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## **Research Sponsoring, Financial Management and Conflict of Interest**

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### **ABSTRACT**

Although project sponsoring usually involves a formal agreement for conducting activities related to research, teaching and service between an institution and the sponsor, many institutions do not prioritise project sponsoring and ensure the inclusion of core components such as statement of work, financial accountability, institutional responsibility for sponsored projects, financial management and conflict of interest (FOCI), and institutional responsibility for FOCI in the agreements. In addition, early career researchers are not engaged to understand the guiding principles and ethics surrounding research implementation. These often accentuate the conduct of unethical research. In this article, the author provides a brief overview of key considerations in research sponsoring.

**Keywords:** *Sponsored Projects, Core components, Guiding principles, Institutional responsibilities*

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### **INTRODUCTION**

Project sponsoring is the support provided wholly or in part by external restricted funds awarded to an institution for the conduct of array of activities originating from members of the institution. It is a transaction in which there is a specified statement of work to be implemented by an institution, with a related, reciprocal transfer of something of value, it usually involves a formal written agreement, i.e. a grant, contract, or cooperative agreement, entered into by an institution and by the sponsor.

### **DIFFERENCE BETWEEN GIFTS/DONATIONS & SPONSORED PROGRAMS**

A gift is any item of value given to an institution by a donor who expects nothing significant of value in return, other than recognition and disposition of the gift in accordance with the donor's wishes. In general, gifts are donative in nature, bestowed voluntarily and without expectation of any tangible compensation, product or outcome while sponsored programs usually include a level of accountability imposed by the donor in the use of support given: Many require extensive technical or fiscal reporting as might be requested by the sponsor as part of responsible conduct of research.

### **Characteristics of gifts and sponsored projects**

- a. **Characteristics of Gifts:** Gifts are not characterized as contractual obligations or "deliverables", they have no formal fiscal accountability to the donor beyond periodic progress reports and summary reports of expenditures. If gifts are unused, donor must be informed and clarification of intent and requirements sought with a discussion on the planned use of the funds.
- b. **Characteristics of sponsored projects:** Sponsored projects should be directly related to the three-fold mission of the institution: research, teaching and service. It should have statement of Work supported by both a project schedule and a line-item budget, both of which are essential to financial accountability.

Sponsored projects should have detailed Financial Accountability which must include conditions as:

- A line-item budget related to the project plan which specifies allowable or unallowable costs, fully negotiated indirect cost, requirements for prior approvals for particular expenditures, etc.
- A requirement to return any unexpended funds at the end of that period

- Regular financial reporting and audit

Sponsored projects should describe disposition of Properties ("Deliverables") (e.g., equipment, records, specified technical reports, theses, or dissertations) or intangible properties (e.g., rights in data, copyrights, and inventions) (Boyd & Bero, 2000).

### **INSTITUTIONAL RESPONSIBILITIES ON SPONSORED PROJECTS**

Institutions should have a structure dealing with sponsored projects. For example, the Catholic University of America has an Office of Sponsored Programs and Research Services headed by a program director or a Principal Investigator. Institutions handle funds for sponsored activities and processes proposals such as research projects (equipment for designated research), research contracts (general curriculum development) and training (graduate fellowships and traineeships). Institutions also handles pre-and post-award administration of a grant or contract and assists faculty members with funding source identification, proposal development assistance, budget development and proposal processing and review. Institutions advocate for institutional enabling climate conducive to the research enterprise such as advising the administration on matters of regulatory compliance, internal sponsorship of scholarly activities and other similar issues. All solicitation of grants and contracts for sponsored activities must be processed through the Office of Sponsored Programs to ensure that the proper university approvals have been obtained prior to submission of the proposal to a sponsoring agency. This exemplifies details inherent in institutional responsibilities in the conduct of responsible research.

### **FINANCIAL MANAGEMENT AND CONFLICT OF INTEREST (FCOI)**

FCOI (real or perceived) occurs when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings (Thompson, 1993). A conflict of interest occurs when a secondary interest distorts or has the potential to distort a judgment related to a primary interest. Primary interest of researchers in their profession are producing generalizable knowledge, ensuring the safety of research subjects and disseminating research results while secondary interests beyond their professional goals include publishing, spending time with his/her family, obtaining a good income, political activism or volunteerism, obtaining future research funding and pursuing other interests such as religion, traveling, social activities, etc. Some secondary interest might threaten valid research design, data integrity, researchers' interpretation of data, dissemination of results and patient safety. This regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under a sponsor (e.g. NIH grants) or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. FCOI Regulations Framework is applicable to each Institution that applies for or receives grants (e.g. NIH) or

cooperative agreements for research (domestic, foreign, public, private), any Investigator (as defined by the regulation) planning to participate in or participating in the research and when an individual, rather than an Institution, is applying for or receives research funding.

### **INSTITUTIONAL RESPONSIBILITIES IN FCOI**

Institutions must establish standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator financial conflicts of interest (Bekelmam, Li & Gross, 2010). Maintain an up-to-date, written, enforced policy that complies with the FCOI regulation and make available via a publicly accessible Website. Other responsibilities according to Pritchard (1996) and the National Institute of Health are:

#### **a. Maintenance of Records**

Maintain records of all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of FCOI) and all actions under the Institution's policy or retrospective review, if applicable for at least three years from the date of submission of the final expenditures report

#### **b. Application Certification**

Certify in each application for funding that the Institution:

- Has in effect an up-to-date written, and enforced administrative process to identify and manage FCOIs related to all PHS research projects.
- Shall promote and enforce Investigator compliance with the regulation pertaining to disclosure of SFIs.
- Shall manage FCOIs and provide initial and ongoing FCOI reports to the sponsor (e.g. NIH)
- Agrees to make information available upon request relating to any Investigator disclosure of financial interest and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI.
- Fully comply with the requirements of the regulation.

#### **c. Designated Institutional Official(s)**

- Designate an Institutional Official(s) to solicit & review disclosure statements from each Investigator planning to participate in, or is participating in funded research (e.g. NIH)
- Provide guidelines to identify conflicting interests related to proposed or funded research
- Designated Institutional Official(s) develop management plans that specify the actions that have been, and shall be, taken to manage FCOI

#### **d. Inform Investigators**

Each Investigator must be informed of the:

- i. Regulation;
- ii. Institution's policy on FCOI; and
- iii. Investigator's responsibilities regarding
- iv. disclosure of SFIs

**e. Investigator Training**

Institutions must require that each Investigator complete FCOI training:

- Prior to engaging in research related to any (e.g. NIH) funded project;
- At least every four years, and
- Immediately when any of the following circumstances apply:
  - i) Institution revises its policy in a manner that affects the investigator;
  - ii) When an investigator is new to the institution; or
  - iii) When the institution finds an Investigator is not in compliance with the Institution's policy or management plan.

**f. Investigator Disclosure of SFIs**

At time of Application: Require that each Investigator, including subrecipient Investigators, if applicable, planning to participate in -funded research (e.g. NIH) to disclose to the designated official(s) at time of application (Thompson, 1993). Annually: Require each Investigator, including subrecipient Investigator, if applicable, to submit an updated disclosure of SFI at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Within 30 days: Require each Investigator, including subrecipient Investigator, if applicable, who is participating in the NIH-funded research to submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

**g. Management of FCOIs**

- Take necessary actions to manage FCOIs of its Investigators, including those of subrecipient Investigators
- Develop a management plan(s) and monitor compliance
- If an Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the designated official(s) shall
- within sixty (60) days review the SFI, determine if an FCOI exists and implement an interim management plan, if needed.
- In cases of non-compliance, complete a retrospective review and submit a Mitigation Report if bias is found.

**h. Retrospective Review**

Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, failure by the Institution to review or manage an FCOI, or failure to comply with the management plan, the institution shall within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research. Notify NIH promptly and submit a Mitigation Report when bias is found.

**i. Subrecipient Requirements**

Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and

include time periods to meet SFI disclosure, if applicable, and FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS/NIH Awarding Component (i.e., to NIH through the eRA Commons FCOI Module) to meet FCOI reporting obligations.

**FCOI REPORTING**

This must be provided to NIH prior to the expenditure of funds, during the period of award, within 60 days of identifying a new FCOI or annually. This includes report on the status of FCOI and any changes in management plan. Elements of an FCOI Report are: Grant number; PD/PI or contact PD/PI; Name of Investigator with the FCOI; Name of the entity with which the Investigator has an FCOI; Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria); Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amts between \$20K-100K by increments of \$20K; amounts above \$100K by increments of \$50K or a statement that a value cannot be readily determined; a description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and key elements of the Institution's management plan.

Prior to expenditure of funds, certain information concerning FCOIs be made available by senior/key personnel publicly accessible via a Web site or provide written response within five business days of a request. Such personnel should update the website annually and within 60 days of identifying any new FCOIs when posting FCOIs to website and retain information for three years. FCOI information to be made publicly available includes the following:

- a) Investigator's name;
- b) Investigator's title and role with respect to
- c) the research project;
- d) Name of the entity in which the SFI is held;
- e) Nature of the SFI; and
- f) Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value.

**CONCLUSION**

Research sponsoring should be prioritized by institutions and early career researchers should be encouraged to understand the guiding principles and ethics surrounding research implementation. In addition, extensive training on conflict of interest to avoid bias in research findings is critical for limiting unethical research practices among investigators.

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