
Principal Investigator Financial Conflict of Interest

1 POLICY:

- NorthShore University HealthSystem (NorthShore) will conduct its research in an objective manner, free from undue influence arising from financial interests.
- The research mission of NorthShore will be conducted in accordance with the following regulations:
 - Public Health Service (PHS), 42 CFR Part 50, Subpart F - Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought;
 - National Institute of Health, 45 CFR Part 94 - Responsible Prospective Contractors;
 - National Science Foundation (NSF) - Investigator Financial Disclosure Policy; and
 - U.S. Department of Health and Human Services (DHHS), Food and Drug Administration (FDA) 21 CFR 54, Centers for Drug Evaluation and Research, Biologics Evaluation and Research, Devices and Radiological Health, March 20, 2001 - Financial Disclosure by Clinical Investigators

These regulations promote “objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.”

- NorthShore’s Principal Investigator Financial Conflict of Interest Policy will be publically accessible on northshore.org, the Research Institute webpage.
- NorthShore will ensure availability of information concerning significant financial interests for responses to written requests for at least three years from the date the information was most recently updated.
- NorthShore will make its conflict of interest information available, including information on how NorthShore manages, reduces, or eliminates any conflicts of interests, upon request to the PHS Awarding Component and the Department of Health and Human Services (HHS).

2 SCOPE:

NorthShore Investigators participating in PHS and/or sponsored clinical trial research and subgrantee/contractor/collaborating Investigators, but excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program.

3 DEFINITIONS:

FINANCIAL CONFLICT OF INTEREST (FCOI) - A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded or sponsor-funded research.

FOOD AND DRUG ADMINISTRATION (FDA) - An agency within the U.S. Public Health Service which is a part of the Department of Health and Human Services.

INSTITUTION - Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research or sponsor-funding.

INVESTIGATOR - Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or proposed for such funding, which may include, for example, collaborators or consultants.

PD/PI - Project Director or Principal Investigator of a PHS-funded or sponsor-funded research project.

PUBLIC HEALTH SERVICE (PHS) – Operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS ACT - Statute codified at 42 U.S.C. 201 et seq.

PHS AWARDING COMPONENT - Organizational unit of the PHS that funds the research that is subject to this subpart.

RESEARCH – Systematic investigation 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 and product development.

Includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, sponsor-funded or investigator initiated research.

RESPONSIBLE PERSONNEL - Any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or proposed for such funding, which may include, for example, collaborators or consultants. It is the role, not the title that is considered of those involved in research and the degree of independence with which those individuals work.

SIGNIFICANT FINANCIAL INTEREST – 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, the value of any remuneration received from the entity in 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. (“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 interests, as determined through reference to public prices or other reasonable measures of fair market value);
2. With regard to any non-publicly traded entity, 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 Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Significant financial interest means that Investigators must also 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:

- Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state or local government agency, 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.

National Science Foundation requires the reporting of any interest of monetary value.

SENIOR/KEY PERSONNEL - Project Director or Principal Investigator and any other person identified as senior/key personnel by the Institution granting the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart as well as sponsor funded and investigator initiated research.

SMALL BUSINESS INNOVATION RESEARCH (SBIR) - Extramural research program for small business established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102–564.

SPONSORED CLINICAL TRIAL - Sponsored clinical trials are typically awarded to NorthShore as a commitment to a specified project plan and budget, both of which are essential to financial accountability.

4 PROCEDURE:

<u>Action</u>	<u>Responsibility</u>
A. Responsibilities of NorthShore Investigators - 42 CFR 50.604	Investigator
<ol style="list-style-type: none">1. NorthShore requires its Investigators to complete training regarding NorthShore's policy on financial conflicts of interest, the Investigator's disclosure regarding disclosure of significant financial interests, and these regulations prior to engaging in research grants or sponsored funded research and at least every 4 years, and immediately when any of the following circumstances apply:<ol style="list-style-type: none">a. NorthShore revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;b. An Investigator is new to an Institution; orc. NorthShore finds that an Investigator is not in compliance with NorthShore's financial conflict of interest policy or management plan.2. NorthShore requires that Investigators planning to participate in a PHS-funded or sponsor-funded research complete and submit, no later than the time of application, a listing of his/her known Significant Financial Interests (and those of the Investigator's spouse and dependent children) on the <i>Certificate of Objectivity in Research – Disclosure of Information</i> form to the Associate Director of Research Administration.3. Investigators participating in PHS-funded or sponsor funded research must update and submit a <i>Certificate of Objectivity in Research – Disclosure of Information</i> form during the period of the PHS-funded award or sponsor funded research on an annual basis AND when the Investigator obtains a new reportable significant financial interest. Investigators must disclose new significant financial interests within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.<ol style="list-style-type: none">a. All Responsible Personnel (including the PI) will submit a <i>Certificate of Objectivity in Research – Disclosure of Information</i> form regardless of the funding source based on the time schedules of Sections A(3) and A(4) of this policy.4. NorthShore requires its Investigator(s) to disclose his/her conflicting interest in public presentations of research if the HHS determines that a PHS-funded project of clinical research, whose purpose was to evaluate the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed to or managed by NorthShore.5. If NorthShore carries out PHS-funded or sponsor funded research through a subrecipient, NorthShore must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:<ol style="list-style-type: none">a. Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of NorthShore or that of the subrecipient will apply to the subrecipient's Investigators;<ol style="list-style-type: none">i. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement that its policy complies with this subpart. If the subrecipient cannot provide certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of NorthShore for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution.ii. If the subrecipient's Investigators must comply with NorthShore's financial conflicts of interest policy, the agreement shall specify the time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to NorthShore.b. Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart (i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI)	
B. Responsibilities for Non-NorthShore Investigators	
<ol style="list-style-type: none">1. It is the responsibility of any Non-NorthShore employed Investigator conducting or participating in research at NorthShore to submit to the Research Institute a Certification of Completion of Financial Conflict of Interest training from their affiliated institution.2. It is the responsibility of any Non-NorthShore employed Investigator who is not affiliated with an Institution that provides Financial Conflict of Interest training to obtain training via the National Institutes of Health (NIH) Financial Conflict of Interest module and to submit to the Research Institute the certificate received upon completion of this training.	

C. Review and Management Responsibilities of NorthShore Research Institute - 42 CFR 50.604, 50.605(a)

1. The Associate Director of Research Administration is responsible for soliciting and reviewing all *Certificate of Objectivity – Disclosure of Information* Forms which indicate any interest from each Investigator who is planning to participate in PHS-funded or sponsor-funded research. Associate Director of Research Administration
2. Based on the recommendation of the Associate Director of Research Administration, the Assistant Vice President of Research Administration will review all *Certificate of Objectivity in Research – Disclosure of Information* forms that report a significant financial interest and will determine whether an Investigator’s significant financial interest is related to funded research, and if so related, whether the significant financial interest is a financial conflict of interest. An investigator’s significant financial interest is related to funded research when NorthShore, through its designated official(s), reasonably determines that the significant financial interest could be affected by the funded research or is in an entity whose financial interest could be affected by the research. If a financial conflict of interest exists, NorthShore shall take such actions necessary to manage financial conflicts of interest. Assistant Vice President of Research Administration
 - a. The Assistant Vice President of Research Administration will initial the reviewed *Certificate of Objectivity in Research – Disclosure of Information* and document in a brief note the results of their review, including whether a financial conflict of interest exist or and, if applicable, how it will be managed.
3. Management of financial conflicts of interest include:
 - a. If a financial conflict of interest is disclosed in excess of \$30,000 in equity, the conflict must be disclosed in the research study’s Consent document.
 - b. If a financial conflict of interest is disclosed in excess of \$15,000 for a payment from the sponsor for services provided by the Investigator to the sponsor (consulting fees, board member remuneration), the Investigator must recuse themselves from the study
 - i. In both cases consultation with the Chief Corporate Compliance Officer will take place to determine appropriate reporting mechanisms.
4. Whenever, in the course of an ongoing funded research project, an Investigator who is a new participant in the research project discloses a significant financial interest to NorthShore or when NorthShore identifies a significant financial interest that was not timely disclosed by an Investigator or was not previously reviewed by NorthShore during an ongoing funded research project, the Assistant Vice President of Research Administration shall, within 60 days: review the disclosure of the significant financial interest; determine whether it is related to funded research; determine whether a financial conflict of interest exists; and, if so, implement at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest.
 - a. When a financial conflict of interest is not identified or managed in a timely manner, including failure by the Investigator to disclose a significant financial interest that is determined by NorthShore to be a financial conflict of interest; failure by NorthShore to review or manage such financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, NorthShore shall, within 120 days of NorthShore’s determination of noncompliance, complete a retrospective review of the Investigator’s activities and the funded research project to determine whether any funded research conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.
 - i. NorthShore shall document the retrospective review, which shall include, but not be limited to, all of the following key elements: project number; project title; PD/PI or contact PD/PI if multiple PD/PI model is used; name of the Investigator with the FCOI; name of the entity with which the Investigator has a financial conflict of interest; reasons for the retrospective review; detailed methodology used for retrospective review; findings of the review; and conclusions of the review.
 - ii. Based on the results, if appropriate, NorthShore shall update the previously submitted FCOI report, specifying actions that will be taken to manage the financial conflict of interest going forward. If bias is found, NorthShore is required to notify the PHS Awarding Component as outlined in Section 4(D)(4)(b) of this policy.
 - b. Whenever NorthShore implements a management plan pursuant to this subpart, NorthShore shall monitor Investigator compliance with the management plan on an ongoing basis until completion of the PHS-funded research project.

D. Reporting of Financial Conflicts of Interest - 42 CFR 50.605(b)

1. If an Investigator reports a conflict of interest via the Certificate of Objectivity in Research – Disclosure of Information form, the Assistant Vice President of Research Administration will review the form to determine if there is a reasonable basis on which to conclude that a project could directly and significantly affect the financial interest of the Investigator and if the financial interest is likely or not to affect the design, conduct, or reporting of the project. Assistant Vice President of Research Administration
2. When discovered, NorthShore will report any conflicting interests of its Investigators to the PHS awarding component or sponsor that issued the award prior to expending any funds and ensure that NorthShore has implemented a management plan in accordance with this subpart.
3. For any significant financial interest that NorthShore identifies as conflicting subsequent to NorthShore’s initial FCOI report during an ongoing PHS-funded or sponsor funded research project, NorthShore shall provide the PHS Awarding Component or sponsor, within 60 days, an FCOI report regarding the financial conflict of interest and ensure that NorthShore has implemented a management plan in accordance with this subpart.
 - a. Where the FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or was not previously reviewed or managed by NorthShore, NorthShore is also required to complete the retrospective review as outlined in Section 4(C)(4)(a) of this policy.
 - b. If bias is found as a result of the retrospective review, NorthShore is required to notify the PHS Awarding Component promptly and submit a mitigation report (including at least key elements documented in the retrospective review and a description of the impact of the bias on the research project and NorthShore’s plan of action[s] to eliminate/mitigate the effect of bias) to the PHS Awarding Component.
4. Any FCOI report required shall 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 the Institution’s management plan. Elements of the FCOI report shall include, but are not limited to the following:
 - a. Project number
 - b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
 - c. Name of the Investigator with the financial conflict of interest
 - d. Name of the entity with which the Investigator has a financial conflict of interest;
 - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - f. 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 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 NorthShore’s determination that the financial interest conflicts with such research; and
 - h. A description of the key elements of NorthShore’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.
5. For any financial conflict of interest previously reported by the Institution with regard to an ongoing PHS-funded research project, NorthShore shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project.
 - a. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists.
 - b. NorthShore shall 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.

E. Managing Financial Conflicts of Interest – 42 CFR 50.605

1. The Chief Compliance Officer is charged with managing conflicts of interests. Chief Compliance Officer; Assistant Vice President of Research Administration
2. Where a Principal Investigator has indicated a financial conflict of interest (as defined by 42 CFR 50.603) exists via the *Certificate of Objectivity in Research – Disclosure of Information* form, the Assistant Vice President (AVP) of Research Administration will

review the potential conflict. If the reported value of the conflict exceeds \$30,000 the AVP, Research Administration will share materials directly with the Chief Compliance Officer to obtain final decision on how the conflict will be managed.

3. In consultation with the Assistant Vice President of Research Administration, actions the Chief Compliance Officer may propose to manage conflicts of interest include, but are not limited to the following:
 - Public disclosure of financial conflicts of interest;
 - For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
 - Modification of the research plan;
 - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research funded by the PHS;
 - Reduction or elimination of the financial interest; or
 - Severance of relationships that create financial conflicts.

F. Enforcement, Sanctions and Remedies - 42 CFR 50.606

Chief Compliance Officer; Assistant Vice President of Research Administration; Vice President of Human Resources

1. In consultation with the Assistant Vice President of Research Administration and Vice President of Human Resources, the Chief Compliance Officer will review any instances of non-compliance to this policy and on a case-by-case basis and make appropriate sanction recommendations as necessary.
2. Actions that may be required for non-compliance include, but are not limited to the following:
 - Probation from participation in future PHS-funded research;
 - Disqualification from participation in future PHS-funded research;
 - Suspension with or without pay;
 - Termination.
3. Assistant Vice President of Research Administration will document and notify the PHS Awarding Component of instances of non-compliance and any sanctions and corrective actions taken.
4. In any case in which HHS determines that a 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 a financial conflict of interest that was not managed or reported, the Investigator involved will be required to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.
5. Human Resources Department will initiate employee corrective action when appropriate management consensus has determined it appropriate.
6. The Chief Compliance Officer will notify, as appropriate, applicable NorthShore personnel and the Corporate Compliance Committee.

G. Contact for Questions - 42 CFR 50.604

1. Questions or issues regarding financial conflicts of interests can be forwarded to the Assistant Vice President of Research Administration.

Assistant Vice President of Research Administration

5 ATTACHMENT:

6 DISTRIBUTION:

Organization Wide

- 7 POLICY RESPONSIBILITY:**
Assistant Vice President, Research Administration

In Coordination With:
Corporate Compliance Office

8 REFERENCES:

Internal

Certificate of Objectivity in Research – Disclosure of Information Form (RI-9.0)

External

Federal Regulations:
21 CFR 54 - Financial Disclosure By Clinical Investigators
<http://www.ecfr.gov/cgi-bin/text->

NorthShore Research Institute Guidelines and Forms

[idx?SID=41966c91f8c2138877831a3ac041219d&node=pt21.1.54&rgn=div5](http://www.nshs.edu/ResearchManual/Forms/idx?SID=41966c91f8c2138877831a3ac041219d&node=pt21.1.54&rgn=div5)

42 CFR Part 50, Subpart F - Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=efaae6e4efacfbfb90ac2e84f8a3d098&rgn=div6&view=text&node=42:1.0.1.4.21.6&idno=42>

45 CFR Part 94 - Responsible Prospective Contractors

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=546a72de7a60e3381e1ff43180ed7daf&tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl

Final Rule – 42 CFR Part 50; 45 CFR Part 94: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors (August 25, 2011)

http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

National Science Foundation - Investigator Financial Disclosure Policy

<http://www.nsf.gov/pubs/stis1996/iin117/iin117.txt>

Illinois State Law:

Illinois Procurement Code, 30 ILCS 500

<http://www.ilga.gov/legislation/ilcs/ilcs5.asp?ActID=532&ChapAct=30%26nbsp%3BILCS%26nbsp%3B500%2F&ChapterID=7&ChapterName=FINANCE&ActName=Illinois+Procurement+Code%2E>

Applicable Guidance Reference:

National Institute of Health (NIH), Office of Extramural Research
Financial Conflict of Interest: Objectivity in Research

http://www.grants.nih.gov/grants/policy/coi/nih_review.htm

NIH, Office of Extramural Research, Conflict of Interests Web Page

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

9 REVISION:

The organization reserves the right to unilaterally revise, modify, review, or alter the terms and conditions of the policy within the constraints of law, with or without reasonable notice.

10 APPROVAL:

_____	Michael S. Caplan, MD, Chief Scientific Officer, Research Institute	_____
Signature	Name and Title	Date

11 DATES:

Origination: 11/06 Last Review: 10/14 Next Review: 10/17