Sponsored Programs Conflict of Interest Policy

Policy Number: 600-002  
Effective Date: April 3, 2007  
Last Updated: March 10, 2010  
Issuing Authority: Vice President for Research and Compliance  
Responsible Offices: Office of Sponsored Programs/Research Administration and Office of the General Counsel

Purpose:
To outline the requirements of the Conflict of Interest disclosure and the management of conflicts of interest related to sponsored programs 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 “Howard University”). The Conflict of Interest disclosure is designed to identify interests on the part of personnel involved in sponsored programs that could bias, or give the appearance of biasing, the design, conduct and reporting of a sponsored project, so that a conflict can be appropriately managed, reduced, or eliminated.

Policy:
It is the policy of Howard University to comply with federal guidelines regarding the disclosure of conflicts of interest in sponsored research and to manage, reduce, or eliminate any conflicts of interest that are identified.

Definitions:

Conflict of Interest – means a significant financial interest (i) that would reasonably appear to be affected by the research for which extramural funding is sought, (ii) in entities whose financial interests would reasonably appear to be affected by the research.

Investigator – means the principal investigator and any other person (including subgrantees, contractors, collaborators and co-principal investigators) who are responsible for the design, conduct, or reporting of research funded by extramural sources, or proposed for such funding. For the purpose of defining significant financial interest in this Policy, “Investigator” includes the Investigator’s Affiliated Persons (as defined below).

Significant Financial Interest – means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The terms does not include (i) salary, royalties or other remuneration from Howard University, (ii) income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities; (iii) income from service on advisory committees or review panels for public or nonprofit entities; (iv) an equity interest that when aggregated for the Investigator and the Investigator’s Affiliated Persons meets both of the following tests: (a) does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; AND (b) does not represent more than a five percent ownership interest in any single entity; (v) salary, royalties or other payments that, when aggregated for the Investigator and the Investigator’s Affiliated Persons over the next twelve months, are not expected to exceed $10,000.
Affiliated Persons – means an immediate family member, close personal acquaintance, and others living within such person’s household. A close personal acquaintance will be deemed to exist when a business or social relationship between individuals is such that a neutral observer could reasonably conclude that a transaction in which both individuals participate may either: (a) be affected in whole or in part by factors extraneous to the merits, or (b) have the appearance of being influenced by such extraneous factors.

Business Process Description:

Howard University requires Principal Investigator/Project Directors (PI/PDs) and key personnel who participate in externally funded sponsored projects to complete a Conflict of Interest disclosure with each proposal/continuation and renewal submission.

Federal law requires that institutions performing Public Health Service (“PHS”) or National Science Foundation (“NSF”) funded research must adopt and enforce certain policies on conflicts of interest. These policies must be consistent with regulatory requirements found in Titles 42 and 45 of the Code of Federal Regulations. The Conflict of Interest disclosure 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.

PI/PDs and key personnel complete a Conflict of Interest disclosure prior to submitting a proposal or award continuation for external funding; and they update it on an annual basis or any other time that they acquire new significant financial interests. The Conflict of Interest disclosure includes:

- The Certification of Conflict of Interest disclosure Statements for Extramurally Funded Research and Educational Activities (Form CI-1 – [http://ovprca.howard.edu](http://ovprca.howard.edu)).

- Form CI-1 is submitted to the Office of Sponsored Programs/Research Administration (OSP/RA) with the proposal submission materials, and annually with the request for additional funds on multi-year awards. OSP/RA forwards a disclosure of potential conflict to the Vice President for Research and Compliance (VPRC) for a determination of whether a conflict of interest exists in conjunction with Howard University’s General Counsel as appropriate. If no conflict of interest exists, or no potential conflict of interest is disclosed, the Research Administrator (RA) files the CI-1 Form in the program files.

If it is determined that a conflict of interest exists, the VPRC works with the PI/PD and other university officials to determine the best course of action. Action may include, but is not limited to:

- Funds will not be released for use or the award will 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).
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- Subsequent conflicts of interest identified for the same award must be reported to the satisfaction of the VPRC and must be managed, reduced or eliminated, at least on an interim basis, within sixty (60) days.

- 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 VPRC after consultation with the General Counsel.

- The VPRC is responsible for making the final decision as to what 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.

- Conditions or restrictions that may be imposed on a PI/PD or project to manage or eliminate 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

Roles and Responsibilities:

Academic Department

- **Principal Investigator/Project Director (PI/PD):** The PI/PD is responsible for disclosing any financial conflict of interest on a sponsored project by completing and submitting the Certification of Conflict of Interest disclosure Statements for Extramurally Funded Research and Educational Activities Form to OSP/RA, and recertifying the form on an annual basis. **If any changes occur, the PI/PD is responsible for immediately notifying OSP/RA.** The PI/PD also assists OSP/RA 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 VPRC, and other University officials, as necessary, to develop a plan of action to address the conflict of interest.

- **Key Personnel on the Project:** All key personnel on a sponsored project are responsible for disclosing any financial conflict of interest on the Certification of Conflict of Interest disclosure Statements for Extramurally Funded Research and Educational Activities Form. They must complete and submit the CI-1 Form to OSP/RA, and recertify the form on an annual basis. **If any changes occur, the key person is responsible for immediately notifying OSP/RA and the PI/PD.** If a financial conflict of interest exists, this individual is responsible for working
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with the VPRC, and other University officials, as necessary, to develop a plan of action to address the conflict of interest.

Office of the Vice President for Research and Compliance

- **Vice President for Research and Compliance (VPRC):** The VPRC is responsible for reviewing the CI-1 Forms that have a potential conflict of interest disclosed, consulting with the General Counsel and other University officials, as necessary, and making the final decision as to what conditions or restrictions, if any, should be imposed by the University to manage, reduce or eliminate the conflict of interest. The VPRC also notifies the sponsor, if required, that a conflict of interest has been identified (without disclosing the actual conflict) and informing the sponsor that the conflict has been managed, reduced, or eliminated.

Office of Sponsored Programs/Research Administration (OSP/RA)

- **Research Administrator (RA):** At the time of proposal submission, the RA is responsible for notifying the PI/PD and any key personnel who do not have an up-to-date Conflict of Interest disclosure on file. When an award is received, prior to approving the award for set-up, the RA collects disclosure forms from the PI/PD and all key personnel if they have not been previously received during proposal preparation and submission. If a potential financial conflict of interest is disclosed, the RA is responsible for bringing it to the attention of the OSP/RA Manager for potential referral to the VPRC. The RA is also responsible for contacting the PI/PD to request that the disclosure be recertified, if necessary. The RA maintains records of all CI-1 forms filed by PI/PDs and key personnel in accordance with the VPRC’s Records Retention Policy. All correspondence and other documentation, such as any restrictions imposed by the VPRC, are retained with the disclosure forms for the same period of time.

- **OSP Manager:** The OSP Manager is responsible for overseeing the RAs. If a potential Conflict of Interest is identified, the OSP Manager works with the RA to collect and forward all information pertinent for the review to the VPRC.

Office of the General Counsel

- **General Counsel:** If a plan of action to address financial conflict of interest has legal ramifications, the VPRC contacts the General Counsel to review the plan and provide assistance with any legal questions that may arise. The University Compliance Officer is the General Counsel of the University. As the Compliance Officer, the General Counsel works with the RA and the PI/PD to coordinate the collection and recertification of disclosure forms when needed.

**Related Processes/Events:**

- Proposal Development, Processing and Submission Policy
- Award Acceptance & Set-up Policy
- Sponsored Programs Records Retention Policy

**Forms and Links:**

- OVPRC Website [http://ovprc.howard.edu](http://ovprc.howard.edu)
- Titles 42 and 45 of the Code of Federal Regulations