate State or Federal law. Please refer the agent to the Office of General Counsel if they request information on any University faculty, staff, students, or any visiting scholar or collaborator.

17. What if the agent presents a search warrant?

[LAST UPDATE: 8/1/2019]

If the agent presents a warrant, subpoena, court order, national security letter, or other legal document *addressed to the University or that describes University property*, immediately contact the University of Maryland Police Department and Office of General Counsel. University personnel other than police and attorneys are not authorized to accept service of these documents on behalf of the University.

A search warrant can require immediate action (as opposed to a subpoena or other document that provides a date by which the University must comply). If presented with a search warrant, carefully review the document and immediately contact the University of Maryland Police Department (Chief David Mitchell: 301-405-5726) or the Office of General Counsel (301-405-4945). If the search warrant is for University property, a University representative should be present during the search, and you are not required to speak or otherwise provide information until you have had an opportunity to consult legal counsel. The Office of General Counsel represents the University, including all faculty and staff acting within the scope of their employment. Faculty and staff also may consider obtaining personal legal representation if there are any personal concerns or uncertainties.

If an agent presents a search warrant or other legal document addressed to *you*, please contact your personal attorney.

18. What is an "export" and what are export laws?

[LAST UPDATE: 8/1/2019]

The legal term "export" refers to both shipping an item out of the country or sharing technical information with a non-U.S. person (wherever located) that could provide details on how to construct the item or its performance characteristics ("deemed export"). Please be aware that simply discussing certain information with a non-U.S. person, even if that discussion occurs on campus, may be a deemed export. In some cases, allowing a non-U.S. person access to an item can be considered an "export" of technical information if that technology is a sensitive prototype that hasn't been released yet in commerce.

U.S. export laws control certain technologies (both military and commercial) and govern what technologies can be sent abroad or shared with non-U.S. person. A U.S. person is defined as a citizen or permanent resident (sometimes called a "green card holder"). Depending on the military or commercial sensitivity, an export license may be required to export the item or technical information. For example, a military sensor would require an export license to export to virtually all foreign countries, where a basic scientific instrument (i.e. optical microscope) could be exported to virtually any country (excluding Iran, Syria, North Korea, Sudan, or Cuba) without any export license. Severe penalties including imprisonment, fines, and funding sanctions can be assessed on export violations.

19. Are my research or service activities export controlled?

[LAST UPDATE: 8/1/2019]

It depends. Fundamental research that is intended to be published without sponsor restrictions (i.e. no non-disclosure agreements, publication approval requirements, foreign national restrictions, etc.) is generally excluded from export laws. The University System of Maryland Policy on Classified and Proprietary Research prohibits the University from accepting research with publication restrictions unless a waiver has been granted by the University President. If the research or service is considered proprietary to the sponsor (cannot be published without approval) then export laws may apply. Depending on the sensitivity of the item, this may require that only U.S.-persons can have access to the item or data. You will need to determine at what level the client's technology is export controlled. Ask the client for the Export Control Classification Number (ECCN) or the United States Munitions List (USML) designation of the item. Most items in commerce that are not an emerging technology, cutting edge, or dual-use (military and non-military application), are designated "EAR99", which have the lowest level of export control. The University of Maryland Export Compliance Office (export@umd.edu) can provide assistance if the researcher or client is not sure or needs help interpreting the information they provide. You should not accept export controlled, or potentially export controlled information without assistance from the University of Maryland Export Compliance Office. If you are considering a collaboration with an entity associated with a foreign military, please contact the University of Maryland Export Compliance Office as soon as possible.

20. What do I do if my research or service is export controlled?

[LAST UPDATE: 8/1/2019]

Contact the University of Maryland Export Compliance Office to determine what controls apply to the item and what restrictions may be necessary to comply with export laws. Export-controlled research may require a waiver to University policy as described above. The Export Compliance Office can help determine what approvals may be required and what security controls should be in place. Controls might include:

1) Limiting testing to U.S. persons;

2) Insuring all personnel are aware of the requirements and subject to non-disclosure;

3) Keeping the client's material in a locked or access-controlled location;

4) Using secure IT systems to store data to limit the access to the approved personnel and the client.

21. How do I report suspected unethical or illegal conduct?

[LAST UPDATE: 8/1/2019]

For suspected illegal conduct, contact the University of Maryland Police if the threat is time sensitive (Chief David Mitchell (301-405-5726) or the Office of General Counsel (301-405-4945).

General reporting contacts can be found in the Reporting Resources (last page) of the Guidance document on <u>Communications of Suspected Unethical or Illegal Conduct (Whistleblower</u> <u>Protections</u>).

22. What if I receive inquiries from the media?

[LAST UPDATE: 8/1/2019]

You are not required to speak to the media. Researchers contacted directly by the media can speak to them at the researcher's discretion but must not provide any information or documents (other than published material) related to University personnel or students (doing so may violate State and Federal privacy laws). If the media inquiry is not about basic research outcomes, direct the reporter to contact the appropriate college communications office or the Office of Strategic Communications as follows:

Office of Strategic Communications 2101 Turner Hall College Park, MD 20742-5411

Email: mediainfo@umd.edu Phone: 301-405-4621 After-hours on-call phone: 301-257-0073

All requests for internal University of Maryland documents must be filed as Public Information Act ("PIA") requests. Direct the media to the Office of General Counsel's PIA website: <u>https://ogc.umd.edu/public-information-requests/</u>.

23. What are my options if I discover that I have made a mistake?

[LAST UPDATE: 8/1/2019]

Due to the complexities of these rules, policies, and regulations, it is not uncommon to inadvertently make a mistake. It is often the case that disclosing a mistake voluntarily and taking corrective action (as opposed to it being discovered by others) can eliminate or significantly reduce the severity of the consequences. In the event that a mistake is discovered, consider taking one or more of the following are options:

- Seek guidance from the faculty ombuds officer.
- Seek guidance from the Chair of the Export Control and International Compliance committee, Daniel Lathrop (lathrop@umd.edu).
- Seek guidance from the University Office of General Counsel (if you have been acting within the scope of your employment) or your personal attorney (if you have been acting outside the scope of your employment) under attorney client privilege.

The Point of Contact for this guidance document is the Director of the Export Compliance Office, Adam Grant, <u>afgrant@umd.edu</u>, 301-405-2612. Depending on the nature of the inquiry, Adam Grant can help you find the answers or find the best point of contact for your specific questions.

Exhibit 1: NSF and NIH Guidelines:

[LAST UPDATE: 8/1/2019]

For NIH:

In December 2018, the NIH <u>ACD Working Group for Foreign Influences on Research</u> <u>Integrity</u> referred to several opportunities for NIH funding applicants to disclose required information on other funding support and collaborations.

The term "other support" is specific to NIH and entails the submission of information regarding research funding that is either active (awarded) or pending review or award. The information needs to be submitted for all key personnel and needs to include all financial resources, whether federal, non-federal, commercial or organizational, foreign or domestic, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Training awards, prizes, or gifts do not need to be included. The full description of NIH "Other Support" is found at https://grants.nih.gov/grants/forms/othersupport.htm

Proposal Phase:

- <u>NIH Application Other Project Information</u> page (Question 6): Applicants are asked to check a box if they have international collaborators. Disclosures of foreign support, collaborations, or sharing of resources initiates a clearance process with the U.S. State Department that must be completed prior to issuance of awards.
 - All financial resources, including support from foreign entities and talent programs, must be included in the Current and Pending Support/Other Support section of research proposals. This includes any direct research support provided to you but not administered by the University.
- <u>Determining whether proposed activities include **foreign component** (taken directly from <u>NOT-OD-19-114</u>):</u>

The existence of any "significant scientific element or segment of a project" outside of the United States, in other words:

- 1. Performance of work by a researcher or recipient in a foreign location, whether or not NIH grant funds are expended; and/or
- 2. Performance of work by a researcher in a foreign location employed or paid for by a foreign organization, whether or not NIH grant funds are expended.
- If a recipient determines that a portion of the project will be conducted outside of the U.S., the recipient then will need to determine if the activities are considered significant. If both criteria are met, then there is a foreign component. To aide with what may be considered significant, click on the FAQ link below. The addition of a foreign component to an ongoing NIH

grant continues to require NIH prior approval, as outlined in the NIHGPS, Section 8.1.2, Prior Approval Requirements.

- If an activity does not meet the definition of foreign component because all research is being conducted within the United States, but there is a non-U.S. resource that supports the research of an investigator and/or researcher, it must be reported as other support.
- For example, if a PD/PI of an NIH-funded grant has a collaborator outside of the U.S. who performs experiments in support of the PD/PI's NIH-funded project, this would constitute a foreign component, regardless of whether the foreign collaborator receives funding from the PD/PI's grant. Additional funding from a foreign source for the NIH-supported research of a PD/PI at a U.S. institution would not constitute a foreign component but would necessitate reporting as other support.

Disclosing Financial Conflict of Interest

<u>NOT-OD-19-114</u> also reminds the extramural community of the requirements in 42 CFR Part 50, Subpart F, Objectivity of Research. This regulation, also known as the FCOI regulation, specifies the minimum requirements for investigators to disclose to their institution their significant financial interests. As outlined previously in <u>NOT-OD-18-160</u>, the requirement to disclose includes financial interests received from a foreign entity. This requirement is distinct and in addition to the reporting of other support and foreign components to the NIH.

The FCOI regulation acknowledges that an applicant/recipient's policy on financial conflicts of interest may have standards that are more stringent than those in the regulation, e.g., that require a more extensive disclosure of financial interests, in which case the institution shall adhere to its policy and shall provide FCOI reports to NIH regarding identified financial conflicts of interest in accordance with its own standards and with the protocol specified in the regulation.

Award Phase:

• Just-in-Time grant application information requests provide potential grantees another opportunity to disclose foreign support. The Office of the Director, NIH published reminders regarding Other Support in July 2019 (NOT-OD-19-114). 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 (NIH Grants Policy Statement).

Other Support (taken directly from <u>NOT-OD-19-114</u>): NIH reminds applicants and recipients that other support includes 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 the institution the researcher identifies for the current grant. This includes resource and/or

financial support from all foreign and domestic entities, including but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.).

NIH applicants must:

- 1. List all positions and scientific appointments both domestic and foreign held by senior/key personnel that are <u>relevant to an application</u> including affiliations with foreign entities or governments. This 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).
- 2. Report all resources and other support for all individuals designated in an application as senior/key personnel including for the program director/principal investigator (PD/PI) and for other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation. Information must be provided about all current support for ongoing projects, irrespective of whether such support is provided through the applicant organization, through another domestic or foreign organization, or is provided directly to an individual that supports the senior/key personnel's research efforts.
- 3. Report all current projects and activities that involve senior/key personnel, even if the support received is only in-kind (e.g. office/laboratory space, equipment, supplies, employees). All research resources including, but not limited to, foreign financial support, research or laboratory personnel, lab space, scientific materials, selection to a foreign "talents" or similar-type program, or other foreign or domestic support must be reported.
- 4. Provide the total award amount for the entire award period covered (including facilities and administrative costs), as well as the number of person-months (or partial person-months) per year to be devoted to the project by the senior/key personnel involved.
- All pending support at the time of application submission and prior to award must be reported using "Just-in-Time Procedures" by providing all information indicated above. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award, including "Other Support" changes that must be assessed for budgetary or scientific overlap. Further, if other support, as described as above, is obtained after the initial NIH award period, from any source either through the institution or directly to senior/key personnel, the details must be disclosed in the annual research performance progress report (RPPR). Post-award, recipients must address any substantive changes by submitting a prior approval request to NIH in accordance with the NIHGPS section on "Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award."

Annual Research Performance Progress Report (RPPR):

- **NIH RPPR Participants (Section D1; pg82 of link):** <u>*required*</u> to list anyone who has worked on the project at least one-person month per year and identify if the individuals' primary affiliation is with a foreign organization.
- **NIH RPPR Personnel updates (Section D2; pg85 of link):** <u>*required*</u> to identify new/senior key personnel and/or changes in other support of senior/key personnel since the last reporting period.
- **NIH RPPR Impact (Section E4; pg88 of link)** <u>*required*</u> to report dollar amount of the award's budget that is being spent in foreign country(ies).
- NIH RPPR Project Performance Site(s) (Section G8; pg98 of link) <u>required</u> to report changes to the project/performance site(s) including any new sites where either human subjects or vertebrate animals will be involved.
- NIH RPPR Foreign Component (Section G9; pg99 of link) requires you to provide the organization name, country, and description of each *foreign component* (note <u>adding Foreign Components</u> require prior approval).

For NSF:

The link to the "For Comment Draft" of the NSF Proposal and Award Policies and Procedures Guide follows: https://www.nsf.gov/bfa/dias/policy/papp/pappg20_1/FedReg/draftpappg_may2019.pdf

Appointments: A list, in reverse chronological order, of all the individual's academic/professional appointments beginning with the current appointment. Appointments include any titled academic, professional, or institutional position whether or not remuneration is received.

Current and Pending Support: Current and pending support information must be separately provided for each individual designated as senior personnel on the proposal through use of an NSF-approved format. Information must be provided about all current and pending support, including this project, for ongoing projects, and for any proposals currently under consideration from whatever source, irrespective of whether such support is provided through the proposing organization or is provided directly to the individual. All projects and activities, current or proposed, that require a time commitment from the individual must be reported, even if the support received is only in-kind (such as office/laboratory space, equipment, supplies, employees, students). The total award amount for the entire award period covered (including indirect costs) must be provided, as well as the number of person-months (or partial person-months) per year to be devoted to the project by the senior personnel involved. Concurrent submission of a proposal to other organizations will not prejudice its review by NSF, if disclosed. If the project (or any part of the project) now being submitted has been funded previously by a source other than NSF, provide the required information describing the last period of funding.

NSF is explicit that this is a policy clarification, as opposed to a modification. Examples of current and pending support have been expanded to include non-profit organizations and consulting agreements. New electronic format (or formats) will be implemented to collect current and pending information. Upload of pdf will no longer be permitted.

In 2018, NSF implemented a template for identifying Collaborators and Other Affiliations Information and provided the following guidance:

"NSF requires the use of the template linked below for identifying Collaborative and Other Affiliations Information (COA) information. The content requirements specified in the template are consistent with <u>Chapter II.C.1.e</u> of the NSF *Proposal and Award Policies and Procedures Guide*. The template has been developed to be fillable, but the content and format requirements must not be altered as this will create printing and viewing errors. This template must be saved in .xlsx format and directly uploaded into FastLane as a Collaborators and Other Affiliations Single Copy Document. FastLane will convert the uploaded .xlsx files to PDF. Using the .xlsx format will enable preservation of searchable text that otherwise would be lost. It is imperative that this document be uploaded in .xlsx only. Uploading a document in any format other than .xlsx may delay the timely processing and review of your proposal. Grants.gov Users: The COA information must be provided through use of the COA template and uploaded as a PDF attachment.

<u>Frequently Asked Questions (FAQ)</u> have been developed for assistance in completion of the template.

NSF uses COA information during the merit review process to help manage reviewer selection. To expedite identification of potential reviewers, having a standard, searchable format for this information is essential. In the past, the submission of COA information was often in formats that resulted in unsearchable text because of the variety of software and document formats used. By having each PI, co-PI and other senior project personnel individually upload an .xlsx document, and having FastLane perform all of the conversions, we preserve searchable text in the resulting PDFs to the greatest extent practicable. This will help reduce the burden on NSF program staff who currently must spend time to manipulate files that are non-searchable. In addition to the benefits to the merit review process, it is hoped that this template will provide a compliant and reusable format for PIs to maintain and update their COA information for use in subsequent proposal submissions to NSF. For system-related questions, please contact FastLane User Support at 1-800-673-6188 or <u>fastlane@nsf.gov</u>. Policy-related questions regarding the content of the COA template should be directed to policy@nsf.gov.

- <u>Collaborators and Other Affiliations Information Template</u>
- FAQs on Collaborators and Other Affiliations Information Template"

Source: https://www.nsf.gov/bfa/dias/policy/coa.jsp