

GUIDANCE FOR INVESTIGATORS REGARDING FOREIGN INFLUENCE IN FEDERALLY SPONSORED RESEARCH

The NIH has recently issued reminders and clarifications regarding the requirement to report foreign influence in federally-funded research. In December 2018, the Advisory Committee to the President issued a report to NIH entitled, “ACD Working Group for Foreign Influence on Research Integrity.” https://acd.od.nih.gov/documents/presentations/12132018ForeignInfluences_report.pdf

Since that report, the NIH has issued several clarifications to NIH-funded institutions regarding institutional and investigator requirements. These requirements clarify the reporting of “Other Support”, the reporting of a foreign component on an NIH grant, and reporting of financial conflict of interest. See links:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html>

Investigator responsibilities are as follows:

1. **Other Support:** NIH requires disclosure of all “other support” for senior/key personnel on NIH grants at the following times: 1) prior to funding, at “JIT”; and 2) each subsequent year of funding at the time of the annual Research Performance Progress Report.

All senior/key personnel are required to self-report the following items:

- a. List all positions and scientific appointments both domestic and foreign that you hold, 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). If you receive any resources from the institution (office space, lab space, materials, staff support) list that as well. You are asked to provide the address of the institution.
- b. List any financial or non-financial support for any of your research (outside of grants or contracts paid directly to MaineHealth). This includes resources provided to you from another organization (foreign or domestic) whether they be financial or non-financial, such as:
 - providing materials, supplies, specimens, or equipment for your research;
 - providing staff paid for by another entity (including fellows, students, technicians, or any staff that work on research but whom we do not pay directly via MaineHealth);
 - providing lab/research space or office space;
 - any additional support (grant, contract, or gift) to you personally or to another institution for your research, that is not awarded through MaineHealth.

- c. The research grants staff will provide a list of other support grants and contracts awarded to the institution on which you have effort, and will ask you to confirm that the list is complete and accurate.
 - d. You will be asked to attest to the accuracy of your “other support” document in writing.
2. Foreign Component on NIH Grant: Prior to submission of a grant proposal and, for funded grants, every year when reporting progress, the grants staff will ask whether you have a foreign component on your grant. This 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. Activities that would meet this definition include, but are not limited to: (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are:
- collaborations with investigators at a foreign site anticipated to result in co-authorship;
 - use of facilities or instrumentation at a foreign site; or
 - receipt of financial support or resources from a foreign entity.

Foreign travel for consultation is not considered a foreign component

For more info on foreign component, see link:

<https://grants.nih.gov/faqs#/other-support-and-foreign-components.htm?anchor=question55616>

If you determine that a portion of the project will be conducted outside of the U.S., you will need to determine if the activities are considered significant in which case it is a foreign component. The addition of a foreign component to an ongoing NIH grant requires prior approval. If you wish to add a foreign component, notify the research grants office immediately, so we may prepare a prior approval request. NOTE: COBRE grants are not allowed to have any foreign components.

3. Financial Conflict of Interest regarding foreign entities: All investigators who design, conduct or report research are required to comply with our institution’s research conflict of interest policy. While the reporting requirements have not changed, the disclosure form now has more clarity on what must be disclosed from foreign entities. Please see Policy on Conflict of Interest in Research [here](#).

For more information, please contact the Research Grants Office at researchgrants@mmc.org or Michele Locker at lockem@mmc.org.