

Memorandum

To: University Research Community

From: Roberto M. Gutierrez

Associate Vice President for Research

Office of Research and Economic Development

Subj.: NIH Financial Conflict of Interest (FCOI) and Other Support Reminder

Date: October 7, 2022

The National Institutes of Health (NIH) recently released Notice Number: NOT-OD-22-210 (available at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-210.html) to remind the research community of longstanding Financial Conflict of Interest (FCOI) reporting requirements as well as other support disclosures submitted during Just-in-Time (JIT) or in Research Performance Progress Reports (RPPRs) for NIH funded investigators.

The NIH defines an "Investigator" as the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of NIH-funded research or proposed for such funding, which could include collaborators or consultants, depending on their role in the project.

FCOI Disclosures

Investigators are reminded that they must disclose foreign and domestic Significant Financial Interests (SFIs) and those of their spouse and dependent children, that reasonably appear to be related to the Investigator's institutional responsibilities.

Upon disclosure, the University is required to review each disclosed SFI to determine (1) if the SFI is related to the research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research), and (2) if the SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

As a reminder, the vehicle to provide institutional disclosures of SFIs for review is via responses to questions in Section 1 of the Report of Outside Activity/Conflict of Interest" Employee Portal in PeopleSoft.

FCOI Training

NIH FCOI regulations require that Investigators be trained prior to engaging in NIH-funded research and at least every four years thereafter.

FIU utilizes the CITI (Collaborative Institutional Training Initiative) program for providing access to an online FCOI training course. The online training course covers the following four modules:

- 1. Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules
- 2. Institutional Responsibilities as They Affect Investigators
- 3. Institution-Specific Policies
- 4. Conflicts of Commitment, Conscience, and Institutional Conflicts of Interest

Instructions on how to access the online course are available at https://research.fiu.edu/coi/training/.

Other Support Disclosure Requirements

Investigator are reminded that information submitted to the NIH on other support forms for senior/key personnel under NIH's JIT process or in RPPRs must include all resources made available to them in support of and/or related to all their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the investigator identifies for the current grant, which includes resources and/or financial support from all foreign and domestic entities.

NIH requires supporting documentation, which includes copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support. If an investigator has such foreign appointments to report, then such contracts, grants, or other agreements must be in English, and if they are not in English, they must provide translated copies.

The NIH has provided a table that summarizes what is required to be disclosed to them and at what stage. The table is available for review at https://grants.nih.gov/grants/forms/NIH-Disclosures-Table.pdf and is attached to this memorandum.

State of Florida Reporting Requirements

Florida Statute Section 1012.977 requires that all University employees <u>engaged</u> in the design, conduct or reporting of sponsored research on behalf of FIU must report his/her financial interests (i.e., anything of value other than that provided directly by the University) and his/her outside activities (i.e., anything the University employee does for an organization or an individual other than the University that is related to the employee's expertise and/or is not part of the employee's assigned duties). Therefore, to the extent that a University employee has a financial interest or an outside activity that is not already reported pursuant to NIH requirements above, the University employee must report those outside activities and financial interests in Section 1 of the <u>Report of Outside Activity/Conflict of Interest" Employee Portal</u> in PeopleSoft.

Additional Resources

Please visit the following resources for additional information:

- 1. FIU Conflict of Interest in Research Policy and Procedure
- 2. FIU Conflict of Interest in Research website
- 3. NIH Financial Conflict of Interest (FCOI) and Other Support Reminders

If there are any questions regarding these FCOI reporting, training or other support requirements then please feel free to contact your ORED representative (http://research.fiu.edu/ored/staff-directory/) for further assistance.

NIH Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Other Support

Type of Activity	Biographical Sketch	Other Support	Annual Project Reports	Post-Award Information Terms & Condition	Disclosure Not Required
Professional preparation (e.g., educational degrees)	Х				
Organizational Affiliations and Appointments	X				
Academic, professional, or institutional appointments, whether or not remuneration is received, and whether full-time, part-time, or voluntary	Х				
All projects currently under consideration from whatever source, and all ongoing projects, irrespective of whether support is provided through the proposing organization, another organization or directly to the individual, and regardless of whether or not they have monetary value (e.g., even if the support received is in-kind such as office/laboratory space, equipment, supplies, or employees.)		Х	X	X	
Recently completed support or support that has ended					Х
Current or pending participation in, or applications to, programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs	X (Appropriate placement may be contract- dependent)	X (Appropriate placement may be contract- dependent)			
In-kind contributions not intended for use on the project/proposal being proposed		X	Х	Х	
Visiting Scholars in Labs funded by an external entity		X		X	
Students and postdoctoral researchers funded by an external entity		X	X	X	
Consulting that falls outside of an individual's appointment; separate from institution's agreement		Х	Х	Х	
Consulting that is considered part of an individual's appointment/agreement with their home institution (e.g., a PI at a foreign institution's retention contracts within their home institution)					X
Travel supported/paid by an external entity to perform research activities with an associated time commitment		Х	Х	Х	
Travel supported/paid by an external entity to attend a conference or workshop					X

NIH Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Other Support

Type of Activity	Biographical Sketch	Other Support	Annual Project Reports	Post-Award Information Terms & Condition	Disclosure Not Required
Honoraria or other payments given for the purpose of conferring distinction or to symbolize respect, esteem, or admiration unrelated to research oversight, supervision, or coauthorship					Х
Teaching commitments					Х
Startup company based on organization-licensed Intellectual Property (IP)					Х
Startup packages provided to the individual from the proposing/home institution					Х
Startup packages from organizations other than the proposing/home institution		X	X	Х	
Training awards, prizes, and gifts. Gifts are resources provided where there is no expectation of anything, (e.g., time, services, specific research activities, money, etc.) in return					Х
Mentoring as part of an appointment, or mentor/mentee arrangements that do not involve the individual's research activities					Х
Academic year salary, or salary provided to the individual by the home institution					Х
Core facilities and/or shared equipment that is broadly available					Х
F&A Reimbursement provided to the proposing/home institution					X
Certification by the individual that the information disclosed is accurate, current, and complete (e.g., signature of the researcher)		X	X		
Supporting Documentation (e.g., contracts, grants, other agreements)		X			
Significant Financial Interests: Disclosure Not Required in Other Support. See NIH FCOI Policy NIH GPS 4.1.10. Disclosures must be made in FCOI module.					Х

NIH Office of Extramural Research

June 8, 2022