I. Policy and General Principles

This Policy implements federal disclosure requirements pertaining to objectivity in research promulgated by the U.S. Public Health Service (PHS) in 42 CFR Part 50 and 45 CFR Part 94 (Federal Regulations). These federal regulations require Winthrop-University Hospital to maintain an appropriate written policy on financial conflict of interest disclosure as a condition for receiving PHS grants. These federal requirements, as implemented in this Policy, are applicable to all proposals for PHS funding.

This policy is an addendum to the Winthrop-University Hospital Research Financial Interests Disclosure Policy and specifically addressed the requirements for PHS research referred to in the above paragraph. The Winthrop-University Hospital Research Financial Interests Disclosure Policy addresses all other non-PHS funded.

All Winthrop-University Hospital Investigators must also carry out Research consistent with the standards of all other applicable Winthrop-University Hospital policies.

II. Purpose and Scope of Policy

A. Purpose

The goal of this Policy is to assure the objectivity with which Research projects are designed, conducted or reported by managing financial conflicts of interest that occur between an Investigator's personal financial interests and his professional Research interests.

This Policy establishes a process of disclosure and independent review when an Investigator (as defined below) has Significant Financial Interest(s) as defined by the Federal Regulations. When Winthrop-University Hospital determines that such an interest might reasonably appear to affect the Research directly and significantly, Winthrop-University Hospital will take steps to manage or to eliminate the conflict.

B. Scope

This Policy applies to Research projects for which Winthrop-University Hospital submits a proposal to, or receives research funding from, PHS. This Policy sets forth requirements that each Investigator (as defined in Section IV, below) who is planning to participate in, or is participating in such Research, must follow; provided, however, that this Policy does not apply to SBIR (Small Business Innovation Research) Program Phase I applications.
III. Disclosure of Financial Interests

When an Investigator has a Significant Financial Interest, a written Significant Financial Interest Disclosure Form (Disclosure Form; located in Attachment A) detailing that interest is required. When an Investigator does not have a Significant Financial Interest, the Investigator must still complete the Disclosure Form but can check the box stating that no Significant Financial Interest exists.

Each investigator must update his or her financial disclosures on an ongoing basis by completing a new Disclosure Form. This update must occur either annually or as new Significant Financial Interests are obtained throughout the period of the award (see Section IV, Part F of this Policy).

IV. Definitions

Chief Academic Officer - The official designated by Winthrop-University Hospital to solicit and review completed Disclosure Forms from each Investigator who is planning to participate in, or who is participating in, PHS-funded Research and to determine whether any reported Significant Financial Interest is a Financial Conflict of Interest.

Disclosure of Financial Interests, Update of Disclosure of Financial Interests - Each Investigator must complete a new Disclosure Form either annually or whenever he or she acquires a new Significant Financial Interest that was not listed in the original Disclosure Form, whichever occurs first.

Financial Conflict of Interest (FCOI) - A Financial Conflict of Interest (FCOI) is a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-funded Research.

All Investigators currently involved in PHS funded research must complete applicable training and submit a Disclosure Form no later than August 24, 2012.

Investigators who are applying for PHS funding and have not yet completed training or a Disclosure Form must do so no later than the time of application for PHS funded Research.

Investigator - An Investigator is any individual responsible for the design, conduct, or reporting of Research funded by the PHS. This includes the Principal Investigator, Co-Investigators, and any other individual, regardless of title or position, who is responsible for designing, conducting, or reporting of this Research.

PHS Awarding Component - PHS Awarding Component means the organizational unit of the PHS that funds the Research.
Public Health Service (PHS) funded research is research sponsored by the United States PHS which includes the National Institutes of Health (NIH). This includes projects funded directly by the PHS to Winthrop, such as NIH grants and any PHS funded projects on which Winthrop is a sub-contractor or collaborator (including all cooperative group studies including but not limited to GOH, COG and SWOG.

Research - 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).

Sub-investigator – A collaborator at an outside institution who is contributing to the design, conduct, or reporting of Research funded by the PHS.

V. Significant Financial Interest

Significant Financial Interest means either of the following:

1. Any interest 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, including, but not limited to, one or more of the following:

   a. 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 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. 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;

   b. 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 months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

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

The term Significant Financial Interest does not include the following types of financial interests:

1. salary, royalties, or other remuneration paid by Winthrop-University Hospital to the Investigator if the Investigator is currently employed or otherwise appointed by Winthrop-University Hospital, including intellectual property rights assigned to Winthrop-University Hospital 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 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, 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.

VI. Training Requirements

All Investigators must complete applicable training requirements. These can be satisfied by completing the NIH on-line course located at:


The certificate obtained at the end of this training will be considered acceptable proof of completion of this training and should be sent to the Office of Sponsored Programs, 222 Station Plaza North, Suite 301.

Training must be completed as follows:

i. Prior to engaging in research related to any PHS funded grant
ii. At least every 4 years
iii. As a new Investigator to Winthrop
iv. If the Investigator is not in compliance with this policy or a FCOI management plan
VII. Disclosure Requirement

Each Investigator who is planning to participate in PHS-funded Research is required to disclose to the Winthrop-University Hospital Reviewing Official the Investigator’s Significant Financial Interests (and those of the Investigator’s spouse and dependent children) no later than the time of application for PHS-funded Research. Each Investigator must do so by completing the Disclosure Form.

Each Investigator who is participating in PHS-funded Research is required to submit an updated Disclosure Form either within 30 days of discovering or acquiring a new Significant Financial Interest, or at least on an annual basis, during the period of the PHS funding award.

Sub-Investigators at non Winthrop controlled (outside) institutions must attest that their institution has an applicable FCOI policy or be subject to the WUH policy. Sub-investigator form included as attachment B.

VIII. Review of Disclosures and Management of FCOIs

A. Initial review and Management: Prior to Winthrop-University Hospital's expenditure of any funds under a PHS-funded Research project, the Winthrop-University Hospital Reviewing Official will review all Investigators' Disclosure Forms; determine whether any Significant Financial Interests relate to PHS-funded Research; determine whether a FCOI exists; and, if so, develop and implement a management plan that specifies the actions that have been, and will be, taken to manage such FCOI.

B. Review and management in the course of a PHS-funded Research project: Whenever, in the course of an ongoing PHS-funded Research project, (1) an Investigator who is new to participating in the Research project discloses a Significant Financial Interest; (2) an existing Investigator discloses a new Significant Financial Interest; or (3) Winthrop-University Hospital identifies a Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by Winthrop-University Hospital during an ongoing PHS-funded Research project, the Winthrop-University Hospital Reviewing Official will, within sixty days: review the disclosure of the Significant Financial Interest; determine whether it is related to PHS-funded Research; determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI. Depending on the nature of the Significant Financial Interest, Winthrop-University Hospital may determine that additional interim measures are necessary with regard to the Investigator’s participation in the PHS-funded Research project between the date of disclosure and the completion of Winthrop-University Hospital's review.
C. **Examples of management:** Examples of conditions or restrictions that may be imposed to manage an FCOI include, but are not limited to:

1. Public disclosure of the FCOI;
2. For Research projects involving human subjects, disclosure of the FCOI directly to participants;
3. 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;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
6. Reduction or elimination of the financial interest; or
7. Severance of relationships that create financial conflicts.

D. **Additional requirements for Retrospective Review:** In addition to the above requirements, whenever an FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest that is determined by Winthrop-University Hospital to constitute an FCOI; failure by Winthrop-University Hospital to review or manage such an FCOI; or failure by the Investigator to comply with an FCOI management plan, Winthrop-University Hospital will, within 120 days of Winthrop-University Hospital’s determination of noncompliance, complete a retrospective review of the Investigator’s activities and the PHS-funded Research project to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research.

Winthrop-University Hospital is required to document the retrospective review, including all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigator with the FCOI; (5) Name of the entity with which the Investigator has an FCOI; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, Winthrop-University Hospital will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Winthrop-University Hospital will notify the PHS Awarding
Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the Research project and Winthrop-University Hospital’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, Winthrop-University Hospital will submit FCOI reports annually. Depending on the nature of the FCOI, Winthrop-University Hospital may determine that additional interim measures are necessary with regard to the Investigator’s participation in the PHS-funded Research project between the date that the FCOI or the Investigator’s noncompliance is determined and the completion of Winthrop-University Hospital’s retrospective review.

E. **Monitoring:** Whenever Winthrop-University Hospital implements a management plan, Winthrop-University Hospital will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded Research project.

IX. **Reporting of Financial Conflicts of Interest**

A. **Initial FCOI Report:** Prior to Winthrop-University Hospital’s expenditure of any funds under a PHS-funded Research project, Winthrop-University Hospital will provide to the PHS Awarding Component an FCOI report regarding any Investigator’s Significant Financial interest found by Winthrop-University Hospital to be an FCOI and ensure that Winthrop-University Hospital has implemented a management plan in accordance with Section VI of this Policy. In cases in which Winthrop-University Hospital identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, Winthrop-University Hospital does not need to submit an FCOI report to the PHS Awarding Component.

B. **Subsequent FCOI Reports:** For any Significant Financial Interest that Winthrop-University Hospital identifies as conflicting after Winthrop-University Hospital’s initial FCOI report during an ongoing PHS-funded Research project, Winthrop-University Hospital will provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the FCOI and ensure that Winthrop-University Hospital has implemented a management plan in accordance with Section VI of this Policy and, if required, a retrospective review and a mitigation report according to Section VI of this Policy.
C. **Contents of an FCOI report**: Any FCOI report required under paragraphs A or B of this Section VII will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Winthrop-University Hospital’s management plan.

Elements of the FCOI report will include, but are not necessarily limited to the following:

1. Project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. Name of the Investigator with the FCOI;
4. Name of the entity with which the Investigator has an FCOI;
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. Value of the financial interest (dollar ranges are permissible: $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 readily be determined through reference to public prices or other reasonable measures of fair market value;
7. A description of how the financial interest relates to the PHS-funded Research and the basis for Winthrop-University Hospital’s determination that the financial interest conflicts with such Research; and
8. A description of the key elements of Winthrop-University Hospital’s management 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 the Research project;
   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.

D. **Annual FCOI Report**: For any FCOI previously reported by Winthrop-University Hospital with regard to an ongoing PHS-funded Research project, Winthrop-University Hospital will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded Research project. The annual FCOI report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Winthrop-University Hospital will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.
X. **Enforcement**

Failure to comply with this Policy, including failure to file a complete or timely Disclosure Form or update or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy, including a management plan, will be grounds for discipline up to and including termination.

In addition, if the failure of an Investigator to comply with this Policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded Research, Winthrop-University Hospital is required to promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Winthrop-University Hospital for further action, which may include directions to Winthrop-University Hospital on how to maintain appropriate objectivity in the PHS-funded Research project.

In addition, federal regulations may require reports to the federal sponsor of any information which may show a violation of Winthrop-University Hospital policy. Sponsors may impose special award conditions or may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of Significant Financial Interests related to federally sponsored projects.

XI. **Records**

Records regarding Disclosure Forms, the Winthrop-University Hospital Reviewing Official's determinations, and Winthrop-University Hospital actions regarding management of an FCOI will be retained by Winthrop-University Hospital for three years beyond the date of the final expenditure report submitted to PHS under an award. (These records will be kept by the Office of Sponsored Programs.)
Attachment A

Significant Financial Interest Disclosure Form

This Disclosure Form is to be completed by each Investigator pursuant to the Winthrop-
University Hospital Policy on Financial Conflicts of Interest in Public Health Service-Funded
Research. Please refer to that Policy for detailed requirements and definitions. Complete this
form and submit it to the Office of Sponsored Programs.

I. Research Project Title and number:

II. Project Director/Principal Investigator or Contact PD/PI if a multiple
PD/PI model is used:

III. Name of Investigator making this report about his/her
financial interest(s):

IV. Check which of the following you are submitting:

A. Initial Disclosure Form: Before the time of application for PHS-funded Research

B. Update Disclosure Form: Within 30 days discovering or acquiring a new
Significant Financial Interest during a PHS-funded Research award

C. Update Disclosure Form: Required Annual Update during a PHS-funded
Research award

V. Indicate whether you, the Investigator, have any Significant Financial
Interests related to the work to be conducted under the PHS-funded
Research project(s):

A. I have no Significant Financial Interest as that term is defined in the Policy (stop
completing this Disclosure Form here and submit it).

B. I do have Significant Financial Interest(s) to report (continue completing rest of this
Disclosure Form)
VI. For each Significant Financial Interest (use additional pages if necessary):

A. Provide the name of each entity in which the Investigator has a Significant Financial Interest:

B. Provide the nature of the financial interest (for example, equity, consulting fee, travel reimbursement, or honorarium):

C. Indicate the value (dollar amount) of the Significant Financial Interest:

D. For Reimbursed or Sponsored Travel required to be reported by the Policy, indicate all of the following:
   1. The purpose of the trip:
   2. The identity of the sponsor/organizer:
   3. The destination:
   4. The duration:

E. Describe how the Significant Financial Interest relates to the PHS-funded Research:

F. Do you believe that the Research project(s) could directly and significantly affect the Significant Financial Interest(s) you are reporting?

VII. For further information about the Policy and how to complete this information, you may contact.
Attachment B
Conflict of Interest Disclosure
for consortium sub-investigators

(A separate form is required to be completed for the Principal Investigator and each additional person identified as Key Personnel under the project.)

Investigator Name: ___________________________

Institution Name: ___________________________ PI at the Institution: ________________

Grant No: ___________________________ Period: ___________________________

1. Subrecipient organization/institution hereby certifies that it has an active and enforced conflict of interest policy that is consistent with the provision of 42 CFR Part 50 Subpart F or 42 CFR Part 94 as applicable.

Please check one:
Yes: ☐
No: ☐

If checked Yes, proceed to (a) or (b) as applicable.
If checked No, proceed to (c) and fill out the Questionnaire attached.

a) The subrecipient organization/institution certifies that the above-named investigator (as defined by 42 CFR Part 50 Subpart F or 42 CFR Part 94 as applicable) does not have any significant financial interests related to this project. Therefore, no conflict of interest has been identified.

b) In accordance with 42 CFR 50.605, subrecipient institution/organization certifies that the above-named investigator has significant financial interests related to this project. Therefore, a conflict of interest has been identified, and:
   a. managed* ☐
   b. reduced* ☐
   c. eliminated* ☐

* Please provide documentation supporting the identification and management of the conflict of interest, such as the management plan, Institution's certification letter, etc.

c) Subrecipient organization/institution does not have an active and/or enforced conflict of interest policy and hereby agrees to comply with WUH's policies and procedures relating to financial conflicts of interest. In accordance with this commitment, each investigator as defined in WUH’s policy has completed WUH’s conflict of interest questionnaire and attached it hereto.

______________________________  ______________________________
Signature of Authorized Representative  Signature of Investigator

______________________________  ______________________________
Printed Name  Printed Name

______________________________  ______________________________
Title  Date  Title  Date

WUH requires both Authorized Representative and Investigator sign this form.