

Commentary on Disclosing Other Support and Other Resources in Research Funded by the National Institute of Health

EXECUTIVE SUMMARY & DETAILED ANALYSIS

The grantee community is cautioned that the interpretations and recommendations in this document have not been sanctioned by NIH. While they represent COGR's best assessment of NIH's disclosure requirements, these recommendations are not official and are subject to change as additional guidance from NIH becomes available.



Executive Summary

The purpose of this document is to guide COGR member institutions in meeting the disclosure requirements under NIH Notice NOT OD-19-114. These statements reflect COGR's best assessment of NIH's disclosure requirements, though NIH has not endorsed them.

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

- Key personnel must disclose funding for all research activities, regardless of where the research will be carried
 out.
- Outside activities that are not considered research do not appear to require reporting to NIH.

2. Training Awards, Gifts, and Prizes / Institutional Support

- o <u>Key personnel must disclose</u> start-up packages and support for research from entities other than the applicant institution, 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.
- o <u>Key personnel are not responsible for disclosing</u> start-up packages from the applicant institution 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

- <u>Key personnel must disclose</u> in-kind resources that are <u>uniquely</u> 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).
- o <u>Key personnel are not responsible for disclosing</u> institution-wide resources such as core facilities or shared equipment that are made broadly available.

4. Reporting of Appointments and Affiliations

o <u>Key personnel must disclose</u> affiliations or appointments that are likely to be cited in NIH-funded publications in the biosketch section of the application.

5. Foreign Component

- o <u>Prior approval</u> is required before initiating a new "foreign component" per current NIH policy (no change).
- OCOGR reminds institutions that 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.



Commentary on Disclosing Other Support and Other Resources in Research Funded by the National Institute of Health – A Detailed Analysis

Introduction:

Over the past year, the FBI has raised concerns regarding undue foreign influence on federally funded research to the attention of lawmakers and the funding agencies. As a result, many federal funding agencies are considering what information from investigators is necessary to appropriately assess budget and scientific overlap with other sources of support and ensure investigators have time available to commit to federally funded awards. Agencies have taken the following steps:

- DOD in March 2019, the Department of Defense issued a <u>memo</u> clarifying that key personnel must disclose current and pending support in grant applications. Reporting had previously been required under some DOD grant programs but is now required across all DOD components.¹
- NSF in May 2019, the National Science Foundation issued their draft 2020 Proposal and Award Policies and Procedures Guide (PAPPG) for comment, which included a requirement for senior personnel to report in grant proposals all sources of funding and payments, whether paid through the applicant institution or paid directly to the individual. COGR's response to NSF's proposed changes is available here. NSF is currently reviewing comments and has not issued any new policies.²
- DOE in June 2019, the Department of Energy issued Order 486.1 that authorizes DOE to prohibit DOE contractors from participating in foreign government talent recruitment programs of countries designated by DOE as a foreign country of risk. The DOE order may be flowed down to research institutions through DOE contracts or subcontracts from DOE national laboratories. The requirement does not yet apply to grants. COGR continues to monitor the implementation of the DOE Order.³

In July 2019, NIH issued Notice NOT OD-19-114 Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components and the accompanying FAQ, which have raised several questions about what and how investigators must disclose Other Support (OS) on applications. It is COGR's understanding that additional clarification is unlikely to be forthcoming in the short term. In the meantime, institutions still need to submit proposals and reports.

¹ COGR reported on the details of the DOD memo in the COGR May 2019 Update.

² COGR submitted a <u>comment letter</u> to NSF in July 2019 on the draft NSF PAPPG and provides an update in the <u>September 2019 Update</u>

³ COGR further discusses DOE Order 486.1 in the COGR <u>September 2019 Update</u>



This document is an attempt to summarize our current understanding of NIH requirements based on what COGR and its members have heard from various NIH representatives in public meetings and other open discussions since the publication of the Notice. As noted above, this is COGR's best assessment of these statements, which have not been endorsed by NIH.

Overarching Message on Disclosing Other Support:

NIH has been clear that it wants to know about research support managed through the applicant institution and outside the applicant institution, and how that support relates to NIH-funded projects. This is at the heart of new findings⁴, as some investigators have been performing research at other institutions without full disclosure of those activities to their home institution or federal sponsors. Reporting of Other Support is a critical element for research institutions and NIH to manage potential relationships that could lead to undue influence and threats to national and economic security (through the loss of intellectual property and intellectual capital), or trigger conflicts of interest. The information is also necessary for NIH to assess scientific, budgetary, or commitment overlap with NIH-funded projects.

Note that reporting of research funding and outside relationships is being discussed as part of OSTP's JCORE (<u>Joint Committee on the Research Environment</u>) effort, which includes participation by NIH and several other federal funding agencies. We are optimistic that JCORE effort will result in rational policy principles regarding disclosure of support for activities beyond the proposed project that will assist in harmonizing regulations across multiple federal agencies.

Key Issues Raised in the Notice:

1. Reporting Consulting and Outside Professional Activities

<u>NIH Statements</u>: NIH Grant Policy Statement (GPS) on <u>Other Support</u> requires disclosure of proposals and awards for sponsored research funding, including an estimated effort for those projects. The GPS states:

⁴ NIH probes of foreign ties have led to undisclosed firings – and refunds from institutions <u>https://www.sciencemag.org/news/2019/06/nih-probe-foreign-ties-has-led-undisclosed-firings-and-refunds-institutions</u>



Other support includes all financial resources whether federal, non-federal, commercial or institution 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."

The Notice includes a requirement to disclose projects with no monetary value and projects administered outside the applicant institution. The Notice states (new concepts are highlighted):

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.

NIH posted FAQs along with the Notice. FAQ #6 included a statement indicating an investigator's outside consulting for a company must be disclosed in Other Support if the consulting is "in any way related to the investigator's research endeavors or expertise." This was a significant shift from what institutions and investigators have historically understood.

Shortly after the FAQ was posted, NIH removed #6 from the NIH website following a discussion with COGR and other associations where it was pointed out that such information would generally already be disclosed under the institution's conflict of interest process.

NIH has stated several times key personnel must disclose all research activities, regardless of where those activities are being carried out. Outside activities that are not research (e.g., serving on a science advisory board for a start-up company where the investigator will not perform research) do not appear to be subject to the reporting requirement but may still require disclosure to the applicant institution under NIH conflict of interest policy. Also, NIH wants investigators to report significant in-kind support, such as a laboratory space or major lab equipment, particularly in support of research performed outside the applicant institution (though the OS form wasn't designed for such reporting). Institutions may choose to report in-kind support in the Facilities and Other Resources or Other Support sections of the application, as long as the information is clearly disclosed.

2. Training Awards, Gifts and Prizes / Institutional Support

<u>NIH Statements</u>: The NIH GPS on OS explicitly excludes the reporting of training grants, gifts, and prizes. However, the Notice says <u>all</u> resources should be disclosed and does not provide for these exclusions. The Notice also includes statements that institutional support must also be included in OS. The Notice includes the following statements:



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.

- 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.
- 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.

<u>Importantly, the GPS has not changed.</u> The Notice is intended to clarify but not supersede the GPS.

It is COGR's understanding that Other Support reporting still excludes gifts. However, there does seem to be a concern that sponsored awards are sometimes incorrectly categorized as gifts, and therefore, should be disclosed as OS. Institutions are encouraged to review their policies and procedures to ensure that funding is classified correctly. Research institutions should follow IRS regulations and when making gift determinations. Further, once a gift is received, institutions may choose to use the funds in different ways, for example, as seed research funding or in general support of an investigator's research. NIH has not provided any specific guidance on these cases. Institutions should develop internal guidance for these cases considering the GPS reporting requirements and internal practices. Also, consider the underlying NIH message that complete information about research resources is essential for assessing scientific, budgetary, or commitment overlap with the proposed project. Failure to report sponsored funding and other resources, primarily when those resources could be related to a proposed project, could be a serious matter.

FAQ #5 included a statement that start-up packages and institutional research grants are direct support of the investigator's research endeavors and must be reported in OS. The inclusion of start-up packages was a significant shift in what institutions understood, and the reference to internal funding has caused confusion given the various types of internal research funds provided to researchers.



Shortly after it was posted, NIH removed FAQ #5 from the NIH website.

It is COGR's understanding that investigators do not need report start-up packages <u>at the applicant institution</u>. However, key personnel must report start-up packages and other forms of research support provided by other institutions.

It is also our understanding that institutional grants and awards that are "separately budgeted and accounted"⁵ per the Uniform Guidance, which are not considered start-up support by the applicant institution, must be reported. Endowed chairs and other endowment allocations do not require reporting.

3. Reporting In-Kind Support

<u>NIH Statements</u>: NIH application instructions have long required reporting of non-financial resources (e.g., office/laboratory space, equipment, supplies, employees) that will benefit the proposed research. Reporting of non-financial resources is required in the Facilities and Other Resources section of the grant application. The Notice includes a requirement to also report in-kind resources and other collaborators (domestic and foreign) as Other Support. Note that in-kind resources could also include visitors to the institution's lab who are paid directly by outside sources. As referenced above, the Notice includes the following statement:

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.

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.

It is COGR's understanding that key personnel are only required to report those resources that are <u>uniquely</u> available. Institution-wide resources such as core facilities or shared equipment that are made broadly available need not be reported. Further, if information is

⁵ Appendix III to Part 200 - Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs), Ref A.1.a, and b.



reported as Facilities and Other Resources, it does not *also* need to be reported as OS if the information is clearly disclosed. Visiting researchers compensated directly through outside resources, or anyone who is expected to work directly on the proposed project, should include details of the individual's contributions in the Facilities and Other Resources or Other Support section of the application. Further, if anyone, including visitors, dedicates at least one month of effort to the project in the budget year, whether or not the effort is compensated, the details must be reported in the annual report (i.e., RPPR) under current NIH policy.

4. Reporting of Appointments and Affiliations

<u>NIH Statements</u>: The Notice includes a requirement that appointments and affiliations must be reported as OS. The Notice contains the following statement:

1. 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).

Previously, the GPS called for reporting appointments in the biosketch, and within an established page limit. The new requirement to report "affiliations" is confusing because affiliations are generally informal, often without the need to do anything of significance in exchange for the designation.

Reporting an affiliation or appointment with another organization likely to be cited in publications, particularly regarding research that is funded by an NIH award may be a reasonable approach to consider. The bio sketch seems an appropriate place for this information, though given the language of the Notice and pending further guidance from NIH, reporting it as OS should be satisfactory as well.

Institutions are encouraged to have reasonable policies, procedures, and education that support transparency. Activities must be reported and managed per institutional and federal regulations/standards.



5. Foreign Component

<u>NIH Statements:</u> The Notice contains a reminder that grant recipients are required to monitor foreign activities and seek prior approval for such activities, including when new activities arise during the term of the award. The Notice includes an additional requirement that even if the activity does not rise to the level of a Foreign Component, it must still be reported as OS. The Foreign Components must meet two criteria, per the GPS:

- A portion of the project will be conducted outside of the U.S., and
- The institution must determine if the activities are considered significant. Some examples of activities that may be considered a significant element of the project include, but are not limited to:
 - o collaborations with investigators at a foreign site anticipated to result in co-authorship
 - o use of facilities or instrumentation at a foreign site
 - o receipt of financial support or resources from a foreign entity

If both criteria are met, then there is a foreign component.

And: 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.

Note that prior approval requirements have not changed. COGR reminds institutions even 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 NIH requirements is essential for PIs and institutions to comply with NIH policy.

We understand that a joint publication with a foreign collaborator is not considered a Foreign Component if the research was performed in the US, even if the publication occurs after the international visitors return to their home institution.

Last Note

This is an evolving issue. COGR will continue to monitor federal policy in this area, especially the work of OSTP and harmonization of federal requirements on the disclosure of outside activities. Contact Wendy Streitz (<u>WStreitz@cogr.edu</u>) or Michelle Christy (<u>MChristy@cogr.edu</u>) with any questions about this document. Please note that COGR will not comment on matters related to an individual award.