

Policy Number	Policy Title	Effective Date
2276.2	Research, Financial Conflict of Interest	August 24, 2012
Policy Type	Area	Applies To
Research	N/A	System

## Policy

### POLICY:

Financial conflict of interest (FCOI) is the existence of a significant financial interest(SFI) that an independent observer might reasonably determine could directly and significantly affect 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. This policy is designed to protect against any such bias.

Conflicts of Interest occur when one or more researcher has a significant financial interest in their proposed research. Norton Healthcare 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 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, Norton Healthcare will comply with the standards outlined in the 2011 revised regulations found at 42 CFR Part 50 Subpart F. 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.

Norton Healthcare 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.

### **PROCEDURE**

1. For Public Health Service (PHS) funded research, all Investigators are required to complete FCOI training at the following times:
  - a. Prior to engaging in research related to any PHS-funded grant;
  - b. Every 4 years; and
  - c. Immediately if:
    - i. Norton Healthcare revises its FCOI policy that affects requirements of the Investigators;

- ii. An Investigator is new to the Institution; and
- iii. 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 Healthcare Office of Research Administration (NHORA) will accept the NIH tutorial or institutionally approved training. The NIH training module can be accessed via the link <http://www.nortonhealthcare.com/financialdisclosure>.

2. Investigators must complete a Norton Healthcare Office of Research Administration (NHORA) 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:
  - a. At least annually;
  - b. Within 30 days of discovering or acquiring a new significant financial interest; and
  - c. 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:
  - a. Norton Healthcare and community (non-University of Louisville) researchers will submit a copy of the NHORA Financial Disclosure Declaration to NHORA.
  - b. NHORA 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.
  - c. If NHORA identifies a potential conflict, NHORA will forward the Financial Disclosure Declaration to the Norton Healthcare Conflict of Interest Committee for assessment as to whether a FCOI exists and whether it requires implementation of a management plan. Should a management plan be required, a person identified as having a conflict must submit a management plan to NHORA containing information indicating the conflict is managed in such a manner that the researcher's bias is removed.
  - d. The management plans will be reviewed by the Norton Healthcare Conflict of Interest Committee which has representation from the NHORA, Norton Healthcare Corporate Compliance and Norton Healthcare Legal Department. 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.
  - e. This same process will be followed for:
    - i. An Investigator who is new to a project;
    - ii. An Investigator with a new Significant Financial Interest;
  - f. For Investigators who did not provide timely disclosure of a significant financial interest or a significant financial interest that was not previously reviewed by the Institution, the review will be conducted within 60 days.
  - g. For PHS funded research in which another institution is a subawardee, NHORA will accept either the compliance with the subawardee's institutional policy for financial conflicts of interest or compliance with the Norton Healthcare policy.



the results of the research and request and addendum to previously published presentations.

7. Subrecipient Requirements

- a. For PHS funded research, Norton Healthcare will allow a subawardee to either follow the financial conflict of interest policy of Norton Healthcare or the subawardee’s institution.
- b. For PHS funded research Norton Healthcare will work to establish via written agreement the following:
  - i. Certification that the subrecipient’s institution complies with the regulation.
  - ii. 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

- a. NHORA will ensure the Financial Conflict of Interest policy is published on the NHORA website.
- b. For PHS funded research, NHORA 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:
  - i. Contain the minimum elements required by the regulation
  - ii. Be provided within 5 calendar days of the a written request;
  - iii. Written requests will include any annually updated information;
  - iv. Written requests will include any newly identified financial conflict of interest within 60 days;
  - v. Information available for written request will remain available for three years from the date the information was most recently updated.

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

The policies and procedures 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 this policy contains reference to clinical literature, the literature cited is 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.

<b>Policy Contact</b>
Bethany Pitino

# Norton Healthcare Office of Research Administration Financial Disclosure Declaration For Those Conducting Research in Norton Healthcare Facilities

- All personnel who are directly involved in research must complete this form each year and answer all questions based on the 12 months preceding disclosure signature date
- All questions must be answered and any yes answer must be explained in the commentary section.
- In accordance with the federal regulations, "You" is defined to include a spouse, each dependent child and partnership interests.
- If the cumulative amounts identified below exceed \$5,000, then a conflict of interest management plan will be required.

Name \_\_\_\_\_ Employed By \_\_\_\_\_

Address \_\_\_\_\_ Title \_\_\_\_\_

\_\_\_\_\_ Email \_\_\_\_\_

\_\_\_\_\_ Telephone Number \_\_\_\_\_

YES  NO  Do you or immediate family members have financial interests/arrangements in any company or business that sponsors your research and could therefore influence the outcome of your research? This should include, for example, compensation to you in the form of an equity interest in a sponsor or a royalty income tied to the sales of a product. If yes, describe below.

YES  NO  Do you or your immediate family members receive significant payments, non royalty payments or entitlements to payments in connection with your research that are not directly related to the reasonable costs of conducting research? This could include, for example, payments made to you or your institution such as compensation in the form of equipment, retainers for ongoing consultation or honoraria. If yes, please describe below.

YES  NO  Do you or your immediate family members have a proprietary or financial interest in a test product such as a patent, trademark, copyright or licensing? If yes, please describe below.

YES  NO  Do you or your immediate family members have a significant equity interest in any sponsor of your research? This would include, for example any salary, consulting fees, honoraria, paid authorship, ownership interest, stock options, or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded or non-publically traded company. If yes, describe below.

YES  NO  Do you or any member of your immediate family occupy any position in a company that sponsors your research? This could include being an officer, director, associate, partner, member or proprietor of a corporation, sole proprietorship, partnership, Limited Liability Company or other business venture that sponsors your research? If yes, describe below.

YES  NO  Have you received sponsored or reimbursed travel directly from an entity supporting your research? This does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Please include sponsor, what kind of company, who received reimbursement, purpose, approximate value, destination and duration, if yes is checked.

**Commentary** (additional pages may be attached if necessary) \_\_\_\_\_

---

---

---

---

---

*I hereby acknowledge that the above information is complete and accurate. I acknowledge that I have a continuing obligation to promptly update information to the NHORA within 30 days, if, during the year, any changes occur regarding the information provided in this declaration.*

Printed Name \_\_\_\_\_ Title: \_\_\_\_\_

Signature \_\_\_\_\_ Date: \_\_\_\_\_