

# HOWARD UNIVERSITY POLICY

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<b>Policy Number:</b>	100-007: Academics and Research
<b>Policy Title:</b>	FINANCIAL CONFLICT OF INTEREST IN RESEARCH POLICY
<b>Responsible Officers:</b>	Provost and Chief Academic Officer Associate Vice President, Regulatory Research Compliance
<b>Responsible Offices:</b>	Office of the Provost and Chief Academic Officer Office of Regulatory Research Compliance
<b>Effective Date:</b>	Conforming Amendment December 3, 2020 [Original Policy: 600-002 Sponsored Programs Conflict of Interest, April 3, 2007, Updated March 10, 2010, Updated November 14, 2016]

## I. POLICY STATEMENT

Howard University (“the University”) encourages faculty, staff and students to participate in Sponsored Research and to do so according to the highest ethical standards. The intent of this Policy is to promote objectivity in research by establishing standards to prevent bias resulting from financial conflicts of interest, or the appearance of such bias, in the design, conduct, and reporting of a sponsored project. It outlines the requirements of conflict of interest disclosure so that potential conflicts can be identified, managed, reduced or eliminated.

This revised Policy is modeled after the federal regulations promulgated by the U.S. Department of Health and Human Services entitled *Responsibility of Applicants for Promoting Objectivity in Research* (42 CFR Part 50, Subpart F, and 45 CFR Part 94) effective August 24, 2012. The Policy was further revised in 2020 in compliance with the 2018 Investigator Disclosures of Foreign Interests (NOT-OD-18-160). The foregoing regulation, though applicable to research activities supported only by the U.S. Public Health Service (PHS), is the most stringent of the federal conflict of interest policies, including the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards (commonly called “Uniform Guidance”), and for that reason the University has modeled its policy after the PHS Financial Conflict of Interest Policy. As a result, other less stringent requirements of other sponsors will be satisfied if the University is in compliance with the PHS regulations. This Policy applies to *all* Sponsored Research including (i) all government- sponsored (state and federal) as well as (ii) all nongovernment-sponsored (commercial and non- profit) research [hereinafter, “Sponsored Research” or “Research Activity(ies)”].

Sponsored Research that is ongoing or awarded prior to the most recent effective date of this Policy shall become subject to this Policy as additional funds are requested when submitting a progress report, competing renewal application, or request for supplemental funding. This Policy applies to Principal Investigators and all other Investigators, who are responsible for the design, conduct and/or reporting of Research Activities and other Sponsored Research. This Policy supersedes all previous versions.

## II. RATIONALE

The University makes it a priority to comply with federal guidelines regarding the disclosure of conflicts of interest in Sponsored Research at Howard University and all related entities, business units, subsidiaries and affiliated organizations including, but not limited to, Howard University Hospital (hereinafter referred to collectively as “the University”). Through compliance with federal guidelines, the University strives to manage, reduce, or eliminate any conflicts of interest that are identified.

## III. ENTITIES AFFECTED BY THIS POLICY

This Policy applies to the entire University research enterprise and any affiliated entities including, but not limited to, Howard University Hospital, its faculty, students and staff.

## IV. DEFINITIONS

As used in this Policy, the following terms mean:

- A. **Designated Institutional Official** – The Associate Vice President for Regulatory Research Compliance is appointed by the President as the DIO to conduct the review of disclosures of Significant Financial Interests from each Investigator to determine whether an Investigator’s Significant Financial Interest is related to the Investigator’s Research Activity and, if related, whether the Significant Financial Interest constitutes a Financial Conflict of Interest.
- B. **Office of Regulatory Research Compliance (ORRC)** – The University office charged with the oversight of research-related compliance activities.
- C. **Research Administrative Services (RAS)** – The University office in the Office of Research charged with administrative oversight of funded research.
- D. **Institutional Review Board (IRB)** – Provides oversight to the Howard University Human Subject Research Protection Programs in accordance with U.S. Department of Health and Human Services regulations, 45 CFR § 46 administered by Office of Human Research Protection (OHRP), and the US Food and Drug Administration 21 CFR § 50 and 56.
- E. **Institutional Animal Care and Use Committee (IACUC)** – Provides oversight to the Howard University Animal Care and Use Program in accordance with the Office of Laboratory Animal Welfare (OLAW) (Public Health Service Policy on Humane Care and Use of Laboratory Animals) and the Guide for the Care and Use of Laboratory Animals and Association for Assessment and Accreditation of Laboratory Animals Care International (AAALAC).
- F. **Institutional Biosafety Committee (IBC)** – Provides oversight to University research involving recombinant Deoxyribonucleic Acid (rDNA), Synthetic Acid Molecules and Infectious Agents, in accordance with the National Institute of Health Guidelines -- Office of Science Policy, Office of Biotechnology Activities (OBA).
- G. **Conflict of Interest in Research Committee (COIRC)** – The President, upon recommendation of the Associate Vice President for Regulatory Research Compliance

(AVP-RRC), shall appoint the COIRC composed of not more than five persons from the faculty. A majority of COIRC members shall constitute a quorum. In making the appointments, the President shall seek to maintain a COIRC diverse among disciplines and departments conducting research at the University. Appointments shall be for a term of three years. Once a COIRC member completes his or her term, or resigns from the COIRC, a replacement shall be recommended by the AVP-RRC to the President. The AVP-RRC shall recommend a member of the COIRC to the President as chair and establish procedures for the COIRC's operation.

The COIRC will review disclosures of significant financial interest that the AVP-RRC has determined constitute a Financial Conflict of Interest and formulate recommendations to the AVP-RRC on how to manage, reduce, or eliminate conflicts of interest as appropriate.

- H. **Financial Conflict of Interest** – A situation that could directly and significantly affect the design, conduct or reporting of a Research Activity.
- I. **Institutional Responsibilities** – Investigators' professional responsibilities on behalf of the University, which include, but are not limited to, activities such as research, research consultation, teaching, professional practice, committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- J. **Investigator** – The Principal Investigator or Project Director, and any other person regardless of title or position, who is responsible for the design, conduct, or reporting of research proposed for funding or funded by PHS and other sponsors. This includes, but is not limited to, Key Personnel named on a proposal budget.
- K. **Key Personnel** – A Research Project Director, Principal Investigator, and any other personnel considered essential to work performance and identified as Key Personnel in the contract proposal, grant, or contract.
- L. **Research Activity(ies) or Sponsored Research** – Any award for which research funding is available from PHS and other sponsors, including research contracts, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards, and conference grants. Only Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) awards programs are excluded.
- M. **Principal Investigator (PI)** – An Investigator, normally an academic appointee, who has primary responsibility for the scientific and technical conduct, reporting, and fiscal and programmatic administration of a sponsored project.
- N. **Significant Financial Interest (SFI)** – Consistent with federal regulations, SFI means a financial interest consisting of one or more of the following interests of the Investigator or the Investigator's spouse and/or dependent children for the following categories that reasonably appears to be related to the Investigator's institutional responsibilities, except in the case of travel:
  - 1. With respect to any publicly traded entity, SFI exists if the value of any remuneration (other than remuneration described in SBIR, STTR and general exclusions described under section "O" below) - 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. Included are salary, consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value.

2. With respect to any non-publicly-traded entity, SFI exists if the value of any remuneration (other than remuneration described in SBIR, STTR and general exclusions described under section “O” below) received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse, or dependent children) holds any equity interest.
3. Intellectual property rights and interests, upon receipt of income, during the twelve months preceding disclosure from such rights and interests.

In the case of travel, investigators must disclose the occurrence of any sponsored travel or reimbursements made to or on behalf of, the Investigator, regardless of amount, by a for-profit or non-profit entity related to the Investigator’s Institutional Responsibilities. However, SFIs do not include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.

**O. Significant Financial Interest (SFI) *does not include***– Interests of any amount in, or income from, investment vehicles, such as mutual funds or retirement accounts so long as the Investigator does not directly control the investment decisions made in these vehicles.

1. Payments to the University, or via the University to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the University.
2. Salary and other remuneration from the University, including approved faculty practice plan earnings and the distribution of those earnings that may be established by departmental or other similar agreements provided that those agreements and departmental/divisional group plans are approved by an authorized University Official.
3. 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 institution of higher education; or
4. 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.
5. Reimbursed or sponsored travel that is reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, or a research institute that is affiliated with an institution of higher education.

**P. Foreign Financial Interests:** The regulation refers to exclusions of Institutions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency

when disclosing financial interests. However, these references refer to a U.S. Institution of higher education or a federal, state, or local government agency within the U.S. Therefore, Investigators, including subrecipient Investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).

- Q. **Research** – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. As used in the University policies, the term "research" encompasses basic and applied research and product development.
- R. **Retrospective Review** – A review conducted of an Investigator's activities, SFIs and Sponsored Research to determine whether any such research, or portion thereof, conducted during the period of non-compliance was biased in the design, conduct, or reporting of such research.

## V. POLICY PROCEDURES

### A. How the Policy Will be Implemented

Howard University requires all Principal Investigators/Project Directors (PIs/PDs) and key personnel proposing or receiving grants, contracts or cooperative agreements from the Public Health Service (PHS) and all other sponsors to disclose at least annually their outside interests related to any University responsibilities as requested on the Financial Conflict of Interest Disclosure (FCOID) form, attached hereto the content of which is subject to periodic review and change. The FCOID must be completed prior to submitting a grant proposal to RAS or a research compliance application to the ORRC (IRB, IACUC, IBC), and with each continuation/renewal submission.

Federal law requires that institutions performing PHS- or National Science Foundation-funded research must adopt and enforce certain policies on financial conflicts of interest. These policies must be consistent with regulatory requirements found in Titles 42 and 45 of the Code of Federal Regulations. The FCOID requires that the individual identify any financial interest (and those of his/her affiliated persons) that could be reasonably expected to bias the design, conduct, or reporting of the project. The foregoing requirement shall apply to all Sponsored Research.

**PI/PDs and key personnel are required to complete a FCOID prior to submitting a proposal or award continuation for external funding or research compliance application (IRB, IACUC, IBC), and they must update it on an annual basis or any other time that they acquire new significant financial interests.** The FCOID process includes:

1. Certification of the FCOID for extramurally- funded research and educational activities, or research compliance applications to the ORRC (IRB, IACUC, IBC).
2. The FCOID shall be submitted to the ORRC with each initial and continuing review application and/or at any point when the PI and/or research personnel establish a new outside relationship or change an existing relationship that creates a potential

conflict under this Policy. The ORRC Senior Compliance Administrator shall supervise the ORRC designated staff's review of each FCOID and forward the reports of potential financial conflicts of interest to the AVP-RRC for a determination on whether a conflict exists. If no financial conflict of interest exists, or no potential conflict is disclosed, the ORRC files the FCOID in the program files.

3. The FCOID shall be submitted to the RAS with the proposal submission materials, and annually with the request for additional funds on multi-year awards. The RAS staff then routes the FCOID to the designated ORRC staff. The ORRC Senior Compliance Administrator shall supervise the ORRC designated staff and review each FCOID and forward the reports of potential conflicts to the AVP-RRC for a determination of whether a conflict exists. If no conflict exists, or no potential conflict is disclosed, the ORRC files the FCOIDS in the program files. FCOID and reviews will be linked into a database for ongoing assessment, monitoring and management.
4. The AVP-RRC affirms whether a conflict of interest in research exists and whether or not it is significant. If it is determined that a conflict exists, the AVP-RRC shall work with the PI/PD and, in the case of a significant conflict, work with the COIRC and the University Chief Compliance Officer or other relevant University officials, to determine the best course of action. The COIRC will make a recommendation to the AVP-RRC as to whether a financial conflict of interest is manageable and, if so, the management plan that should be implemented. In making the final determination, the AVP-RRC will consult with the University Chief Compliance Officer and the Office of the General Counsel (OGC). Action may include, but is not limited to:
  - 4.1 Funds shall not be released for use or the award shall not be accepted by the University until a plan for managing, reducing, or eliminating the conflict of interest has been established and until the appropriate funding source has been notified of the existence of a conflict of interest (but not the nature of the interest or other details, unless required by the appropriate funding source).
  - 4.2 PI/PD will not be permitted to begin any Research Activity before receiving written determination as to how to manage the conflict.
  - 4.3 Subsequent conflicts of interest identified for the same award must be reported to the satisfaction of the AVP-RRC and must be managed, reduced or eliminated, at least on an interim basis, within sixty (60) days.
  - 4.4 The plan for managing, reducing or eliminating a conflict of interest must include resolution strategies. The plan initially will be formulated by a PI/PD and must be approved by the AVP-RRC in consultation with the University General Counsel and other institutional officials as appropriate.
  - 4.5 The AVP-RRC working with the Chief Compliance Officer and in consultation and coordination with the OGC is responsible for making the final determination on whether the conditions or restrictions, if any, should be imposed by the University to manage, reduce or eliminate the conflict of interest and for notifying the sponsor that a conflict of interest exists. The AVP-RRC shall also be responsible for reporting such decision to the President and the Provost.
  - 4.6 PIs/PDs must comply with all elements of the management plan as approved by the AVP-RRC. The Senior Compliance Administrator or other ORRC designated staff will monitor and report to the AVP-RRC. Monitoring of

management plans will also become part of the ORRC protocol post-approval monitoring process.

- 4.7 Conditions or restrictions that may be imposed on a PI/PD or project to manage or eliminate financial conflicts of interest may include, but are not limited to, one or more of the following:
  - i. Public disclosure of significant financial interests
  - ii. Monitoring of research by independent reviewers
  - iii. Modification of the research plan
  - iv. Disqualification from participation in all or a portion of the research
  - v. Divestiture of financial interests
  - vi. Severance of relationships that create actual or potential conflicts
  - vii. For research projects involving human subjects, disclose financial conflict of interest directly to participants

## B. Roles and Responsibilities

1. **Principal Investigator/Project Director (PI/PD)** – The PI/PD is responsible for disclosing any **financial conflict of interest** on a sponsored project application by completing the Financial Conflict of Interest Disclosure (FCOID) and submitting it to the ORRC and/or RAS as appropriate, and recertifying the form on an annual basis. **If any changes occur, the PI/PD is responsible for immediately notifying the ORRC and or RAS within (30) days.** The PI/PD shall also assist the ORRC and or RAS to obtain disclosure forms from key project personnel on their project, if necessary, and assists with obtaining verification of disclosure forms from subcontract personnel. If a financial conflict of interest exists, the PI/PD is responsible for working with the AVP-RRC, and other University officials, as necessary, to develop a plan of action to address the conflict of interest.
2. **Key Personnel on the Project** – All key personnel on a sponsored project are responsible for disclosing any **financial conflict of interest** on the Financial Conflict of Interest Disclosure (FCOID). They must complete and submit the form to the ORRC and or OSP/RA, and recertify it on an annual basis. **If any changes occur, the key person is responsible for immediately notifying the ORRC and or RAS as appropriate and the PI/PD.** If a SFI exists, this individual is responsible for working with the AVP-RRC, OGC and other University officials as necessary to develop a plan of action to address the conflict of interest.
3. **All Howard University Investigators Applying to Conduct Sponsored Research:**
  - 3.1 Are required to familiarize themselves with this Policy and identify all SFIs as described herein during all annual or updated FCOID submissions;
  - 3.2 Are required to complete required training at least every four (4) years, and as otherwise required by the University;
  - 3.3 Must file, on at least an annual basis, an FCOID using the ORRC approved disclosure form. Copies of the FCOID are to be retained by the Investigator's department chair. When a new financial conflict of interest develops, the

Investigator must also revise and add new disclosures. This annual disclosure is in addition to the annual FCOID covering outside activities;

3.4 When conducting Sponsored Research, Investigators must:

- i. Submit an updated FCOID within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
- ii. Submit a FCOID no later than the time of application.

**4. Office of Regulatory Research Compliance (ORRC):**

4.1 ORRC Senior Compliance Administrator (SCA) –The ORRC SCA is responsible for overseeing the ORRC compliance staff. If a potential financial conflict of interest is identified, the SCA works with the ORRC staff to collect and forward all information pertinent for the review to the AVP-RRC.

4.2 Associate Vice President for Regulatory Research Compliance – The AVP- RRC shall review the FCOID reports prepared by the SCA to affirm the existence of a financial conflict of interest. When an SFI is identified and a determination is made that a FCOI exists, the AVP-RRC will work with the COIRC to determine what conditions or restrictions, if any, should be imposed by the University to manage, reduce or eliminate the conflict of interest. Upon a final determination, the AVP-RRC will notify the sponsor, if required, that a FCOI has been identified (without disclosing the actual conflict) and inform the sponsor that the conflict has been managed, reduced, or eliminated.

5. **Research Administrative Services (RAS)** – At the time of proposal submission, the PI/PD and Key Personnel are responsible for providing an up-to-date conflict of interest disclosure. When an award is received, and prior to approving the award for set-up, the RAS collects disclosure forms from the PI/PD and all Key Personnel if they have not been previously received during proposal submission. The disclosure forms are routed to the ORRC for review and assessment. If an SFI is disclosed, the ORRC informs RAS and brings the potential conflict to the attention of the AVP-RRC. The ORRC is also responsible for contacting the PI/PD to request that the disclosure be recertified, if necessary. The ORRC maintains records of all FCOIDs filed by PI/PDs and Key Personnel in accordance with 45 CFR 74.53(b) and 92.42(b). Records of financial disclosures and the University’s review of, and/or response to such disclosures, whether or not a disclosure resulted in the University’s determination of an FCOI shall be maintained for at least three (3) years from the date of submission. The primary records will be kept by ORRC with copies made available to RAS for grant submissions.

6. **Office of the University Chief Compliance Officer** – As needed, especially when FCOI in research overlaps with corporate or academic compliance, the AVP- RRC contacts the Chief Compliance Officer to provide assistance on prevailing questions. The Chief Compliance Officer assists the AVP-RRC and the PI/PD to formulate appropriate strategies to manage identified FCOI.

7. **Office of the General Counsel (OGC)** - As needed, the AVP-RRC coordinates with the OGC. The OGC works with the AVP-RRC and as needed, the Chief Compliance Officer, to formulate appropriate strategies to manage identified

financial conflicts of interest. If the AVP-RRC has a conflict, the Office of the General Counsel will work with the COIRC to manage the related conflict.

## **C. Significant Financial Interests and Sponsored Research**

### **1. Overview**

- 1.1 It is expected that Investigators will work with the designated official in a timely manner to create a complete and correct FCOID for institutional review. Unless otherwise specified by the law or regulation, any review required by Howard University shall not be deemed to have started until a complete and correct submission of the FCOID has been provided to the designated official.
- 1.2 Reviewing for SFIs for Financial Conflict of Interest: The designated official may determine if an SFI requires additional review to determine if a financial conflict of interest exists. Prior to funds being spent on a new award, or within sixty (60) days of determining a new SFI requiring a review, the designated official reviewing the SFI shall determine whether financial conflict of interest exists and implement a conflict management plan, at least on an interim basis. The FCOI determination is risk-based and is made according to established guidance.
- 1.3 Determination of need for retrospective review: Only a designated official may make a determination that a retrospective review is required. When required, the institution shall complete a retrospective review. A retrospective review must occur in the following circumstances: failure by the Investigator to disclose an SFI that is determined by the designated official to constitute financial conflict of interest; failure by the institution to review or manage such a conflict; or failure by the Investigator or institution to comply with a financial conflict of interest management plan.
- 1.4 Retrospective reviews: Retrospective reviews are not required for SBIR and STTR Phase I applications.

### **2. Subrecipient Investigators**

- 2.1 Howard University shall incorporate as part of a written agreement with the subrecipient, terms that establish whether the policy of Howard University or that of the subrecipient Institution will apply to the subrecipient Investigator.
- 2.2 Howard University's default position is that a subrecipient Investigator shall comply with the subrecipient's institution's financial conflict of interest policy. In so doing, the subrecipient Investigator shall certify as part of the written agreement that its policy complies with all applicable PHS regulations.
- 2.3 If the subrecipient cannot provide certification confirming the subrecipient Institution's compliance with all applicable PHS policy, the subrecipient agreement shall state that the subrecipient Investigator is subject to the Howard University Policy for disclosing significant financial interests that are directly related to the subrecipient's work for the Howard University Investigator.
- 2.4 Regardless of which policy applies, subrecipient Investigators shall disclose financial conflicts of interest at the initiation of a subagreement, during subagreement renewal and within (30) days of any new SFI.

### 3. Review and Reporting Process

- 3.1 Disclosed **SFIs** will be reviewed prior to acceptance of new and renewal awards, and before submission of progress reports, proposals for supplemental funding, or requests for no-cost time extensions. Investigators may be asked to provide additional information about the SFIs that they previously disclosed. This information will be used by the University to conduct a preliminary review in order to reasonably determine whether any of an Investigator's **SFIs**:
- 3.2 Could be affected by the Research Activity; or
- 3.3 Are in an entity whose financial interest could be affected by the research. If after review by the SCA, it is determined that an **SFI** is related to the proposed Research Activity, a second review will be conducted by the AVP-RRC, and in the case of **an SFI**, by the COIRC to determine whether the SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the Research Activity and thereby constitutes a financial conflict of interest that may need to be managed.
- 3.4 In accordance with the PHS regulations that this Policy is modeled on, plans put into place to manage identified financial conflicts of interest will be monitored for compliance until the completion of the Research Activity. Each management plan will specify the way in which that will be accomplished.
- 3.5 Initial reports of financial conflicts of interest must be made to the PHS or other sponsors prior to the University's expenditure of any funds provided under a Research Activity. The University is not required to submit a report to the sponsor if conflicts of interest are eliminated before research funds are expended.

### 4. Additional financial conflict of interest reports may be submitted to Sponsors under the following circumstances:

- 4.1 Throughout the lifetime of an award when progress reports are submitted, and/or when an award is extended, either through extension notification by or prior approval request of NIH/other sponsor. When during the course of an ongoing Research Activity a financial conflict of interest ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.
- 4.2 Within sixty (60) days of determining that a financial conflict of interest exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing Research Activity.
- 4.3 Within sixty (60) days of determining that a financial conflict of interest exists for an Investigator who joins an ongoing Research Activity.
- 4.4 If during the course of an ongoing Research Activity, the University identifies an SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the designated official will review the SFI within sixty (60) days to determine whether it is related to Research Activities and whether a financial conflict of interest exists. If a conflict is identified after such a review, a management plan must be implemented, at least on an interim basis.

- 4.5 Whenever a financial conflict of interest is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an SFI that was later determined to be financial conflict, or the University did not review or manage the conflict, or because the Investigator failed to comply with a previously implemented management plan, the University must, within one-hundred-twenty (120) days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the Research Activities. The purpose of this retrospective review is to determine if the ongoing Research Activity was biased in its design, conduct or reporting.
- 4.6 Based on the results of the retrospective review, the previously submitted financial conflict of interest report must be updated to specify the actions the University will take to manage the identified conflict.
- 4.7 If bias was found during the retrospective review, the University will promptly notify the sponsor and will draft a mitigation report that, at a minimum, documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the University's plans to eliminate or mitigate the effect of the bias.
- 4.8 If a financial conflict of interest was later found in a funded study assessing the safety or effectiveness of a drug, medical device or treatment, the Investigator is required to disclose the conflicting interest in each public presentation of the results of the research and provide an addendum to any previous presentations.

**D. Access and Retention of Records**

PHS regulations require that the University provides a written response within five (5) business days to any request for information about SFIs held by Key Personnel when the University has determined that the disclosed SFIs are related to Research Activities or other Sponsored Research and constitute financial conflicts of interest.

Information provided in the FCOID may be released or transmitted to the sponsor upon request. Completed FCOIDs also may be released in response to a public records request, pursuant to the terms of the Freedom of Information Act, if applicable.

Records of financial disclosures, designated officials' determinations, COIRC recommendations, and University actions regarding management of a financial conflict of interest will be retained for at least three (3) years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by the sponsor involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

**E. Training**

Each Investigator, including collaborators, consultants or subcontractors, must complete NIH-compliant training (CITI Financial Conflict of Interest Modules) about the University's Financial Conflict of Interest Policy prior to engaging in research related to any Sponsored Research project and at least every four (4) years thereafter, while receiving Sponsored Research funding, and at other times as may be required by the University in accordance with pertinent regulations. For those who are joining an ongoing Research Activity at Howard University, alternative previously completed training will be accepted for the first year. Subsequently, such Investigators must complete the Howard University approved CITI

financial conflict of interest modules within one (1) calendar year. Those already on faculty but who are newly funded Investigators must complete the CITI financial conflict of interest modules prior to initiating Research Activities.

#### **F. Related Processes and Events**

1. Proposal Development, Processing, and Submission Policy
2. Award Acceptance & Set-up Policy
3. Sponsored Programs Records Retention Policy
4. Research Compliance application (IRB, IACUC, IBC) submitted to the ORRC

### **VI. INTERIM POLICIES**

The Research Administrative Services Policy Number 600-002, effective as of April 3, 2007 and last updated on March 10, 2010, which served as the Interim Policy on Conflict of Interest in Research, shall be superseded by this Policy.

### **VII. SANCTIONS**

In cases of noncompliance with this Policy by anyone to whom this Policy applies, appropriate sanctions will be imposed, including inability to draw-down on research funds or withholding of IRB, IACUC, or IBC approval. In addition, the noncompliant individuals will be subject to disciplinary action in accordance with the Faculty Handbook, the Employee Handbook, and other University policy, as applicable, up to and including termination.

### **VIII. HYPERLINKS**

[www.howard.edu/policy](http://www.howard.edu/policy)

ORRC Website <http://www.howard.edu/orrc>

Title [42 CFR Part 50](#) and [Title 45](#) (Definitions: [42 CFR Part 50.603](#) and [45 CFR Part 94.3](#))

Funded Research and Educational Activities (Form CI-1 – <http://www.howard.edu/orrc>)

Financial Conflict of Interest Disclosure (Form -- <http://www.orrhoward.com/Financial-Conflict-of-Interest.html>)

Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests - <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html>