#### NIH- Other Support and Identifying Foreign Components

#### Proposal and Post Award Resource including updated Current and Pending Email Template

NIH Notice <u>NOT-OD-19-114</u> reminds institutions of NIH policies on Other support and Policies related to financial conflict of interest and foreign components. The Council of Government Relations prepared a commentary in Disclosing Other Support and Other Resources in Research Funded by NIH that contains helpful analysis. It is attached.

### **OVERVIEW**

Overarching Messages from NIH: Complete and accurate reporting of research support from internal and external sources, and the relationship to NIH funding, is critical for NIH and grantee institutions to assess scientific and budgetary overlap, and availability of time to commit to NIH funded projects.

- 1. Reporting Consulting and Outside Professional Activities
  - a. Key personnel must disclose funding for all research activities, regardless of where the research will be carried out.
  - b. Outside activities that are not considered research do not appear to require reporting to NIH.
- 2. Training Awards, Gifts, and Prizes / Institutional Support
  - a. Key personnel must disclose start-up packages and support for research from entities other than Mason, even if the research will be carried out at another institution; and institutional grants and awards that are "separately budgeted and accounted for" per the Uniform Guidance.
  - b. Key personnel are not responsible for disclosing start-up packages from the Mason in any form; gift funds that meet the formal definition of a gift; endowed chair funds and other endowment allocations.
- 3. Reporting In-Kind Support
  - a. Key personnel must disclose in-kind resources that are uniquely available to key personnel (office/laboratory space, equipment, supplies, employees) including those available outside the applicant institution; details about in-kind personnel who are expected to work directly on a proposed project; report details of in-kind support in the Facilities and Other Resources section or in Other Support section of the application; report details of individuals who have expended at least one month of effort during the year (compensated or uncompensated) in the annual report (no change).
  - b. Key personnel are not responsible for disclosing institution-wide resources such as core facilities or shared equipment that are made broadly available.
- 4. Reporting of Appointments and Affiliations
  - a. Key personnel must disclose affiliations or appointments that are likely to be cited in NIH-funded publications in the biosketch section of the application.

- 5. Foreign Component
  - a. Prior approval is required before initiating a new "foreign component" per current NIH policy (no change).
  - b. Informal collaborations with international researchers **could meet** the NIH definition of a Foreign Component; therefore, it will not always be apparent to the sponsored programs office when a foreign component arises. Educating PIs about the NIH requirement is essential for PIs and institutions to comply with NIH policy.

### **OTHER SUPPORT**

### Proposals

- 1. What is Other Support: 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.). Foreign scholarship support is a type of financial support for laboratory personnel and as such must be reported.
- 2. In proposals submitted to NIH, Other Support must:
  - a. List all positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application 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).
  - b. 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.
  - c. 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.

- d. 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.
- 3. 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.
- 4. OSP has created a separate Current and Pending Cover Letter for NIH Just in Time submissions that includes guidance to PI's from the Council of Government Relations (COGR) regarding what needs to be included in Other support versus what does not.
- 5. In the <u>NIH FAQ on Other Support</u> they state including the following examples of scenarios where a PIs activities must be included in Other Support
  - a. A researcher with a 9-month appointment that spent two months at a University outside of the United States during the summer conducting research under a foreign award. Available resources in support of and/or related to an investigator's research endeavors should be disclosed even if they relate to work that is performed outside of a researcher's appointment period.
  - b. A Principal Investigator on an NIH award to a domestic university has an unpaid appointment at a foreign university. At the foreign site, the PI has access to lab space, research materials, and staff. This should be reported as Other Support. While the researcher is not receiving monetary compensation, the lab space, materials, and staff are resources made available to them in support of and/or related to their research efforts. Other payments, such as travel or living expenses must also be reported. NIH requires applicants to list all positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application 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)
  - c. A faculty who is listed as key personnel on an NIH grant in the United States collaborates with another scientist in the US, whose experiments have directly benefitted his research. The experiments were conducted with funds awarded to their institution. This should be reported as Other Support as that includes domestic research collaborations that directly benefit the researcher's research endeavors.

### Post Award

1. If Other Support, as described as in the proposal, 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).

2. 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."

# FOREIGN COMPONENT

# Definitions

- 1. NIH requires recipients to determine whether activities it supports include a foreign component. Foreign component is defined as: The existence of any "significant scientific element or segment of a project" outside of the United States, in other words
  - a. performance of work by a researcher or recipient in a foreign location, whether or not NIH grant funds are expended and/or
  - b. 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.
- 2. NIH defines a foreign institution as an organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed PD/PI.

## Determining Foreign Components

- 1. The PI and OSP need to evaluate the element of the project that is being conducted outside of the United States within the context of the project as a whole when making determinations about "significance."
- 2. Some examples of activities that may be considered a significant element of the project include, but are not limited to:
  - 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
- 3. 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.
- 4. To aide with what may be considered significant, NIH has published an FAQ
- 5. 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**.
  - a. 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.

### Foreign Component versus Foreign Support

- 1. Work being done in the United States but funded by a foreign source generally will NOT count as a foreign component, but must be reported in "Other Support." Here is an example provided by NIH:
  - One model could be that a PI on an NIH grant may have an appointment and a lab at a foreign university. The research being done at the foreign lab is unrelated to the PI's NIH project. This would not qualify as a foreign component of the NIH research, as the foreign work is not part of the NIH-funded project. However, it is a resource made available to the researcher in support of their research. Therefore, it must be reported as Other Support.
- 2. Cases where the PI has visiting post-doctoral fellows or visiting fellows will be case specific. If the work is being conducted in the US, and if so, there is no foreign component. However, if the salary of the visiting fellows is funded by the foreign institution, NIH recommends we consult with the Grants Manager Officer regarding whether Prior approval is needed.
- 3. In all cases, PIs with questions about whether an activity constitutes a foreign component should contact OSP. If questions remain, OSP's Research Administration Manager will contain the NIH Grants Management Officer regarding proper classification of Other Support and Foreign Components.

# CONTACTS

If you have questions about foreign components or inclusion of items in your Other Support document, please contact Becky Hartley or Chris DiTeresi in ORIA, or Mike Laskofsky in OSP if you would like assistance in determining what relationships and support they must disclose, or should consider disclosing, and the best way to do so. The RDIA website has information concerning sponsors' requirements, enforcement developments, congressional consideration of these issues, and similar topics. (See, https://rdia.gmu.edu/topics-of-interest/foreign-support-and-outside-professional-activities/federal-government-action/