Adelphi University Research Financial Conflict of Interest Policy

Adelphi University supports its faculty in pursuing research for the public good. To ensure the highest quality research free from bias and financial conflict of interest (FCOI), the university has designed and implemented the following policy based upon federal guidelines. This policy applies to all Adelphi University faculty, staff and students engaged in federally funded research.

I. Background

Ensuring objectivity in research has always been a concern to the research community and universities. One of the keys to ensuring the public interest and our best research is to manage possible FCOIs. Originally passed in 1995, and revised in August, 2011, the Public Health Services documents Responsibility for Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors is the most comprehensive federal regulation regarding FCOIs. It requires institutions to reasonably ensure that Public Health Service-funded research is free from bias resulting from Investigator FCOI. For more information including this policy, AU’s FCOI form, educational materials, and NIH requirements, please see http://administration.adelphi.edu/osp/.

II. Definitions

1. A “Financial Conflict of Interest” (FCOI) exists when an Investigator’s Significant Financial Interest (SFI), as defined below in II.2, is related to a federally-funded research project and could directly and significantly affect the design, conduct or reporting of the research. For example, if an investigator owns a large amount of stock of a company whose medical device he or she is testing in a federally-funded clinical trial, the stock ownership creates a FCOI. The existence of a FCOI for an Adelphi University-affiliated Investigator will be determined by the Director of the Office of Research and Sponsored Programs at Adelphi University, in accordance with the guidelines given here and in consultation with the Provost or her designee.

2. a. “Significant Financial Interests” (SFI) are defined as any of the following financial interests of the Investigator (and the Investigator’s spouse and dependent children) that reasonably appear to be related to an Investigator’s institutional responsibilities:
   i. Compensation received from a publicly-traded entity in the previous 12 months, and/or any equity interest in such a publicly-traded entity, that together exceed $5,000. Compensation may include salary, honoraria, consulting fees, and paid authorships.
   ii. Compensation received from a non-publicly-traded entity in the previous 12 months that exceeds $5,000, and any amount of equity held in a non-publicly traded entity.
   iii. Intellectual property rights and interests such as patents or copyrights, upon receipt of income related to such rights and interests.

   b. Additionally, non-reimbursed or sponsored travel may represent a Significant Financial Interest and must be disclosed. Such travel is paid on behalf of the Investigator and its exact monetary value may not be readily available. This does not include travel that is reimbursed by a federal, state or local government agency, an institution of higher education, a medical center, etc. The information disclosed to Adelphi must include the purpose of the trip, the identity of the sponsor/organizer and of those affiliated with the Investigator who traveled, the destination, and the duration (see non-included travel defined below.) Based on this information,
Adelphi may determine an approximate monetary value of the travel and the Director of the Office of Research and Sponsored Programs, in consultation with the Provost if necessary, will determine if a Significant Financial Interest exists.

c. Significant Financial Interests do not include the following:

i. Salary, royalties and other remuneration from the University, where the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights.

ii. Income from seminars, lectures, or teaching engagements and service on advisory committees or review panels for a federal, state or local government agency, an institution of higher, medical center, or research institute affiliated with an institution of higher education.

iii. 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.

iv. Travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

v. Compensation received from a publicly-traded entity in the previous 12 months, and/or any equity interest in such a publicly-traded entity, that together is $5,000 or less. Value shall be determined through reference to public prices or other reasonable measures of fair market value.

vi. Compensation received from a non-publicly-traded entity in the previous 12 months that is $5,000 or less. Any equity interest in a non-publicly traded entity shall be considered a Significant Financial Interest.

3. “Investigator” means the principal investigator or program director and any other person, regardless of title or position and including collaborators and consultants, who is responsible for the design, conduct or reporting of federally-funded research or proposed for such funding, “Investigator” does not include the spouse and dependent children of investigators, but as indicated above their Significant Financial Interests must also be disclosed.

4. “Research and Other Sponsored Projects” means any internally or externally funded research, training or professional service project conducted at or under the auspices of Adelphi University. However, for this policy, research and other sponsored projects refers to federally funded programs only.

5. “Management Plan” refers to the implementation of a plan to minimize the risk of bias in the design, conduct and reporting of the research, should a FCOI be determined.

6. “Subrecipients” are other institutions or other personnel involved in an Adelphi federal grant or contract through an Adelphi specified subcontract. These other institutions or investigators are required to comply with Adelphi’s FCOI policy as described in this document.
III. Guidelines and Procedures
A. Investigator Responsibilities
1. Investigators are responsible for knowing about and complying with university policies and procedures and federal regulations regarding FCOI, as described in the following sections.

2. An Investigator who is applying for funds for a federal grant or project must, prior to submission of the proposal and as a condition of receiving Adelphi University approval of the proposal submission, complete a Significant Financial Interest Disclosure form for him/herself, his/her spouse, and his/her dependent children and submit the completed form to the Director of the Office of Research and Sponsored Programs (Dr. Mary Cortina, cortina@adelphi.edu, Social Work Building, Room 119).

3. A current Investigator of a federally funded grant or project must do the following as a condition of Adelphi University’s continued support and administration of the grant or project:
   a. Complete FCOI training through the Office of Research and Sponsored Programs as follows:
      i. Prior to engaging in research related to any federally-funded grant or project (although Investigators are encouraged to complete FCOI training at the time of funding application in order to be able to complete the SFI Disclosure form most accurately);
      ii. At least once every 4 years;
      iii. Immediately, if Adelphi revises its FCOI policy in a way that affects Investigators, if an Investigator is new to Adelphi, or if the Investigator is found to be not in compliance with the FCOI policy or management plan.
      iv. A link to online training is available at http://administration.adelphi.edu/osp/. Please complete this training and send the completion certificate to cortina@adelphi.edu
   b. Complete a Significant Financial Interest Disclosure form for him/herself, his/her spouse, and his/her dependent children annually (by September 1st) during the period of the award, and within 30 days of discovering or acquiring a new Significant Financial Interest, and submit it to the Office of Research and Sponsored Programs as described above in III.A.2.

B. University Responsibilities
1. The university is responsible for establishing an appropriate FCOI policy (this document), informing Investigators about FCOI, training Investigators in FCOI, monitoring FCOI compliance, maintaining FCOI records, and reporting FCOI to federal agencies whose funds are supporting Investigators’ research, as described in the following sections.

2. The person responsible for dissemination and implementation of this policy at Adelphi is the Director of Adelphi’s Office of Research and Sponsored Programs (hereafter called the “Director of ORSP”). Adelphi’s Provost may designate another individual to fulfill this responsibility.

3.a. The Director of ORSP will inform all Adelphi-affiliated individuals who seek to submit applications for federal funding of projects or research through Adelphi (i.e. new and potential Investigators) that to ensure compliance with federal regulations, Adelphi will require the new and/or potential Investigators, in order to receive Adelphi’s official approval and support for such applications for funding, to submit a completed Significant Financial Interest Disclosure form on
behalf of him/herself, his/her spouse, and his/her dependent children to Adelphi’s Office of Research and Sponsored Programs.

b. The Director of ORSP will also encourage these new and/or potential Investigators to complete FCOI training through Adelphi’s Office of Research and Sponsored Programs before submission of the applications for funding.

4. The Director of ORSP will inform all Adelphi-affiliated Investigators with ongoing federal funding of research or projects (i.e. continuing Investigators) that, to ensure compliance with federal regulations, each Investigator must do the following in order to receive Adelphi’s continued support and administration of such ongoing federally-funded grants or projects:
   a. Complete FCOI training through the Office of Research and Sponsored Programs prior to engaging in federally-funded research, at least every 4 years, and immediately if Adelphi revises its FCOI policy relative to Investigators, if an Investigator is new to Adelphi, or if an Investigator is found not to be in compliance with the policy or management plan.
   b. Complete and submit to the Office of Research and Sponsored Programs a Significant Financial Interest Disclosure form by the time of submission of an application for federal funds for a research or project, at least annually during the period of an award, and within 30 days of discovering or acquiring a new Significant Financial Interest.

5. The FCOI training provided through Adelphi’s Office of Research and Sponsored Programs includes information on Adelphi’s FCOI policy, on Investigator’s disclosure responsibilities, and on federal FCOI regulations.

6. SFI Review and FCOI Determination
   a. Review of SFI Disclosure forms, determination of FCOI, and additional actions described in part 6.b below will take place in the following situations:
      i. Before Adelphi spends federal funds for grants or projects awarded to an Adelphi-affiliated Investigator;
      ii. When a new Investigator participates in a research project;
      iii. When an existing Investigator discloses a new SFI;
      iv. If Adelphi identifies an SFI that was not disclosed in a timely manner by an Investigator or not previously reviewed by Adelphi.

   b. In the situations described in 6.a above, the Director of ORSP will do the following (for situation 6.a.iv, within 60 days):
      i. Review all Investigator SFI Disclosure forms in accordance with this policy and with federal regulations and guidelines.
      ii. Determine if any Investigator SFIs relate to federally-funded research.
      iii. Determine if an FCOI exists, i.e. a SFI that could directly and significantly affect the design, conduct or reporting of the federally-funded research or project.
      iv. If an FCOI does exist, develop and implement a management plan.
      v. Monitor Investigator compliance with the management plan, including that of any subrecipient Investigators, until completion of the project.
7. Reporting to Federal Agencies
   a. The Director of ORSP is responsible for timely submission of proper FCOI reports to federal agencies such as NIH and NSF in accordance with their respective regulations.
   b. For NIH-funded projects at Adelphi, the Director of ORSP will submit to the NIH all initial, annual (i.e. ongoing) and revised FCOI reports including all the required reporting elements for Adelphi and any subrecipients at the following times:
      i. Prior to the expenditure of funds;
      ii. Within 60 days of identification of an FCOI for an Investigator who is newly participating in the project;
      iii. Within 60 days for new FCOIs or newly identified FCOIs for existing Investigators;
      iv. For ongoing projects, at least annually (at the same time as the submission of required annual progress reports on the project, or at the same time as the submission of a multi-year progress report, if applicable, or at time of extension). In such cases, the status of the FCOI and any changes to the management plan will be submitted, until the completion of the project.
      v. Following a retrospective review, to update a previously submitted report.
   c. For NIH-funded projects at Adelphi, the Director of ORSP will promptly notify NIH (within 30 days, sooner if possible), will submit a Mitigation Report if appropriate, and will promptly take corrective action in the following circumstances:
      i. If bias is found with the design, conduct or reporting of NIH-funded research conducted by an Adelphi-affiliated Investigator.
      ii. If an Investigator fails to comply with Adelphi’s FCOI policy or an FCOI management policy.
      iii. If an FCOI management plan appears to have biased the design, conduct or reporting of NIH-funded research conducted by an Adelphi-affiliated Investigator.
         The Director of ORSP is responsible for ensuring that all reporting elements required by the regulation are included.

8. Maintenance of Records
   The Director of ORSP is responsible for maintaining all FCOI-related records for at least 3 years from the date that a final expenditures report for the project or research is submitted to the federal funding agency.

9. Enforcement Mechanisms and Remedies and Noncompliance
   a. Federal regulations require the university to take appropriate administrative actions to ensure compliance with this policy and with federal FCOI regulations. The Director of ORSP will report to the University’s Provost any real or potential FCOI and any instance of non-compliance with this policy or with an FCOI management plan relevant to a federally-funded project or research awarded to an Adelphi-affiliated Investigator. The Provost will render a decision regarding the specific actions that need to be taken. Adelphi maintains the right to impose sanctions consistent with the Collective Bargaining Agreement (“CBA”) between the University and the Adelphi chapter of the American Association of University Professors for failure to disclose FCOI, for failure to comply with this policy, or for failure to comply with an FCOI management plan relevant to a federally-funded project or research award. Such sanctions could
include restrictions on future research submissions or other appropriate actions consistent with the CBA.

b. If it is determined that this policy has not been properly complied with, including proper and timely SFI disclosure or proper and timely FCOI identification or management, the Director of ORSP will complete and document within 120 days a retrospective review, which will be submitted to the Provost. Following a retrospective review, an update must be submitted to the relevant federal agency as in 7.b.v above.

c. In the specific case that an NIH-funded clinical research project evaluating the safety or effectiveness of a drug, medical device, or treatment was designed, conducted or reported by an Investigator with an FCOI that was not managed or reported by Adelphi as required, the Investigator is required to disclose the FCOI in all public presentations of the research and is also required to request an addendum disclosing the FCOI to the relevant previously published articles or presentations.

10. Subrecipient Responsibilities
As noted above, Adelphi University’s FCOI also applies to subrecipients (subgrantee/subcontract.) The subcontractor may either complete AU’s online training and submit FCOI forms to the Director of the ORSP or the institution must certify in writing to the Director of the ORSP director that it has its own FCOI policies in keeping with federal guidelines and that compliance with these FCOI policies has been obtained. These documents will be kept by the Director of ORSP. Investigators who are affiliated with or employed by an institution of higher education, medical center, academic teaching hospital or research institute or other institution without a Financial Conflict of Interest Policy must complete Adelphi University’s training and submit Adelphi University’s FCOI forms. The subcontractor must disclose how it will comply with federally mandated FCOI regulations and provide the necessary documents to Adelphi University with the signed subcontract agreements before the expenditure and transfer of any funds.

11. Public Accessibility of FCOI Information
Adelphi University is committed to transparency in its research endeavors. To meet this goal, this FCOI policy will be posted on the Adelphi ORSP Web site. Also, any identified FCOI relevant to the institutional responsibilities of a federally-funded Investigator, Investigator’s spouse or dependent children, key members of the research team (as defined above under Investigator and subrecipient), will be posted on the ORSP Web site and updated on an annual basis. Information about newly identified FCOI will be updated on the ORSP Web site within 60 days of identification. Information about identified FCOIs will remain available on the ORSP Web site for 3 years from the most recent date that the information was updated. In addition, FCOIs will be made available upon written request within five working days of receipt of that request. All reasonable attempts to provide updates of FCOIs will be made.

This policy was developed by Dr. Mary Cortina, Director of Adelphi’s Office of Research and Sponsored Programs, and Dr. Lawrence Hobbie, Associate Provost, using resources from the
NIH and Haverford College, and reviewed by Dr. Gayle Insler, Provost, and Ms. Maryanne Panebianco, Director of Internal Audit at Adelphi University. 
Approved by the Provost, August, 23, 2012