

## FINANCIAL CONFLICT OF INTEREST AND OBJECTIVITY IN RESEARCH

### I. PURPOSE

Monmouth University believes that it is vital to maintain objectivity in research and that all research must be conducted with the highest scientific and ethical standards and in a manner that assures the integrity of the scientific record. The purpose of this policy is to ensure that there is a reasonable expectation that the design, conduct, or reporting of research will not be biased by any financial interest of an investigator.

### II. PROCEDURES

Each investigator applying for external funding must, at the time the proposal is being submitted, provide and submit to the designated institutional official, full disclosure of all significant financial interests, and those of his/her spouse/domestic partner and/or dependent children, that would reasonably appear to be potentially affected by the research or program for which funding is being sought. Furthermore, Investigators must update the disclosures for the duration of the funding, at least once yearly or as new reportable significant financial interests are maintained.

If Monmouth University is carrying out external funded research through a grantee, contractor, or collaborator, Investigators working for such entities must comply with this policy and provide written assurances to Monmouth University identifying conflicting interests and which actions will be taken to ensure that the conflicting interests will be managed, reduced or eliminated.

It is ***strongly recommended*** that every investigator interested in or about to apply for external funding access take the NIH web based financial conflict of interest tutorial at <http://grants.nih.gov/grants/policy/policy.htm>

#### A. DEFINITIONS:

- 1. Disclosure of Significant Financial Interest** means an Investigator's disclosure of significant financial interests to Monmouth University.
- 2. Financial Conflict of Interest (FCOI)** means a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of federally funded research.
- 3. FCOI report** means Monmouth University's report of a financial conflict of interest to either a PHS Awarding Component or other federal organizational unit that funds the research.
- 4. Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.
- 5. Federal Awarding Component** means the organizational unit of a federal department or agency that provides federal funding through a grant or cooperative agreement

- 6. Investigator** means the project director (PD) or the principal Investigator (PI), co-principal investigator (Co-PI), or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or educational activities federally funded or proposed for funding, which may include, for example, collaborators or consultants. **Note: Significant financial interests of spouses/domestic partners and dependent children must also be disclosed.**
- 7. Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as research ethics committees ( e.g., Institutional Review Boards, Institutional Animal Care and Use Committees) and other bodies monitoring the conduct of research.
- 8. Manage** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.
- 9. Management Plan** means the prospective plan for financial conflict of interest mitigation.
- 10. Mitigation Report** means a retrospective report for financial conflict of interest compliance with a federal funding agency/sponsor's requirements.
- 11. PD/PI** means project director or principal Investigator of a federally funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.
- 12. Research** means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a federal Awarding Component through a grant or cooperative agreement, whether authorized under the Public Health Service (PHS) Act (42 U.S.C. 201 et seq.) or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- 13. Senior/Key personnel** means the PD/PI and any other person identified as senior/key personnel by Monmouth University in the grant application, progress report or any other report submitted to the Federal Funding Agency by Monmouth University.
- 14. Significant Financial Interest** means:

  - (a) A significant financial interest exists if the following situations apply to the Investigator and/or the Investigator's spouse, domestic partner and dependent children, involving companies that reasonably appear to be related to the proposed research:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated exceeds **\$5,000.00**. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregate exceeds **\$5,000.00**, or when the Investigator or the Investigator's spouse, domestic partner or dependent children hold any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(b) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institution's responsibilities, provided however, that this disclosure requirement does not apply to 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. Investigators must disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. Monmouth University's Designated Officials will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the federally funded research.

(c) The term **significant financial interest does not include** the following types of financial interests:

(i) Salary, royalties or other remuneration paid by Monmouth University to the Investigator if the Investigator is currently employed or otherwise appointed by Monmouth University, including intellectual property rights assigned to Monmouth University and agreements to share in royalties related to such rights;

(ii) Any ownership interest in an Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; income from seminars, lectures, or teaching engagements sponsored by a Federal, state or local government agency, and Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for 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.

**11. Subrecipient** means any Investigator outside the Monmouth University community receiving research funds from Monmouth University through subaward, subcontract, or consortium agreement.

## **B. FINANCIAL CONFLICT OF INTEREST DISCLOSURE FORM**

### **a. Disclosure Requirements**

No later than the time of application for submission of a grant to a federal agency, all participating investigators are required to fill out and submit a FCOI form to the Director of OGAC with the OGAC Routing Sheet which will be reviewed by the Director of OGAC (and if a conflict is noted, by the FCOI Review Team). In addition, all investigators must submit an updated FCOI form annually during the period of the award (by deadlines established by OGAC) to include any information that was not disclosed previously to Monmouth University, and to include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of previously disclosed equity interest). Any newly discovered or acquired significant financial interest (e.g., through purchase, marriage, or inheritance) must be disclosed within thirty days.

### **b. Subcontracts**

If the federally funded research involves a subrecipient (e.g. subcontractors or consortium members), Monmouth University (as the awardee institution) will take reasonable steps to ensure that any recipient investigator complies with the federal policies by:

- i. Establishing in writing with the subrecipient whether the financial conflicts of interest policy of MU or that of the subrecipient will apply to the subrecipient's investigators.
  - a. If the subrecipient's investigators must comply with the subrecipient's financial conflict of interest policy, the subrecipient shall certify that its policy is in compliance with federal policies. In the absence of this certification, the agreement will state that subrecipient investigators are subject to the financial conflicts of interest policy of Monmouth University for disclosing significant financial interest that are directly related to the subrecipient's work for Monmouth University.
  - b. Additionally, if the subrecipient's investigators must comply with the subrecipient's financial conflicts of interest policy, the written agreement will specify a deadline for the subrecipient to report all identified financial conflicts of interest to Monmouth University so that Monmouth University can provide timely FCOI reports, as necessary, to the relevant federal agency.
  - c. Alternatively, if the subrecipient's Investigators must comply with Monmouth University's financial conflict of interest policy, the written agreement will specify a deadline for the subrecipient to submit all Investigator disclosures of significant financial

interest to Monmouth University so that Monmouth University can provide timely FCOI reports, as necessary, to the relevant federal agency.

- ii. Providing FCOI reports to the federal agency regarding all financial conflicts of interest of all subrecipient investigators consistent with this policy, i.e., prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

## **C. REVIEW OF FCOI AND MANAGEMENT OF CONFLICTS**

### **1. Initial Review**

The initial review of the Financial Conflict of Interest Disclosure Form shall be done by the Director of the Office of Grants and Contracts (OGAC). An Investigator's significant financial interest is related to federally funded research when Monmouth University determines that the significant financial interest:

- a. Could be affected by the research, or
- b. Is in an entity whose financial interest could be affected by the research.

A FCOI exists when Monmouth University reasonably determines that the significant financial interest could directly and significantly affect the design, conduct or reporting of the federally funded research. At the time of the submission of a grant to a federal agency, all participating investigators are required to fill out and submit a FCOI Form along with a proposal and the Internal Approvals for Grant or Contract Proposals (OGAC Routing Sheet). If the Director of OGAC determines that no potential conflict of interest is revealed or indicated, the Director of OGAC shall approve the Financial Conflict of Interest Disclosure Form and forward it appropriately. If there is any indication of a potential conflict of interest, the Director of OGAC shall notify and confer with the Financial Conflict of Interest Review Team.

### **2. Financial Conflict of Interest Review Team**

(a) The University designates the following officials as the review team:

- i. Director of the Office of Grants and Contracts
- ii. Representative of the Office of the General Counsel
- iii. Representative of the Controller's Office

(b) The designated officials will review the financial disclosure and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate the conflict.

### **3. Conflict Management Plan**

(a) The University's designated officials may determine that it is in the best interest of the Investigator and the University to jointly develop and agree to a conflict management plan prior to the expenditure of any grant funding, and to then monitor compliance with the plan. The conflict management plan will include all actions, restrictions, and conditions,

including timelines, that the Investigator will be required to take to manage or eliminate the conflict. **All conflicts of interest must be resolved and management plans approved before the research project can begin.**

(b) If a disclosure of a new conflict arises or the discovery of an undisclosed conflict is uncovered, the FCOI Review Team will review and make recommendations within 60 days of the new conflict disclosure or unreported disclosure recovery.

(c) The FCOI Review Team will review all of the submitted material and either accept or suggest modifications to further eliminate the conflict. This could involve, at either the Review Team's request or at the Investigator's request, a meeting with the Review Team, involving the Department Chair, School Dean, or Provost as needed. Expert opinions may also be sought by the Review Team.

(d) Examples of conditions or restrictions that might be imposed to manage or eliminate conflicts of interest include, but are not limited to:

1. Public Disclosure of significant financial interests (e.g. when presenting or publishing the research);
2. For research projects involving human subjects research, disclosure of FCOI directly to participants;
3. Monitoring of research by independent reviewers capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
4. Modification of the Research Plan;
5. Change in personnel or personnel responsibilities, or disqualification of personnel from participating in all or a portion of the funded research that would be affected by the significant financial interests;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
7. Severance of the relationships that create the conflict of interest.

(e) Whenever Monmouth University implements a management plan, the FCOI Review Team will monitor compliance with the management plan on an ongoing basis until completion of the affected federally funded research project. In the event of any significant conflicting financial interest that is discovered subsequent to initial reports to federal agencies, the FCOI Review Team shall within sixty (60) days: review the significant financial interest; determine whether it is related to the federally funded research; determine whether a financial conflict of interest exists; and if so:

i. implement a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward; and

ii. (A) in addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the FCOI Review Team to constitute a financial conflict of interest; failure by the FCOI Review Team to review or manage such a financial conflict of interest; or failure by the Investigator

to comply with a financial conflict of interest management plan, Monmouth University, shall within 120 days of Monmouth University's determination of noncompliance, complete retrospective review of the Investigator's activities and the federally funded research project to determine whether any federally funded research, or portion thereof, conducted during the time period of noncompliance was biased in the design, conduct or reporting of such research, and, if so, provide a mitigation report if required by the relevant federal agency.

(B) Monmouth University is required to document the retrospective review. Such documentation shall include, but not be limited to all of the following key elements:

- Project Number;
- Project Title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Reason(s) for retrospective review;
- Detailed methodology used for retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

iii. based on the results of the retrospective review, if appropriate, Monmouth University shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, Monmouth University is required to notify the Federal Awarding Component promptly and submit a mitigation report to the Federal Awarding Component. The mitigation report must include, at minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and Monmouth University's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, Monmouth University will submit FCOI reports annually as specified in the policy.

(f) If an Investigator fails to comply with this conflict of interest policy and the University determines that the conflict has or can bias the design, conduct, or reporting of research findings, the University will promptly notify the program sponsor and corrective action will be taken or proposed. The University will seek direction and advice from the program sponsor concerning appropriate corrective action. Monmouth University may, at its own discretion, cease the expenditure of any funds under the award until the University determines that the conflict has been managed, reduced, or eliminated and that the research is protected from bias.

(g) If the University's designated officials determine that imposing conditions or restrictions would be ineffective or inequitable, and that the potential negative impacts that may arise from significant financial interest are outweighed by interests in scientific progress, technology transfer or the public health and welfare, the designated officials may allow the research to go forward without imposing such conditions or restrictions.

#### **D. REPORTING OF CONFLICTS**

1. Monmouth University must certify in each application for funding to which this policy applies, that:

i. Monmouth University has a written and enforced administrative process to identify and manage conflicts of interest and that they will ensure compliance with all such related federal policies regarding FCOI;

ii. Shall promote and enforce Investigator compliance, including those pertaining to disclosure of significant financial interests;

iii. Shall manage conflicts of interest and provide initial and ongoing FCOI reports to the federal awarding agency as required;

iv. Agrees to make information available, promptly upon request to the federal agency relating to any Investigator disclosure of financial interests and Monmouth University's review of, and response to such disclosure, whether or not the disclosure resulted in Monmouth University's determination of a conflict of interest and all actions under Monmouth University's policy, or retrospective review, if applicable, for at least for five years from the date the final expenditures report is submitted to the federal agency, or as required by the specific agency.

v. Monmouth University must also monitor Investigator compliance with approved management plans throughout the duration of the funded project.

2. Prior to Monmouth university's expenditure of any funds under a federally funded research project, Monmouth university shall provide to the Federal Awarding Component, if required, an FCOI report regarding any Investigator's significant financial interest found by Monmouth University to be conflicting and ensure that Monmouth University has implemented a management plan. In cases in which Monmouth University identifies a financial conflict of interest and eliminates it prior to the expenditure of federally awarded funds, Monmouth University shall not submit an FCOI report to the Federal Awarding Component.

3. For any significant financial interest that Monmouth University identifies as conflicting subsequent to Monmouth University's FCOI report during an ongoing federally funded research project (e.g., upon the participation of an Investigator who is new to the research project), Monmouth University shall provide to the Federal Awarding Component, within 60 days, and FCOI report regarding the FCOI and ensure that Monmouth University has implemented a management plan. Where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by Monmouth University (e.g., was not timely reviewed or reported by a subrecipient), Monmouth University also is required to complete a retrospective review to determine whether any federally funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct or report of such research. If bias is found, Monmouth University is required to



notify the Federal Awarding Component promptly and submit a mitigation report to the Federal Awarding Component.

4. Any FCOI report required shall include sufficient information to enable the Federal Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Monmouth University's management plan. Elements of the FCOI report shall include:

- i. Project number;
- ii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- iii. Name of the Investigator with the FCOI;
- iv. Name of the entity with which the Investigator has a financial conflict of interest;
- v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- vi. Value of the financial interest (dollar ranges are permissible) or a statement that the interest is one the value of which cannot be readily determined through reference to public prices or other reasonable measures of market value;
- vii. A description of how the financial interest relates to the federally funded research and the basis for Monmouth University's determination that the financial interest conflicts with such research; and
- viii. A description of the key elements of the plan, including:
  - A. Role and principal duties of the conflicted Investigator in the research project;
  - B. Conditions of the management plan;
  - C. How the management plan is designed to safeguard objectivity in research;
  - D. Confirmation of the Investigator's agreement to the management plan;
  - E. How the management plan will be monitored to ensure Investigator compliance; and
  - F. Other information as needed.

5. For any FCOI previously reported by Monmouth University with regard to an ongoing federally funded research project, Monmouth University shall provide to the Federal Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the federally funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. Monmouth University shall provide annual FCOI reports to the Federal Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the Federal Awarding Component.

## **E. PUBLIC ACCESSIBILITY TO FCOI INFORMATION**

1. Prior to Monmouth University's expenditure of any funds under a federally funded research project, Monmouth University shall ensure public accessibility via a written response to any requestor within five (5) business days of a request, of information concerning any significant financial interest disclosed to Monmouth University that meets the following three criteria:

- i. The significant financial interest was disclosed and is still held by the senior/key personnel;
- ii. Monmouth University determined that the significant financial interest is related to federally funded research; and
- iii. Monmouth University determines that the significant financial interest is a financial conflict of interest.

2. The information that Monmouth University shall make available via written response to any requestor within five (5) business days of a request shall include:

- i. the Investigator's name;
- ii. the Investigator's title and role with respect to the research project;
- iii. the name of the entity in which the significant financial interest is held;
- iv. the nature of the significant financial conflict of interest;
- v. the approximate dollar value of the significant financial interest (either by dollar ranges or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value).

#### **F. INVESTIGATOR'S NON-COMPLIANCE**

1. Investigators will not be able to access funds prior to disclosure of a FCOI and approval of a management plan. Noncompliance must also be reported to the appropriate federal funding agency. Certain agencies (e.g., NIH grants for clinical research) require public disclosure of FCOI on all public presentations (including addendums for previously published items) for any funded research that did not comply with federal disclosure regulations.

2. Failure of Investigators to comply with this policy, including restrictions by the management plans, will be grounds for discipline and sanctions under the appropriate University policy or provisions of any applicable Collective Bargaining Agreement.

#### **G. INVESTIGATOR TRAINING**

In order to facilitate compliance with federal policy, Monmouth University is responsible for investigator training, collection and evaluation of FCOI forms, and enforcement of this policy. In addition to making this policy and associated forms available on the OGAC website, training will be provided by OGAC for all investigators prior to engaging in federally funded research. Training must be repeated every four (4) years, and immediately with Monmouth University revises its FCOI policies or procedures in any manner that affect the requirements of Investigators; and investigator is new to Monmouth University; or an Investigator is found to be in non-compliance with Monmouth university's FCOI policy or management plan.

#### **H. RETENTION OF RECORDS**

Monmouth University will maintain all records of financial disclosures and Monmouth University's review of, and response to such disclosures (whether or not a disclosure resulted in Monmouth

University's determination of a financial conflict of interest) and all actions under Monmouth University's policy or retrospective review, if applicable, for at least three (3) years from the date the final expenditure report is submitted to the federal funding agency.

## **I. RESOURCES**

[http://www.nsf.gov/pubs/policydocs/pappguide/nsf09\\_1/aag\\_4.jsp#IVA](http://www.nsf.gov/pubs/policydocs/pappguide/nsf09_1/aag_4.jsp#IVA)

<http://grants.nih.gov/grants/policy/coi/index.htm>