Standard Operating Procedures for
P209: Investigator Conflict of Interest Policy

Table of Contents

Applicability

This Policy applies to:

A. Stony Brook University (University) faculty, staff or students who are responsible for the design, conduct, or reporting of activities * and any University faculty who are identified in a budget or who are acting as a consultant or collaborator in any and all:
    - Externally supported activities for University programs, projects, activities and services, solicited and unsolicited, including gifts and donations specifically made to support the activities of identified individuals;
    - Internally supported activities, where support is granted following formal application to a University program in response to a request for proposals (e.g., Targeted Research Opportunity 'TRO' Grants); and
    - Internally supported research activities for the benefit of an external entity (e.g. non-funded research projects where deliverables such as reports/data are provided to an external entity)

**Exceptions:*

Not included: Individuals who do not make independent decisions regarding the design, conduct, or reporting of the activity in question, and only work on or are engaged in the activity (for example, in most cases research assistants, undergraduates and secretaries will not be considered responsible for the design, conduct, or reporting of activities of a research project). However, for PHS funded activities: collaborators or consultants are considered responsible for the design, conduct, or reporting of activities of a research project.

B. University faculty, staff or students who are named as study personnel on any externally funded research studies involving human subjects.

C. University faculty, staff or students who hold a financial interest or obligation in a company that is negotiating an agreement with the Office of Technology Licensing and Industry Relations (OTLIR) for technology developed by the respective faculty, staff or student.

Note: *If any provision in this document is in conflict with the governing legal and policy requirements for review and management of conflicts, the governing legal and policy requirements shall prevail*

Note: *Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) applications are exempt from the additional specific requirements referenced in this policy pertaining to PHS/NIH activities. University Investigators on such applications are NOT exempt however, from any other requirements (e.g., disclosure, need to comply with Management Plans, etc.) set forth in this Policy.*

Institutional Roles

Conflict of Interest (COI) Committee

The COI Committee is a multidisciplinary faculty peer committee responsible for the review of any potential conflicts of interest placed on the COI Committee's agenda and (where required) recommendations for the elements of a Management Plan.

Designated Institutional Official (DIO)

The DIO is responsible for soliciting and reviewing Certifications from Investigators and developing Management Plans that specify the actions that have been and shall be taken to manage the FCOI or SO.

Investigator

The Investigator is responsible for reporting of external interests as defined in this Policy, compliance with any Management Plans, and submission of any Publications that require disclosure of an interest per a Management Plan.

Vice-President for Research (VPR)

The VPR appoints the DIO and serves as the final arbiter in the appeals process.

Definitions

Certification:

A confirmation by an Investigator to the DIO that the reporting of his /her Disclosures, or absence of any Disclosures, are up to date.

Conflict of Interest (COI):

When an Investigator is, or may be, in a position to influence activities or decisions in the conduct of externally and applicable internally supported activities in ways that could lead to personal financial gain for the Investigator (and/or the Investigator's Immediate Family Member), or give an improper advantage to third parties in their dealings with the University.

Conflicts of interest may also arise when Investigators (and/or the Investigator's Immediate Family Member) have outside obligations of any kind that are in substantial conflict with the Investigator's University responsibilities or the public interest.

Conflict of Obligation (CO):

A Significant Obligation (SO) that is related to, and that could (or could be perceived to) directly and significantly affect, the design, conduct, or reporting of externally and applicable internally supported activities. The DIO makes the determination that an SO constitutes a CO.

Note: Where a CO exists, the University will not permit cost sharing. The applicable Dean may grant waivers to this policy on a case-by-case basis.

Disclosure:

Report of any outside financial interest or obligation, through myResearch.

Equity Interest:

Any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Financial Conflict of Interest (FCOI):

A Significant Financial Interest (SFI) that is related to, and that could (or could be perceived to) directly and significantly affect, the design, conduct, or reporting of externally and applicable- internally supported activities. The DIO makes the determination that an SFI constitutes a FCOI.

Note: Where a FCOI exists, the University will not permit cost sharing. The applicable Dean may grant waivers to this policy on a case-by-case basis.

Financial Interest (FI):

1. Any remuneration to the Investigator (and/or those of the Investigator's Immediate Family Member) from outside the University, and/or
2. Any equity holdings or ownerships of the Investigator (and/or those of the Investigator's Immediate Family Member), and/or
3. Intellectual property rights and interests (e.g., new technology disclosures, patents, copyrights) where a company has entered into an option to license, or license, such rights and interests from the University.
4. Intellectual property rights and interests upon receipt of income related to such rights and interests.

Note: At this University, all royalties, including those received by the Investigator from this University, are to be disclosed.

Financial Interest (FI) Exclusions:

- 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, a (United States) institution of higher education as defined at 20 U.S.C. 1001 (a), 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, a (United States) institution of higher education as defined at 20 U.S.C. 1001 (a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

myResearch – Conflict of Interest Module:

The University's electronic system for submitting disclosures and certifications.

Immediate Family Member:

In this Policy, the term "Immediate Family Member" includes the Investigator's spouse, domestic or civil union partner and dependent children.

Institutional Responsibilities:

All professional responsibilities and activities for which the Investigator was hired to perform, and is paid by, this University, includes but is not limited to research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator:

Collectively, the persons identified in the Applicability section above.

Management Plan:

A written plan for proactively managing any potential conflicts. The Management Plan typically includes:

- The role and principal duties of the conflicted Investigator in the research project;
- Conditions of the Management Plan;
- How the Management Plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the Management Plan;
- How the Management Plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

Obligation:

An unpaid position - held as an officer, trustee, director, advisor, scientific advisor, board member or consultant - of a for-profit or not-for-profit entity.

Publications:

Any public dissemination of research results, including but not limited to: journal articles, poster presentations, or speeches.

Related to an Investigator's Institutional Responsibilities:

An activity (or interest) that relies upon the same expertise that an Investigator uses to carry out his/her Institutional Responsibilities or when it has the potential to influence the duties that University considers part of the work it pays or otherwise engages the Investigator to perform.

Related to an Investigator's Research Project:

Any of the following entities: a supplier of a product or services to the project, a business related to the product or research, a research project sponsor, or any other party that has financial interests tied to the project.

Remuneration:

Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Reviewer:

Individual members of the COI Committee.

Senior / Key Personnel (PHS / NIH Only):

The PD/PI and any other person identified as senior/key personnel in the grant application or contract, progress report, or any other report submitted to PHS/NIH (including those required by this policy) are Investigators. The PHS/NIH Public Disclosure Requirement pertains specifically to this group of individuals.

Significant Financial Interest (SFI):

One or more of the following types of Financial Interests of the Investigator (and/or those of the Investigator's Immediate Family Member) ***that reasonably appears to be related to the Investigator's Institutional Responsibilities*** is considered an SFI:

> Publicly Traded Entity: Value of any remuneration received from the entity in the twelve months preceding the disclosure and/or the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.
>
> Non-Publicly Traded Entity**:** Value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, and/or the Investigator (and/or the Investigator's Immediate Family Member) holds any equity interest.
>
> Intellectual Property: rights and interests (e.g., patents, copyrights), royalties from such rights, and agreements to share in royalties related to such rights (upon receipt of income related to such rights and interests). At the University, all royalties are to be disclosed, including those received by the Investigator from this University.
>
> Travel (PHS/NIH only): Investigators also must disclose the occurrence (over the preceding 12 months) of reimbursed travel or sponsored travel (i.e., that which is paid on behalf of the Investigator) that is related to their Institutional Responsibilities and which totals > $5,000 per reimbursing / paying entity. The disclosure must include the sponsor, destination, duration, and purpose of the travel. Excluded from this requirement are travels that are reimbursed or sponsored by federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an Institution of higher education.

Significant Obligations (SO):

Significant Obligations (SO) includes Obligations that would reasonably appear to be related to an Investigator's Institutional Responsibilities.

Technology Transfer Agreements:

Agreements (e.g. licenses or options to licenses) facilitated by the Office of Technology Licensing and Industry Relations (OTLIR) for University owned intellectual property to outside entities.

Training

What Training is Required?

Each Investigator must complete University's FCOI training requirement:

- Prior to engaging in research related to any grant and at least every four years, and
- Immediately under the designated circumstances:
    - University COI policies change in a manner that affects Investigator requirements;
    - An Investigator is new to the University; or
    - University finds an Investigator noncompliant with Institution's COI policy or Management Plan.

How is Training Conducted?

- The Office of Research Compliance uses CITI for COI training.

How is Training Documentation Recorded?

- CITI maintains an electronic record of all completed training
- CITI COI Training data is transferred daily to myResearch

How is Investigator Training Monitored?

The DIO will check training on all Triggering Event notifications from OSP. The DIO will also run monthly reports to monitor compliance with the at least every four year training requirement.

Disclosures and Certifications

Who Must Submit an Annual Certification?

- See Applicability

When are Annual Certifications Required?

During the initial roll out period the following groups will be required to complete Annual Certifications. These groups are:

- Faculty members that participate in research;
- Staff that meet the definition of Investigator and are named on a current funded project or proposal submitted within the last year; and
- Staff named as study personnel on IRB submissions that have current or pending funding.

After this initial certification, it is highly recommended that faculty and staff, new to research or the University, submit an Annual Certification prior to the submission of any proposals or IRB protocols.

Subsequent Annual Certifications are required between May 1st and May 31st of each year.

How are Certifications Made?

- Certifications are made in the myResearch Conflict of Interest module.

What External Interests Must be Reported?

- Obligations
- Financial Interests, where when aggregated for any one entity is greater than $5,000
- Equity interests
- Intellectual Property Rights and Interests, where royalty and other forms of payment are in excess of $5,000
- Travel (for PHS/NIH only)

Note: The above include obligations and financial interest for both you and any Immediate Family Members.

When Is It Required to Report a Change in External Interests?

- Within thirty (30) days of discovering or acquiring a new FI or Obligation.
- At the time of establishing a faculty owned company.
- At the request of the DIO, where new FIs have come to the attention of the DIO.
- For PHS/NIH funded investigators, applicable travel must be disclosed within thirty (30) days of said travel. Alternatively, travel that is anticipated can be disclosed anytime in advance and would satisfy the thirty (30) day requirement.

When May Research Certifications be Required?

- Prior to the establishment of any new award or University endorsement on any non-funded research agreement.
- Prior to the IRB Committee review of any non-funded IRB application.
- Prior to the final institutional endorsement of a Technology Transfer Agreement.

How are Annual Certifications Reviewed?

Annual Certifications that indicate that the Investigator holds no interests and/or obligations receive no further action and are stored in the myResearch module.

Annual Certifications that indicate that the investigator holds interests and/or obligations are reviewed by the DIO.

- If there have been any changes in the disclosures, the DIO will conduct a review of the Investigator's awards to determine if any of the changes created a new FCOI or SO.
- Once the review is complete and any necessary actions are taken on existing awards, the Annual Certifications are kept on file in the myResearch COI module.

How are New Projects, Changes in PI, Addition of Faculty, and Agreements Identified for Review?

Sponsored Projects

The Office of Sponsored Programs (OSP) will refer proposed projects (as referenced in Applicability) to the DIO through a Triggering Event Notification. OSP will also refer changes in PI and the addition of any faculty to the DIO through a Triggering Event Notification.

Note: In any such case where human subjects research is involved, the DIO will work with the Office of Research Compliance to ensure that the Institutional Review Boards (IRBs) are aware of the case being reviewed. The fully convened IRB will conduct independent review of the potential conflict in compliance with its own conflict of interest policy to ensure the protection of human subjects.

IRB Applications

Conflict of Interest review of IRB applications that have no outside sponsorship or support and do not include a benefit for an outside entity are under the authority of the IRBs. If an IRB requires a review of an Investigator's Certification, the Office of Research Compliance (ORC) will refer the application to the DIO through a Triggering Event Notification.

Technology Transfer Agreements

The Office of Technology Licensing and Industry Relations (OTLIR) will refer proposed Technology Transfer Agreements involving a potential COI or CO to the DIO through a Triggering Event Notification.

How are Certifications Reviewed?

Administrative Review

Where the DIO has received a Triggering Event Notification, the DIO will review each Investigator's record. If no Disclosures are on file or if it is evident that the Disclosures are not Related to the Investigator's Research Project and/or Related to the Investigator's Institutional Responsibilities, the Administrative Review is complete and the file will be notated. If there are Disclosures on file that may be Related to the Investigator's Research Project and/or Related to the Investigator's Institutional Responsibilities one, or more, of the following three reviews may be completed. The DIO may send a Research Certification to the Investigator for additional information.

If:

a) it is evident that the Disclosures are not Related to the Investigator's Research Project and/or Related to the Investigator's Institutional Responsibilities, the Administrative Review is complete and the file will be notated.
b) It is evident that the Disclosures are Related to the Investigator's Research Project and/or Related to the Investigator's Institutional Responsibilities, the DIO may issue a Management Plan or forward for a Reviewer Review or COI Committee Review.
c) It is not evident that the Disclosures are Related to the Investigator's Research Project and/or Related to the Investigator's Institutional Responsibilities, the DIO will forward for either a Reviewer Review or a COI Committee Review.

Reviewer Review

If the DIO forwards a Research Certification to the Reviewer, the Reviewer will conduct a review of the Disclosures and the Research Certification in coordination with the project. The Reviewer will recommend – no FCOI or CO exists, FCOI or CO exists and Management Plan is required or forward for COI Committee Review.

COI Committee Review

For cases placed on the COI Committee meeting agenda, the convened COI Committee reviews the Disclosures and Research Certification in coordination with the project to recommend if an FCOI or CO exists. The COI Committee will recommend – no FCOI or CO exists, FCOI or CO exists and Management Plan is required, FCOI or CO exists and cannot be managed.

Subawards

PHS / NIH Only: Where the proposal involves sub-recipient's institution will apply to the sub-recipient's Investigators.

1. If the sub-recipient's institutional FCOI policy will apply to the sub-recipient investigators, the agreement will include a requirement that the sub-recipient's institution must:
    1. Provide certification that its FCOI policy complies with PHS regulation.
    2. Report to the University identified FCOI's for its Investigators in a time frame that allows the University to report said FCOI's to the NIH as detailed below (Reporting to External Sponsors, 'for PHS / NIH only').
2. If the University's FCOI policy will apply to sub-recipient investigators, the agreement will include a requirement that said investigators will submit disclosures to the University for review, identification, and handling of FCOI's as required by this policy (including those required only for PHS / NIH activities).

Documentation

The University will maintain records of all Investigator Certifications and the University's review of, and response to, any Disclosures (whether or not a Disclosure resulted in the University's determination of FCOI or CO) and all actions under the University's policy or retrospective review (in the case of PHS/NIH funds) for at least three years from the date of submission of the final expenditures report or, in the case of PHS/NIH, from other dates specified in 45 C.F.R. 74.53(b) and 92.42 (b) for different situations.

Management of FCOI and CO

Management Plan

For all identified FCOI's and CO's, the DIO will develop and implement a Management Plan. If the University is unable to resolve a real or potential conflict of interest or the appearance of same, it will decline to perform the activity in question. Where human subjects are involved, the IRB may modify and/or add to the Management Plan. Where there is discrepancy or disagreement, the IRB's decision will supersede that of the DIO.

The DIO sends the Management Plan to the Investigator. The Investigator must then provide concurrence and certification for compliance (signature) with the Management Plan in order for the award to be established or the unfunded agreement to be institutionally endorsed. The DIO will convey the notice of FCOI and/or CO and associated signed Management Plan to the Chair of the COI Committee, Assistant Vice-President of Research Compliance, Investigator, associated Chair, and associated Dean (the VPR will serve in this capacity when the investigator is a dean or vice president, or is otherwise conflicted).

Management Plan Compliance

The Investigator is required to comply with all terms of a Management Plan, including the submission of any resulting Publications via myResearch.

Management Plan Monitoring

For all identified FCOI's and CO's, the DIO will monitor compliance with the Management Plan. Such monitoring will be documented.

Public Disclosure of FCOI's (PHS / NIH Only)

The University will make certain information concerning FCOIs held by senior/key personnel available via a written response to any requestor within five business days of a request, and update such information as specified in the regulation. In response to such request, the University will provide:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Name of the entity in which the SFI is held;
- Nature of the SFI; and
- Approximate dollar value of the SFI (dollar ranges will be provided, e.g., $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 references to public prices or other reasonable measures of fair market value.

Reporting to External Sponsors

PHS/NIH

Where the DIO identifies a FCOI, the DIO will report the details concerning the FCOI (including Management Plan) to NIH via the eRA Commons FCOI Module. Prior to expenditure of any funds under the award. These reports are completed:

- Within 60 days of identifying a new FCOI for an existing investigator, during the period of the award (FCOI must be determined, and Management Plan implemented within those 60 days), or
- Within 60 days of identifying an FCOI for an investigator who is newly participating in the project, or
- Annually report on the status of FCOI and any changes in Management Plan (Due same time as annual progress report is submitted, including multi-year progress report, or at time of extension - with or without funds.

The FCOI Reports includes:

- Grant number;
- PD/PI or contact PD/PI;
- Name of Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
- Value of the financial interest $0-4,999; $5K-9,999; $10K-19,999; amounts between $20K-100K by increments of $20K; amounts above $100K by increments of $50K or a statement that a value cannot be readily determined;
- A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- Key elements of the Institution's Management Plan, including:
- Role and principal duties of the conflicted Investigator in the research project;
- Conditions of the Management Plan;
- How the Management Plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the Management Plan;
- How the Management Plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

The FCOI Reports are accessible under FOIL.

If upon receipt of the FCOI report, NIH decides that the FCOI will bias the objectivity of research, NIH may impose special award conditions, suspend funding or impose other enforcement mechanisms until the matter is resolved.

In any case in which NIH determines that an PHS-funded 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 an FCOI that was not managed or reported by the University as required by regulation, the University will 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.

Other External Funding Agencies

The DIO will report to the external funding agency/agencies as applicable:

- Any instances in which the University finds it is unable to satisfactorily manage an actual or potential conflict of interest, and
- Any instances where an Investigator participating in externally or selected internally supported research has not complied with this policy, and the specific corrective measures taken by the University.

Compliance with this Policy

If the DIO finds that an Investigator has failed to comply with this Policy or the means determined to resolve a Financial Conflict of Interest (FCOI) and/or Conflict of Obligation (CO), the DIO shall report the findings promptly in writing, including mitigating reasons behind the non-compliance and the proposed corrective action plan moving forward, to the Assistant Vice President for Research Compliance.

Upon review of the report, Assistant Vice President for Research Compliance (AVPRC), with concurrence by the Vice President for Research, will determine if:

- the mitigating reasons adequately provide reasonable explanation that the noncompliance was committed unintentionally,
- the corrective action plan is adequate to prevent recurrence
- affected journals and/or funding agencies require notification to protect the public record, and
- the noncompliance was isolated, i.e., not involving potential violations of other University policies and/or federal regulations, including but not limited to human research protections

Depending on outcome of review, appropriate action will be taken by AVPRC, as follows:

- **If the noncompliance is deemed unintentional with acceptable corrective action plan**, and no other policies or regulations are impacted, the AVPRC will direct the DIO to notify the investigator, with copy to chair and dean, that the noncompliance has been acknowledged and the corrective action plan is to be initiated. Correspondence will also indicate if journals and/or funding agencies must be notified regarding the non-compliance.
- **If other University policies and/or federal regulations have been potentially violated**, appropriate University offices will be notified, and applicable processes initiated. The investigator will be notified of such by AVPRC, with copy to chair and dean.
- **If the noncompliance is deemed intentional, regardless of other determinations,** the VPR may proceed with initiation of disciplinary sanctions, which may include termination or alteration of the employment or academic status of persons against whom charges have been substantiated (and must be consistent with established University and Board of Trustees policies and applicable collective bargaining agreements). Article 19 of the UUP Agreement will be the sole source of University discipline for members of the UUP-represented unit. Additional sanctions may be rendered in accordance with applicable University policies. Upon completion of all disciplinary proceedings, the DIO will report to the cognizant federal agencies when federal funds are involved and to all other parties as necessary. The VPR will report this matter to the President.

Compliance with this Policy – Additional Actions Required for NIH/PHS Awards

Anniversary Review for Funded Awards

All NIH/PHS awards (grants, cooperative agreements, contracts and subawards) will be reviewed by the DIO to ensure that all Investigators are compliant with both the training and annual certification requirements. In accordance with NIH/PHS policy, no funds may be spent until all Investigators are in compliance with the NIH/PHS regulations.

The Office of Sponsored Programs (OSP) will refer all PHS/NIH awards, at the time of their anniversary, to the DIO through a Triggering Event for review of current training and annual certification for all named Investigators. If any Investigator is not in compliance, the DIO will contact the Investigator. The DIO will confirm training and annual certification to OSP.

Retrospective Review

Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI or comply with a Management Plan, or failure by the University to review or manage an FCOI, the University will, within 120 days of a determination of non- compliance, complete a Retrospective Review of the Investigator's activities and the NIH-funded research project to determine if there was bias in the design, conduct, or reporting of such research.

The Retrospective Review will document the following:

- 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 an FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings and conclusions of the review.
- If results of the retrospective review warrant, update previously submitted FCOI report

Mitigation Report

If bias is found through Retrospective Review, the DIO will notify the NIH Awarding Component promptly (through the eRA Commons) and submit a Mitigation Report.

The Mitigation Report will document the following:

- Key elements documented in retrospective review
- Description of the impact of the bias on the research project
- Plan of action(s) to eliminate or mitigate the effect of the bias

Thereafter, the University will submit FCOI reports annually as described above in the Procedures section.

Appeals

Should an Investigator fail to concur with the Management Plan recommended by the DIO, he/she may transmit comments to the Vice President for Research (VPR) within ten working days from receipt of the DIO's decision. In such a case, the VPR will review the case (which may include seeking the advice of appropriate impartial experts and holding discussions with the Investigator, DIO and/or the COI Committee) and will render a judgment within twenty working days of the time that the DIO's initial determination is made known to the Investigator. Awards for external and selected internal support of a program, project, activity or service may not be activated by the University unless a Management Plan is in place or the issue is otherwise resolved.

When the VPR serves as the reviewer of a disclosure statement (for Deans/VPs), the appeal shall be to the President.

Appendix 1 Conflict of Interest Scenarios

The potential for conflicts of interest may arise from an Investigator's:

- specific actions (e.g., consultant arrangements), or
- the nature of positions they hold at the University and outside the University (e.g., board positions, paid or unpaid), or
- the financial interests they or their immediate family holds.

A conflict can result when:

- The significant financial interests of an investigator could directly and significantly affect the design, conduct, or reporting of his or her externally and applicable internally supported activities.

General Scenarios

An Investigator has a significant non-University obligation to either:

- an individual or a private organization that provides support for a University research, educational or public service activity; or
- an organization (or individual) with which (whom) the University has an agreement to provide support for the conduct of a program project, activity or service supervised by the Investigator.

The Investigator has a consulting arrangement with a business enterprise that either:

- supports, or is supported by, University programs involving the Investigator; or
- is licensed to commercialize University technologies invented by the Investigator

The Investigator has significant financial interest (see definition) in a business enterprise that either:

- supports, or is supported by, the Investigator's University research; or
- owns, or has applied for the patent, or manufacturing or marketing rights to a drug, device, product, or procedure that either:
    - is a subject of, or will predictably result from, the Investigator's University research, or
    - can reasonably be expected to compete with a drug, device, product or procedure that will predictably result from the Investigator's University research.

The Investigator holds a position as consultant, officer, director, trustee or owner of a non-University business enterprise that supports or is supported by the Investigator's University research.

Appendix 2 Managed Conflicts of Interest Examples

Possible Resolutions to Financial Conflict of Interest or Conflict of Obligation:

- Management Plan
- Modification of the research plan
- Disqualification from participation in the portion of the externally funded research that would be affected by the significant financial interests
- Severance of relationships that create actual or potential conflicts
- Removal of investigator as Principal Investigator/Project Director

Scenarios Determined to be a Financial Conflict of Interest (FCOI) or Conflict of Obligation (CO) and Managed via a Management Plan – this is not an all-inclusive list:

CO: Investigator has an unpaid position (e.g. board member, scientific advisor) with the sponsor.

CO: Investigator is performing research in an area of interest to their startup company.

CO: Sponsor has entered into an agreement with the University for an option to license a pending patent for the technology that is the subject of the research.

FCOI: Investigator receives royalty income from the sponsor for the technology that is the subject of the research.

FCOI: Investigator receives royalty income from the University for the technology that is the subject of the research.

FCOI: Investigator performs a service (e.g. consulting, educational services) for the sponsor of a project.

FCOI: Investigator owns equity or shares in the sponsor.

FCOI: NIH/PHS only – Investigator has received reimbursement or had paid on their behalf travel by the sponsor.

Appendix 3 Management Plan Examples

All Management Plans include:

- You are to disclose your role and interests in ["Company Name"] in any publication or public presentation that either references results derived from the above referenced grant/contract, or that directly references support by the above referenced grant/contract (i.e. if you list the grant/contract award number you must also make the disclosure).

- You are reminded that consulting activities must be consistent with the Provost's guidelines for outside consulting work, which includes receiving approval from your Dean prior to initiating the work. http://www.stonybrook.edu/commcms/provost/resources/consult.html

- Investigators must comply with SUNY and RF intellectual property and patent policies and procedures. http://research.stonybrook.edu/policies/ip-and-patent-policies

- You are required to report any changes to the information provided in your Investigator Disclosure Form within 30 days of discovering or acquiring a new interest.

- These requirements are in addition to those mandated by applicable professional organizations.

Management Plans where there are human research subjects include:

- Although you may briefly explain the various clinical and/or research options available to a patient given his or her clinical condition, you are not otherwise permitted to specifically recruit or consent study participants for the study in question.

- The consent process and consent documents must disclose the conflict of interest that you have with ["Company Name"]. The IRB Consent form templates contain language to be used.

Management Plans where there are students include:

- [Dr. Y] will serve in the role as student advocate to monitor the student's academic progress and to be available to assist the student with any questions or concerns regarding their participation in the above referenced grant/contract.

Management Plans that require a monitor include:

- The University has appointed [Dr. Y] as an independent and disinterested Compliance Monitor for the [Project] who is reasonably skilled in the design and conduct of X experiments, especially in the discipline of X, to monitor and oversee the conduct of the research under the agreement. The role of the Compliance Monitor will be to:
  - monitor the conduct and performance of the research;
  - to validate that the research is being performed in a professionally responsible manner by certifying in writing that each milestone, as set forth in the contract's scope in the work, are complete and were performed, documented, and reported in a professionally responsible manner; and
  - to report such progress to [Name, Title, University, or his/her designee].
- [Name, Title, University, or his/her designee] shall review and accept the certification of the reviewer before any data or other information generated in the course of the project is disclosed to the Company.

Management Plans where the sponsor is the Investigator's faculty startup company include:

- Any use of University Resources by or for ["Company Name"] must be authorized by an independent and disinterested agent of Stony Brook University in writing and for consideration at fair market value.

    - In this context "University" means any Stony Brook University, SUNY, Research Foundation for SUNY, campus auxiliary services, Stony Brook Foundation, and any other SUNY-affiliated entity.

    - "Resources" means

        a. financial support, funds and grants administered by the University;
        b. inter-institutional collaborations facilitated by the University;
        c. equipment, facilities, services, laboratories, or space;
        d. computers and computer or communications networks not publicly or routinely-available;
        e. research, clinical, or other scientific instruments;
        f. time spent by University faculty, students and staff, including secretarial, clerical, administrative staff, and research and teaching assistants;
        g. confidential information;
        h. Inventions and other proprietary or intellectual property owned by the University; and
        i. any privileged access that results from [Dr. X] affiliation with the University.

- [Dr. X] shall not use her position at Stony Brook University to influence, directly or indirectly, any contractual negotiations between the University and [Company X].

- [Dr. X], with any University collaborators, shall submit a New Technology Disclosure covering any work performed to date using University resources that will inure to the benefit of [Company X]. [Dr. X], with any University collaborators, shall file new technology disclosures for any future developments created with the use of University resources, unless this requirement is waived in a writing signed by both parties (e.g., within an incubator client agreement or facilities use agreement).

- For any future research and/or testing proposed to be performed at the University for the benefit of [Company X], Stony Brook University may engage an independent reviewer who is reasonably skilled in the design and conduct of the work to be performed, to monitor and oversee the conduct of the research, for which [Company X] shall compensate Stony Brook University at fair market value.

- [Dr. X] acknowledges that his/her employment relationship with Stony Brook University is in no way dependent or contingent upon any action or performance by or for [Company X]. [Dr. X] also certifies that his/her compensation by/from the Company is neither dependent nor contingent upon any action by the University.

Other terms that may be Included in Management Plans:

- Modification of the research plan;
- Disqualification from participation in the portion of the externally funded research that would be affected by the significant financial interests;
- Divesture of significant financial interests;
- Severance of relationships that create actual or potential conflicts;
- Removal of investigator as Principal Investigator/Project Director.