

POLICY



Volume: Academic

Chapter: 15. Grants
Management

Responsible Executive: Provost

Responsible Office(s): Director, Grants
Administration

Originally Issued: November, 2012

Revised:

Financial Conflict of Interest Policy for Sponsored Projects

I. Policy Statement

The intent of this policy is to comply with U.S. Public Health Service (PHS) regulations that seek to preserve the public's trust by ensuring that research supported by it is conducted without bias and with the highest scientific and ethical standards.

II. Reason for Policy

This is a regulatory compliance policy. Any Institution applying for or receiving PHS funding from a grant, cooperative agreement, or contract that is covered by the FCOI regulation (*see below*) must be in compliance. While this policy is expressly applicable to all applications to a PHS agency for funding and to any grants, contracts or cooperative agreements issued by a PHS agency to Manhattan College, it shall also be relevant and applicable to all Federal funding.

Additionally, Manhattan College shares PHS's concerns about preserving the public trust and undertaking research without bias and with the highest scientific and ethical standards.

III. Entities Affected By This Policy

All units of the College and all investigators that are involved with applying for, accepting, performing or administering any grant, contract or cooperative agreement from a PHS agency or any sub-award, hereunder.

IV. Who Should Read This Policy

All applicants for and recipients or sub-recipients of PHS funding to Manhattan College and those responsible for administration of any grant or cooperative agreement from PHS. This includes all faculty investigators, co-investigators or associates, the Director of Grants Administration, the Grants Accountant, the Associate Provost and the Executive Vice-President and Provost.

V. Website Address for This Policy

TBD - The Office of Marketing and Communications will provide

VI. Related Documents, Forms, and Tools

College Policies

Manhattan College Employee Conflict of Interest Policy https://inside.manhattan.edu/uploads/hr/Manhattan_College_CONFLICT_OF_INTEREST.pdf
Other Documents
Final Rule: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors (<i>commonly referred to as the Financial Conflict of Interest (FCOI) regulation</i>) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf (last access 11/4/12) 42 CFR 50, F: http://grants.nih.gov/grants/compliance/42_cfr_50_subpart_f.htm (last access 11/4/12)
Forms and Tools
<i>Significant Financial Interest (SFI) Disclosure Form</i> – see Appendix

VII. Contacts

Subject Matter	Office	Telephone Number	E-mail/Web Site
Policy Implementation Notices/Reporting Management & Oversight plans	Director, Grants Administration DLS201	718-862-7160	GrantsAdministration@manhattan.edu Ejinks01@manhattan.edu
Policy Clarification and Interpretation	Associate Provost DLS206D	718-862-7268	AssociateProvost@manhattan.edu Walter.matystik@manhattan.edu
Approvals under this Policy	Provost MEM2FL	718-862-7303	Provost@manhattan.edu William.clyde@manhattan.edu

VIII. Definitions

Term	Definition
Conflict Management Plan	a written plan instituted by the College and agreed to by the Investigator for the management, reduction or elimination of a Financial Conflict of Interest
FCOI	Financial Conflict of Interest
Financial Conflict of Interest	a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS funded research
Institutional Responsibilities	Institutional responsibilities means an Investigator's professional responsibilities on behalf of the College which may include activities such as research, research consultation, teaching, professional practice, College committee memberships, and service on panels such as the Institutional Review Board (<i>IRB</i>) for human subjects or the Institutional Animal Care and Use Committee Board (<i>IACUC</i>).

Investigator	Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
PHS	U.S Department of Health and Human Services, Public Health Service
PHS agency	any PHS operating division listed at http://www.hhs.gov/about/orgchart/#text (last access 11/4/12)
SBIR	Small Business Innovation Research Program for small businesses established by the awarding components of the Public Health Service and certain other Federal agencies under Public Law 97–219.
STTR	Small Business Technology Transfer Program, which was established by Public Law 102–564.
SFI	Significant Financial Interest
Significant Financial Interest	<p>anything of monetary value, including but not limited to: salary or other payments for services (<i>e.g., consulting fees or honoraria</i>); equity interests (<i>e.g., stocks, options, other ownership interests</i>); and intellectual property rights (<i>e.g., patents, copyrights, royalties</i>) that could directly and significantly affect the design, conduct, or reporting of research.</p> <p>For any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.</p> <p>With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (<i>or the Investigator’s spouse or dependent children</i>) holds any equity interest (<i>e.g., stock, stock option, or other ownership interest</i>); or (iii) Intellectual property rights and interests (<i>e.g., patents, copyrights</i>), upon receipt of income related to such rights and interests.</p> <p>Investigators also must disclose the occurrence of any reimbursed or sponsored travel.</p> <p>The term does not include travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.</p> <p>The term “significant financial interest” does not include the following: salary, royalties, or other remuneration paid by the College to the Investigator if the Investigator is currently employed or otherwise appointed by the College, including assigned intellectual property rights and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an</p>

	<p>Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.</p> <p>This term does not apply to SBIR/STTR Program Phase I applications.</p>
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IX. Responsibilities

The College, through its designated administrators, is responsible for complying with the applicable regulations, including maintaining a written and enforced FCOI policy; managing, reducing, or eliminating identified conflicts; and reporting identified conflicts to the PHS that denote the existence of an FCOI and the College’s assurance that it has been managed, reduced, or eliminated.

Investigators are responsible for complying with this written FCOI policy and for disclosing their SFIs to the College.

Party	List of Responsibilities
Director, Grants Administration	<p>Inform investigators of this policy.</p> <p>Receive reports of significant financial interests and report same to the Associate Provost. Report SFIs to PHS.</p>
Associate Provost	<p>Review reports of significant financial interests and work with the reporting investigator and the Director, Grants Administration to manage, reduce or eliminate such conflicts.</p>
Provost	<p>Receive reports of SFIs and approve conflict management plans submitted by the Director, Grants Administration and/or Associate Provost. Maintain an institutional file in accordance with recordkeeping requirements.</p>
Investigator	<p>Complete and submit an SFI Disclosure Form. Cooperate towards mitigating or eliminating any SFIs. Complete required training.</p>
Grants Accountant	<p>Notify the Director of Grants Administration upon submission of the final financial expenditure report for any PHS grant, contract or cooperative agreement to which this policy is applicable.</p>

X. Principles

The College recognizes that interactions among government, educational institutions undertaking research, and the private sector have become increasingly complex. This complexity, as well as a desire to strengthen accountability, leads to a need to add transparency to and formal processes for an Investigators’ disclosure of Significant Financial Interests (SFIs). The College also seeks to enhance its regulatory compliance through this policy by providing effective oversight and management of Investigators’ financial conflicts of interests.

XI. Procedures

- Investigators must submit a completed *SFI Disclosure Form* to the Director of Grants Administration no later than the time of submitting their application for review, approval and submission. Investigators must then resubmit an updated form annually, prior to submission of annual progress for any funded PHS project.
- The Director of Grants Administration shall determine whether the Investigator's SFI is related to PHS funded research and, if so, whether the SFI constitutes a Financial Conflict of Interest.
- If the Director of Grants Administration finds that the SFI is related to PHS funded research and constitutes an FCOI, s/he shall promptly forward the SFI Disclosure Form to the Associate Provost.
- Upon receipt of the SFI Disclosure Form, the Associate Provost shall schedule a meeting with the Investigator to review the FCOI and assess the Director of Grants Administration's determination that the SFI is both related to PHS funded research and constitutes a FCOI. If he/she concurs, the Associate Provost shall notify the Provost and then work with the Investigator to develop a conflict management plan. Conflict management may include: public disclosure of the FCOI (*e.g. when publishing or presenting research*); disclosure to participants if there are human subjects involved; modification of the research plan to mitigate significant conflicts; changes to personnel responsibilities; elimination of the FCOI or severance of relationships that result in the FCOI; or withdrawal of the application.
- A conflict management plan must be jointly developed by the Director, Grants Administration And/or Associate Provost and Investigator and implemented prior to the expenditure of any related PHS funds.
- The Investigator shall review, approve and sign the conflict management plan. The Director, Grants Administration and/or Associate Provost shall submit the plan to the Provost for approval and recordkeeping. The Provost's Office shall retain all disclosure forms and any resulting management or oversight plans for at least three years from the date of submission of the final expenditure report by the Grants Accountant.
- From the time of proposal submission to award and through project closeout, the Investigator shall submit a SFI Disclosure Form to the Director of Grants Administration within 30 days of discovering or acquiring a SFI. Responsible parties shall then follow the same procedures detailed above.
- The Director, Grants Administration shall submit a FCOI report to the PHS agency awarding component. The report shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of the College's conflict management plan. Elements of the FCOI report shall include at least the following information: project number; principal investigator; name of the Investigator with the FCOI; name of the entity with which the Investigator has an FCOI; nature of the financial interest (*e.g., compensation, equity, intellectual property, consulting fees, sponsored travel, reimbursed travel*); value of the financial interest (*dollar ranges acceptable*); description of how the FCOI relates to the PHS-funded research and the basis for the College's determination that it is an FCOI; and a description of the key elements of the College's conflict management plan. The online FCOI module, accessed via eRA Commons, may be used to electronically submit FCOI reports and supporting documents.
- Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years. The training must be

completed immediately if FCOI policies change in a manner that affects Investigator requirements or an Investigator is new to the College. All Investigators who submit proposals are required to complete the FCOI training through NIH at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> (last access 11/4/12). After completion of the NIH training module (*which takes about 15-20 minutes*) the Investigator shall then print and save their certificate and send it to the Director of Grants Administration.

XIII Appendix

<p><i>Significant Financial Interest (SFI) Disclosure Form (available from Director, Grants Administration)</i></p>

XIV Distribution

- This policy is approved for distribution through the College intranet and for external distribution.