

**NATIONAL COLLEGE OF NATURAL MEDICINE
HELFGOTT RESEARCH INSTITUTE
POLICY AND PROCEDURE**

Number: RE.2.2
Subject: Managing Financial Conflicts of Interest in Research
Approved By: Associate Director of Research
Revised: January 2012

Policy

The National College of Natural Medicine (the College) shall require the highest standards of quality, ethics and integrity in the conduct of scientific research by its faculty, students and other affiliated investigators. The College is committed to assuring and maintaining the public trust that scientific research is conducted objectively and that results are not biased by the external commitments and financial interests of those who are responsible for the design, conduct, and reporting of research findings.

In August 2011, the Department of Health and Human Services substantially revised the 1995 federal regulations for Promoting Objectivity in Research. The NCNM Policy on Managing Financial Conflicts of Interest in Research is written to be in compliance with these regulations, codified under *Final Rule 42 Code of Federal Regulations Part 50, subpart F: Promoting Objectivity in Research* (§ 50.601-607). (See link to references below.)

This policy is intended to accomplish three objectives; 1) to define the terms of this policy in accordance with the 2011 HHS Final Rule, 2) to clarify the obligations of investigators to disclose all significant financial interests to the College, and 3) to outline the obligations of the College to properly manage and report all significant financial interests that the College, not the investigator, deems are both related to the research and could reasonably appear to affect the design, conduct or reporting of research.

I. Key Definitions. (The following definitions are directly derived from the 42 CFR §50.603)

Financial Conflict of Interest (FCOI) means a significant financial interest that has been determined could directly and significantly affect the design, conduct, or reporting of research. A significant financial interest could rise to the level of a financial conflict of interest even if the financial interest is determined to not be a real conflict but yet could still be reasonably perceived as a conflict.

Institutional responsibilities means an investigator's professional responsibilities on behalf of the College, which may include activities such as: research, research consultation, teaching, professional practice, committee membership, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the principal investigator/program director (PI/PD), co-investigator(s), clinical investigator(s) and any other person, including those who are subrecipients, contractors, or consultants, regardless of title or position, who are responsible for the design, conduct or

reporting of research, which typically may include but may not be necessarily limited to, senior/key personnel. The determination of which persons are Investigators of a given research project is generally made in the application phase by the PI/PD and the research department of the College but may also be at the discretion of the College's designated financial conflict of interest official(s).

Key/Senior Personnel means the PI/PD and any other person who is materially and substantively responsible for the design, conduct, or reporting of research and identified as such, by the research department of the College and the project's PI/PD, in the formal grant application, budgetary, and/or progress report phases of the project.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, the design, conduct and reporting of research will be free from bias.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this policy and procedure (e.g. National Institutes of Health).

Significant Financial Interest (SFI) means monetary interests held by the investigator, or those of the investigator's spouse (including domestic partner or spousal equivalent), and/or dependent children, that is reasonably related to *any* of the investigator's institutional responsibilities.

For purposes of this definition, *significant financial interest includes*:

- A. Salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, paid authorship, etc, in which the value from the entity in the twelve months *preceding* the disclosure, when aggregated, exceeds \$5,000.
- B. Equity interests, such as stock, stock options, ownership interests, etc, as determined through reference to public prices or other reasonable measures of fair market value as of the date of disclosure, in which the value from the entity in the twelve months *preceding* the disclosure, when aggregated, exceeds \$5,000.
- C. Licensed intellectual property rights (e.g. patents, copyrights), royalties from such rights, and agreements to share in royalties related to such rights that in the twelve months preceding the disclosure exceeds \$5,000.
- D. Travel expenses that are either reimbursed to the investigator or paid directly on behalf of the investigator, that are related to any of the investigator's institutional responsibilities, provided that the travel is *not* reimbursed or sponsored by a Federal (e.g. NIH), state, or local government agency, an Institute of higher education (e.g. NCNM), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institute of higher education (e.g. Helgott Research Institute).

For purposes of this definition: *significant financial interest does not include*:

- A. Salary, royalties, or other remuneration paid by the College, if the investigator is an employee or otherwise appointed by the College, including intellectual property rights assigned to the College and agreements to share in royalties related to such rights.
- B. 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.
- C. Income from seminars, lectures, teaching engagements or service on advisory committees or review panels provided they are sponsored by a Federal, state, or local government

agency, an Institute of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institute of higher education.

II. Key Policy Changes in the August 2011 Final Rule

A. Significant Financial Interest Threshold

The threshold for a financial interest being significant is an aggregated \$5,000, down from the previous \$10,000 of the previous rule. It also includes equity of both publically and non-publically traded entities. In addition, SFI amounts are calculated based upon the *preceding* 12 months rather than an estimation of the *following* 12 months.

B. SFI to be disclosed to the College

The investigator no longer discloses only the SFI s/he believes is related to their research, but now must disclose all SFI that is related to any of their institutional responsibilities. Both the determinations of which SFIs are related to research and which SFIs constitute a financial conflict of interest are now made by the designated official(s) of the College.

C. Exclusions from disclosure requirements

Income from seminars, lectures, teaching engagements, and service on advisory or review panels are now excluded if they are sponsored by or in service 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. Income from investment vehicles are now expressly excluded from disclosure requirements, provided that the investigator does not directly control the investment decisions made by said vehicle.

D. Intellectual Property

Intellectual property that flows through the College is excluded from the disclosure requirements, as are unlicensed intellectual property that does not generate income. The threshold of \$5,000 applies to licensed intellectual property rights (e.g. patents, copyrights), royalties from such rights, and agreements to share in royalties related to licensed intellectual property rights.

E. Travel

Any travel, either reimbursed or directly sponsored, must now be disclosed as a financial interest, provided that the travel is NOT 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. Investigators must initially disclose the purpose of the trip, as well as the destination, duration and sponsor. The College, subsequently, will determine if it requires additional information and/or the monetary value of the travel. Note: if the travel is paid directly by the sponsor on behalf of the investigator, the monetary value of travel may not be readily available. For this reason, this added burden on the investigator is not required for initial disclosure but only upon the College's determination that the disclosed travel 1) may constitute a financial conflict of interest or 2) the monetary value is needed for making such a determination.

F. Subrecipient Investigator FCOI requirements

If research involves a sub-contract/award to a consortium institution, the written agreement between the College and the subrecipient institution must now expressly stipulate, whenever possible, that the investigator(s) at the consortium institution will be held to their own institution's FCOI policy, provided that they further certify their FCOI policy is in full compliance with federal requirements. If they can not or are otherwise unwilling to provide such certification, the written agreement shall stipulate that the consortium investigators are subject to the Managing FCOI Policy and Procedure of NCNM.

G. Public Accessibility

One of the driving purposes for the changes to the Final Rule is the increased congressional pressure to strengthen accountability in reporting financial conflicts of interest and for increased public transparency in such matters. As such, under the Final Rule, the College must make accessible on its public website this Policy and Procedure on Managing Financial Conflicts of Interest. Additionally, the College is required to respond within 5 business days to any public request for **FCOI** information, including the investigator's name, title, role on the research project, the name of the entity in which interest is held, the nature of the interest (e.g. salary, equity, consulting, etc), and whenever possible the approximate dollar value (expressed in ranges) of the interest. Only investigators that are identified as "key personnel" are subject to this public disclosure requirement.

H. FCOI Training

The College must provide FCOI training 1) to new investigators when they join a research project, 2) when the College updates the requirements of its Managing FCOI policy, and 3) when an investigator is found to be in noncompliance. Furthermore, the College must provide refresher training for all investigators at least every four years.

Procedure

I. Responsibilities of the College (Compliance with 42 CFR §50.604)

- A. The primary responsibility of the College is to create, maintain and enforce a written policy and procedure (herein) concerning the management of financial conflicts of interests in research and to make such a policy available through a publically accessible website (www.ncnm.edu). Said policy must be in full compliance with the *Final Rule 42 Code of Federal Regulations Part 50, subpart F: Promoting Objectivity in Research*.
- B. The further responsibility of the College is to fully disseminate this policy to all its investigators and inform them of their responsibilities regarding the disclosure of significant financial interests. All investigators must be trained in the Policy and Procedure herein before engaging in research and re-trained at a minimum of every four years. New training must occur if and when this Policy or Procedure is revised by the College in any manner which affects the requirements of the investigators.
- C. If the College carries out research through a subrecipient (e.g. subawardees, consortium agreements, or subcontractors), then it must take reasonable steps to ensure that any subrecipient investigator complies with the federal requirements concerning financial conflicts of interest. This shall be accomplished in the following manner:
 - i. The written agreement with the subrecipient institution (e.g. consortium agreement or contract) shall clearly stipulate that the subrecipient investigator(s) shall comply with the policies and procedures of the subrecipient institution concerning financial conflicts of interest.
 - ii. The subrecipient institution, in turn, must certify in said agreement that its policy and procedures concerning financial conflicts of interest are in compliance with all pertinent federal requirements.
 - iii. If the subrecipient institution is unable or unwilling to provide such certification, then the agreement shall stipulate that the subrecipient investigator(s) are subject to the financial conflict of interest policy of the College and shall disclose all SFI that are directly related to the subrecipient investigator's scope of work for the project, as outlined in the agreement.
- D. The College shall designate an institutional official(s) to solicit and review disclosures of significant financial interests from each investigator who is planning to participate in, or

- is participating in, research. The designated official shall oversee the management, reporting, and remedy procedures outlined below. The College may elect to designate more than one official to oversee these procedures or, conversely, the designated official may fulfill these responsibilities within the role of a wider charge (e.g. NCNM Research Integrity Officer).
- E. Investigator Disclosure of Significant Financial Interests to the College
 - i. The College shall require that all investigators who are planning to participate in PHS-funded research to disclose significant financial interests no later than the time of application for funding. In the case of non-PHS funded research, the disclosure must occur on or before the commencement of the research project.
 - ii. The College shall further require that all investigators submit an annual disclosure of significant financial interest to the institutional designated official.
 - iii. The College requires that investigators disclose to the institutional designated official any new significant financial interest within 30 days of the discovery or acquisition of said interest. Examples of a new significant financial interest would be those acquired through marriage, inheritance or purchase.
 - F. It is the responsibility of the College to require its investigators to disclose all significant financial interests regardless of whether or not the investigator feels that the financial interest is related to their research or rises to the level of a financial conflict of interest. Both the determinations of which SFIs are related to research and which SFIs constitute a financial conflict of interest are made by the designated official(s) of the College. The College shall provide its official(s) with guidelines to make such a determination. A financial conflict of interest exists if the designated official(s) determine if the disclosure:
 - i. Is related to the proposed research.
 - ii. Could reasonably affect the design, conduct, or reporting of the proposed research.
 - G. Furthermore, it is the responsibility of the College to require its investigators to disclose all reimbursed or sponsored travel, regardless of whether or not the investigator feels that the travel is related to the proposed research or represents a conflict of interest. The initial disclosure of travel shall include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. Upon review of the travel disclosure, the designated official(s) of the College will determine if further information is needed to resolve whether the travel constitutes a financial conflict of interest. This additional information will include, at a minimum, a disclosure of the monetary value of the travel in question.
 - H. The College shall retain all records pertaining to the disclosure and review of significant financial interests; and all records pertaining to the management and reporting of significant financial interests that rise to the level of a financial conflict of interest for at least three years after the closure of the applicable research.
 - I. The College must certify, in each application for PHS funding, the following:
 - i. The College has an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received.
 - ii. The College shall promote and enforce investigator compliance with this Policy and Procedure.
 - iii. The College shall manage financial conflicts of interest and provide all proper reports to the PHS Awarding Component consistent with the Code of Federal Regulations.
 - iv. The College agrees to make information available, promptly upon request, to the HHS relating to any investigator's disclosure of significant financial interests and

- the College's review of and response to such disclosure, whether or not said disclosure was determined by the College to be a financial conflict of interest.
- v. The College shall fully comply with all the requirements of *42 Code of Federal Regulations Part 50, subpart F: Promoting Objectivity in Research*.

II. Managing and Reporting Financial Conflicts of Interest: (Compliance with 42 CFR §50.605)

A. Management of Financial Conflicts of Interest

- i. Prior to any expenditure of funds, the designated official(s) shall review all disclosures of SFI, determine whether any SFI relate to the funded research, determine whether a financial conflict of interest exists, and, if so, develop and implement a **management plan** that shall specify the actions that have been, and shall be, taken to manage such financial conflicts of interest.
- ii. **Examples** of conditions and restrictions that might be imposed to manage a financial conflict of interest may include things such as:
 - a) Public disclosure of financial conflicts of interest (for example when the investigator is presenting or publishing the research).
 - b) For clinical trials, disclosure of financial conflicts of interest to potential participants at the time of informed consent.
 - c) Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the research against possible bias resulting from financial conflicts of interest.
 - d) Modification of the research plan.
 - e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
 - f) Reduction or elimination of the financial interest (e.g. sale of an equity interest) or severance of relationships that create the financial conflict(s).
- iii. Whenever an investigator, who is new to the research project, discloses a significant financial interest or an existing investigator discloses a new significant financial interest, the College shall review the disclosure within 60 days. If upon review, the disclosed significant financial interest is found to be a financial conflict of interest related to the project, the College shall implement a management plan that specifies the actions that have been and will be taken, if need be, to further manage the conflict.
- iv. Whenever the College identifies a significant financial interest that was not properly disclosed by an investigator or, for whatever reason, was not previously reviewed by the College during the course of the research, the designated official(s) shall review the significant financial interest within 60 days. If upon review, the disclosed significant financial interest is determined to be a financial conflict of interest related to the project, the official(s) shall:
 - a) Implement a management plan that specifies the actions that have been and will be taken, if need be, to further manage the conflict.
 - b) Complete, within 120 days of the finding of noncompliance, a **retrospective review** of the investigator's activities to determine if, during the period of noncompliance, there was bias in the design, conduct or reporting of said research. The written documentation of the retrospective review shall include, but not necessarily be limited to, the following **key elements**:
 1. Project/Grant identification numbers
 2. Project title

3. PD/PI or Contact PD/PI
 4. Name of the investigator with the identified financial conflict of interest
 5. Name of the entity with which the investigator has a financial conflict of interest
 6. Reason(s) for the retrospective review
 7. Detailed methodology used for the retrospective review (e.g. methodology of the process, composition of the panel, document reviewed, witnesses interview, etc)
 8. Findings of the review
 9. Conclusions of the review
- c) Based on the results of the retrospective review, the College shall update any previously submitted FCOI reports, if appropriate and specify steps taken to manage the conflict. If bias is found, the College shall notify the funding agency (e.g. the PHS Awarding Component) and submit a **mitigation report**. This report must include, at a minimum, the key elements of the retrospective review above and a description of the impact of the bias on the research project and the College's plan of action to eliminate or mitigate the effect of that bias (e.g. extent of harm, including any qualitative and quantitative data to support any actual or future harm, analysis of whether the research is salvageable).
- v. The College, whenever it implements a management or mitigation plan, shall monitor the investigator's compliance with the plan on an ongoing basis until the completion of the research project.
- vi. The College shall ensure that there is public accessibility to information concerning significant financial interests that have been disclosed to the College.
- a) The College will provide a written response to a public request for SFI information within five business days.
 - b) Information will be provided to public request only under the following four conditions, 1) the information requested pertains to an Investigator that further meets the definition of key personnel, 2) if the SFI was disclosed and is still held by investigator (as defined), 3) the College has determined that the SFI is related to the research, and 4) the College has determined that the SFI is in fact a financial conflict of interest.
 - c) The information disclosed to the public must contain the following:
 1. The investigator's name, title, and role on the project,
 2. The name of the entity in which the SFI is held,
 3. The nature of the SFI (e.g. stocks, salary, travel, consulting).
 4. The approximate dollar value of the SFI in ranges (\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; \$20,000-\$100,00 in increments of \$20,000; \$100,000 and greater by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public process or other reasonable measure of fair market value.
 5. An explanation that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the College's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.
 - d) Information must remain assessable to the public, upon request, for a minimum of three years after the closing of the research project.

- B. Reporting of Financial Conflicts of Interest
- i. Prior to the expenditure of funds, the College shall provide the funding agency (e.g. PHS Awarding Component) a FCOI Report. In cases where the College has identified a financial conflict of interest but successfully eliminated that conflict prior to the expenditure of funds, a FCOI report is not necessary.
 - ii. For any financial conflict of interest that is identified during an ongoing research project (e.g. new investigator, new interest), the College shall provide the funding agency with an updated FCOI within 60 days of disclosure.
 - iii. A **Financial Conflict of Interest Report** must contain, at a minimum, the following elements:
 - a) Project/Grant identification numbers
 - b) Project title
 - c) PD/PI or Contact PD/PI
 - d) Name of the investigator with the identified financial conflict of interest
 - e) Name of the entity with which the investigator has a financial conflict of interest
 - f) The nature of the SFI (e.g. stocks, salary, travel, consulting).
 - g) The approximate dollar value of the SFI in ranges (\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; \$20,000-\$100,00 in increments of \$20,000; \$100,000 and greater by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public process or other reasonable measure of fair market value.
 - h) A description of how the financial interest relates to the research and the basis for the College's determination that the interest represents a conflict with the research
 - i) A description of the College's management plan, including but not necessarily limited to the following elements:
 1. Role and principal duties of the investigator
 2. Conditions of the management plan
 3. How the management plan is designed to safeguard objectivity in the research project
 4. Confirmation of the investigator's agreement to the management plan
 5. How the management plan will be monitored to ensure investigator compliance
 - iv. For any financial conflict of interest that is not properly disclosed, for whatever reason, the College is required to complete a retrospective review to determine if, during the period of noncompliance, the research was biased in design, conduct or reporting of research. In these cases, the College shall submit to the funding agency a mitigation report, as is described above.
 - v. For those research projects that are PHS funded, the College will provide the PHS Awarding Component, in compliance with the 42 CFR 50.605(b)(4), an annual FCOI report that addresses the status of the FCOI and any changes to the management plan, for the duration of the project including cost and no-cost extensions.

III. Remedies concerning PHS Funded Research (Compliance with 42 CFR §50.606)

- i. If in the course of a retrospective review, a PHS-funded research project has been found to have been biased in design, conduct or reporting of research due to a financial conflict of interest, the College shall promptly notify the PHS Awarding Component of the corrective actions taken or to be taken. Corrective actions will be implemented by the appropriate institutional officials of the College (i.e. Dean

- of Research, Provost, etc). The PHS Awarding Component will consider the situation and, if necessary, take additional, appropriate action (e.g. sanctions, debarment, corrective actions to the College, etc).
- ii. The PHS Awarding Component and/or the Department of Health and Human Services may inquire at any time into the records of significant financial interest, regardless of whether the College determined the SFI was a financial conflict of interest. Furthermore, the College is required to submit, or allow an onsite review, of all records pertinent to the College's compliance with 42 CFR 50 Subpart F. The PHS Awarding Component may determine that imposition of conditions, suspensions, or other enforcement actions is necessary.
 - iii. In any case in which the 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 FCOI that was not managed or reported by the College as required by 42 CFR 50 Subpart F, the College shall require the investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

IV. References and Informational Web Links

To the Federal Register detailing the Final Rule 42 CFR 50: Promoting Objectivity in Research, from which this entire Policy and Procedure is substantially quoted and derived:
http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

To the Key differences between the new Final Rule and the previous 1995 Rules and Regulations:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-109.html>