College Policy on Financial Conflict of Interest Pertaining to Public Health Service and the National Institutes of Health Sponsored Projects

The teaching, research, and service mission of Agnes Scott College (ASC) must be conducted in an objective manner, free from undue influence arising from private or other special interests. The purpose of this policy is to establish guidelines for recognizing, disclosing, and managing significant financial conflicts of interest in relation to Public Health Service and the National Institutes of Health sponsored research. The policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from financial conflicts of interest. This policy operates in conjunction with other College policies governing conflicts of interest.

This policy sets forth procedures and guidelines that are to be followed in resolving actual and potential conflicts of financial interest related to research sponsored by the Public Health Service and the National Institutes of Health.

The College, its employees, and the public often benefit from the employee's participation in both public and private outside activities. The College has no interest in setting forth detailed rules that may interfere with the employee's legitimate outside interests. Employees, however, must ensure that their outside obligations, financial interests, and activities do not conflict or interfere with their commitment to the integrity of the research, the Public Health Service, the NIH, and the College. This obligation pertains to both full-time and part-time employees.

1. General Principles:
   A. Employees must arrange their financial interests so as not to impede or conflict with their duties and responsibilities to ASC.
   B. All employees must notify the College of potential conflicts of interest, and employees may not maintain unacceptable conflicts of interests.
   C. No person employed by the College may have interests incompatible with the College.
   D. Employees must disclose potential financial conflicts of interest that could affect the design, conduct, or reporting of PHS/NIH funded research.

2. Definitions:
   A. **Conflict of Interest** means a state of affairs in which an investigator or his or her immediate family has significant financial interests that could lead an independent observer to reasonably question whether the design, conduct, or reporting of PHS/NIH-funded research might be influenced by the possibility of financial gain.
   B. **Immediate family** means an investigator’s spouse, domestic partner, and anyone who receives directly or indirectly, more than one half of his or her support from the investigator or from whom the investigator receives, directly or indirectly, more than one half of his or her support.
   C. **Investigator** means the project director or any other person regardless of title who is responsible for the design, conduct, or reporting of research funded by the PHS/NIH, which may include collaborators, subcontractors, and consultants.
D. **Institutional Responsibilities** means an investigator’s professional responsibilities on behalf of ASC, including research, research consultation, teaching, professional practice, and College committee membership.

E. **Significant Financial Interest** means one or more of the following interests of the investigator and those of his/her immediate family that reasonably appears to be related to the investigator’s institutional responsibilities:

   i. A significant financial interest exists if the value of any remuneration received from any publicly traded entity in the 12 months preceding the disclosure and the value of any equity interest in the entity totals to exceed $5000. Remuneration includes salary and any payment for services not otherwise identified as salary as well as equity interest including stock, stock option or ownership interest. In regard to non-publicly traded entities, a significant financial interest exists if the value of remuneration exceeds $5000 or when the investigator and his/her family hold any equity interest or any intellectual property rights and interests. Note that there is no minimum value for equity interest in non-publicly traded entities.

   ii. A significant financial interest includes any reimbursed or sponsored investigator travel related to his or her institutional responsibilities. Reimbursed or sponsored travel includes travel which is paid on behalf of the investigator but not reimbursed directly to the investigator.

The following are excluded from the definition of significant financial interests:

   a. salary, royalties or other remuneration paid by ASC to the investigator for appropriate grant activity;

   b. intellectual property rights assigned to ASC and agreements to share royalties related to those rights;

   c. 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;

   d. income from seminars, lectures or teaching engagements sponsored by ASC or some other federal, state, or local agency or institution of higher education or academic hospital, medical center or research institute affiliated with a college;

   e. income from service to advisory committees or review panels associated with the same agencies identified in item 4 above.

3. Financial Disclosure:
ASC must report promptly to the PHS/NIH any conflicts of interest ASC has identified, including those of its subrecipients and subcontractors, and provide assurance that the interests have been managed prior to expending any funds under a PHS/NIH award if:

   - bias is found with the design, conduct or reporting of PHS/NIH-funded research
   - an Investigator fails to comply with ASC’s FCOI policy or a FCOI management plan
   - a FCOI management plan appears to have biased the design, conduct, or reporting of the funded research.

4. Procedures
Procedures for this policy will be managed by the Office of Sponsored Programs in compliance with all state and federal rules and regulations. These procedures may be revised by the Office of Sponsored Programs as necessary.
5. Training
Each investigator must complete FCOI training prior to engaging in research related to any PHS/NIH funded project. Investigators must complete training every four years and immediately when any of the following occurs:

- the investigator is new to ASC
- ASC finds the investigator noncompliant with its policy or a management plan
- the ASC policy changes in a manner that significantly affects requirements.

6. Record Keeping
The College must maintain FCOI-related records for at least three years after the termination of the activity (date of the final financial report and progress report to the funding agency). Records will be maintained by the Office of Sponsored Programs.

7. Sanctions
Charges of violations of this policy shall be carefully examined. Charges shall be processed in the normal reporting channels. Disciplinary sanctions may range from reprimands to dismissal. When the Department of Health and Human Services determines that a PHS/NIH-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by ASC as required by regulation, the Investigator shall:

- disclose the FCOI in each public presentation of the results of the research
- request an addendum to previously published presentations.

This policy was developed in response to U.S. Department of Health and Human Services requirements published in 42 CFR part 50, Subpart F and applies only to projects funded by PHS granting agencies.