Policy

Policy Number	Policy Title	Implementation Date	Applies To
2276.5	Research, Financial Conflict of Interest	Jan 29, 2017	System

Definitions:

Financial conflict of interest (FCOI) - An FCOI is the existence of a significant financial interest (SFI) that an independent observer might reasonably determine directly and significantly affects the design, conduct, reporting or management of research. The effect or compromise contemplated might relate to the collection, analysis and interpretation of data, the hiring of staff, the procurement of materials, the sharing of results, the choice of protocol, the involvement or consenting of human participants and/or the use of statistical methods.

Senior/Key Personnel - The Project Director/Principal Investigator and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Senior or Key Personnel.

Purpose:

This policy is designed to identify standards and expectations to protect against any such bias that may be perceived to affect the design, conduct, reporting or management of the research due to a financial conflict of interest.

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Conflicts of Interest occur when one or more researcher has a significant financial interest in their proposed research. Norton Healthcare (NHC) requires full disclosure of any financial arrangements and/or benefit that research personnel have in relation to research studies in which they participate; whether it is in the form of items, grants, other funds, contracts, ownership, investments, reimbursed travel expenses or otherwise, as set out in the Financial Disclosure Declaration. Covered in this is the Principal Investigator, Physician, Research Nurse, Clinical Research Associate and any other key personnel involved with the treatment or evaluation of a research subject. Each person is defined to include their spouse and dependent children.

For research funded by the Public Health Service, NHC will comply with the standards outlined in the 2011 revised regulations found at 42 CFR Part 50 Subpart F (as revised). The regulations apply to basic and applied research and product development authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

NHC reserves the right to take necessary action and/or terminate the research being conducted in its facilities for non-disclosure of financial conflicts of interest and notify the NIH.

EXPECTATIONS

1. For Public Health Service (PHS) funded research, all Investigators are required to complete FCOI training at the following times:

- Prior to engaging in research related to any PHS supported grant;
- Every 4 years; and
- Immediately if:

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- NHC revises its FCOI policy that affects requirements of the Investigators;
- An Investigator is new to the Institution; and
- An Investigator is not in compliance with the policy or management plan.

Any researcher participating in PHS funded research must provide a training certificate of financial conflict of interest training. The Norton research Institute provides NIH training through the CITI Program. Registration for the course is available at https://about.citiprogram.org/#none .

Additionally, NIH requires that award recipients must implement trainings, in addition to maintaining a written and enforced policy, on requirements for the disclosure of other support to ensure Senior/Key Personnel fully understand their responsibility to disclose all resources made available to the researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant.

2. Investigators must complete a Norton Research Institute Financial Disclosure Declaration and disclose significant financial interests of themselves, their spouse and dependent children as related to the Investigator's institutional responsibilities at the following times:

- At least annually;
- Within 30 days of discovering or acquiring a new significant financial interest; and
- If participating in PHS funded research, no later than at the time of application for the PHS funding.

3. Financial Conflict of Interest will be reviewed in the following manner:

- NHC and non-UofL community researchers will submit a copy of the Norton Research Institute Financial Disclosure Declaration to the Norton Research Institute Regulatory or Compliance team.
- NRI will review all Financial Disclosure Declarations, determine whether the significant financial interest is related to PHS funded research and determine if a potential financial conflict of interest exists.
- If the Norton Research Institute Compliance team identifies a potential conflict, the Norton Research Institute Compliance team will forward the Financial Disclosure Declaration to the Norton Research Institute Conflict of Interest Committee and any associated documentation for assessment as to whether a FCOI exists and whether it requires implementation of a management plan. Should a management plan be required, the Committee will approve a management plan to mitigate financial conflict of interest.
- The management plans will be reviewed by the Norton Healthcare Conflict of Interest Committee which has representation from the Norton Research Institute. The Committee may request annual review of the Financial Disclosure Declaration, additional documentation to support the Financial Disclosure Declaration, perform or authorize an audit of any and all research records, require additional management strategies based upon review of their plan, take additional actions deemed necessary to manage financial conflicts of interest, ensure compliance with the policy, and address noncompliance with this policy
- This same process will be followed for:
  - An Investigator who is new to a project;
  - An Investigator with a new Significant Financial Interest;
- For Investigators who did not provide timely disclosure of a significant financial interest or a significant financial interest that was not previously reviewed by Norton Research Institute, the review will be conducted within 60 days. Failure to provide timely disclosure may result in withholding, suspension, or withdrawal of institutional approval to conduct research.
- For PHS funded research in which another institution is a subawardee, the Norton Research Institute will accept either the compliance with the subawardee's institutional policy for financial conflicts of interest or compliance with the Norton Healthcare policy.
- For University of Louisville faculty who are listed on the IRB application, the research office will confirm with the University of Louisville's Research Integrity Program to confirm compliance with the University's financial conflict of interest policy.

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4. Reporting Requirements for PHS Funded Research:

- For PHS funded research, the research office will send initial, annual and revised Financial Conflict of Interest Reports to the NIH for Norton Healthcare and any award subrecipients, as required, prior to:
    - The expenditure of funds;
    - Within 60 days of the identification of a new project Investigator;
    - Within 60 days for new, or newly identified FCOIs for existing Investigators;
    - At least annually (at the same time as when the Institutions is required to submit the annual progress report, multi- year progress report, if applicable or at the time of extension) to provide the status of the Financial Conflict of Interest and any changes to the management plan, if applicable, until the completion of the project;
    - Following a retrospective review to update a previously submitted report, if appropriate.
- For PHS funded research, the research office will notify NIH promptly of all reporting requirements as required by the regulation, if bias is found with the design, conduct or reporting of NIH-funded research and submit a mitigation report as required by regulation.
- For PHS funded research, the research office will notify NIH promptly if an Investigator fails to comply with this policy or if a management plan appears to have biased the design, conduct or reporting of the NIH funded research. Reporting will include any NHC corrective action for noncompliance.

5. Maintenance of Records:

Norton Research Institute will maintain all FCOI related records that meet or exceed the regulatory requirements for at least 3 years from the date of the final expenditures report is submitted to PHS (NIH) or as required by other applicable regulations such as 45 CFR 74.53(b) and 45 CFR 92.42(b).

6. Enforcement, Remedies and Noncompliance:

- For PHS funded research and other research as applicable, NHC will provide enforcement mechanisms, employee sanctions and administrative actions to ensure Investigator compliance consistent with existing personnel policies at NHC.
- For PHS funded research and other research as applicable, NHC will complete and document retrospective reviews within 120 days of the determination of noncompliance by NHC for significant financial interests not disclosed timely, not previously reviewed or whenever an FCOI is not identified or managed in a timely manner. The research office will maintain documentation of the reviews consistent with the regulation.
- When the Department of Health and Human Services determines that clinical PHS funded research whose purpose is to evaluate the safety of 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 as required by the regulations, NHC will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and request and addendum to previously published presentations.

7. Subrecipient Requirements:

- For PHS funded research, NHC will allow a subawardee to either follow the financial conflict of interest policy of NHC or the subawardee's institution.
- For PHS funded research NHC will work to establish via written agreement the following:
    - Certification that the subrecipient's institution complies with the regulation.
    - Require the subrecipient to report identified financial conflicts of interest for its Investigators in a time frame that allows the awardee Institution to report identified financial conflicts of interest to the NIH as required by the regulation or to require disclosures to be submitted to Norton Healthcare for review, management and reporting to NIH.

8. Public Accessibility Requirements:

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- The research office will ensure the Financial Conflict of Interest policy is published on the NHC external internet and internal intranet website.
- For PHS funded research, the research office will make available information concerning identified financial conflicts of interest held by senior and key personnel, as defined by the regulation, publicly accessible prior to the expenditure of funds.

The information will:

1. Contain the minimum elements required by the regulation
2. Be provided within 5 calendar days of the a written request;
3. Written requests will include any annually updated information;
4. Written requests will include any newly identified financial conflict of interest within 60 days;
5. Information available for written request will remain available for three years from the date the information was most recently updated.

Related Documents (Attachments and Hyperlinks):

http://www.nortonhealthcare.com/financialdisclosure

References:

eCFR :: 42 CFR Part 50 Subpart F -- Promoting Objectivity in Research

Legal Statement:

The policies set forth in this policy library do not establish a standard to be followed in every case. It is impossible to anticipate all possible situations that may exist and to prepare policies for each. These policies should be considered guidelines with the understanding that departures from them may be required at times. Accordingly, it is recognized that those individuals employed in providing healthcare are expected to use their own judgment in determining what is in the best interests of the patient based on the circumstances existing at the time. If a policy contains references to clinical literature or other resources, such as Lippincott, Ovid, and/or Elsevier, these resources are only intended to support the reasoning for adoption of certain guidelines contained herein. It is not an endorsement of any article or text as authoritative. Norton Healthcare specifically recognizes there may be articles or texts containing other opinions on point that may be helpful and valid which would support other care or actions, given a particular set of circumstances. No literature is ever intended to replace the education, training and experience or exercise of judgment of the healthcare providers.

Replaces Policy Dated: 2007
Review Revision Reviewed/Approved by: (Group or Individual)
1/1/07 Legal Department, VP Medical Affairs, VP Corporate Compliance
8/23/12 Office of Research Administration

Policy Approval:

Policy Owner/Subject Matter Expert	Date
Stephanie Deetsch	May 30, 2018
Stephanie Deetsch	July 24, 2020
Dawn Diehl	March 1, 2026