

# Principles for Evaluating Conflict of Commitment Concerns in Academic Research

Version 2.0

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This Framework is provided as a tool to the COGR Membership with the understanding that COGR is not providing legal, regulatory, or policy advice.



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### **Update to the First Version of this Framework**

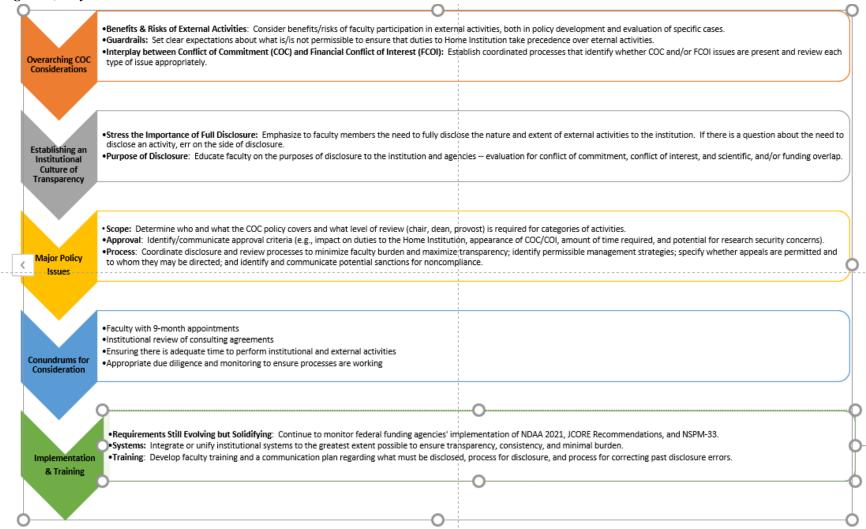
Since the first version of this paper was published in February 2021, federal agency and legislative efforts directed towards addressing inappropriate foreign influence on federally funded research have continued apace. Agency efforts have begun to solidify in some respects, with a continued focus on guidance designed to ensure that researchers are fully disclosing their external activities and sources of research support, particularly those that could entail overlaps of commitment, science, or funding. Additionally, there have been legislative efforts on both federal and state levels. COGR has updated this paper ("Framework") to reflect recent agency guidance and to include more specific recommendations and tools for institutions to consider as they review their policies and processes in this area. All new and updated sections are flagged, and COGR expects to further update this paper as additional legislation and agency guidance are issued.

### Overview (*Updated*)

Institutions began evaluating their policies and processes concerning conflict of commitment, in part, as a response to federal research funding agencies' focus on disclosure of international research activities and support. Although funding agency requirements have continued to evolve during 2021, the major principles that institutions may consider in evaluating policies/processes remain the same. This document discusses those principles followed by illustrative case studies. The figure on the following page summarizes this Framework's key points.



Figure 1, Key Points: Evaluation of Conflicts of Commitment





### **Introduction** (Updated)

Research institutions have long maintained policies that address the concept of "conflict of commitment." These policies may date back many years and focus on engagements that a faculty member enters as a private individual and that may interfere, or appear to interfere, with the faculty member's primary obligations to their institution. These competing engagements may be compensated, such as consulting, or uncompensated, such as serving as a volunteer member of an editorial board. Typically, concerns have focused on whether faculty members are fulfilling their obligations of teaching, research, service, and, for academic medical centers, clinical care, or whether time, attention, and potentially institutional resources, are being diverted inappropriately to the outside activity.

Over the past few years, many institutions began to review and evaluate their conflict of commitment (COC) policies in response to questions about the possibility of inappropriate foreign influence on federally funded research (referred to here as "Inappropriate Foreign Influence"). Key points in this area include faculty member involvement in research and activities at institutions other than the researcher's home institution ("External Entities"), especially when these activities take place outside of the U.S. As such activities have come to light, they have presented COC questions, among other issues.

In mid-January 2021, institutional concerns regarding COC policies and processes took on new urgency with the release of the following three documents:

- National Science and Technology Council (NSTC) Joint Committee on the Research Environment's (JCORE) Subcommittee on Research Security: Recommendations for Strengthening the Security and Integrity of America's Science and Technology Research Enterprise ("JCORE Recommendations"). <sup>1</sup>
- Presidential Memorandum on United States Government-Supported Research and Development National Security Policy" ("NSPM-33"), which contains directives to federal research funding agencies to strengthen conflict of commitment disclosure requirements for funding recipients.

<sup>&</sup>lt;sup>1</sup> Available at <a href="https://trumpwhitehouse.archives.gov/wp-content/uploads/2021/01/NSTC-Research-Security-Best-Practices-Jan2021.pdf">https://trumpwhitehouse.archives.gov/wp-content/uploads/2021/01/NSTC-Research-Security-Best-Practices-Jan2021.pdf</a>.

<sup>&</sup>lt;sup>2</sup> Available at <a href="https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-united-states-government-supported-research-development-national-security-policy/">https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-united-states-government-supported-research-development-national-security-policy/</a>.



• The National Defense Authorization Act for Fiscal Year 2021<sup>3</sup> ("NDAA 2021"), which includes in Section 223 requirements similar to those in NSPM-33.

Although NSPM-33 and the JCORE Recommendations were issued under the Trump administration, they have remained in place under the Biden administration. On August 10, 2021, the Office of Science and Technology Policy (OSTP) announced a 90-day timeline for the development of cross-agency guidance for NSPM-33's implementation.<sup>4</sup>

There is no "one size fits all" policy or process for addressing COC because institutions vary tremendously in terms of research portfolio, size, culture, and employment models. In addition, institutional risk assessment also influences policy and process development. Despite this heterogeneity, there is consensus among institutions and agencies on the need for researchers to be fully transparent regarding their external activities. This is especially true when these activities are undertaken pursuant to a formal employment agreement and involve non-U.S. entities, as such activities may introduce concerns regarding research security and export controls, as well as COC and/or conflict of interest (COI).

The JCORE Recommendations acknowledge the role of risk assessment and advocate the use of a "balanced, risk-based approach" that recognizes the benefits and risks of international collaboration.<sup>5</sup> Institutional implementation of this risk-based approach in the broader context of research security is discussed in COGR's August 2021 white paper "Federal Focus on Inappropriate Foreign Influence on Research: Practical Considerations in Developing an Institutional Response."

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<sup>&</sup>lt;sup>3</sup> <u>Pub. L. 116-283 (Jan. 1, 2021)</u>(see, "Enrolled Bill" text ver.). See, also, <u>Conference Report 116-617</u> (Dec. 3, 2020). <sup>4</sup> Lander, E., "Clear Rules for Research Security and Researchers' Responsibility," (Aug. 10, 2021) (OSTP announced

<sup>&</sup>lt;sup>4</sup> Lander, E., "<u>Clear Rules for Research Security and Researchers' Responsibility</u>," (Aug. 10, 2021) (OSTP announced that it "will develop clear and effective implementation guidance for NSPM-33, working in close partnership with the National Security Council staff, fellow Cabinet agencies, and other federal agencies through the National Science and Technology Council").

<sup>&</sup>lt;sup>5</sup> <u>JCORE Recommendations</u> at p. 4 ("This approach must seek to apply protective measures commensurate with identified risks, accounting for both likelihood of occurrence and impact, weighed against tangible benefits and any accompanying cost or administrative burden resulting from mitigation measures.")



#### **Less Risk & Fewer Controls**

#### **More Risk & Greater Controls**

Non-federally funded researcher involved in occasional, traditional non-compensated academic activity at U.S. academic institution.

Federally funded researcher who has committed to work four months per year in a laboratory at a non-U.S. research institution in the same area of research they conduct at their Home Institution.

This document ("Framework") focuses on providing a reference framework for institutions as they evaluate their COC policies and processes.<sup>6</sup> It recognizes that Inappropriate Foreign Influence is just one of many issues that institutions must consider in evaluating COC policies and processes, and thus it begins by discussing the broader principles that underlie COC policies and practices and the distinction between financial conflict of interest (FCOI) and COC. This Framework next examines agency expectations regarding transparency and points to consider when drafting or evaluating COC policies and practices, taking account of the 2021 JCORE Recommendations, NSPM-33, Section 223 of NDAA 2021, and recent NIH,<sup>7</sup> and NSF<sup>8</sup> guidance. Finally, the Framework explores common conundrums that institutions encounter with COC oversight and concludes with several illustrative case studies, set forth in **Appendix A**, that may serve as a basis for institutional discussion and training.

<sup>&</sup>lt;sup>6</sup> Such policies and processes may take many forms including external/outside activity policies, COC policies, combined COI and COC policies, and faculty handbook provisions. *See, e.g.,* University of North Carolina Charlotte, <u>University Policy 102.1</u>, "External Professional Activities of Faculty and Other Professional Staff," (rev. Aug. 28, 2019); Vanderbilt University, <u>Faculty Manual, Chapt. 3</u>, "Conflict of Interest and Commitment," (accessed Sept. 8, 2021).

<sup>&</sup>lt;sup>7</sup> See, e.g., NOT-OD-21-073, "Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021" (Mar. 12, 2021)(effective date extended to Jan. 25, 2022 by NOT-OD-21-110 (Apr. 28, 2021); NIH Other Support webpage (last updated Mar. 12, 2021); and "NIH FAQs on Other Support and Foreign Components" (accessed Sept. 8, 2021). These materials are collectively referred to herein as the "NIH Materials").

<sup>8</sup> See, e.g., "NSF Approved-Formats for Current and Pending Support" webpage (accessed Sept. 8, 2021); Proposal & Award Policies & Procedures Guide (PAPPG) NSF 22-1 (effective Oct. 4, 2021); "NSF Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending Support" table (Sept. 1, 2021). These materials are collectively referred to herein as the "NSF Materials."



### **Scope & Relevant Definitions**

### Scope:

This discussion focuses on the activities of tenured or tenure-track faculty members at academic research institutions. The Framework takes this approach because many academic research institutions permit only these faculty members to spend some portion of their institutional time engaged in outside activities. Nonetheless, the principles that are discussed also may be applied to other research personnel.

#### **Definitions:**

As used in this Framework, the terms below have the following definitions:

**Conflict of Commitment (COC)**: A situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities.<sup>9</sup>

(Many institutional policies reference "COC" but only cover a faculty member's distribution of time and responsibilities between their Home Institution and their outside activities. <sup>10</sup> Until the publication of the 2021 JCORE Recommendations and NSPM-33, there was no official definition of COC at the federal level that applied to research funding recipients; both documents include the foregoing definition.)

**Financial COI (FCOI):** A situation in which an individual, or the individual's spouse or dependent child, has a financial interest or financial relationship that could directly and significantly affect the design, conduct, reporting or funding of research.<sup>11</sup>

Foreign Government Sponsored Talent Program (FGTP) or Recruitment: An effort, directly or indirectly organized, managed, or funded by a foreign government or institution to recruit science and technology professionals or students (regardless of citizenship or national origin, and

<sup>&</sup>lt;sup>9</sup> JCORE Recommendations at p. 2, n. 2; NSPM-33 at Section 2(d).

<sup>&</sup>lt;sup>10</sup> See, e.g., University of Arizona, "Conflict of Commitment Policy," (rev. Jun. 2017); Oregon State University, "Conflict of Commitment Policy," (eff. Feb. 1, 2012).

<sup>&</sup>lt;sup>11</sup> <u>JCORE Recommendations</u> at p. 2, note 1; <u>NSPM-33</u> at Section 2(c). This definition is similar to that used for "financial conflict of interest" in the Public Health Service regulations for "Promoting Objectivity in Research" at <u>42 CFR § 50.603</u> ("PHS Regulations"). The PHS Regulations, however, do not address FCOI in the context of the funding of research, only in "design, conduct or reporting," and they also focus on "Significant Financial Interests" as defined therein.



whether having a full-time or part-time position). <sup>12</sup> Academic leaders and researchers should understand that these programs are constantly being re-branded and re-named

**External Entity:** An institution, company, government entity, foundation, professional organization, or other type of entity that is not the faculty member's Home Institution.

**Home Institution**: The academic research institution or other entity that is the primary employer of the faculty member.

**Institutional Responsibilities**: A faculty member's Home Institution responsibilities including, e.g., research; teaching; administration; clinical care; conference attendance; research presentations or lectures at other universities; uncompensated publication review; and service on institutional committees.

Outside Activity: An activity that a faculty member performs, or commits to perform, at or for an External Entity.

## Major Principles and Objectives to Consider when Formulating/Evaluating COC Policies

### **Benefits of Faculty Participation in External Activities**

Academic research institutions ("institutions") are unique because they often have policies that explicitly permit faculty to spend a specific portion of their time (e.g., one day per week) engaged in Outside Activities, and may even encourage them to do so.<sup>13</sup> This approach differs from that of commercial research enterprises, which typically disallow employee participation in any compensated external activity and may require employees to enter into non-compete and non-disclosure agreements as a prerequisite for employment.

<sup>11</sup> 

<sup>&</sup>lt;sup>12</sup> NSPM-33 at Section 2(e). As drafted, the definition is unclear as to whether a private institution's private recruitment efforts could be considered a FGTP but encompassing solely private action seems inconsistent with the notion of a "government-sponsored...program." Note that there are other definitions that preceded the definition for FGTP found in the 2021 JCORE Recommendations and NSPM-33. *See, e.g.*, NSF, "Personnel Policy on Foreign Government Talent Recruitment Programs," n. 1, (Jul. 11, 2019). Finally, pending legislation contains yet other definitions for "malign foreign talent recruitment programs." *See,* "National Science Foundation for the Future Act," H.R. 2225, § 7(a)(3), 117th Cong. (passed House Jun. 28, 2021).

<sup>&</sup>lt;sup>13</sup> See, e.g., Rice University, "Conflicts of Commitment and Outside Activities for Faculty," (rev. Jun. 2020), ("As a general rule, it is a COC if Faculty Members spend more than 20% of their total professional effort, on non-Rice professional Outside Activities, the equivalent of one day a week on average, cumulative for all Outside Activities.); Georgetown University, Office of Research Oversight/Regulatory Affairs, "Approval of Extramural Activity," (accessed Sept. 8, 2021) (outside activity "does not exceed an average of eight hours a week").



Institutions take a more flexible approach to Outside Activities because participation in Outside Activities enables faculty to:

- Disseminate knowledge and education to the broader public
- Improve teaching and scholarship skills
- Gain real-world experience to help ensure that teaching and research are applicable to the "real world" and that resulting findings can be broadly applied
- Identify research questions that are relevant to communities outside of academia
- Collaborate and share expertise with industry to answer broad questions
- Promote community engagement with research institutions
- Enhance funding opportunities and enable access to unique resources
- Strengthen technology transfer
- Develop professional growth opportunities for faculty and trainees
- Engage globally in research, education, and service

### Funding Agency Expectations Regarding Transparency and Mitigating Inappropriate Foreign Influence (New)

Transparency is the common theme that runs through federal guidance regarding disclosures that investigators should provide to permit agencies and institutions to evaluate activities and interests for COC, FCOI. and potential Inappropriate Foreign Influence. NSPM-33 sets forth the basic disclosure standards that agencies are expected to incorporate in their policies, and the memorandum places OSTP in charge of coordinating agency efforts in this regard. These standards call for principal investigators (PIs), project directors, and other senior/key personnel to make the following broad disclosures as part of the proposal or award process with updates occurring at least annually:

- Organizational affiliations and employment (including honorary appointments)
- All financial and other resources that support research and development efforts (e.g., contractual, in-kind, and gifts with associated terms or conditions, whether domestic, foreign, public, or private)
- Current or pending participation in programs sponsored by foreign governments (including FGTPs)
- Any positions and appointments including affiliations with foreign entities/governments, whether or not compensated (including adjunct, visiting or honorary)<sup>14</sup>

<sup>&</sup>lt;sup>14</sup> NSPM-33, § 4(b).



Although the OSTP is currently working on its NSPM-33 implementation plan, both NIH and NSF have already moved ahead by issuing guidance that emphasizes the need for investigators to make full disclosure of funding, affiliations, appointments, and employment. In July 2021, NIH added a preamble to its Other Support FAQs that drives home the agency's focus on transparency by advising institutions and investigators to err on the side of disclosure and to "ask early and often" if they have questions about what to disclose. The preamble also makes clear that in evaluating information that is disclosed, institutions must consider whether there are any factors that present issues of scientific, budgetary, or commitment overlap.

The need for transparency also has been addressed in federal legislative efforts concerning Inappropriate Foreign Influence. Section 223 of the NDAA 2021 is currently the primary statute regarding research disclosures, and it requires investigators to disclose the amount, type, and source of all current and pending research support. As of the date of this paper, there are two other major bills in the legislative process that include requirements for funding agencies to communicate "reporting and disclosure requirements to awardees and applicants for funding": <sup>17</sup> United States Innovation and Competition Act of 2021 (USICA)<sup>18</sup> and the National Science Foundation for the Future Act. <sup>19</sup> Both bills also contain provisions that prohibit grant awards from being made to PIs (and certain other individuals) who participate in FGTPs with specified countries including China, North Korea, Russia, or Iran. <sup>20</sup> At least one state's legislature also has addressed Inappropriate Foreign Influence on research with Florida's passage of an act that requires institutions of higher education and applicants for state grants to report gifts from, and other connections (e.g., financial, employment) with, countries other than the U.S., along with screening of non-U.S. researchers and certain U.S. researchers who have been employed by a "foreign country of concern."

The U.S. Department of Justice's (DOJ) enforcement efforts similarly point to the federal government's focus on transparency regarding applicants' external activities. This focus is illustrated in DOJ's announcement of its indictment of a former University of Florida investigator for "fraudulently obtaining \$1.75 million in federal grant money from NIH by concealing support he received from the Chinese government and a company that he founded in China" in which Assistant Attorney General John C. Demers stated:

<sup>&</sup>lt;sup>15</sup> NIH Materials, supra n. 7 & NSF Materials, supra n. 8.

<sup>&</sup>lt;sup>16</sup> NIH, "<u>Important Applicant/Recipient Considerations</u>," FAQS Other Support and Foreign Components (accessed Aug. 19, 2021).

<sup>&</sup>lt;sup>17</sup> U.S. Innovation & Competition Act of 2021, S. 1260, 117th Cong. (passed Sen. Jun. 8, 2021). ("USICA").

<sup>&</sup>lt;sup>18</sup> USICA at § 2301(a)(4).

<sup>&</sup>lt;sup>19</sup> National Science Foundation for the Future Act, H.R. 2225, § 7(a)(3), 117th Cong. (passed House Jun. 28, 2021).

<sup>&</sup>lt;sup>20</sup> <u>USICA</u> at § 2303 and <u>National Science Foundation for the Future Act</u> at § 7.

<sup>&</sup>lt;sup>21</sup> See, Foreign Influence, H. 7017, (2021 Regular Sess. Fl. Leg.), Chapter No. 2021-76 (passed Jun. 9, 2021).



Transparency about foreign funding sources allows federal agencies to allocate finite resources fairly. Transparency about foreign government affiliations, like business affiliations, allow the research community and the American people to assess any impact on the integrity of the research . . ."<sup>22</sup>

Given the federal government's emphasis on the need for investigator transparency on external activities as a means to mitigate COC, COI, and Inappropriate Foreign Influence concerns, institution's policies and processes must address these issues head-on. At a minimum, institutional policies regarding COC will need to meet regulatory, agency, and institutional requirements encompassing research support. Further, institutions also must consider how policies and disclosures in the areas of COI, tech transfer, intellectual property, export control, collaborations and publications will intersect with each other and work together. These policies should be in concert and not in contradiction, to collectively support and help meet institutional requirements. An issues checklist or similar tools may be particularly useful.<sup>23</sup>

Agency disclosure requirements have evolved since the first version of the Framework, and will continue to do so, especially after OSTP finalizes the NSPM-33 implementation plan. **Appendix B** sets forth an updated chart comparing COC-related requirements of the 2021 JCORE Recommendations, NSPM-33, NDAA 2021, and current NIH and NSF requirements, to facilitate institutional implementation.

### Protecting Openness and Avoiding Xenophobia or Prejudice (New)

As institutions respond to the call for transparency in relation to concerns about undue foreign influence, they also must protect the openness that is critical to the success of American institutions of higher education and take care to avoid basing policies, or their implementation, on stereotypes or prejudice. As Dr. Eric Lander, the Director of OSTP recently stated:

Prejudice is fundamentally unacceptable and will backfire because it will make it harder to attract the best scientific minds from around the world. . . . [I]t should never be acceptable to target scientists for investigation based on their race or ethnicity. In protecting our nation, we must uphold its fundamental values."<sup>24</sup>

<sup>&</sup>lt;sup>22</sup> DOJ, "<u>Former University of Florida Researcher Indicted for Scheme to Defraud National Institutes of Health and University of Florida</u>," (Feb. 3, 2021).

<sup>&</sup>lt;sup>23</sup> See Appendix C for some links to and examples of tools that some institutions have developed in this area.

<sup>&</sup>lt;sup>24</sup> "Clear Rules for Research Security and Researchers' Responsibility," supra n. 4.



### The Need for Guardrails to Address Conflicts and Ensure Transparency (*Updated*)

As discussed above, institutions permit faculty to engage in Outside Activities, however, such participation should not take precedence over the duties owed to the Home Institution. This is particularly important in the case of tenured faculty who are provided with a lifetime academic appointment and tremendous freedom in their research and teaching activities, in exchange, in part, for making their primary commitment of time and intellectual resources to the Home Institution and its students, fellow faculty, and programs. To ensure that faculty may participate in Outside Activities without jeopardizing their ability to perform their Institutional Responsibilities, COC policies (and other documents that may define the faculty member's responsibilities, such as employment contracts and faculty handbooks) should focus on addressing the following objectives:

- Clearly establish that the faculty member's primary obligation is to the Home Institution and ensure faculty commitment to their Institutional Responsibilities.
- Protect university resources and intellectual property from being diverted to External Entities via Outside Activities or being used inappropriately for the personal gain of the faculty member.
- Safeguard the reputation of the Home Institution and its faculty from the appearance of undue influence by an External Entity.
- Provide faculty members with the flexibility to conduct Outside Activities but set boundaries and establish expectations for those activities.
- Ensure transparency and accountability about the type, nature, and extent of faculty members' Outside Activities, including identification, management, and/or elimination of any COIs (financial or non-financial) and/or COCs.
- Ensure that responsibilities to research sponsors are met.
- Ensure students, trainees, and staff are not adversely affected by faculty participation in Outside Activities.

In the preamble to its FAQs regarding Other Support and Foreign Components, NIH identified other points for consideration that go to the issue of research integrity. Specifically, in addition to review for overlap and FCOI, institutions are advised to address the following question:

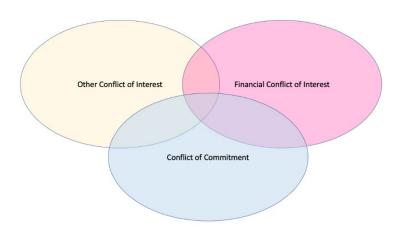
Does the relationship affect the integrity of the research by impacting established professional norms and ethical principles in the performance of all activities related to scientific research? In answering this question, institutions should consider the following factors:



- a. The "relationship" could be with a collaborator, an outside employer, an external appointment relationship, etc.
- b. The "impact" could be real or apparent
- c. The "compensation" could be of any type or level<sup>25</sup>

For example, foreign institutions may have drastically different policies around intellectual property (IP) ownership and disposition, publication allowances, and what is considered confidential research. These policies can affect IP ownership, ability to publish fundamental research results, and other academic freedoms. Further, researchers' agreements with these institutions may require certain acknowledgement or authorship practices that are not consistent with established norms of scholarly communication.

### Delineating the Boundaries between COC and COI



The boundaries between COC and the various types of COIs, financial and otherwise, are not always clear and may overlap. For example, a faculty member who owns a start-up company related to their research and spends three days a week focusing on company business may have both a FCOI and a COC. If the faculty member is a "silent partner" who does not spend any time on the start-up, they would not have a COC, but may still have a FCOI. Moreover, if they "volunteer" (without receipt of any compensation or ownership interest) to work three days a week at the company to gain access to company data for their overall research, they may have a COC, and their receipt of company data may create a non-financial, "other" COI concern. Institutions,

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<sup>&</sup>lt;sup>25</sup> NIH, Preamble to <u>FAQs Other Support and Foreign Components</u> (NIH "has not established a *de minimis* level of compensation and considers all types of support, in-kind or otherwise").



therefore, need to review each fact pattern carefully to discern what types of COCs and COIs are involved and to ensure that relevant policies and procedures are applied appropriately.<sup>26</sup>

### **Special Concerns Raised by FGTP Recruitment Programs**

Faculty participation in a FGTP may raise special COC concerns. As previously noted, pending federal legislation -- not yet enacted – contains provisions that prohibit recipients of federal funding from participation in these programs.<sup>27</sup> Such programs may require participants to sign contracts that bind faculty to obligations that could interfere with or appear to divert faculty time and attention away from obligations to the Home Institution. The chart below sets forth actual examples of common provisions found in FGTP contracts<sup>28</sup> along with the potential COC issues they present:

FGTP Provision Category	FGTP Contract Specific Provision	Concern
Teaching & Recruitment Provisions	"On average, teach one graduate course per year."  "On average, advise two undergraduate students and recruit three graduate students."  "Provide letters of recommendation for students."	Obligations such as teaching, advising, and recruiting students could interfere or compete with obligations to carry out these activities for students at the Home Institution.
Copyright & Intellectual Property Provisions	"Any copyrightable or patentable materials, and other related or similar intellectual properties which are created or developed by [U.S. faculty member] at [non-U.S. institution] shall be applied and publicized in the names of both [non-U.S. institution] and [U.S. faculty member]. [Non-U.S. institution] shall be the first author affiliation."	Unless there is a clear boundary between the Outside Activity and the U.S. Home Institution activity, intellectual property that would otherwise be the sole property of the U.S. Home Institution now becomes jointly owned with the External Entity. This shared ownership may run afoul of multiple Home Institution policies and federal funding agency requirements.

<sup>2</sup> 

<sup>&</sup>lt;sup>26</sup> Recently, some federal agencies have used the term "non-financial conflict of interest" (NFCOI) to describe conflicts of commitment and possibly other types of conflicts as well, such as the impact a NFCOI may have on where, by whom, and how research is conducted and published. *See*, General Accounting Office's (GAO), "Federal Research - Agencies Need to Enhance Policies to Address Foreign Influence," (Dec. 2020). It is difficult to define the activities encompassed by the term NFCOI; to determine whether, or how, such activities affect research pursuits; and whether regulation of such pursuits may, in some cases, be perceived to impermissibly chill freedoms of association and speech. *See, also*, Editorial, "Nature journals tighten rules on non-financial conflicts," *Nature* 554, p. 6 (Jan. 31, 2018) (Requiring disclosure of "…non-financial competing interests" including "membership of governmental, non-governmental, advocacy or lobbying organizations, or serving as an expert witness.").

<sup>&</sup>lt;sup>27</sup> USICA at § 2303 and National Science Foundation for the Future Act at § 7(d)(7).

<sup>&</sup>lt;sup>28</sup> U.S. Senate, Permanent Subcommittee on Investigations, "<u>Threats to the U.S. Research Enterprise: China's Talent Recruitment Plans</u>," <u>Appendix A</u> (Nov. 18, 2019).



FGTP Provision Category	FGTP Contract Specific Provision	Concern
Team-Building Provisions	"Assist in introducing the research institution to core domestic and international talent, helping build a high-level research team."	Helping to build a team at an External Entity could divert energy away from similar activity at the Home Institution and could compete against the Home Institution's recruitment efforts for the same talent.
Publication Provisions	"[W]e expect that you will author publications based on your work in our country. You will have the right to publish the results of your research in our country without restriction. In any publication describing research that was conducted in your country, you will list our institution as your primary affiliation and your other place of employment as your secondary site of appointment."	Publications that list another institution as the primary affiliation may dilute the Home Institution's academic reputation and leadership in the field and do not appropriately acknowledge the Home Institution's investment in the faculty member's research. In the case of Inappropriate Foreign Influence, such provisions also may raise concerns if the affiliations were not appropriately disclosed.
Extensive Time Commitments & Work Obligations	"The job objectives and tasks that [U.S. faculty member] should complete include : leading the development of the school's transitional medicine discipline, advancing the building of the discipline and the talent team, undertaking tasks of teaching undergraduate and postgraduate courses and talents training work, and vigorously introducing outstanding talents, providing teaching and research skills, expanding international exchanges and cooperation, enhancing the international influence of the discipline, achieving innovative research results, and promoting the plan of building our university into a first-class university."	Carrying out such an extensive portfolio, which appears to include leadership activities, teaching, recruiting, and talent development could interfere with obligations to the Home Institution and could compete against, and divert energy from, the Home Institution.
	"Each year the work time shall be not less than 2 months."	Contracts that contain specific periods of work commitment must be evaluated against time commitments to the Home Institution, including time committed on sponsored projects.

### **Points to Consider for COC Policies and Processes**

As noted, no universal COC policy exists that could address the unique circumstances of each research institution. Despite the variety in institutional requirements, however, each COC policy should address the following core questions:



### • Whom does the policy cover?

Although discussion in this document is focused on tenured faculty members, institutions must consider whether COC policies also should apply to non-tenured faculty and staff. This decision may be impacted by factors such as:

- The Home Institution's status as public or private
- Applicable provisions of collective bargaining agreements (if any)
- Level of risk that dual employment may pose to the Home Institution
- Sponsor/funding agency requirements

### • How will the Home Institution establish and promote a culture of transparency? (New)

Institutions will need to consider how best to promote transparency among faculty, the institution, and funding agencies in a manner that continues to encourage faculty to undertake international collaborations without fear of negative reactions. Establishing institutional policies and processes that clearly delineate disclosure requirements is only the first step. Institutions next should determine effective methods for educating researchers on these requirements and instilling a culture of transparency regarding all non-institutional, professional activities. Investigators are accustomed to navigating FCOI processes, which have been in place for many years, but they may be unaccustomed to disclosing uncompensated academic activities (e.g., honorary appointments, research collaborations), as required by some funding agencies.<sup>29</sup> They also may be unaccustomed to considering COC issues in relation to their consulting activities.

Similarly, institutions are generally accustomed to taking faculty disclosures at face value without the need for validation or monitoring activities. Yet, the current enforcement climate and the federal government's expectations for institutions to implement "effective means of discovering violations of disclosure policies and other activities that threaten research security and integrity" will require institutions to consider monitoring processes that meet these expectations without undercutting the necessary trust institutions must have in their faculty, and vice versa. Such trust may be particularly at risk with respect to faculty members who come from, or have close ties with, countries outside of the United States considering the federal government's focus on certain "foreign countries of concern." For this reason, institutions must, in Dr. Lander's words:

<sup>&</sup>lt;sup>29</sup> See, NOT-OD-21-073; NIH FAQs Other Support and Foreign Components, FAQ I.B.12.

<sup>&</sup>lt;sup>30</sup> JCORE Recommendations, p. 12 (Recommendation #15).

<sup>31</sup> National Science Foundation for the Future Act at § 7(a)(2)).



[A]ssiduously avoid basing policies or processes on prejudice — including those that could fuel anti-Asian sentiments or xenophobia.... [and] ... must affirm the integral role of Asian-Americans, Native Hawaiians, Pacific Islanders, and people of all national origins in this country; welcome international students and scholars; and avoid casting aspersions on people because of their identity or origins.<sup>32</sup>

### • What activities must be disclosed for review/approval? Will some types of activities be considered pre-approved or exempt? (*Updated*)

The types of activities that are required to be disclosed for institutional review/approval will be influenced by funding agency requirements, applicable laws, existing institutional policies, and risk tolerance. Institutions should consider how to address a variety of scenarios, including faculty who have numerous Outside Activities; a single Outside Activity that requires a significant time commitment; or an Outside Activity with a minimal time commitment, but which competes with Institutional Responsibilities. Additionally, institutions should be prepared to address *quid pro quo* appointments, where a faculty member is offered an affiliation or other benefit by an External Entity with an expectation that the faculty member will, in return, host visiting students or scientists from the External Entity. These arrangements could undermine the institution's authority to determine to whom this privilege should be granted.

Institutions may require different levels of review depending on the type of activity and its perceived risk level. Some activities may require prior approval, others, just disclosure. For example, serving as an editor for a scholarly journal, as a peer reviewer for a funding agency, or as an officer for a professional society are traditional academic activities with a much lower risk of conflict, and thus may require limited, disclosure and/or review. Such activities, however, may require an extensive time commitment that interferes with academic activities on which the Home Institution places higher priority (e.g., teaching assigned classes), or they may present foreign influence concerns depending on the parties involved.<sup>33</sup> Thus, disclosure of even these lower-risk activities remains fundamental to establishing full transparency.

<sup>32 &</sup>quot;Clear Rules for Research Security and Researchers' Responsibility," supra n. 4.

<sup>&</sup>lt;sup>33</sup> See, e.g., University of California Office of the President (UCOP), APM-025, "Conflict of Commitment and Outside Activities of Faculty Members," (Jan. 15, 2020); University of Texas Rio Grande, "Decision Matrix for Approval of Outside Activities and Conflict of Interest Disclosures," (accessed Jan. 17, 2021).



### • What are the criteria for approval?

For activities that require prior approval, institutions should consider addressing the following questions in their COC policies:

- What standards will be used to evaluate the commitment? For example, the University of Minnesota's *Policy on Outside Consulting and Other Commitments* calls for the institution to evaluate Outside Activities to determine if they interfere with the performance of regular employment duties, compete with coursework offered by the university, and/or compete with services offered by the employee's unit.<sup>34</sup>
- How reviewers should consider activities that give rise to the appearance of COC, as well as actual COC?
- Does the activity being reviewed pose a potential research security risk considering federal standards and regulations?
- Is the scope of the Outside Activity sufficiently distinguished from the scope of research commitments at the Home Institution?
- What is the duration of approval? When should the activity be re-reviewed?

### • How will the amount of time spent on Outside Activities be measured?

Institutions must determine: (a) whether and how to establish a maximal time allowance for institutional time that faculty can spend on Outside Activities; and (b) how faculty should quantify the time spent on Outside Activities to ensure that they do not exceed any such limits. In terms of an upper limit, many institutions allow faculty to devote an average of one day per week to Outside Activities.<sup>35</sup> Quantifying time spent is much more difficult, however, and raises the issue of how the denominator should be defined (e.g., Five or seven-day week? Eight-hour day or longer? Average over 52 weeks, or only weeks actually worked, excluding vacation days?).<sup>36</sup> Institutions also need to consider whether documentation or tracking mechanisms are appropriate or necessary.

### • What overarching factors should be considered in developing a governance process? (New)

Institutions will need to consider the following basic concepts in designing governance processes for the reporting and review of information related to COCs:

<sup>&</sup>lt;sup>34</sup> (Dec. 7, 2020), available at https://policy.umn.edu/operations/outsideconsulting

<sup>&</sup>lt;sup>35</sup> See institutional materials supra n. 10.

<sup>&</sup>lt;sup>36</sup> See, e.g., Princeton University, Dean of the Faculty, "Outside Professional Activities," (accessed Sept. 8, 2021) ("The University interprets the one-day-a-week rule as permitting one working day per calendar week (i.e., one eight- to twelve-hour day out of seven) to be devoted to outside professional activities.").



- Centralization v. Decentralization: One fundamental question with which institutions must grapple is the level of system centralization or decentralization. Many institutions have a high level of decentralization with several different units (e.g., COI office, sponsored programs office, school, department) involved in the review of activities that may present COC and COI activities. Decentralization may lead to silos of information and inconsistent decisions/policies regarding COC and COI across the institution, while total centralization may lack the information needed from academic units (e.g., perspective of a department chair on where a faculty member should be focusing their efforts).
- Integration of Administrative Units and Systems: Similarly, institutions must consider to what extent the administrative units and information systems should be integrated and whether such integration should be formal or informal. For example, institutions may view funding agencies' focus on disclosure and Inappropriate Foreign Influence as an opportunity to establish unit reporting lines (e.g., lines between conflict of interest and sponsored programs offices) that are coordinated under a single administrative head and/or to work on the development of interfaces between currently separate information systems. Alternatively, smaller institutions or institutions with a strong culture of unit independence may want to rely on more informal integration methods such as working groups, periodic meetings for cross-unit information sharing, and/or criteria for when one unit "should pick up the phone" and involve others. Further, the integration of information technology systems is typically a costly and time-consuming enterprise. Thus, institutions will need to consider the advantages and disadvantages between homegrown and commercial systems, and institutional resources necessarily will be a major consideration.
- Privacy and Confidentiality Issues: Information regarding faculty's external activities, including copies of contracts that may require review and/or production under current agency guidance present inherent confidentiality and privacy issues (e.g., scope of work, pay rate, etc.). Faculty may not have previously disclosed such details to their institution and/or provided disclosure to only one or a few personnel (e.g., department chair or school dean). In developing governance processes, institutions will need to be sensitive to these concerns in determining which units and individuals are permitted access to the information and the systems used to house it.
- Timing and Frequency of Reporting: As discussed in examples presented in this document, it is possible for a single Outside Activity to present both COC and COI concerns, forcing institutions to consider how to coordinate review to ensure the activity is thoroughly vetted for both types of concerns. The timing and frequency of reporting (COC vs. COI) is another important consideration (e.g., annually vs. rolling).



### • Who will perform the review, and will there be an appeals process? (*Updated*)

Processes should include an opportunity for review at the supervisory, departmental and/or dean's office level to ensure that institutional leaders who are most knowledgeable about the faculty member's Institutional Responsibilities have an opportunity to evaluate the Outside Activity's impact on those responsibilities. Some institutions may choose to have COCs evaluated by a faculty review committee. Certain types of Outside Activities may require review by central administrative units, such as export control, conflict of interest, or technology transfer offices. Review and approval by the provost's office also may be warranted for some situations. Further, assessing senior leaders' Outside Activities may require particular care to ensure transparency and a fully independent review.

Outside Activities that go to the heart of the academic mission, such as teaching or performing research for an External Entity, may require special permissions.<sup>37</sup> Finally, institutions also must consider whether their processes will incorporate an appeals process, and if so, who will be responsible for reviewing appeals.

• How will the review process for COC interface with other disclosure, review, and approval processes? (*Updated*)

There are distinct criteria for the review of COC and COI concerns, and review processes typically encompass distinct reviewing/approving units as well. Thus, many institutions have separate COC and COI disclosure/review/approval processes. For example, the University of California system has one system for the disclosure/review/approval of Outside Activities for COC and another for COI.<sup>38</sup> Other institutions may have a combined system for collection of information pertaining to Outside Activities, and this system then disseminates the information that is collected to the various units that are responsible for COC and COI review/approval.<sup>39</sup>

Disclosure mechanisms such as forms, routing, software systems, and review processes should be tailored to promote:

(accessed sept. 6, 2021).

<sup>&</sup>lt;sup>37</sup> See, Virginia Commonwealth University, "Outside Professional Activity & Employment Policy, Research and Continuing Education," (Jan. 1, 1983). See, also, Harvard University, Office of the Provost, "Statement on Outside Activities of Holders of Academic Appointments," (accessed Sept. 8, 2021), ("Persons holding full-time academic appointments at Harvard should devote their teaching efforts primarily to the education of Harvard students. Faculty members may not hold a regular faculty appointment at another institution, except in connection with a Harvard-sponsored joint program with that institution, or similar arrangement as approved by their Dean.").

<sup>&</sup>lt;sup>38</sup> See, University of California, Outside Activity Tracking System (OATS) webpage (accessed Sept. 8, 2021).

<sup>&</sup>lt;sup>39</sup> University of Chicago, "COI-COC Processing," (accessed Sept. 8, 2021).



- Reduction of duplicative data entry by faculty members through well-constructed entry forms, the ability to carry-over information from one reporting period to the next, and the use of a single disclosure system accessed by multiple offices where possible
- Ease of use and ability to update the collected information
- Appropriate involvement by departmental and central administrative units (e.g., conflict of interest office, office of sponsored programs, export controls office, provost's office)
- Receipt of complete and consistent information by those offices
- Consistency between information reported to federal sponsors and what is reported to the Home Institution
- Provide readily available and appropriately staffed units to help troubleshoot technical and or policy-related questions

As federal funding agencies prepare to roll out new policies for COC disclosure, institutions may want to consider combining COC and COI disclosure and review processes for efficiency and thoroughness or employing other mechanisms to ensure complete and consistent disclosures. In this regard, the 2021 JCORE Recommendations suggest that institutions maintain a repository of disclosure filings from all employees involved in the research enterprise, whether they receive federal research funding or not.<sup>40</sup> Additionally, high-level "cross-training" of personnel involved in COC and COI review processes may be helpful.

### • What are potential management strategies for conflicts of commitment?

Institutions should consider including potential COC management strategies in COC policies, as well as the development of COC management plans for individual cases. Possible strategies could include the following items:

- Transparency and disclosure
- Enhanced, mandatory COC training
- Full or partial leave of absence or use of sabbatical leave for the Outside Activity
- Restructuring research responsibilities to manage the conflict, such as adding an additional PI or mentor
- Oversight by senior faculty or administrators, such as regular check-ins to ensure appropriate mentoring and lab supervision
- Elimination, reduction, or suspension of the Outside Activity
- Reduction in the Home Institution appointment to accommodate the Outside Activity

<sup>&</sup>lt;sup>40</sup> JCORE Recommendations at p. 8.



#### • What are the Sanctions for Failure to Disclose?

In the context of FCOI, institutions are required to include in their FCOI policies the sanctions for failure to disclose and other policy violations. In the context of COC, institutions should assess whether the same sanctions should apply, or whether there should be a different approach.

JCORE suggests that institutions prescribe "appropriate and effective consequences for violation of disclosure requirements and other activities that threaten research security and integrity." The recommendations go on to suggest a range of possible consequences from removing an individual from performing activities on a research contract or grant to termination of tenure and expulsion. <sup>42</sup>

Institutions should consider that some FGTPs and other programs require participants to withhold information on participation from their Home Institutions, and they should make clear that any such requirement violates the Home Institution's disclosure policies. Such withholding of information, in and of itself, could indicate that a COC is present. In many cases, however, non-disclosure may result from an innocent omission or confusion regarding requirements. Thus, sanctions should take into account a range of scenarios and mitigating factors.

### Addressing Common COC Conundrums (*Updated*)

Most institutional policies regarding faculty External Activities have three similar elements, which are listed here:

- An assertion that the faculty member's primary allegiance should be to the Home Institution. 43
- The specification of a certain number of days, or a percentage of time (generally equivalent to one day per week), of institutional time during which faculty members can engage in External Activities.<sup>44</sup>

<sup>&</sup>lt;sup>41</sup> *Id.* at p. 13.

<sup>&</sup>lt;sup>42</sup> *Id*.

<sup>&</sup>lt;sup>43</sup> See, e.g., Emory University, Faculty Handbook, Chapt. 13, Section 13.3, "Conflict of Commitment," (accessed Sept. 8, 2021)("Emory faculty owe their primary professional allegiance to the university; their primary commitment of time and intellectual energies is to the education, research, and other programs supporting the university's mission."); New York University, "Academic Conflict of Interest and Conflict of Commitment Policy," Section III.A, (Sept. 1, 2013)("Full-time NYU faculty members owe their primary professional allegiance to NYU, and their primary commitment of time and intellectual energies should be to NYU's teaching, research, and clinical programs.").

<sup>&</sup>lt;sup>44</sup> See, e.g., University of Pittsburgh, "<u>Faculty Use of University Time for Outside Professional Activities</u>," (accessed Sept. 8, 2021)("University time spent on outside professional activity must not exceed an average of one (1) day per week, up to 35 days (for 8-month appointees) or 48 days (for 11-month appointees) each academic year."); University of Washington, "<u>Outside Professional Work Policy</u>," Section 2.B., (May 20, 2015)("Subject to approval in advance, full-time members of the faculty, librarians, and academic personnel may engage in outside consulting work for remuneration to the maximum extent of 13 calendar days each academic quarter in which the individual is employed (averaging no more than one day per seven-day week.")).



 A description of the process for Outside Activity disclosure, review, and approval to ensure that the activities do not interfere with the faculty member's Institutional Responsibilities.<sup>45</sup>

Although to date institutions have generally not placed outright prohibitions on participation in FGTP activities, they may begin to consider doing so in view of legislative provisions currently being considered by Congress. <sup>46</sup> Additionally, Outside Activity policies also must consider other specific conundrums that frequently arise in this space. These conundrums are discussed in the following subsections.

### Nine-month Faculty Appointments (*Updated*)

Faculty in some disciplines traditionally have nine-month appointments, and frequently pursue employment or other activities with External Entities during the prescribed summer break. Although this situation may not create a COC based on the time involved, it may still involve activities that compete with Institutional Responsibilities. Faculty, however, may assert that the institution does not have authority over Outside Activities during a period in which the faculty are not compensated. On the other hand, the PHS Regulations on FCOI require disclosure of any Significant Financial Interests, regardless of when these interests are acquired. Funding agencies require disclosure of payments from non-U.S. institutions of higher education as well as disclosure of unpaid or honorary appointments. Additionally, summer activities (or, in some cases activities undertaken during a sabbatical period) - especially those involving research - may "bleed over" into the academic year. Thus, institutions may have a reasonable basis to seek disclosures of activities outside the academic year, and in its recent FAQs on Other Support and Foreign Components, NIH made clear that "resources in support of and/or related to an investigator's research endeavors" should be disclosed to NIH as Other Support "even if they relate to work . . . performed outside of a researcher's appointment period."

<sup>&</sup>lt;sup>45</sup> See, e.g., University of Alabama at Birmingham, <u>Faculty Handbook</u>, "External and Internal Activities" Section 3.11.1, (Aug. 2020)(requiring advance written approval to participate in external activities from dean through department chair).

<sup>&</sup>lt;sup>46</sup> USICA at § 2303 and National Science Foundation for the Future Act at § 7.

<sup>&</sup>lt;sup>47</sup> Note that institutions may take different approaches regarding faculty with 9-month appointments. Generally, such faculty members remain employees of the institution throughout the year and continue to receive benefits. Some institutions may pay the faculty member's 9-month salary over a 12-month period, and faculty may continue to access and use the Home Institution's resources during this time.

<sup>&</sup>lt;sup>48</sup> 42 CFR §50.604(e).

<sup>&</sup>lt;sup>49</sup> See, e.g., NIH NOT-OD-19-114.

<sup>&</sup>lt;sup>50</sup> Institutions may want to consult with legal counsel when establishing the basis and parameters of disclosure and review of such activities.

<sup>&</sup>lt;sup>51</sup> NIH FAQs Other Support and Foreign Components, FAQ I.B.13.



### **Review of Agreements for Outside Activities – Consulting (***Updated***)**

As discussed above, agreements between faculty and External Entities may contain numerous provisions that are problematic for the Home Institution such as employment conditions, authorship requirements, and provisions affecting intellectual property. Prior to current federal agency emphasis on Inappropriate Foreign Influence, some institutions reviewed consulting agreements, typically as part of their COI processes, while others did not. Recent NIH and NSF guidance, encouraging institutions to be aware of the agreements into which their researchers are entering, however, has caused many institutions to reexamine their policies and processes for the review of consulting activities.

NIH requires that consulting activities that involve the conduct of research and fall "outside of an individual's appointment, separate from institution's agreement" must be disclosed as Other Support. Further, for "Other Support submissions that include foreign activities and resources," NIH requires the institution to provide "copies of agreements that are specific to senior/key personnel's foreign appointments, affiliations, and/or employment with a foreign institution" as of January 25, 2022. NSF requirements are similar and require reporting as Current and Pending Support of consulting activities "in support of and/or related to all of [the researcher's] research effort" that "[fall] outside of an individual's appointment." NSF excludes from reporting consulting that "is permitted by an individual's appointment and consistent with the proposing organization's 'Outside Activities' policies and procedures and does not routinely require copies of agreements with foreign institutions.

In light of these NIH and NSF requirements, institutions may want to evaluate their policies for reviewing consulting activities, weighing the following pros and cons:

#### • Potential Advantages

- Helps ensure that Outside Activities are permissible and in accordance with all relevant institutional policies
- Protects Home Institution interests such as intellectual property (IP)
- Allows for Home Institutions to understand breadth and scope of Outside Activities
- Promotes compliance with funding agency requirements, including any requirements to provide agreements 56

<sup>53</sup> NIH NOT-OD-21-073.

<sup>52</sup> Id. at FAQ I.B.4.

<sup>&</sup>lt;sup>54</sup> NSF PAPPG 22-1, §II.2.C.h.

<sup>&</sup>lt;sup>55</sup> "NSF Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending Support" table (Sept. 1, 2021).

<sup>&</sup>lt;sup>56</sup> See, e.g., NIH NOT-OD-21-073 (requirement to provide copies of certain agreements as supporting documentation).



 Provides an opportunity to discuss with faculty the pros and cons of entering into particular agreements

### • Potential Disadvantages

- o Demands additional resources and processes dedicated to agreement review
- May give rise to inconsistent review outcomes, based on different reviewer perspectives
- May delay Outside Activity approval and/or COI/COC determinations
- Increases the risk that review will be construed as providing legal advice to faculty members and thus increase institutional legal exposure
- Increases potential reputational and regulatory risk from implied endorsement of the Outside Activity by the Home Institution

When an institution decides to incorporate review of consulting agreements as part of its Outside Activity review and approval process, additional conundrums are raised:

- How will the institution review and approve Outside Activities for which the faculty member states that no agreement exists?
- What does "review" of the agreement imply? A clear differentiation between a review for permissibility versus individual legal representation must be established in policy and practice.
- Will institutional resources be allocated for direct negotiations with External Entities, or will the affected faculty members act as the go-between?
- Who will review the agreements on behalf of the institution? The COI office or program? Office of General Counsel? Office of Sponsored Programs? Office of Technology Management? Other?

Some institutions have addressed these issues by providing faculty with template consulting agreements or boilerplate provisions that address Home Institution concerns for incorporation into consulting agreements.<sup>57</sup>

### **Effort Reporting and Certification (***Updated***)**

Federal agencies are understandably concerned that Outside Activities may interfere with effort commitments on sponsored projects. Grants management approaches to effort reporting, however,

<sup>&</sup>lt;sup>57</sup> See, e.g., Penn State University Altoona, "<u>Guidelines for Faculty Consulting Agreements</u>," (accessed Sept. 8, 2021) (sets forth terms recommend for inclusion in faculty consulting agreements and terms that should be avoided); University of Rochester, "<u>Faculty Consulting Agreement Template</u>," (accessed Sept. 8, 2021).



exclude, by definition, effort outside the institution. As set forth in the Uniform Guidance, "effort" is based on Institutional Base Salary (IBS), which does not include external activities by definition and is not based on a particular number of hours per week or another metric. Thus, in accordance with longstanding grants management regulations, "100% effort" is the total time spent on activities for which the individual receives IBS. Recent NIH guidance in this area affirms that consulting "will not count towards the 12 months calendar effort," and thus supports this approach.

At some point, however, a faculty member's commitment to perform an Outside Activity may require a "real-world" evaluation, i.e., do they have the capacity to perform the outside activity along with all their other commitments to the Home Institution? This analysis requires some type of quantification of the amount of time that the faculty member has committed to Institutional Responsibilities and comparing that commitment to the time that the faculty member will commit to the Outside Activity. Of course, this quantification can never be precise, given that faculty do not punch time clocks or work a 40-hour week, rather they have schedules that constantly shift among their Institutional Responsibilities.

### **Managing Collaborations (New)**

Agency requirements for the reporting of collaborations that provide support for research endeavors, 60 coupled with potential Inappropriate Foreign Influence and/or export control considerations that may arise in international collaborations, have caused institutions to consider how to identify collaborations that may require action. Efforts in this sphere are particularly difficult because these collaborative relationships are generally academic in nature, often informal, and change continuously. Yet, when reportable collaborations are not disclosed, it can often lead to inquiries, such as when an agency performs a publication search and identifies a collaborative co-authorship that was not reported. Such failure can be particularly problematic in the case of NIH-supported research where the collaboration is "with investigators at a foreign site [and] anticipated to result in co-authorship," thus constituting a "foreign component" and requiring advance agency approval.

<sup>&</sup>lt;sup>58</sup> 2 CFR §200.430.

<sup>&</sup>lt;sup>59</sup> NIH, FAQs Other Support and Foreign Components, FAQ I.B.21

<sup>&</sup>lt;sup>60</sup> *Id.*, <u>FAQ I.B.12</u> (Other Support includes "domestic research collaborations that directly benefit the researcher's research endeavors").

<sup>&</sup>lt;sup>61</sup> *Id.*, <u>FAQ II.2</u>



### Communication and Training (New)

Solid lines of communication with faculty regarding reporting requirements is essential. Many institutions are reluctant to develop comprehensive in-person and/or online educational programs as agency requirements remain in flux. Accordingly, institutions may utilize less formal communication methods such as newsletters, emails, web content, faculty department meetings, and administrator forums, to keep faculty and administrators up to date. As the deadline for implementing the new NIH and NSF requirements approaches, however, institutions will need to move ahead now with more formalized training on these agencies' requirements.

Training should address not only what must be disclosed, but also items that do not require reporting. Given the current enforcement environment, faculty may be inclined to utilize the "everything and the kitchen sink" approach to reporting. Although agencies have emphasized that there is no penalty for overreporting, such an approach may overwhelm institutional reviewers. For example, training regarding the reporting of collaborative relationships should include methods for distinguishing the characteristics of minor collaborations that need not be reported, as opposed to those of substantive collaborations that require review, and in some cases advance approval for export control or foreign component issues.

The use of checklists and similar tools (including those listed in **Appendix C**) may assist faculty and the administrative staff who assist them in completing their disclosures. Faculty also should be trained on the significance of certifications that they sign attesting to the accuracy of their disclosures, and the need to view this certification as more than just more administrative paperwork. Finally, training should provide clear direction regarding where to pose questions, as well as the need to seek guidance from institutional resources first and use only approved channels for submitting questions to funding agencies.

### **Detecting Undisclosed Outside Activities & Due Diligence**

The 2021 JCORE Recommendations state that institutions "need to develop the means to identify instances where disclosures are incomplete or inaccurate, or when disclosure policies are otherwise violated." A recent survey conducted by the Department of Health and Human Services Office of the Inspector General regarding academic institutions' responses to Inappropriate Foreign Influence may supply some clues in this regard. <sup>63</sup> This survey asked institutions whether they

<sup>&</sup>lt;sup>62</sup> JCORE Recommendations at p. 12.

<sup>&</sup>lt;sup>63</sup> "HHS OIG Survey for NIH Grantee Institutions on Actions institutions are Taking to Address Foreign Influence," <u>COGR October 2020 Meeting Report.</u> On its <u>workplan summary webpage</u>, HHS OIG states that in 2022 it anticipates



employed certain monitoring or due diligence efforts, including collecting copies of agreements with External Entities, contacting External Entities to confirm disclosure details reported by researchers, and comparing information disclosed by researchers with information found in external sources such as web searches and journal articles. Yet, given most institutions' limited resources for monitoring activities, such efforts may not be feasible, or at best, applied to a sample of cases through a risk-based approach. This use of sampling, coupled with training regarding disclosure requirements, may provide an alternate method for quality assurance in this area.

### Conclusion (*Updated*)

Federal agencies and Congress continue to focus on the nexus between COC issues and foreign influence. Additional laws, regulations, and agency guidance is expected through the end of 2021 and into 2022, including, OSTP's anticipated guidance for NSPM-33, with its promised goal of promoting cross-agency harmonization of disclosure requirements. Given this evolving situation, COGR anticipates further updates to this Framework.

In the meantime, many institutions are moving ahead in evaluating their current COC policies and processes and the ways in which those policies/processes intersect with COI and Inappropriate Foreign Influence concerns. In evaluating modifications to COC policies/processes, institutions should examine the factors outlined in this Framework and consider how to best promote a culture of full transparency regarding external activities, while taking care not to stifle the openness and international collaborations that are vital to scientific progress.

issuing a report entitled "Grantee Institutions' Actions To Strengthen Policies in Response to Concerns Regarding Potential Foreign Influence on NIH-Funded Research"



### Appendix A: Case Studies and Possible Review Considerations

### Case Study No. 1: Leadership of a Not-for-Profit Association

\*\* Key Words: Travel, not-for-profit, officer

Prof. Washington is elected as president of a prestigious national not-for-profit association. This position aligns with the Home Institution's mission, although there is no relationship, including no research funding, between the association and Home Institution. As president, Prof. Washington receives no compensation, only reimbursement of travel expenses. However, the position requires multiple trips a year to various engagements and involves much more of a time commitment than the one day/week the Home Institution permits for faculty Outside Activities.

- Could there be a risk that the association would compete against the Home Institution for donations, sponsored funding, talent, or other resources? What facts would be needed to assess this potential risk?
- Is there a possibility, in some cases, that Prof. Washington might be required to prioritize responsibilities to the not-for-profit over those to the Home Institution?
- Whose input would be needed to assess this potential COC? The department chair could provide input regarding departmental obligations such as teaching and service, but is dean or provost input needed as well? Why or why not?
- Should a partial leave of absence be considered for this Outside Activity? Could the president's term be limited? Are there other management strategies?

### Case Study No. 2: Expert Witness for Software Company

**Key Words:** IP, software, consulting, non-disclosure or confidentiality agreement, agreement review

Prof. Adams created software-related intellectual property (IP) several years ago. The Alpha Company has a non-exclusive license for the IP through Prof. Adams' Home Institution, and Prof. Adams receives a portion of the licensing revenue, per Home Institution policy. Alpha Company asks Prof. Adams to consult regarding its legal actions against Bravo University, which licensed related technology to the Alpha. The consulting agreement has a non-disclosure agreement covering all information Prof. Adams receives about or related to the Alpha Company. Prof. Adams fears the consulting agreement could interfere with her responsibility to support her Home Institution if problems arise concerning the licensing agreement between Bravo University and Alpha Co.



- Who, if anyone, should review the agreement to advise Prof. Adams as to whether this proposed consulting activity could result in a COC?
- Should Prof. Adams confer with others at her Home Institution to gain advice?
- Who should decide whether the proposed consulting arrangement is a COC?
- If it is, could it be managed? How?
- Can Prof. Adams' Home Institution prohibit Prof. Adams from participating in the consulting activity if it finds a COC?

### Case Study 3: Deanship at a Non-U.S. University

Key Words: Dean, honorary appointment, sabbatical, summer/winter break

Prof. Jefferson took sabbatical to serve as a visiting professor at Charles University in China. During his sabbatical, he accepted an appointment as the dean of academic affairs at Charles University. After his sabbatical, he returned to his U.S. Home Institution, but he maintained his role as a dean at Charles U. Prof. Jefferson did not disclose his appointment as a dean to his Home Institution, and he continues to spend several weeks in the summer and during winter break travelling back to Charles University.

- Under what circumstances, if any, would this scenario not create a COC?
- What additional information is needed to evaluate the risk here? Questions could include:
  - Is Charles University a restricted entity? Is it known to have ties to the Chinese military?
  - What is the nature of Prof. Jefferson's research, if any? Does his work involve any export controlled or proprietary information?
  - Has Prof. Jefferson signed a contract with Charles University? What is the term of his commitment? What does the contract require?
  - What are Prof. Jefferson's responsibilities as a dean? Are they similar to the expectations of such a position in the U.S.?
  - How much time does Prof. Jefferson spend on Charles University activities?
  - How is Prof. Jefferson described on the Charles University website?
- Prof. Jefferson states that his role at Charles University is purely honorary and that he is just a "figurehead." How might his statement be validated? Even if his role is truly non-substantive, does it nonetheless create an appearance of a COC? How harmful is such an appearance?

### Case Study 4: Consultant to Perform Company Research

\*\*Key Words: Consulting, part-time job



Prof. Madison is a professor of ceramic engineering at Home Institution. Home Institution allows faculty to spend one day per week on Outside Activities that are related to their field of expertise. Faculty members who want to exceed the time limit must request approval from their dean and justify it with an explanation of how the activity will benefit the Home Institution.

Prof. Madison also is a consultant for Delta Company, a cutting-edge ceramics manufacturer. Prof. Madison works for Delta one day a week, on average, providing scientific advice. Delta asks Prof. Madison to begin performing research work for the company, and this new activity would increase the time she works for Delta to 20 hours per week.

The Dean denies Prof. Madison's request to engage in 20-hours per week of Outside Activities. Prof. Madison argues the work will help her keep her students current with industry trends. The Dean states the commitment will reduce the time Prof. Madison spends with her students and views the 20-hour per week consulting commitment as a part-time job. Prof. Madison insists that she works 80 hours or more per week for Home Institution.

- Rather than conducting the research consulting as an Outside Activity, could Prof. Madison carry out this work as sponsored research at Home Institution? Under what circumstances would that be appropriate, or inappropriate?
- Is there an opportunity to involve graduate students in the work to gain real world experience? Would this be allowed under institutional policies (e.g., involving students in Outside Activities)?
- Is Prof. Madison's institutional intellectual property (IP) licensed to Delta Company?
- Is the work Prof. Madison will perform for Delta Company sufficiently separate and distinct from her ongoing institutional research (i.e., no scientific overlap which could lead to IP ownership concerns between Home Institution and Delta)?
- Can the Dean offer Prof. Madison a reduced institutional appointment to allow for the additional consulting time per week?
- Should the Dean be required to explain his reasoning in support of his decision? Does the Dean have facts to support his decision (e.g., complaints about Prof. Madison's lack of availability)?
- Does the policy allow for an "appeal" if so, to whom? What should the criteria be for review?

#### Case Study 5: Co-direct a Laboratory at another Institution

\*\* Key Words: Grant proposal, thesis committee, lab co-director, collaboration

Prof. Monroe is a professor of pharmacology at Home Institution. Prof. Monroe travels frequently to conferences and to collaborate with other scientists. Echo University recently



invited Prof. Monroe to be co-director of a lab at Echo. This position will require Prof. Monroe to spend, on average, one day per week working on projects at Echo. Prof. Monroe will submit grant proposals through Echo in which Monroe will be listed as Key Personnel. Prof. Monroe also will chair a doctoral student's thesis committee at Echo.

Prof. Monroe's dean states that Prof. Monroe is not permitted to be a lab co-director or a thesis committee chair at another institution. Prof. Monroe argues that scholarly collaboration with peers at other institutions is expected of faculty. The dean cites the significant time commitment and states that the nature of the activities impermissibly diverts Prof. Monroe's intellectual energy and creativity, and potential grant funding, away from Home Institution.

- Does Home Institution's policy explicitly state activities such as this are prohibited or is it "assumed"? Is an explicit statement necessary?
- What if Echo University was an international institution? Would this make a difference?
- What if Prof. Monroe accepted the position at Echo University without disclosing it to Home Institution?
- Is there a way for Prof. Monroe to collaborate with Echo University that would take into account the dean's concerns? What might that relationship look like (e.g., institutional collaboration agreement with a defined statement of work and research objectives)?
- Would the dean or someone in leadership need to be involved in negotiating the relationship with Echo University?
- Are there other possible management strategies? For example, could Prof. Monroe take a sabbatical for a year to work on this collaboration? Instead of chairing the doctoral committee, could Prof. Monroe be a member?

### Case Study 6: Highly Compensated Consultant with Access to Company's Proprietary Data Set

\*\* Key Words: Data set, proprietary, leave, employment offer

Prof. Jackson is a computer science professor who is being recruited by Foxtrot Company. Prof. Jackson wants to remain in academia, but Foxtrot is offering a very significant salary increase and will provide Prof. Jackson access to a unique data set collected from users of Foxtrot's technology. Prof. Jackson negotiates an alternative offer. She will take one semester of leave from Home Institution to work full-time at Foxtrot Co. Thereafter, she will spend one day a week at Foxtrot, for which Foxtrot will pay her an amount equivalent to one-third of her annual Home Institution salary. Foxtrot also will provide Prof. Jackson, and two of her six graduate students, with access to the proprietary data set.



Prof. Jackson will be allowed to publish research on the data set but the data themselves cannot be made publicly available, per a data use agreement between Prof. Jackson and Foxtrot Co. Prof. Jackson explains to her dean that the subject matter of her engagement with Foxtrot Co. will be similar to the subject of her NSF grant, and she will be able to validate her research results using Foxtrot's unique data set. When Prof. Jackson's dean expresses some concerns about the arrangement, Prof. Jackson says maybe she was wrong to reject Foxtrot Co.'s offer of full employment, and she threatens to leave Home Institution.

- Does the fact that Prof. Jackson's time commitment is one day per week alleviate any COC concern? Does the analysis change when the significant compensation from Foxtrot is considered? Is there a COC, or the appearance of a COC, although there is not compensation?
- Does the Foxtrot payment create a FCOI with respect to the NSF grant? What factors should be considered in this regard? How might such a conflict be managed?
- What are the ramifications of the data use agreement? If the data set cannot be made public, is there a risk that Prof. Jackson may not be able to comply with funding agency or journal data sharing requirements?
- What about the fact that only two of Prof. Jackson's graduate students will have access to the Foxtrot Co. data? Will such limited access create an appearance of preferential treatment for those students or other issues in the lab?
- What are the benefits of access to the Foxtrot data? Will it enable a more robust application of Prof. Jackson's research to real-world requirements?
- What impact does Prof. Jackson's engagement with Foxtrot have on her ongoing research activities and resulting institutional IP? Is there a possibility that Foxtrot will push for joint ownership of institutional IP because the research scope and company business are so closely related?
- Will access to the data by the graduate students require a separate agreement? If so, is it an employment agreement requiring assignment of IP to Foxtrot?

### Case Study 7: Adjunct Faculty Position at Non-U.S. University

Key Words: 9-month appointee, adjunct faculty, access to laboratory and office space

Prof. Van Buren is the world's expert in a rare disease that is prevalent in southern India, but not in the United States. Golf University in southern India wants to develop expertise in this field to help patients there. Golf University invites Prof. Van Buren to become an adjunct faculty member so that Prof. Van Buren will help the university build capacity in this area.



Prof. Van Buren is a 9-month appointee at Home Institution. Golf University asks Prof. Van Buren to commit to spending 2 months a year on site and offers him access to laboratory and office space during those months, as well as a 2-month salary. Golf University expects Prof. Van Buren to help set up the laboratory with appropriate equipment, to develop research ideas and projects, and to mentor junior faculty and trainees.

Ultimately, if any new treatments emerge from these collaborations, Golf University plans to work quickly to bring them to market. Prof. Van Buren recently lost all U.S. federal funding for this line of research because the disease in question is so rare in the U.S.

- Does Prof. Van Buren's arrangement with Golf University constitute a COC? As Prof. Van Buren is on a 9-month appointment at Home Institution, isn't he allowed to spend his summer months on activities outside Home Institution?
- Is it realistic to assume that Prof. Van Buren's activities at Golf University (i.e., lab activity, mentoring junior faculty and trainees) will be confined to two summer months? Could the activities at Golf University interfere with Prof. Van Buren's commitment to Home Institution?
- Isn't part of the academic mission to disseminate expertise so that others around the world can learn and build upon the progress made, to benefit their own communities? How is this mission reconciled with concerns about "diversion of intellectual capital"?
- Does the fact that Prof. Van Buren lost U.S. funding for his research on the rare disease establish a boundary between the work he would do in India and the work he does at Home Institution?
- Prof. Van Buren argues there is a moral obligation to assist a developing country to develop new treatments for diseases common in that region. How should the institution respond?

### Case Study 8: Founding a Non-profit Spin-out

**Key Words:** Non-profit, co-founder, spin-out, failed to report

Prof. Harrison is a department head who endorsed an institutional 'affiliation' with a non-profit entity – the Juliette Company – spun out of a departmental program he created without Home Institution's review and approval. Prof. Harrison is listed as a co-founder and advisor at the Juliette Company. Juliette Company's mission is to help underprivileged youth and students gain access to training opportunities in the biotech sector, an area unrelated to Prof. Harrison's research at Home Institution or to the research interests of his department.

At the very public announcement by the Juliette Company of this "collaboration," the mayor of the city where Juliette Company is headquartered expressed his excitement at collaborating with Prof. Harrison and Home Institution. Prof. Harrison was present at the event with his Home



Institution credentials on full display. Also present at the 'launch' with her Home Institution credentials on display, was Prof. Tyler, a senior researcher who reports to Prof. Harrison at Home Institution. Prof. Tyler also serves as the vice-president and co-founder of the Juliett Company. Prof. Harrison failed to report his engagement with the Juliette Company in his annual Outside Activities report, but Prof. Tyler did.

- Were Home Institution policies for reporting outside professional activities followed? Would other policies be applicable (e.g., interactions with the media, use of Home Institution name and logo)?
- Is Prof. Harrison required to review and get approval from his dean prior to entering into an affiliation agreement with External Entities?
- Are Prof. Harrison and Prof. Tyler required to disclose Outside Activities annually even if the activity is uncompensated?
- Is it appropriate for a faculty member to involve a subordinate in the faculty member's Outside Activities?
- Is there possible misuse of Home Institution's name when a collaboration is not approved by an appropriate institutional official?
- Were the titles assumed by Prof. Harrison and Prof. Tyler in line with what is permitted for full-time researchers and faculty at Home Institute engaging in Outside Activities?
- Were Home Institution resources being used to support Outside Activities?
- What risks may have been assumed by the Home Institution and/or Prof. Harrison and Prof. Tyler? Reputational? Legal? Financial?
- Can this case be effectively managed?

### Case Study 9: Academic Medical Center Case Study

\*\* Key Words: Hospital, clinical trials, recruit, consultant, mentorship

Dr. Wilson is a leading orthopedic surgeon with an extensive practice at Home Institution academic medical center. Dr. Wilson also leads several clinical trials on hip and knee replacements. He has been invited by a rural hospital – Oscar Hospital – in Peru to help establish a best-practice joint replacement program. Most of the work will be conducted via Zoom, but Dr. Wilson will need to spend at least two weeks a year at Oscar Hospital.

Oscar Hospital also hopes that Dr. Wilson will encourage medical students from Home Institution to participate in internships at the hospital and help recruit newly qualified surgeons to join the hospital's practice. Dr. Wilson will act as a consultant physician for specific patients at Oscar Hospital, but he will never be the physician of record. He will be paid an hourly consulting fee for his activity at Oscar Hospital, and the hospital plans to publicize his "mentorship" to patients and the public.



- Does this engagement constitute a COC for Dr. Wilson? What information would be needed to assess the potential conflict?
- If this engagement constitutes a COC, could it be managed? What changes might be required to manage the conflict?
- How could the arrangement be monitored to ensure that Dr. Wilson continues to meet his commitments at Home Institution?
- Does this engagement involve the practice of medicine in Peru? If so, does that present additional risks? Will Dr. Wilson be covered by malpractice insurance? If so, whose insurance will cover these activities?
- Are there any patient privacy concerns regarding Dr. Wilson's consulting physician activities? If so, are they only issues under Peruvian law, or could U.S. law be implicated?

### Case Study 10: International Health Initiative Case Study

Key Words: Fundraiser, satellite clinical care, federal grants

Dr. Polk is the chief of Sierra Academic Medical Center's (AMC) Global Health Initiative. Dr. Polk spends 100% of his time working in Kenya at Tango Hospital, which is owned by Sierra and supported by federal agencies, private foundations, and individuals. Dr. Polk is a successful fundraiser, and he has generated significant donor revenue that he has used to develop satellite clinical care offerings for Tango.

Sierra AMC allows clinical faculty to spend one day per week on outside professional activities related to their field of expertise. These activities must be approved by the faculty member's chief of service or Sierra's president if the faculty member is a chief of service.

Dr. Polk approached Sierra's president seeking approval to consult for Victor International Hospital (Victor) for 40 hours/month. Dr. Polk's consulting would focus on assisting Victor in fundraising within Kenya and obtaining U.S. federal grants, as well as establishing a satellite clinical care program for Victor. Dr. Polk maintains that his work for Victor will not impinge on his responsibilities to Sierra and will only increase medical and humanitarian services in Africa.

### Questions

- Does the arrangement proposed by Dr. Polk constitute a COC? A COI? If so, how?
- Could Dr. Polk's proposed consulting activity be modified in a way to make it acceptable to Sierra? If so, how?



### **Appendix B: Chart Comparing Disclosure Requirements**

COGR developed and regularly updates a chart that compares the disclosure requirements and other pertinent provisions and recommendations found in the JCORE Recommendations, NSPM-33, NDAA 2021, and the NIH Materials and NSF Materials referenced in footnotes 7 and 8 of the Framework.

A link to that chart appears below:

"Chart Comparing Disclosure and Other Requirements/Recommendations Among JCORE, NSPM-33, NDAA 2021, NSF & NIH (including NIH NOT-OD-21-073)"



### **Appendix C: Useful Tools**

Some of the institutions who assisted in drafting this document provided sample tools that other may find useful as they consider their own COC policies/process, particularly how those policies/processes intersect with Inappropriate Foreign Influence concerns.

The following samples have been institutionally de-identified and are included in this appendix:

**Appendix C-1**: Sample standard operating procedure for the review of contract and personal agreements

**Appendix C-2**: Sample checklists identifying factors in the following areas that institutions should consider when evaluating potential international research collaborations or potential international visiting scientists or trainees:

- Export controls,
- Technology transfer/intellectual property,
- COI
- External activities/employment
- COC
- Information security
- Publications

**Appendix C-3**: Points to consider when evaluating opportunities for COC/COI concerns

**Appendix C-4**: Sample addendum to consulting agreement

Additional, institutional tools can be found at the following links:

- Penn State University Questionnaires for Faculty on Other Support/Current and Pending Support
  - <a href="https://www.research.psu.edu/NIH\_Other\_Support\_Questionnaire\_for\_PSU\_Facu\_lty">https://www.research.psu.edu/NIH\_Other\_Support\_Questionnaire\_for\_PSU\_Facu\_lty</a>
  - https://www.research.psu.edu/NSF\_Current\_Pending\_Support\_Questionnaire\_for\_ PSU\_Faculty
- University of Pittsburgh webpage regarding disclosure of information concerning COI/COC
  - https://www.coi.pitt.edu/mydisclosures



### **Appendix C-1:**

### Sample University's Standard Operating Procedure Conflict of Interest Review of Contracts and Personal Agreements

#### A. Purpose

a. The purpose of this SOP is to describe the process by which the COI Office reviews personal agreements as part of an outside activity or employment request, review of the annual COI disclosure, or on an as needed basis.

#### B. Procedure

- a. The Office conducts reviews of personal agreements for outside activities or employment (OAE) for permissibility and completeness as a routine step in processing OAE requests, assessing the annual COI disclosure, and upon request.
- b. Personal agreements are usually provided by outside entities for consulting, speaking, and advisory board activities.
  - i. If there is an existing personal agreement between an employee with an outside entity, the agreement must include the required Sample University personal agreement language to be considered permissible.
    - 1. If there is no existing personal agreement, one does not have to be drafted except in the case of international activities. An agreement, translated in English, needs to be provided for any internationally based activity.
- c. The COI Office reviews agreements to determine completeness and permissibility.
  - i. The agreement is permissible if it describes only activities that are permissible according to Sample University's Policy.
    - 1. The personal agreement must include a scope of work and be in-date (not expired). Undated agreements are acceptable if they otherwise meet the criteria of this SOP.
  - ii. The agreement is considered complete if it contains the required Sample University personal agreement language.
    - 1. The personal agreement must not reference Sample University in any way.
- d. The COI Office will not act as a liaison between the individual and the outside entity or negotiate on an individual's behalf. The COI Office's role is to advise the individual on requirements for permissible agreements.
  - i. Any legal challenges regarding the incorporation of the required Sample University language should be escalated Sample University's legal office.
  - ii. The COI Office will not communicate directly with the outside entity or request to be copied on emails with an outside entity.
  - iii. The COI Office does not suggest edits to agreements. The COI Office can only advise on what can and cannot be included in an agreement, without redlining.

#### C. Documentation

- a. Personal agreements are documented in an individual's annual disclosure or Outside Activity request.
  - i. If the personal agreements are sent to the COI Office via email, the COI Office will attach the agreement to the disclosure or request.
- b. Documents will be retained in accordance with Sample University's record retention requirements.



### Appendix C-2

## Inappropriate Foreign Influence in Research Guidance: Research Collaborations and Visiting Scientists, Postdoctoral Fellows, & Other Trainees

Collaborations with international colleagues are important to our mission and the advancement of science. However, concerns raised by the National Institutes of Health (NIH), National Science Foundation (NSF), Department of Defense (DoD), and other government agencies regarding the "foreign influence in research," require that specific measures be taken when engaging in foreign research collaborations and hosting international visiting scientists, postdoctoral fellows, and other trainees.

The actions outlined in this document involve several areas of research compliance, information security, and intellectual property (IP) protection relevant to foreign research collaborations as well as foreign visiting scientists, postdoctoral fellows, and other trainees.

Checklists provided in this document are a "jumping off point" to safeguard your research and funding, but other actions may be required depending on the research, funding, and institutions involved.

### **Export Control**

Prior to engaging in a collaboration, provide the information below to the Export Control Office so that they can screen the following items to determine if any individuals, institutions, and/or research technologies are restricted by the United States federal government.

Visiting scientists, postdoctoral fellows, and other trainees requiring J-1 and H-1 visa sponsorship are automatically screened by the Export Control Office. If any such restrictions are in place for the collaboration and/or visiting individual, the Export Control Office will help determine next steps.

Research Collaborations		
Do	Provide the Export Control Office the name of the PI and other individuals	
	involved (if known) in the collaboration and/or who will visit the lab.	
	Provide the Export Control Office the names, addresses, and locations of any	
	collaborating institutions.	
	Provide the Export Control Office with PI name(s), addresses, and institutional affiliations of individuals who may receive international shipments.	
	Provide the Export Control Office an overview of the proposed research collaboration, including key words and names of equipment/technologies to be used for a voluntary review.	
	Visiting Scientists, Postdoctoral Fellows, & Other Trainees	
Do	Provide complete and accurate answers to all questions, including an accurate description of the anticipated research activities, asked in the Export Control Screening Form for support for a visa application or renewal when requested. Contact the Export Control Office if there is a significant change in research activities for the visiting individual.	



Answer any screening-related questions asked by the Export Control Office promptly.
Attend any meetings requested by the Export Control Office, including meetings to discuss Technology Control Plans (TCPs). Ensure compliance to any issued Technology Control Plans.
Provide complete and accurate information when completing international travel authorizations.

### **Technology Transfer and Intellectual Property (IP) Protection**

Government guidelines for technology transfer help ensure that intellectual property developed at US institutions is not lost or inappropriately given to foreign entities. By working with the Office of Technology Development (OTD) and providing them with the information described below, the security of intellectual property can be assured.

below, the security of intellectual property can be assured.		
Research Collaborations		
Do	Prior to engaging in a collaboration, contact OTD to review any new and novel materials, compounds, and other items for the need for IP protection.	
	Prior to signing any collaborative research agreements provided to you as part of the collaboration, have them reviewed by OTD.	
	<ul> <li>Such agreements should <u>not</u> request the transfer of any confidential information including certain types of research data, grant proposals, or controlled items. Additionally, the agreements should not include any prohibitions on publication without prior approval.</li> </ul>	
Visiting Scientists, Postdoctoral Fellows, & Other Trainees		
	Ensure appropriate research data-handling.	
_	Discuss how to appropriately handle unpublished/confidential data with	
	visiting scientists, postdoctoral fellows, and other trainees.	
	Provide assistance to any individuals who must complete progress reports for	
	funding agencies to ensure that research updates are appropriately described,	
Do	and data is only shared in accordance with university guidelines.	
	Provide copies of data to individuals leaving Sample University according to	
	relevant institutional policies and guidelines. In some instances, data cannot be	
	provided to an individual when they leave Sample University if that person is associated with certain entities as defined by the United States government or if	
	other confidentiality or other agreements prohibit the sharing of data.	
Do Not	Do not insinuate or state to any individual that they will automatically be given all	
	raw data, or that they are entitled to take any data they want, when they leave	
	and that they will be able to continue the research once they depart Sample	
	University. These decisions must be made in accordance with institutional	
	policies and pertinent agreements.	

### **Grants Management**

Foreign support for research, including financial compensation or other support, may have to be disclosed to federal granting agencies such as the NIH and NSF. The following steps should be taken to meet these requirements as they apply to foreign research collaborations.



Research Collaborations		
Do	Prior to engaging in any research collaboration or accepting new or different support for an ongoing collaboration, contact Sample University's Grants Management office to determine if this foreign support needs to be disclosed to a funding agency and/or if it would be considered to be "Other Support."  • Disclosure of support may be needed at the time of the grant submission, grant funding and/or interim/progress report submission to the funding agency. If you disclose, be as thorough and complete as possible.  • Disclosure of support for visiting personnel by a foreign entity may also need to be included.	
Do Not	Do not provide copies of grant proposals to foreign collaborators unless they are appropriately approved joint proposals. Funding information outside of joint proposals should also not be provided to foreign collaborators.  Do not share materials from peer review activities (e.g., NIH study section or journal articles under review) with any unauthorized individuals, including foreign individuals, entities, or governments.	
Visiting Scientists, Postdoctoral Fellows, & Other Trainees		
Do	Disclose foreign support for individuals participating in your research program in	
	funding proposals, progress reports, and publications as directed by Grants  Management.	

### <u>Conflict of Interest and Outside Activities & Employment (OAE)/Conflict of Commitment</u> (COC)

Sometimes, foreign collaborations may include foreign sponsorship of travel to a foreign site. While there may be times when conducting research at a foreign institution is acceptable, depending on funding, it may be inappropriate to have a separate lab established for purposes of research at another institution.

Researchers need to be cautious when approached with "faculty appointments" that include no compensation or actual duties other than including the institution's name on publications. In general, Sample University's faculty and staff should not accept such positions.

On rare occasion, foreign collaborations may result in the opportunity for the Sample University researcher to consult for that foreign institution. This outside activity may or may not be permissible, depending on the foreign institution and results of prior export control screening. Such opportunities for consulting should be sent to the Conflict of Interest Office as an OAE request.

Visiting scientists, postdoctoral fellows, and other trainees must request PI approval for outside activities. The approval or denial of outside activities must be consistent with Sample University's policies. PIs must also ensure that there is no conflict of commitment for any outside activities.



Research Collaborations		
Do	Disclose any sponsored international travel unless it is considered to be "preapproved." See Sample University's Policy on Outside Activities for details on pre-approved activities.	
	Disclose any research activities conducted at international locations on your annual COI Statement, <u>unless</u> the activities are included in a project administered through Sample University. Any separate laboratory maintained outside of Sample University must be disclosed.	
	Prior to accepting any non-Sample University faculty appointment, please discuss the position with your supervisor and contact the Provost's Office for formal approval.	
	All non-Sample University faculty appointments must be disclosed on the COI Statement of Financial Interests.	
	Prior to engaging in any outside activity, include it in your COI Statement (for Covered Individuals) or submit an OAE form (for non-Covered Individuals) so that the position may officially be approved by your supervisor(s).  • NOTE: Consulting agreements for domestic activities should be included with the COI Statement and OAE disclosure for consulting work. Copies of agreements, translated in English, are required for international activities (in other words, you must have an agreement, available in English, for any international activity). These agreements must meet Sample University's guidelines.	
Do Not	Do not accept any gifts, or signing any agreement for gifts, without first discussing the gift with the COI Office.	
	Visiting Scientists, Postdoctoral Fellows, & Other Trainees	
Do	Encourage individuals to complete their required annual COI Statements of Financial Interest Statements on-time and accurately.	
	Review requests for outside activities and employment (OAE) that you receive.  Ensure that your approval or denial follows Sample University's policies on	
	Outside Activities, and Conflict of Interest, including outside activities for post-doctoral fellows and students.	

### **Information Security**

Extreme caution should be used when accessing any foreign systems as a part of the research collaborations. Passwords for Sample University and research software systems should never be shared with other individuals. If there are any questions about any foreign computer system contact Information Security.



Research Collaborations		
Do	Prior to traveling international, contact Information Security so that you can take a "loaner laptop" with you to decrease the potential for data theft or computer system compromise.	
	Report promptly any potential breaches to computer or data systems to Sample University's Information Security team.	
Do Not	Never share your Sample University Username and Password.	
Visiting Scientists, Postdoctoral Fellows, & Other Trainees		
	Inform individuals working for you about the Sample University "loaner laptop" program and encourage its use.	
Do	Discuss if or how research data might be taken by individuals with them during international trips. Depending on the nature of the trip and/or destination, such transport of data may need to be disallowed.	

### **Publications**

Journal and funding agency guidelines must always be followed when determining coauthorship and acknowledgements for publications. Special consideration should be given to both when foreign collaborations are involved or when visiting scientists, postdoctoral fellows, or other trainees leave Sample University but continue to work on data analysis and manuscript preparation.

Research Collaborations		
Do	Clarify in all publications what components of the work were performed outside of the United States when NIH or other federal support is acknowledged and there is at least one foreign co-author, and/or if the publication includes acknowledgement of support from a foreign entity, individuals, or government.  State in the publication that the work conducted by the foreign component was included in the NIH proposal <i>when NIH funding</i> supported the research.	
	Visiting Scientists, Postdoctoral Fellows, & Other Trainees	
Do	Determine if anyone is planning on publishing research results based without your direct involvement or if after they leave Sample University. If so, consult with Grants Management to determine the best way to capture this foreign support and involvement.	



### **Appendix C-3**

# Points to consider when evaluating an opportunity for potential COI/COC concerns whether for a faculty member or a researcher.

If presented with an opportunity to engage in an Outside Activity that may add value to your training and education, and a similar opportunity does not exist at your institution, please discuss first with your faculty advisor:

- Whether your faculty advisor approves
- Whether the work and deliverables of your Outside Activity are separate and distinct from your institutional research (to avoid research bias, maintain objectivity in research)
- What conflicts of interest in research issues may arise
- Whether those conflicts of interest can be managed
- How the opportunity adds value to your training and consulting
- The time commitment of the consulting
- How close you are to finishing your training
- Whether the sponsor of your current institutional research would permit a reduction in appointment to allow for the consulting activity
- Are you authorized to work outside of your institution (visa status?)?

For those institutions which do not currently and do not plan to review individual Outside Activity agreements of their faculty and researchers, guidance to offer if the Outside Activity is with a foreign entity:

- How does the foreign institution define your role (i.e., visiting scholar, adjunct professorship, honorary professor, etc.)?
- What are the duties associated with your role, what do they expect, what are the deliverables? It's all in the DETAILS!
- Will the faculty/staff's research activities be separate and distinct from your Institutional Responsibilities including your research?
- What are the foreign institution's policies as they apply to ownership and assignment of intellectual property and publishing research results?
- Will your home institution's students or staff interact with the foreign institution or perform any work related to your deliverables as an adjunct professor?
- Will any students or staff from the foreign institution interact with your lab in your home institution? If so, how?
- Is it expected that you will secure any appointments at your home institution for visitors from the foreign institution?
- NOTE: U.S. export control law prohibits faculty from US research and teaching institutions from teaching or doing business in certain countries (known as the <u>OFAC Sanctioned Countries</u>) and with certain foreign people and institutions.



### **Appendix C-4**

# Potential Addendum/rider for Consulting Agreements Addendum to Consulting Agreement dated [---] (the "Agreement") between ("Company") & ("Consultant")

Company acknowledges that Consultant's primary responsibilities are to the Home Institution ("HOME INSTITUTION") and that Consultant is required to comply with HOME INSTITUTION policies, including HOME INSTITUTION's Policies on Intellectual Property, Conflicts of Interest, Outside Activities, and other matters, as amended from time to time (collectively, "HOME INSTITUTION Policies"). Company further acknowledges that the HOME INSTITUTION Policies take priority over any obligations that Consultant may have to Company under or by reason of the Agreement.

Company agrees that it will not request or require Consultant, in the performance of his or her services to the Company, to employ proprietary information or intellectual property of HOME INSTITUTION, to make use of HOME INSTITUTION's time, facilities or resources, or to involve HOME INSTITUTION undergraduate or graduate students, employees, post-doctoral trainees or any other HOME INSTITUTION personnel other than Consultant.

Nothing in the Agreement shall be construed to restrict or hinder Consultant's ability to conduct current or future research or teaching assignments or activities with HOME INSTITUTION, regardless of the source of sponsorship if any, to limit Consultant's ability to publish work generated in the performance of Consultant's research or teaching at HOME INSTITUTION, or to infringe on Consultant's academic freedom.

Company further acknowledges that Consultant, in his or her capacity as a consultant, is not an agent or representative of HOME INSTITUTION for any purpose and has no authority to act for or bind HOME INSTITUTION. Without limiting the foregoing, any obligations pertaining to any confidential or other information provided to Consultant by Company will apply only to Consultant and not HOME INSTITUTION.

Company may not use the name or any trademarks or logos of HOME INSTITUTION or any of its schools or departments, labs, or centers, other than to identify HOME INSTITUTION as Consultant's employer, without prior written permission from HOME INSTITUTION's Technology Licensing Office or similar.

To the extent that there is a conflict between the terms of the HOME INSTITUTION Policies or this Addendum, on the one hand, and the terms of the Agreement, on the other, the terms of the HOME INSTITUTION Policies and this Addendum shall control. Without limiting the foregoing, Company



specifically acknowledges that Consultant cannot assign or convey or license to or vest in Company any rights in any intellectual property whatsoever, whether or not patentable or copyrightable, that conflict with HOME INSTITUTION's rights in or to such intellectual property under the HOME INSTITUTION Policies.

COMPANY	CONSULTANT
Signature:	Signature:
Date:	Date: