Draft Notes: 1/11/16 FDP Research Compliance Subcommittee Meeting: COI

1/11/16, 2:00 p.m.

Hyatt Regency Hotel, Glacier Room, Washington DC

Co-Chairs: Diane Dean: National Institutes of Health | Clint Schmidt: Pennsylvania State University

1. **Update on and discussion around three working groups established at September FDP meeting:**
    a. ***Working group one: Best practices with regard to contracting between Universities and faculty start-up companies, including but not limited to SBIR/STTR collaborations***
        i. Update: Has met by phone three times and has created draft best practices document outlining inventory of understandings and practices among institutions in certain areas, and outlining outstanding questions for which clarification is sought
        ii. Discussion:
            1. It was noted that group should consider accessing and incorporating relevant pieces of best practices from institutions that may have them established already in certain areas
            2. Research institution subcontracts to faculty start-up companies/Faculty start-up company subcontracts to research institutions through SBIR/STTR or other award mechanisms: most institutions allow under various COI management strategies
                a. One institution noted that they will often assign research institution "administrative PI" versus "scientific PI" as one COI mitigation strategy when the PI has personal financial interests in company engaged in the University research
                    i. NIH representative noted that they do not make this distinction (scientific versus administrative PI) and that institutions should be careful not to limit a PIs role in the research to the extent that they are not fulfilling responsibilities/expectations of a PI
            3. Same individual serving as PI on company side and research institution side of SBIR/STTR collaborations: most institutions do not allow, but some allow in certain circumstances
                a. It was noted that the requirements do not specifically prohibit the same person serving as PI on both sides of the collaboration, but the PI effort requirements and percentage of work required on each respective side of the collaboration make it difficult to argue that the same person could serve as PI on both sides
                b. NIH representative noted that the fact that it is not expressly prohibited does not mean it is allowed or a good idea: the requirements are silent on the issue
            4. Company primary employment obligations: for SBIRs, the company PI must be "primarily employed" by the company; is primary employment measured by percentage FTE? Hours? Percentage appointment? Other?
                a. Most institutions present indicated they considered % FTE to be indicator of primary employment (i.e. 51% = primarily employed). NIH representative concurred.
                    i. It was noted that one institution had experiences in which certain DoD agencies provided vague/conflicting responses relative to measuring primary employment in answer to a faculty member's argument that if someone is employed 50% company and %50 University, the number of hours worked should dictate primary employment.
                b. It was noted that often the SBIR company PI is an individual either fully or primarily employed by the research institution; therefore, how can they be primarily employed by the company

and meet the SBIR company PI eligibility requirements? Research institutions often become aware of this information and this scenario.

c. It was inquired whether the federal government is looking at effort commitments on federal projects across organizations for the same individual (e.g., a faculty member with effort commitments at a research institution that total 100% institutional effort, and that same individual with effort committed to/supported by company sides of SBIRs/STTRs to companies)

    i. NIH representative noted that the federal government does consider total effort, and reminded attendees that awareness of overcommitments of or irregularities in effort should be reported to the applicable federal agency

5. Due diligence of research institutions in assessing company partners (including faculty start-up companies) when collaborating on SBIRs/STTRs

    a. It was noted that research institutions find themselves feeling responsible for performing some level of review/risk assessment of small companies, particularly faculty start-up companies, when agreeing to collaborate as a subrecipient under a company SBIR/STTR due to concerns that (in some cases) the research may in fact be occurring fully in research institutions space using research institution resources

        i. Potential concerns: does the company have the space, equipment, infrastructure and resources necessary to carry out the company portion of the research?

        ii. Various institutions noted examples of due diligence they perform: requiring company to provide full proposal and company scope of work, including attestations to the funder for resources needed and provided for the company side of the research, place of performance, etc.

    b. It was inquired whether or not federal agencies are performing adequate due diligence in assessing feasibility of SBIR/STTR applicants with regard to their having adequate ability to undertake the research

        i. NIH representative noted that as part of the reauthorization of SBIR/STTR funding, there have been ongoing discussions with OIG in this arena. They are looking at publicly available information (company websites, incorporation records, etc.) as one mechanism of checking viability of companies.

        ii. NIH representative noted that there was a sample of company SBIR/STTR recipients included as part of the NIH's proactive compliance review relative to the adequacy of COI policy documents, and they looked very good on the whole; however, it was acknowledged that actual practices identified through site visits and other means are the only way to asses compliance in a meaningful way

6. Faculty start-up company use of University space and equipment

    a. It was noted that many institutions allow this to a limited/specified degree

        i. For lease of space, some institutions noted approving in some circumstances, with assurances of the scientific need for use of the space (e.g., proximity to the lab/research team/specialized equipment needed for collaboration), fair market pricing for the space, specified limited duration, and other COI management strategies to ensure separation of company and research institution activities.

        ii. For equipment, institutions noted ensuring documented agreement and a rate agreement consistent with other users

b. ***Working group two: Case studies to address handling of a variety of COI issues***

i. Update: has met by phone once and discussed general framework for scope and format of case studies: online platform available to FDP members to touch on all kind of COI issues

ii. Discussion:

1. The case studies can address whatever scope the group decides (e.g., FCOI, nepotism, institutional COI, students, purchasing, etc.)
    a. Group consensus appeared to indicate a broader scope of case study area is desirable (i.e. including but not limited to solely FCOI)
2. It was noted that COI case studies created by COGR and available online should be referenced as a resource
3. It was noted that the UIDP principled partnerships taskforce report includes COI guidance that may be useful to reference for case study development

c. ***Working group three: Risk-based matrix/approaches for COI management***

i. Update: has not yet met, but will by next meeting

ii. Discussion:

1. Some institutions have established criteria and templates for COI management plan strategies based on various levels of risk – there is great interest among institutions in an FDP version of resources in this area
2. It was proposed that consideration be given to addressing more than just management plans in this risk-based approach discussions; consider decentralizing compliance oversight, engaging tech transfer offices, and tying in to RCR

2. **Tone and approach of COI efforts**

a. It was noted that we should remember the purpose of the SBIR/STTR award mechanisms, and the value and benefit they bring to the research enterprise and society

b. It was noted that while there are inherent risks and complexities individuals in COI roles and with compliance perspectives see in this area, most companies/individuals do it right and the research fulfills the intended federal purpose. Institutional representatives from research institutions in the room noted that there was a major and genuine interest in helping faculty, while protecting them and the institution from compliance risks in these collaborations.

c. It was noted that research institutions are increasingly promoting focus on initiatives and programs targeted at entrepreneurship, innovation, and technology transfer. This provides a unique opportunity – in addition to pressure – for individuals responsible for COI programs to facilitate such efforts in a way compliant with applicable regulations and in a way that preserves research objectivity if/when personal investigator financial interests are involved

3. **Handling of contracts versus grants: NIH representative inquired whether or not institutions were experiencing differences in administering COI requirements for contracts as opposed to grants**

a. Consensus among institutions present was that they handled contracts and grants consistently from a COI perspective

b. Reference to organizational COI language in the FAR to which contracts are subject was raised; it was noted that the FAR organizational COI language did not encompass financial COI

4. **Unrestricted research grants from faculty start-up companies to the faculty member's research institution lab**

a. It was noted that most institutions do not allow this, but at times, there is disconnect/miscommunication between compliance/COI offices and gift/development offices in this area

5. **Next Steps**

a. Sign-in sheet was passed around room and included sign-up for additional involvement in three working groups

b. Clint Schmidt will forward on draft best practices document established by working group one to attendees for feedback and contributions

c. Clint Schmidt and Diane Dean will schedule additional meetings with all volunteers to continue progress in all areas, beginning with the best practices group. It was noted that the best practices work may naturally flow into the case studies and then the risk matrix/model management plan project.

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