SUNY DOWNSTATE MEDICAL CENTER
POLICY AND PROCEDURE

Subject:	**Research Conflict of Interest Policy**	**No:** RFDMC-01	
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Approved by:	**Dr. Wayne J. Riley, MD** **President**		
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I. Purpose:

As a public institute entrusted with public funds to carry out its research and educational missions, the State University of New York (SUNY) Downstate Medical Center (DMC) must ensure that its activities are conducted in an ethical, transparent, and bias-free environment to maintain the public trust. In conjunction with the SUNY/Research Foundation's Conflict of Interest Policy (COI), COI in Public Health Service Sponsored Programs Policy and DMC's Code of Conduct, DMC's Research COI Policy is in place to guide DMC Investigators in their everyday work, to outline required and prohibited conduct, and to provide guidance on how actual or perceived COI can be ***managed*** **so as to enable industry and commercial partnerships**, which are essential to advance our missions.

II. Policy:

It is DMC's policy that Investigators may not have any interest, financial or otherwise, direct or indirect, or engage in business, transactions or professional activities or incur obligations of any nature that is in conflict with the proper discharge of their duties in the best interests of DMC or that can be reasonably expected to bias the design, conduct or reporting of research unless these conflicts are appropriately declared and properly managed in accordance with the procedures and guidelines outlined below. Investigators must disclose their interests and outside activities, and those of a related party, which may affect their independent and objective performance of their duties.

III. Definitions:

Clinician – For the purpose of this policy, any clinical personnel named on an IRB application for either 1) Expanded Access to Investigational Drug/Biologic for treatment use or 2) Use of a Humanitarian Use Device (HUD) for Clinical Purposes.

Conflict of Interest ("COI") - Conflicts of interest in the conduct of externally and applicable internally supported activities may take various forms, but typically arise when an Investigator is or may be in a position to influence activities or DMC decisions in ways that could lead to personal gain for the Investigator or the Investigator's family or give an improper advantage to third parties in their dealings with DMC. Conflicts may arise when Investigators have outside obligations of any kind that are in substantial conflict with the Investigator's DMC responsibilities or the public interest.

1. The potential for conflicts of interest may arise from:
   a. Specific actions such as consulting arrangements;
   b. Nature of positions such as paid/unpaid Board positions; or
   c. Financial interests of the Investigator and his/her family members.

2. An actual conflict can result when:
   a. An Investigator's significant financial interest directly and significantly affects the design, conduct or reporting of his/her research activities;
   b. An Investigator has a significant external obligation to an individual/organization that provides support for a DMC research, educational or public service activity;
   c. An Investigator has a consulting agreement with a business enterprise that either supports/is supported by DMC programs involving the Investigator or is licensed to commercialize DMC technologies invented by the Investigator;
   d. An Investigator has significant financial interest in a business enterprise that either supports/is supported by the Investigator's research or owns/has applied for the patent or manufacturing or marketing rights to a drug, device, product or procedure that either:
      i. Is a subject of, or may predictably result from, the Investigator's research or
      ii. Can reasonably be expected to compete with a drug, device, product or procedure that will predictably result from the Investigator's research.
   e. An Investigator holds a position as consultant, officer, director, trustee, board member or owner of an external business enterprise that supports/is supported by the Investigator's research.
   f. An Investigator receives direct payments related to the accrual of patients to a clinical trial (i.e. recruitment incentives).

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.

Financial Interest- Anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities- All activities within an Investigator's field of scientific expertise or medicine for which DMC has hired the Investigator to perform and for which the Investigator is paid by DMC. This may include activities such as research, research consultation, teaching, professional practice, administrative, purchasing, institutional committee memberships and service on panels such as IRB or Data and Safety Monitoring Boards.

Investigator- The project director, Principal Investigator, co-Principal Investigator, personnel who are considered to be essential to work performance or any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research. The PI is responsible for identifying all Investigators involved in their research activities. If the role of an individual is unclear and that individual is listed as an Investigator, compliance with all training and filing requirements will be expected.

Note - Transient staff and trainees, such as medical students, residents and fellows, who may recruit patients and/or collect and handle data under supervision, but are not key to the design, conduct or reporting of research are not considered Investigators for purposes of COI. In addition, staff or trainees who merely implement a protocol developed by an Investigator or enter data into an electronic data capturing system are also not considered Investigators for purposes of COI. However, if a medical student, resident and/or fellow is applying for a research grant, s/he is considered an investigator for COI purposes and, therefore, must complete COI requirements.

Manage- Taking action to address a financial COI, which can include reducing or eliminating the financial COI to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

Outside Activity- Any outside business or employment activity including: (A) ownership or investment in any outside business or enterprise, (B) serving as a director, officer, partner, consultant, broker, agent, or representative of any outside enterprise; (C) outside professional activity or other activity; or (D) other employment.

PHS Award(s)- Any grant, contract, award, or sub-award including SBIR/STTR Phase II applicants/awardees, but not Phase I SBIR/STTRs, issued or awarded by the United States Public Health Service and its agencies: Agency for Healthcare Research and Quality; Agency for Toxic Substances and Disease Registry; Centers for Disease Control and Prevention; Food and Drug Administration; Health Resources and Services Administration; Indian Health Service; National Institutes Health; and the Substance Abuse and Mental Health Services Administration; and their sub-agencies.

Related- An Investigator's significant financial interest is related to the research or activity when the DMC designated official reasonably determines that the significant financial interest could be affected by the funded research or is an entity whose financial interest could be affected by the research.

Related Party- Spouse and/or dependent child of an Investigator.

Remuneration- Includes salary and any payment for services not otherwise identified as salary (such as consulting fees, honoraria, paid authorship). Remuneration excludes 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; and income from seminars, lectures or teaching engagements sponsored by and service on advisory 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.

Significant Financial Interest (SFI)- A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a SFI 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 the disclosure, when aggregated, exceeds $5,000;
2. With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds $5,000 or when the Investigator (or his/her spouse or dependent children) hold any equity interest; or

3. Intellectual property rights and interests (such as patents or copyrights), and royalties from such rights, upon receipt of income related to such rights and interests. Royalties are included in this section, except when received by the Investigator from DMC if the Investigator is currently employed or otherwise appointed by DMC.

SFI does not include the following types of financial interest:

1. Salary, royalties or other remuneration paid by DMC to the Investigator if the Investigator is currently employed or otherwise appointed by DMC, including intellectual property rights assigned to DMC and agreements to share in royalties related to such rights;
2. 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;
3. Income from seminars, lectures or teaching engagements 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 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.

Sponsored Travel- Includes any reimbursed or sponsored travel related to the Investigator's institutional responsibilities (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). This does not apply to travel that is reimbursed 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. Disclosures are required once the $5,000 threshold in value of travel from a single non-exempt entity has been reached.

IV. Responsibilities:

Responsible Party	Responsibility
Clinicians	• Complete DMC's Annual Transactional Questionnaire when submitting any of the following documents to the IRB if a COI is present or declared: o Expanded Access to Investigational Drug/Biologic for Treatment Use • Use of a Humanitarian Use Device for Clinical Purposes
Department Chairs	• Ensure that faculty members' comply with the Financial Conflicts of Interest (FCOI) policy and file the appropriate disclosure form(s), as necessary. • Ensure faculty members comply with required management plans, when requested.
FCOI Committee	• Develop and implement management plans to manage COI. • Complete retrospective reviews of Investigator's activities and research projects (within one hundred twenty (120)

Responsible Party	Responsibility
	days of a determination of non- compliance in identifying/managing a FCOI) to determine whether there was bias in the design, conduct or reporting of such research. • Complete Research Compliance training program, as required.
Institutional Review Board	• Ensure that IRB approval is not granted unless all applicable disclosures have been reported and reviewed for the IRB applications described above. • Review approved management plans for a project to determine if any additional protections are necessary for research participants.
Investigators (as defined above)	• Complete DMC's Annual Disclosure Questionnaire on an annual basis. • Complete DMC's Transactional Questionnaire at the time of submission of an application for an award/ grant/ study/ project. • Complete DMC's Transactional Questionnaire when submitting any of the following documents to the IRB: o Initial IRB Application of the following types, when submitting an application at least 30 days after the submission date of Annual Disclosure Questionnaire: ▪ Expedited Review ▪ Convened (Full) IRB Review ▪ External IRB Review ▪ Exempt IRB Review for FDA Regulated or Federally Funded/ Conducted Research o An amendment to be added to the IRB application (Full Board or Expedited review only) o An Application for Progress Report (Continuing IRB) when the progress report is required by the IRB. • Revise Annual Questionnaire within thirty (30) days of discovering a new SFI. • Submit confirmation or rebuttal of management plans within thirty (30) days and comply with final, binding management plan. • Certify compliance with management plan, as necessary. • Disclose reimbursed or sponsored travel related to research and/or institutional responsibilities as specified in the policy.

Responsible Party	Responsibility
	• Complete Research Compliance training program, as required.
Office of Compliance & Audit Services (OCAS)/ Designee	• Serves as the Conflicts of Interest (COI) Administrator responsible for COI administration. • In collaboration with the FCOI Committee Chair, provides support, guidance and training for the establishment of the COI administrative processes, contributes to the establishment of policies and procedures associated with Federal and State regulations. Provides highly efficient and seamless customer service to the research community at DMC. • In collaboration with Research Administration, takes a leadership position in the establishment of the electronic disclosure form tracking system and workflow procedures. • Coordinates the review and processing of the Financial COI Disclosure Forms for Investigators to meet submission requirements of: 1) Submission with Application for Grant /Award/Project, 2) New Disclosures submissions, and 3) Annual Disclosures submissions. • Coordinates and plans all COI training activities for the Responsible Parties, including Investigators, FCOI Committee and Administration at DMC. Assists Research Administration with the development of policies and training programs that ensure adherence to Federal mandates on research compliance, works with applicable parties to develop campus-wide implementation plans. • Monitors Federal and State regulation and related compliance issues concerning COI and provides written interpretations of the potential impact to DMC research operations. • Provides advice and counsel on risk management issues to the FCOI Chairperson and Committee concerning the results of the evaluation of the submitted Financial COI Disclosure Forms. • Provides research and analysis via Internet and other publicly available information sources to determine and or verify potential relationships of significant financial interest to better inform the Chair and Committee evaluation process. • In the event that a FCOI (FCOI) is determined to exist, the COI Administrator will coordinate and document the Committee's prescribed management plan that specifies actions to be performed by the Investigator and provide the appropriate follow up for the Committee. Coordinates the communication to the President and/or Designee, Department Chair and the Office of Research

Responsible Party	Responsibility
	Administration to perform any required actions to protocols or grant activity. • Responsible to develop and distribute metrics on COI Disclosure Form submissions and documentation of Investigator's successful completion of COI training to the Chair and the Committee. • As needed, assists in responding to public requests for COI information in accordance with current PHS regulations. • Runs reports to determine if annual disclosure forms were submitted. • Notifies and follows up with individuals who have not submitted the form.
Office of Technology Commercialization	• Provide commercialization information to the Conflicts of Interest Administrator and other relevant parties.
President and/or Designee: Currently, the President has designated the Institutional Official as his Designee	• Appoint and maintain a FCOI Committee. • Review rebuttals of management plans and make final, binding determination within thirty (30) days. • Institute disciplinary proceedings against an Investigator, when necessary.
Principal Investigator	• Properly identify Investigator roles on studies submitted to the IRB Office and/or Research Administration Pre-Award Office. • See additional responsibilities delineated under "Investigators."
Research Administration Office of Sponsored Programs	• Ensure an application for grant or contract funding has a disclosure form on file for all Investigators. • Place flags on grants that have a management plan for the Investigator in the proposal file of record. • Determine at the time of proposal whether sub-recipients have their own PHS-compliant policy or will instead follow Downstate's Research COI Policy. If the latter, assure that disclosures have been made prior to proposal submission. • At the time of award, coordinate with RF Central to incorporate into sub-recipient agreements which COI policy will apply and ensure sub- recipient certification of compliance is received before agreement is finalized either by (1) receiving an individual certification or (2) by documenting that the sub-recipient has provided its certification of institutional compliance with Public Health Services Financial COI requirements in the Federal Demonstration Partnership (FDP) Institutional Clearinghouse or (3) incorporating Downstate's Research COI policy in the terms of the sub-award. • Make the necessary certifications of compliance with the COI

Responsible Party	Responsibility
	requirements in each grant or contract proposal, individually or via the FDP Institutional Clearinghouse, for all activity supported by PHS or organizations that follow the PHS policy.
Research Administration Post-Award Division	• Place holds on accounts that have management plans to prevent expenditure of funds until a FCOI Report is submitted or until confirmation of the approved management plan is received. • Check to confirm that all Investigators on a research project have submitted disclosures and completed training at time of award setup and when out-year funds are authorized, supplemental funds extending the life of award are received, or no-cost extensions approved; release holds on accounts once compliance is verified. • Place flags on grants that have a management plan for the Investigator in the award file of record.

V. Procedures/Guidelines

A. Submission of Financial COI Disclosure Form

Disclosures are required in four instances:

- ✓ Annual Disclosures: The Disclosure form for all Investigators must be submitted on an annual basis.
- ✓ Submission of Application for Grant/Award: Investigators are required to submit the DMC Transactional Disclosure Form at the time of an application for a sponsor grant or award.
- ✓ Submission of an IRB Protocol for Human Research: Investigators and Clinicians are required to submit the DMC Annual and/or Transactional Disclosure Forms at the time of submission noted in Section IV above.
- ✓ New Disclosures: An updated Disclosure Form must be submitted within thirty (30) days of a new Outside Activity or interest that falls under this policy.

1. On an annual basis, an updated Disclosure form must be filed for each Investigator.
2. At the time of submission of a study to the IRB Office and/or Pre- Award Division, the Principal Investigator is responsible for identifying all Investigators and designating their role on the IRBNet registration form or Pre- Award Division templates. This will enable the IRB Office & Pre- Award Division staff to flag the application for COI purposes.
   * For a description of personnel that fall under "Investigators," please see Section III. Definitions.
3. All Investigators are required to submit the DMC Disclosure form describing their external activities and significant financial interests (SFI), as well as those of their Related Parties, that reasonably appear to be related to the individual's institutional responsibilities.
4. The DMC Disclosure form must be submitted via the electronic disclosure filing system.
5. The Research Administration Pre-Award Division will not submit any proposal for grant/contract funding unless all of the Investigators named in the proposal have submitted a Disclosure form in the electronic system. The IRB will review the protocol and will not provide IRB study

approval unless all of the Investigators named in the proposal have submitted a Disclosure form and have received COI review approval. The latter is applicable for all Federal and non- Federal studies. However, non- federal exempt studies (as defined by IRB policies) are excluded from the COI requirements.

6. Initial and out- year award funding and project extensions will not be released until annual disclosures have been filed for all Investigators, including those who have been added to the project since the proposal or most recent progress report was submitted, and all Investigators are in compliance with COI training requirements.
7. The COI Administrator will routinely run management reports to determine those members who have not submitted an Annual Disclosure form and will notify the individual and/or chair, as necessary.
8. Whenever SFI's, external activities or internal responsibilities change materially from those described in the Disclosure form, the individual is required to submit an updated Annual Disclosure form as soon as possible and no later than thirty (30) days from discovering or acquiring the new SFI.

B. Review of Financial COI Disclosure Form- DMC is responsible for reviewing the SFI's documented in the Disclosure form to determine whether these interests relate to the Investigator's research programs and objectives. This review will be conducted upon receipt of the Annual Disclosure form and again upon receipt of the Transactional Disclosure, which occurs in tandem with the proposal or protocol submission. A SFI is related to the research when it is reasonably determined that the research could be affected by the SFI or an outside activity may potentially compromise the objective performance of the individual's professional duties.

1. For all disclosed SFI's, both the relatedness determination and the FCOI analysis will be performed by the COI Administrator.
2. The assessment will require access to the funding application, progress reports, and any other technical and programmatic documentation, and may also require scientific expertise in order to understand whether the aims of a specific project affect the identified SFI's or the financial interests of the disclosed entities would be affected by the research. The following methods will be utilized:

    a. A scientist from a related field may be included in making the relatedness determination;
    b. The company sponsors or manufacturers listed in the grant/protocol will be reviewed to determine whether they are a wholly owned subsidiary or direct competitor of the companies listed in the Disclosure form;
    c. If only drug compounds are listed, without an associated manufacturer, the compounds will be reviewed to determine whether they reflect a drug that is marketed or licensed by a company represented on the Disclosure form;
    d. The relatedness determination will include an assessment of the nature of the research and/or business activities of the SFI related entity as they may relate to the Investigator's academic programs or objectives.

3. The rationale supporting the relatedness determination will be documented and maintained by the Conflicts of Interest Administrator.

C. Financial COI Analysis & Development of Management Plans

1. If the Investigator's SFI's are determined to be related to the research, a financial COI (FCOI) analysis must be performed. A FCOI exists when it is reasonably determined that the SFI could directly and significantly affect the design, conduct or reporting of the research or when the Investigator's activities on behalf of a SFI- related entity relate to the Investigator's DMC research programs, scholarly duties or intellectual property.
2. If a FCOI is determined to exist, the COI Administrator, FCOI Chair and/or FCOI Committee will develop and implement a management plan that specifies the actions that have been/will be taken to manage such FCOI's. Examples include:

    a. Public disclosure of FCOI's (e.g., before presenting or publishing the research and disclosing commercial relationships to trainees such as students, technicians and post-docs);
    b. For research projects involving human subject research, disclosure of the FCOI's directly to the participants (e.g., in the IRB study Consent Form);
    c. Appointment of an independent committee to oversee and monitor the educational goals and progress of students performing research at a commercial facility as part of their degree training;
    d. Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the research against bias resulting from the FCOI (this is often the Chair);
    e. Modification of the research plan(s);
    f. Change of personnel or personnel responsibilities or disqualification of personnel from participation;
    g. Review of ongoing/ future IP development to identify potential conflicts that may emerge between academic and new IP commercialized entities that come into existence;
    h. Prohibiting the PI from influencing DMC's purchasing decisions;
    i. PI's requirement to disclose and receive approval for not- insignificant use of shared resources (for example, lab space, equipment, supplies and staff).

Should the previous actions be insufficient, there will be an evaluation as to whether:

    a. Reduction or elimination of the financial interest; or, in rare instances;
    b. Severance of relationships that create financial conflict are necessary to address the conflict.

4. The COI Administrator will ensure an executed copy of the management plan is available in the electronic disclosure filing system and will make additional details available to the following parties, as necessary:

    a. Investigator's Department Chair;
    b. Institutional Review Board;
    c. Research Administration Pre-Award Division;
    d. Research Administration Post-Award Division.

5. The Research Administration Pre-Award Division, the Institutional Review Board (when applicable), and the Research Administration Post-Award Division will place a flag on the grant/contract/project to indicate the presence of a management plan.

6. Within thirty (30) days of receipt of a management plan, the Investigator is required to submit the following to the COI Administrator/ Chair:

Either:

a. Indication of acceptance/ approval of the management plan- the Investigator should electronically submit the approval;

Or:

b. Specific requested revisions to the management plan;
   a. The COI Administrator, FCOI Chair and/or FCOI Committee will evaluate the requested revisions and if appropriate, prepare a revised management plan within thirty (30) days for the Investigator's review;
   b. Within fifteen (15) days of receipt of the revised plan, the Investigator will either indicate acceptance/ approval of the revision or proceed with the rebuttal process as specified below.
   c. If no revisions are deemed appropriate, the Investigator will have fifteen (15) days of receipt of such decision to either accept/ approve the original management plan or proceed with the rebuttal process specified below.

c. Rebuttal of the management plan:
   i. If the Investigator rebuts the management plan, it will be sent, along with the Investigator's specific requested changes, to the President and/or Designee for reconsideration.
   ii. The President and/or Designee will make a determination within thirty (30) days and submit the determination in writing to the Investigator and the Investigator's Chair.
   iii. The management plan approved by the President and/or Designee is final and binding. The Investigator is required to immediately abide by the terms of this management plan.

If the Investigator neither accepts the management plan nor submits requested submissions or a rebuttal within thirty (30) days of receipt of the management plan, the management plan will default to "Accepted/ Approved" and the Investigator will be required to abide by its requirements.

7. The Research Administration Post-Award Division will place a hold on the account to prevent any expenditure of funds.

   a. For PHS funded research, or for research that is funded by sponsors that adhere to PHS FCOI regulations, the hold will not be removed until the submission of the FCOI Report (see Section V.D. below);
   b. For all other research, the hold will be removed when an approved/confirmed management plan is on file.

D. Submission of FCOI Reports- ***This policy section currently applies only to PHS Awards (see definition in Section III above).***

Prior to DMC's expenditure of funds under a PHS funded research project, the COI Administrator will submit to the PHS awarding agency an Initial FCOI Report regarding the Investigator's SFI's

determined to be conflicting and the management plan implemented. In cases where a FCOI was identified but was eliminated prior to the expenditure of funds, a FCOI Report will not be submitted.

1. The Initial FCOI Report will include sufficient information to enable the PHS awarding agency to understand the nature and extent of the financial conflict, as well as to assess the appropriateness of the management plan. The following elements will be included in the report:

    a. Project/Contract number;
    b. Principal Investigator/Contact Principal Investigator;
    c. Name of Investigator with the financial COI;
    d. Name of the entity with which the Investigator has a financial COI;
    e. Nature of the financial interest (Ex: Equity, consulting fee, travel reimbursement, honorarium);
    f. Value of the financial interest (May include dollar ranges as follows: $0- $4,999; $5,000- $9,999; $10,000- $19,999; amounts between $20,000- $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) 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;
    g. A description of how the financial interest relates to the PHS funded research and the basis for DMC's determination that the financial interest conflicts with such research; and
    h. A description of the key elements of DMC's management plan, including:
        i. Role and principal duties of the conflicted Investigator in the research project;
        ii. Conditions of the management plan;
        iii. How the management plan is designed to safeguard objectivity in the research project;
        iv. Confirmation of the Investigator's agreement to the management plan;
        v. How the management plan will be monitored to ensure Investigator compliance; and
        vi. Other information, as needed.

2. Once the Initial FCOI Report has been submitted, the COI Administrator will notify the Research Administration Post-Award Division to remove the hold on the Investigator's account and allow funding expenditures or will notify the IRB Office so that it can move forward with protocol review and approval.
3. For each project that required the submission of an Initial FCOI Report, an Annual FCOI Report that addresses the status of the FCOI and any changes to the management plan will be submitted on an annual basis.

    a. The Annual FCOI Report will specify whether the FCOI is still being managed or will explain why the FCOI no longer exists.
    b. Annual FCOI Reports will be submitted for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS awarding agency.

E. New Disclosures of SFI's- If, during the course of an ongoing PHS funded or otherwise funded project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI, or there is new information regarding a SFI that was not disclosed timely or not previously reviewed, the COI Administrator will, within sixty (60) days:

1. Review the disclosure of the SFI;
2. Determine whether the SFI is related to the research;
3. Determine whether a FCOI exists;
4. If so, implement, on at least an interim basis, a management plan that specifies the actions that have been/will be taken to manage the FCOI.

F. Retrospective Reviews and Mitigation Reports- If there is information regarding a SFI that was not identified or managed in a timely manner, including failure by the Investigator to disclose a SFI determined by DMC to constitute a FCOI, failure by DMC to review or manage the FCOI or failure by the Investigator to comply with the FCOI management plan, the FCOI Committee will, within one hundred twenty (120) days of DMC's determination of non- compliance, complete a retrospective review of the Investigator's activities and the research project to determine whether any research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct or reporting of such research.

1. A determination of bias may be difficult to determine. However, the following metrics may be utilized:

    a. Reviewing enrollment to determine whether inclusion/exclusion criteria have been met;
    b. Looking at systemic protocol deviations for irregularities that might indicate that scientific integrity was undermined;
    c. Assessing whether the design of the study was suspect.

2. The research staff associated with the project may be interviewed to determine whether there were any intentional or unintentional instances of misinterpreting data.
3. The retrospective review will be documented with the following elements:

    a. Project number;
    b. Project title;
    c. Principal Investigator or Contact Principal Investigator;
    d. Name of the Investigator with the FCOI;
    e. Name of the entity with which the Investigator has a FCOI;
    f. Reason(s) for the retrospective review;
    g. Detailed methodology used for retrospective review (Ex: Methodology of the review process, composition of the review panel, documents reviewed);
    h. Findings of the review; and
    i. Conclusions of the review.

4. Based upon the results of the retrospective review, if appropriate, the COI Administrator will update previously submitted FCOI reports and specify the actions taken to manage the FCOI going forward.
5. If a determination of bias is made, the COI Administrator will promptly prepare and submit a Mitigation Report to the PHS awarding agency. The Mitigation Report will include the following:

    a. Elements included in retrospective review, as delineated in Section V.A.6.c. above;
    b. A description of the impact of the bias on the research project; and
    c. DMC's plan of action(s) taken to eliminate or mitigate the effect of the bias (Ex: 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).

6. Thereafter, the COI Administrator will submit FCOI reports on an annual basis.
7. Depending upon the nature of the FCOI, the FCOI Committee may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the FCOI or the Investigator's non- compliance was determined and the completion of the retrospective review.

G. Public Transparency- ***This policy section currently applies only to PHS Awards (see definition in Section III above).***

1. The COI Administrator will respond to any written request, within five (5) business days from the date the COI Administrator receives the request, of information concerning any SFI disclosed to DMC that meet the following criteria:

   a. The SFI was disclosed and is still held by Investigator;
   b. The COI Administrator/ FCOI Committee determined that the SFI is related to the research; and
   c. The COI Administrator/ FCOI Committee determined that the SFI is a FCOI.

2. The information provided to the requestor will include the following:

   a. The Investigator's name;
   b. The Investigator's title and role with respect to the research project;
   c. The name of the entity in which the SFI is held;
   d. The nature of the SFI; and
   e. The approximate dollar value of the SFI (dollar ranges are permitted, as specified in Section V.D.1.f. above) 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.

3. Information relative to Section V.G.1. above will be maintained for a period of three (3) years from the date that the information was most recently updated.

H. Travel- Investigators receiving PHS funding must disclose all reimbursed or sponsored travel related to their research and/or institutional responsibilities when the aggregated value exceeds $5,000 per entity. This disclosure requirement does not apply to travel that is reimbursed or sponsored by: (1) a Federal, State or local government agency; (2) an institution of higher education; (3) an academic teaching hospital; (4) a medical center or a research institute that is affiliated with an institution of higher education.

1. The following information must be provided for all covered travel:

   a. Identity of the sponsor/organizer;
   b. Destination;
   c. Duration;
   d. Purpose of trip;
   e. Relationship to institutional responsibilities; and
   f. Estimated dollar value of expenses.

2. The COI Administrator is responsible for reviewing the Investigator's travel related to the research and determining whether it directly or significantly affects the design, conduct or reporting of the research, constituting a FCOI. The following potential red flags will be utilized to make FCOI determinations:

    a. International travel;
    b. Inclusion of an Investigator's spouse or family;
    c. Travel that appears unnecessary in terms of location, duration or scheduled recreational activities;
    d. Travel for a duration beyond typical timeframes necessary for the intended purpose of the travel;
    e. Many trips from one entity in a short period of time.

3. Travel determined to be a FCOI will be referred to the FCOI Committee for review and development of a management plan, if necessary.

I. Sub-Recipient Requirements Regarding COI Policies- For PHS funded research and for research funded by organizations that follow PHS policy that is carried out through a sub-recipient, the Research Administration Pre-Award Division will, in conjunction with RF Central, incorporate into a written agreement the terms that establish whether the financial COI policy of DMC or that of the sub-recipient will apply to the sub-recipient's Investigators.

1. If the sub-recipient's Investigators are required to comply with their own financial COI policy, the sub-recipient must either be registered in the FDP Institutional Clearinghouse, or submit a certification as part of the agreement that its policy complies with the Federal requirements.

    a. The Research Administration Pre-Award Division will not authorize RF Central to finalize the agreement until this certification has been documented.
    b. Sub-recipients who cannot provide such certification, or who have not registered in the FDP Institutional Clearinghouse will be required to be subject to DMC's COI policy and will be required to disclose SFI's directly related to the sub-recipient's work for DMC.
    c. If the sub-recipient's Investigators are required to comply with their own financial COI policy, the agreement will specify the following time- periods for the sub- recipient to report all identified FCOI's to DMC's COI Administrator: (1) At the time of the initial agreement execution, prior to expenditure of funds; (2) On an annual basis; and (3) Within thirty (30) days of any subsequently identified SFI.

2. If the sub-recipient's Investigators are required to comply with DMC's COI policy, the agreement will specify the following time- periods for the sub- recipient to report all identified FCOI's to DMC's COI Administrator: (1) At the time of the initial agreement execution, prior to expenditure of funds; (2) On an annual basis; and (3) Within thirty (30) days of any subsequently identified SFI.

J. Consultant or Collaborator Requirements Regarding COI Policies – For PHS funded research and for research funded by organizations that follow PHS policy that is carried out with the participation of a non-DMC consultant or collaborator who meets the definition of Investigator, the consultant or collaborator will follow DMC's COI Policy and provide disclosures and complete DMC training in the same time-frame as DMC investigators, if the consultant/ collaborator does not

have his/her own COI policy. These individuals will be subject to DMC's COI management plan, when applicable.

K. Education- DMC will educate its Investigators, and any others who come under DMC's policies, on the COI policy and Investigators' responsibilities regarding disclosure of SFI's and complying with the regulations.

1. Investigators will be required to complete DMC's COI training program under the following circumstances:

    a. Upon hire;
    b. Prior to engaging in research related activities;
    c. Routinely every four (4) years;
    d. When DMC's COI policy or procedures are revised in a manner that affects all Investigators;
    e. If DMC determines that an Investigator is not in compliance with the COI policy or a particular management plan.
2. The Office of Compliance and Audit Services will coordinate the provision of such training to the Investigators, in accordance with DMC's policy, "Compliance Training."

L. Administrative Requirements

1. DMC will maintain an up- to- date, written and enforced COI policy, in compliance with applicable requirements, which will be available on its public website.
2. DMC will maintain adequate enforcement mechanisms for the COI policy.
3. DMC will maintain the following records for a period of three (3) years from the date of final payment, unless another requirement applies to retain the information for a longer time frame:

    a. All Investigators' disclosures of financial interest;
    b. DMC's review of and response to such disclosures, whether or not the disclosure resulted in a management plan;
    c. All DMC actions under the COI policy;
    d. All retrospective reviews.

4. DMC will certify, when required by the sponsor, in the grant or contract proposal, that it:

    a. Has in effect an up- to- date, written and enforced administrative process to identify and manage FCOI's with respect to all research projects for which funding is sought or received from Federal sources;
    b. Shall promote and enforce Investigator compliance with these requirements, including those that pertain to disclosure of SFI's;
    c. Shall manage FCOI's and provide initial and ongoing FCOI reports to the PHS awarding agency consistent with the requirements;
    d. Agrees to make information available, promptly upon request, to the Department of Health and Human Services (HHS) relating to any Investigator disclosure of financial interests and DMC's review of, and response to, such disclosure, whether or not the disclosure resulted in DMC's determination of a FCOI; and
    e. Shall comply fully with the COI requirements.

M. Non- Compliance

1. All instances in which an Investigator has failed to comply with this COI policy or a FCOI management plan appears to have biased the design, conduct or reporting of the research must be reported immediately to the COI Administrator or to DMC's Compliance Line. The COI Administrator will consult with the President and/or Designee, the Pre Award, Post Award & IRB Offices to determine appropriate corrective actions.
2. In cases where disciplinary action is necessary and depending on the facts and circumstances of each case, the President and/or Designee may take one or more of the following actions, in compliance with the applicable collective bargaining agreements & SUNY Board of Trustees policies:
   a. Reprimand;
   b. Probation or other alteration of employment/academic status with DMC;
   c. Suspension;
   d. Dismissal/Termination;
   e. Referral for criminal prosecution; and/or
   f. Demand of reimbursement to DMC for any losses or damages resulting from the failure to comply with this COI policy.
3. Upon completion of the disciplinary proceedings, the COI Administrator will report to the appropriate parties and to the applicable PHS agencies when PHS funds are involved.
4. DMC will comply with any further action required by the PHS agencies on how to maintain appropriate objectivity in PHS funded research projects, including suspending the research project, if required.
5. In any case in which HHS determines that a PHS funded project of clinical research whose purpose is to evaluate the safety and 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 DMC, as required, DMC shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations. Similar action will be taken if a FCOI was not managed or reported by DMC if the research is non-funded or funded by a non-PHS organization that implements PHS COI requirements.

VI. Attachments

NONE

VII. References

- RF Conflicts of Interest in Public Health Service Sponsored Programs Policy
- RF Conflict of Interest Policy;
- RF Procedure for Managing Conflicts of Interest
- RF Managing Conflicts of Interest Guidelines
- NYS Public Officer's Law Sections 73 & 74; Section 107;
- SUNY Outside Activities of University Policy Makers;
- SUNY Patents, Inventions and Copyright Policy