

PURPOSE:

The purpose of this policy is to provide guidance on the disclosure and management of actual or apparent conflicts of interest related to sponsored research projects and other research conducted at Northside Hospital.

POLICY:

Conflicts of interest in research involve situations in which an Investigator or other individual involved in research has a financial or other interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, reporting or results of research. It is the policy of Northside Hospital to comply with applicable laws, regulations and guidelines that set forth when a conflict of interest must be disclosed, what information must be disclosed, how disclosed information is to be evaluated and when measures should be taken to manage a conflict of interest. A current version of this Policy will be made available on Northside's publically available internet website.

Definitions:

For purposes of this policy, the following definitions shall apply:

- (A) "Central Research Department" or "CRD" means the department at Northside Hospital which manages Northside Hospital clinical research trials and other research projects.
- (B) "Compensation" means any income or other remuneration paid during the preceding 12 months or reasonably anticipated at any time during the research or the 12 months following the research by an entity including but not limited to consulting fees, salaries, wages, retainers, honoraria and expense and travel reimbursements.
- (C) "Conflict of Interest" means a divergence between an individual's financial or other interests and that individual's professional obligations either to a patient or to society such that an independent observer might reasonably question whether the performance of the individual's obligations are adversely affected (or have the potential to be) by considerations of personal gain, and includes the existence of a Significant Financial Interest of an Investigator that could directly and significantly affect the design, conduct, reporting or results of research.
- (D) "Equity Interest" means any interest in the profits of or other ownership interest in any entity, including common stock and other equity securities, and any right to acquire any of the foregoing such as an option, warrant or other convertible security.
- (E) "Financial Conflict" means collectively, Significant PHS Financial Interests and Significant Non PHS Financial Interests.
- (F) "Financial Conflict of Interest Report" means the report of a Significant PHS Financial Interest to a PHS Awarding Component.
- (G) "Immediate Family" means the spouse, parent, child, grandparent, grandchild or sibling of an individual.
- (H) "Investigator" means any individual responsible for the design, conduct, reporting or results of research. It includes, but is not limited to, a Principal Investigator, Co-Principal Investigator, and key scientific personnel. For purposes of disclosure, the term "Investigator" includes the Investigator's Immediate Family. Additionally, "Investigator"

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may include any individual who meets any of the following criteria: signs the Form 1572, is identified as an Investigator in initial submissions or protocol amendments under an IND, or is identified as an Investigator in the NDA/BLA – which could include individuals identified as sub-investigators on a Form FDA 1572.

- (I) “Management Plan” means a written plan for the management, reduction or elimination of a potential or existing Conflict of Interest relating to research.
- (J) “PHS” means the Public Health Service of the U.S. Department of Health and Human Services and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.
- (K) “PHS Awarding Component” means the organizational unit of the PHS that funds PHS Supported Research.
- (L) “PHS Supported Research” means research that is funded by a grant, contract, or cooperative agreement with PHS or a PHS Awarding Component.
- (M) “Significant PHS Financial Interest” means a financial interest consisting of one or more of the following interests of the Investigator or Investigator’s Immediate Family that reasonably appears to be related to the Investigator’s responsibilities at Northside Hospital or as the Investigator that could directly and significantly affect the design, conduct or reporting of the research, including but not limited to:
 - 1. Any financial arrangement, including any intellectual property rights or Equity Interests, entered into between the Sponsor of the covered study and the Investigator involved in the conduct of the research clinical trial or his Immediate Family, whereby the value of the Compensation could be influenced by the outcome of the study;
 - 2. Any Significant Payments of Other Sorts from the Sponsor of the research study, such as a grant to fund ongoing research, Compensation in the form of equipment, a retainer for ongoing consultation, or honoraria;
 - 3. Any reimbursed or sponsored travel paid on behalf of the Investigator related to the Investigator’s responsibilities at Northside Hospital or as the Investigator.

The term does not include:

- 1. Compensation from Northside;
 - 2. Compensation from seminars, lectures or teaching engagements sponsored by public or nonprofit entities;
 - 3. Compensation from service on advisory committees or review panels for public or nonprofit entities;
 - 4. An Equity Interest in a publicly traded entity that, when aggregated for the Investigator and the Investigator’s spouse and dependent children, does not exceed \$5,000 or does not represent more than 5 percent ownership for any one entity;
 - 5. Compensation that, when aggregated for the Investigator and the Investigator’s spouse and dependent children, does not exceed \$5,000 per annum or does not represent more than 5 percent ownership for any one entity.
- (N) “Significant Non-PHS Financial Interest” means a financial interest consisting of one or more of the following interests of the Investigator or Investigator’s Immediate Family that reasonably appears to be related to the Investigator’s responsibilities at Northside Hospital or as the Investigator including but not limited to:

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1. Any financial arrangement, including any intellectual property rights or Equity Interests, entered into between the Sponsor of the covered study and the Investigator involved in the conduct of the research clinical trial or his Immediate Family, whereby the value of the Compensation could be influenced by the outcome of the study;
2. Any Significant Payments of Other Sorts from the Sponsor of the research study, such as a grant to fund ongoing research, Compensation in the form of equipment, a retainer for ongoing consultation, or honoraria;
3. Any Equity Interest of an Investigator or his Immediate Family in a non-publicly traded company;

The term does not include:

1. Compensation from Northside;
 2. Compensation from seminars, lectures or teaching engagements sponsored by public or nonprofit entities;
 3. Compensation from service on advisory committees or review panels for public or nonprofit entities;
 4. An Equity Interest in a publicly traded entity that, when aggregated for the Investigator and the Investigator's spouse and dependent children, does not exceed \$50,000 or does not represent more than 5 percent ownership for any one entity; or
 5. Compensation that, when aggregated for the Investigator and the Investigator's spouse and dependent children, does not exceed \$25,000 per annum or does not represent more than 5 percent ownership for any one entity.
- (O) "Significant Payments of Other Sorts" means payments made by the Sponsor of a study to the Investigator or the institution to support direct activities of the Investigator that have a monetary value of more than \$5,000 (for PHS Supported Research) or \$25,000 (for all other research), exclusive of the costs of conducting the study, during the time the Investigator is carrying out the study and for one (1) year following the completion of the study. Additionally, all entertainment costs and/or providing lodging and meals for Immediate Family members of Investigators, regardless of the dollar amount, should be tracked as Significant Payments of Other Sorts.
- (P) "Sponsor" of a study means the party supporting a particular study at the time it was carried out.

Policy Actions:

- 1.0 Disclosure of Conflicts of Interest for all research.
 - 1.1 Every Investigator holding a Conflict of Interest or Financial Conflict must disclose this interest in writing to the Central Research Department prior to the submission of a grant or contract application or prior to the initiation of research at Northside Hospital.
 - 1.2 In addition to the need to disclose any Conflict of Interest to Northside, Investigators holding a Conflict of Interest or a Financial Conflict should disclose this interest to federal, state, and local officials, as required; to research funders or Sponsors, as required; and to the editors of any

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publication or substantive public communication to which the Investigator submits a manuscript concerning the research.

- 1.3 If a new Conflict of Interest or Financial Conflict is discovered or acquired (e.g., through purchase, marriage or inheritance), or if a new Investigator is hired to work on the research project, the Investigator must prepare and submit a disclosure form identifying Conflicts of Interest to the Central Research Department.
- 1.4 Investigators holding a Financial Conflict must not delegate the conduct of research to individuals over whom the Investigator has direct supervision without the approval of the Central Research Department.
- 1.5 Investigators must update the Conflict of Interest information on file with the Central Research Department at least annually, and for one (1) year following the time of completion of the study.

2.0 Review and Management of Conflicts of Interest of all Research

Disclosure is an essential element of the Conflict of Interest review and management process. In some cases the extent of a Financial Conflict and the nature of the research may be such that disclosure alone is adequate. Some projects in which an Investigator holds a Financial Conflict will require management in addition to disclosure. This determination will be made through the established procedure for review of Conflicts of Interest.

3.0 Reporting Financial Conflicts of Interest for PHS Supported Research

- 3.1 Prior to beginning PHS Supported Research, and every four-years thereafter, all Investigators must complete training on Northside's Conflict of Interest Policy, the Investigator's responsibilities regarding disclosure of Financial Conflicts, and the regulations located at 42 CFR Part 50 and 45 CFR Part 94.
- 3.2 Prior to expending any funds for PHS Supported Research, the Research Program Director must provide a Financial Conflict of Interest Report to the PHS Awarding Component regarding all Conflicts of Interest related to a Significant PHS Financial Interest, if applicable.
- 3.3 The Research Program Director (or his/her designee) must submit the Financial Conflict of Interest Report to the PHS Awarding Component.
- 3.4 The Research Program Director (or his/her designee) must submit an annual Financial Conflict of Interest Report to the PHS Awarding Component that addresses the status of previously reported Conflicts of Interest and any changes to their Management Plans for the duration of the PHS Supported Research.

4.0 Retrospective Reviews of PHS Supported Research

If the Central Research Department identifies a Significant PHS Financial Interest that was not timely disclosed or was not previously reviewed by the



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Central Research Department, the Central Research Department and the Outside Interests Task Force shall follow the established procedure for review of Conflicts of Interests.

5.0 Public Accessibility of Significant Financial Interest Disclosures for PHS Supported Research

The Central Research Department will provide a written response within five (5) business days of receiving a request for information regarding a Conflict of Interest that was disclosed to the Central Research Department, that is still held by an Investigator of the PHS Supported Research, and is related to the PHS Supported Research. The Central Research Department will keep on file all responses to written requests for at least three (3) years.



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Authors and Reviewers

POSITION	NAME	DATE	VERSION #
Manager Research Services	Lisa Austin	5/07/2013	1.0
Research Program Director	Madiha Shakir	5/07/2013	1.0
Research Compliance Coordinator	Latania Oldham	2/27/2015	2.0
Research Program Director	Madiha Shakir	2/27/2015	2.0
Research Program Director	Margaret Ferreira	2/10/2016	3.0
Research Program Director	Margaret Ferreira	5/15/2018	4.0
Research Compliance Manager	Latania Oldham	5/15/2018	4.0



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Acknowledgement Page

I acknowledge that I have read the above policy/training document and that I understand the content in its entirety.