1. **Policy Statement**

Manhattan College has a responsibility to manage conflicts of interests that arise during the performance of externally-sponsored research projects. This responsibility arises from its Lasallian mission, which emphasizes ethical conduct, as well as the need to remain in compliance with federal, New York State and other external sponsor requirements.

Conflict of interest disclosure and management requirements vary depending upon the specific sponsor. The most stringent conflict of interest reporting and management requirements have been imposed by the United States Public Health Service (PHS). The following policy and procedures for disclosing and managing financial conflicts of interest are intended to be compliant with PHS regulations.

2. **Who Should Read the Policy**

This Financial Conflict of Interest policy applies to all Manhattan College employees who are involved with the design, implementation conduct and/or reporting of research projects that are funded by external sponsors.

3. **Links and Resources**

- 2 CFR 200 (Uniform Guidance)
- 42 CFR 50 Subpart F
- 45 CFR 94

4. **Terms and Definitions**

**External Sponsor:** A third-party entity, which includes federal agencies, agencies within the City and State of New York, and private entities (such as corporations and foundations) that award funding to Manhattan College employees to conduct research projects with a scope and deliverables that are specified within the terms and conditions of said award.
Financial Conflict of Interest (FCoI): For the purposes of this policy, Col means a Significant Financial Interest that the Institutional Official reasonably determines could directly and significantly affect the design, conduct, or reporting of externally funded research.

Financial Conflict of Interest Management Plan: A written plan instituted by Manhattan College and agreed to by the Investigator for the management, reduction, or elimination of a Financial Conflict of Interest.

Investigator: The principal investigator (PI), co-principal investigator (co-PI), and any other identified on the project (regardless of title or position) who is responsible for the design, conduct, or reporting of research or educational activities funded - or proposed for funding - to an external sponsor.

Institutional Official: The Manhattan College individual designated as responsible for collection and review of disclosures and Significant Financial Interests, including those of the investigator’s or family related to their Institutional Responsibilities. For the purpose of Financial Conflict of Interest evaluation and reporting, Manhattan College’s Institutional Official is designated as the Director of Grants Administration.

Institutional Responsibilities: A Manhattan College employee’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 (IRB) for human subjects or the Institutional Animal Care and Use Committee Board (IACUC).

Public Health Service (PHS): Within the U.S. Department of Health and Human Services (HHS), eight agencies are designated components of the Public Health Service. A list of PHS agencies is provided under Exhibit A of this policy.

Significant financial interest: Anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

This term does not include:
- a. salary, royalties or other remuneration from Manhattan College;
- b. any ownership interests in the organization, if the organization is an applicant under the Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer Program (STTR);
- c. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- d. income from service on advisory committees or review panels for public or nonprofit entities;
- e. an equity interest that, when aggregated for the investigator and the investigator’s spouse and dependent children, meets both of the following tests: (i) does not

As policies may be amended periodically, please refer to the Manhattan College Policy Library website [manhattan.edu/policies] for the most recent version of this policy.
exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and (ii) does not represent more than a 5% ownership interest in any single entity; or

f. salary, royalties, or other payments that, when aggregated for the investigator and the investigator’s spouse and dependent children, are not expected to exceed $10,000 during the prior twelve-month period.

5. The Policy

I. Introduction

Manhattan 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 by implementing 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.

II. Requirements

A. Training

Any Investigator engaging in Public Health Service (PHS)-funded research is required to take FCoI training prior to conducting research related to the PHS-funded project. Therefore, this training shall be completed before a proposal for funding is submitted to a PHS agency.

PHS-funded Investigators must also refresh FCoI training every four years, or immediately if found to be non-compliant with Manhattan College’s FCoI policy or FCoI management plan.

Manhattan College utilizes the free FCOI tutorial provided by National Institutes of Health (NIH) for training purposes. In addition to reviewing Manhattan College’s FCOI policy, PHS-funded Investigators, regardless of which PHS entity is funding their project, must provide assurance they have completed the NIH tutorial by sending a copy of the Certificate of Completion to the College’s Director of Grants Administration. The NIH tutorial is accessible on-line at: https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

Proof of completion of the Collaborative Institutional Training Initiative (CITI) Col training course may be accepted in lieu of the aforementioned NIH tutorial.

Other Investigators who have research that is sponsored by federal, non-PHS agencies are not required to complete the NIH tutorial, but are encouraged to do so. A list of federal agencies within the PHS is provided in Appendix A.
Private foundations may have unique FCOI reporting requirements. Investigators are encouraged to consult with the Office of Grants Administration to determine if a private foundation has specific requirements related to FCOI.

B. Reporting

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. This form can be accessed at: https://manhattancollege.formstack.com/forms/financialconflictofinterestdisclosure.

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 the SFI Disclosure Form to the Director of Grants Administration.
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.
APPENDIX A

Agencies within the United States Public Health Service (PHS)

As of September 2021, the following grant making federal agencies follow PHS regulations:

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of the Assistant Secretary for Health (OASH)
9. Office of the Assistant Secretary for Planning and Evaluation
10. Office of the Assistant Secretary for Preparedness and Response (ASPR)
11. Substance Abuse and Mental Health Services Administration (SAMHSA)
12. Administration for Community Living (ACL)
13. Administration for Children & Families (ACF)
14. Office of National Coordinator for Health Information Technology (ONC)