Dartmouth-Hitchcock

Policy Title:	Conflicts of Interest (COI) in Research Policy	Policy ID:	2870
Keywords	COI, FCOI, Sponsored Program, PHS		

I. Purpose of Policy

To promote objectivity in research at Dartmouth-Hitchcock ("D-H", comprised of Mary Hitchcock Memorial Hospital and Dartmouth-Hitchcock Clinic) and ensure that the personal financial interests of Investigators do not compromise, have the ability to compromise, or give the appearance of compromising the objectivity with which research is designed, conducted, and reported, nor to allow interests to compromise the safety or welfare of human research subjects.

II. Policy Scope

This policy applies to Investigators and Key Personnel (hereinafter, collectively referred to as "Investigators"), who are responsible for designing, conducting, or reporting activities related to research performed under the auspices of D-H, which may include non-D-H collaborators or non-D-H consultants.

D-H has adopted the Public Health Service of the U.S. Department of Health and Human Service (PHS) requirements for financial disclosures in research *regardless of the source of project funding*. This policy shall apply to Investigators on any sponsored research agreement that is in preparation, has been submitted to a sponsor, or that is currently executed or funded. Further, this policy applies to Investigators involved in any D-H-sponsored research.

This policy is written to include portions of, and to comply with, the Federal regulations governing financial conflicts of interest for PHS-funded activities. This policy specifically references 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research," and 45 CFR Part 94, "Responsible Prospective Contractors," which promote objectivity in research and establish standards to provide a reasonable expectation that the design, conduct, and reporting of research performed under PHS/NIH contracts shall be free from bias related to financial conflicts of interest.

III. Definitions

CITI Program: A subscription service providing research ethics and compliance education to all members of D-H's research community. To participate fully, learners must be affiliated with a CITI participating organization.

Compelling Circumstances: Facts to support proceeding with the proposed research despite the existence of certain Significant Financial Interests (SFI).

Conflict of Interest (COI): A potential conflict of interest exists whenever personal, professional, commercial, financial, or organizational interests or activities outside of D-H have the possibility (either in actuality or in appearance) of one or more of the following: (1) compromising an Investigator's judgement; (2) biasing the nature or direction of scholarly research; (3) influencing an Investigator's decision or behavior with respect to teaching and student affairs, appointments and promotions, uses of

D-H resources, interactions with human subjects, or other matters of interest to D-H; or (4) resulting in a personal or Family Member's gain or advancement at the expense of D-H.

Entity: An institution, business, company, or other such organization, and includes, but is not limited to, any partnership, corporation, limited liability corporation, unincorporated association, or other institution or organization, whether for-profit, academic, or professional.

Family Member: Includes any of the following: husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.[1]

FCOI Report: An institution's report of a financial conflict of interest to a PHS Awarding Component.[2]

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Institutional Official (IO): The person with institutional authority to legally bind the institution in grants administration matters and is responsible for institutional compliance with FCOI. The Vice President of Research Operations is the Institutional Official.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of D-H, which may include, for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships and service on panels, such as the Institutional Review Board or Data and Safety Monitoring Boards.[3]

Investigator: The Project Director/Principal Investigator (PD/PI) 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.[4]

Key Personnel: Includes the PD/PI but also includes any other personnel that are considered to be "essential to work performance" on a project. Furthermore, D-H defines Key Personnel on human subjects protocols as 'Research personnel directly involved in conducting research specific interventions with study participants, or their private identifiable information (PII), or protected health information (PHI), and also includes faculty mentors/advisors providing direct oversight to research personnel.'

Manage: To take action to address an FCOI, which can include reducing or eliminating the FCOI and/or to ensure, to the extent possible, that the design, conduct, and reporting of the research shall be free from bias.[5]

[1] 42 C.F.R. §50.603.
[2] 42 C.F.R. §50.603.
[3] 42 C.F.R. §50.603.
[4] 42 C.F.R. §50.603.
[5] 42 C.F.R. §50.603.

Principal Investigator (PI)/Project Director (PD): The PI/PD of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.[6]

Public Health Service (PHS) Awarding Component: The organizational unit of PHS that funds the research subject to this policy.[7]

Remuneration: Any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind.

Research: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. This term encompasses basic and applied research (e.g., a published article, book, or book chapter), and product development (e.g., a diagnostic test, device, or drug).

SBIR Program: the Small Business Innovation Research program: an extramural research program for small business established by the awarding component of the PHS under federal law. The SBIR Program also includes the **Small Business Technology Transfer Program (STTR)** program also established by Public Law.

Significant Financial Interest (SFI): For purposes of this Policy, a Financial Interest that exceeds a financial threshold as specified below.

1. A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's Family Members) that reasonably appear to be related to the Investigator's Institutional Responsibilities:

    a. With regard to any ***publicly traded Entity***, an SFI exists if the value of any Remuneration received from the Entity is in the twelve (12) months preceding the disclosure and the value of any equity interest in the Entity as of the date of disclosure, when aggregated, exceeds $1,000. For purposes of this definition, remuneration includes salary and payment for services not otherwise identified as salary, equity interest or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

    b. With regard to any ***non-publicly traded Entity***, an SFI exists if the value of any Remuneration received from the Entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds $1,000, or when the Investigator (or the Investigator's Family Members) hold any equity interest;

    c. Intellectual Property (IP) rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests;[8] or

    d. An offer or a promise of future employment (or engagement as independent contractor) made by a sponsoring Entity to an Investigator.

[6] 42 C.F.R. §50.603.
[7] 42 C.F.R. §50.603.
[8] 42 C.F.R. §50.603.

2. Investigators also must 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. Such disclosures shall include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with D-H's FCOI policy, the Institutional Official and the Research Conflict of Interest Committee shall determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research. Reimbursed or sponsored travel related to an Investigator's Institutional Responsibilities to include luxury travel, including without limitation use of private jets, is not permitted without advance written consent of the Institutional Official and the Research Conflict of Interest Committee.

3. An SFI does not include the following types of Financial Interests: salary, royalties, or other Remuneration paid by D-H to the Investigator if the Investigator is currently employed or otherwise appointed by D-H, including IP rights assigned to D-H and agreements to share in royalties related to such rights; income arising solely from investment vehicles, such as mutual funds, pensions, 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.

IV. Policy Statement

Investigators involved in research must disclose all Financial Interests to Compliance and Audit Services (CAS), whether or not the value of the Financial Interest(s) is readily ascertainable and whether or not the Financial Interest meets the definition of a Significant Financial Interest as defined herein. It shall be the responsibility of the PD/PI to verify that all personnel involved in the research project are aware of the following disclosure requirements.

A. Education and Training Requirements

D-H requires Investigators to participate in COI training through the CITI Program prior to engaging in research related to any PHS-funded grant and again at least once every four (4) years.

COI training is required immediately when:

1) D-H revises its COI in research policy that affects requirements of Investigators;
2) an Investigator is new to D-H; or
3) an Investigator is not in compliance with this policy or an applicable Management Action Plan (MAP).

Investigators shall be held responsible for maintaining certification of completion of CITI Program training and understanding the information in this Policy.

B. When to Report or Disclose Financial Interests

Investigators planning to participate, or currently participating in, PHS or non-PHS funded research must disclose their Financial Interests related to their Institutional Responsibilities (including those of their Family Members) in D-H's COI questionnaire:

1) Within the twelve (12) months prior to the time of application for research funding;
2) Each time human subject proposals are submitted to Dartmouth College's Institutional Review Board (IRB) or to any other IRB for research to be conducted at D-H or under the auspices of D-H, including initial submissions and each continuing review;
3) At least annually during the period of the funding award; and
4) Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

C. How are Financial Disclosures Made?

Investigators shall complete a COI questionnaire in accordance with Section B above.

D. What Must be Disclosed for Purposes of PHS Reporting?

Any one (or more) of the following Significant Financial Interests of an Investigator planning to participate in PHS-funded research (including the Investigator's Family Members) must be disclosed by way of the COI questionnaire:

1) Financial Interest in any ***publicly traded Entity***, if the value of Remuneration (e.g., salary, payment for services such as consulting fees, honoraria, paid authorship) and/or equity interest (including equity, stock, and/or ownership interest – value determined through reference to public prices or other measures of reasonable market value at the time of the disclosure); received in the twelve (12) months preceding the disclosure, when aggregated, exceeds $5,000.
2) Financial Interest in any ***non-publicly traded Entity***, if the value of any Remuneration (e.g., salary, payment for services such as consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds $5,000;
3) Financial Interest in any ***non-publicly traded Entity*** when the Investigator (including Family Members) holds ANY equity interest (i.e., >$0 value) such as stock, stock option, or other ownership interest;
4) Intellectual Property (IP) rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; and
5) **Travel**: PHS-funded Investigators must disclose any reimbursed or sponsored travel that ***relates to the Investigators' Institutional Responsibilities***, individually, or when aggregated from a single Entity, exceeds $5,000 in value. Reimbursed and sponsored travel taken by the Investigator's Family Members if the travel relates to the Investigator's Institutional Responsibilities. Travel events meeting these conditions, and which occurred over the last twelve (12) months or are expected over the next twelve (12) months, must be disclosed.
    a. The following information must be provided in connection with any travel disclosures that meet the above criteria:
        i. Purpose of trip,
        ii. Identity of the sponsor/organizer of the trip,
        iii. Destination/location, and
        iv. Duration of trip.

Exclusions

The following interests are excluded from the disclosure requirements in this Section D:

1) Salary, royalties, or other Remuneration paid by D-H to the Investigator, if the Investigator is currently employed or otherwise appointed by D-H, including IP rights assigned to D-H and agreements to share in royalties related to such rights;
2) Any financial interest arising solely by means of investment in a mutual, pension, or other fund wherein the Investigator does not manage the assets;
3) 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; and
4) SBIR and STTR Phase I federal grants are exempt.

Additional Disclosures Required for Human Subject Research
Department Chairs, through research review committees established within their respective Departments, are responsible for reviewing research protocols for ethical considerations and scientific merit prior to submitting the protocol and informed consent documents to the Committee for the Protection of Human Subjects (CPHS).

Investigators involved in human subject research must adhere to the policies of Title 45 Code of Federal Regulations Part 46 and other applicable federal and state regulations, for the protection of human subjects participating in clinical research. D-H delegates to the Dartmouth College CPHS the responsibility for reviewing and approving research projects involving human subjects. All research projects involving human subjects must be approved or exempted from further review by CPHS, or an external IRB, prior to initiating the study.

For human subject research, disclosures are also required in IRB-approved consent forms, as required by the IRB, with an explanation that additional information would be provided to the research subjects upon request, to the sponsor of multi-center trials, and to the IRBs of other participating institutions.

E. Research Conflict of Interest Committee (RCOIC)

The D-H RCOIC is a committee that makes recommendations on courses of action designed to manage, reduce, or eliminate financial conflicts of interest in research in order to reduce the potential for the financial conflict of interest to compromise the validity of the research and the safety of the human subject. The D-H RCOIC is a subcommittee of D-H Organizational Ethics Committee and is comprised of members appointed by the D-H Executive Vice President of Research and Education. The Vice President of Research Operations will serve as an ex officio member of the RCOIC.

F. Conflict Decisions and Considerations

The D-H RCOIC shall determine if there exists an FCOI.

An FCOI exits if both of the following are present:

A. A Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research, and

B. The Financial Interest is an SFI.[9] The determination as to whether there is an FCOI begins with the disclosure of a Significant Financial Interest. The existence of an SFI does not necessarily result in an FCOI.

The conflicted person(s), the Investigator, the Supervisor and/or Section Chief, and CAS, in consultation with the RCOIC, are responsible for determining whether an FCOI exists.

If an FCOI exists, a MAP must be prepared with PHS details as outlined in the Management Action Plan Procedure, linked below.

For all projects with FCOIs (i.e., projects funded with PHS awards that contain an FCOI), prior to expenditure of funds, D-H is required to report to the PHS Awarding Component the existence of any FCOI. For more information about these requirements, see the Management Action Plan Procedure, linked below.

An approved MAP must be in place before the research begins. In human subjects research, IRB approval shall not be granted until the COI MAP has been established and approved.

Federal grant applications may be submitted while D-H is considering a possible FCOI with the understanding that the research shall not be conducted unless the possible FCOI is managed or eliminated. There shall be no expenditure of funds unless and until the MAP has been executed.

Once a MAP is in place for a specific FCOI, it shall be reviewed annually. Investigators are required to notify D-H of any changes that occur related to the FCOI promptly upon becoming aware of such changes.

G. PHS Reporting Responsibility

D-H shall provide to the PHS Awarding Component an FCOI report regarding any SFI found to be an FCOI in accordance with the Conflict of Interest Management Action Plan Procedure linked below. The report shall include documentation that D-H has implemented a MAP in accordance with the applicable regulations (*NOTE*: for any FCOI that is eliminated prior to the expenditure of PHS-awarded funds, D-H is NOT required to submit a report).

[9] Please see the definition of Significant Financial Interest in the Definitions section of this policy.

H. PHS Funded Subrecipient Agreements

If D-H is the prime awardee of PHS-funded research and conducts some or all of the research through a subrecipient, then the D-H Institutional Official shall incorporate, as part of a written agreement with the subrecipient, terms that establish whether the D-H FCOI policy or that of the subrecipient, shall apply to the subrecipient's Investigators.[10]

(1) *Subrecipient's PHS Financial Conflict of Interest Policy Applies*

If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the subrecipient agreement that its policy complies with the current PHS regulations.[11]

Additionally, the subrecipient agreement must specify time-period(s) for the subrecipient to report all identified FCOI to D-H. Such time-period(s) shall be sufficient to enable D-H to provide timely FCOI reports, as necessary, to PHS as required.[12]

(2) *D-H's PHS Financial Conflict of Interest Policy Applies*

If the subrecipient cannot provide certification that its policy complies with the current PHS regulations, the subrecipient agreement shall state that subrecipient Investigators are subject to the D-H policies for disclosing SFIs that are directly related to the subrecipient's work for D-H.[13]

The subrecipient agreement must specify time-period(s) for the subrecipient to report all disclosures of SFIs to D-H. Such time-period(s) shall be sufficient to enable D-H to comply timely with its PHS review, management, and reporting obligations.[14]

I. Non-Compliance/Failure to Disclose

Noncompliance with this policy as determined by may result in institutional sanctions up to and including termination in accordance with applicable disciplinary procedures.

In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or biologic treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by D-H, the Investigator shall be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

J. Transparency/Public Accessibility for PHS Funded Research

Prior to D-H's expenditure of any funds under a PHS-funded research project, D-H shall ensure public accessibility, via written response to any requestor within five (5) business days of receipt of a request, of information concerning any SFI disclosed to D-H that meets all three of the following criteria:

(1) The SFI was disclosed and is still held by the Investigator;

[10] 42 C.F.R. §50.604(c)(1).
[11] 42 C.F.R. §50.604(c)(1)(i).
[12] 42 C.F.R. §50.604(c)(1)(ii).
[13] 42 C.F.R. §50.604(c)(1)(i).
[14] 42 C.F.R. §50.604(c)(1)(iii).

(2) D-H determines that the SFI is related to the PHS-funded research; and
(3) D-H determines that the SFI is an FCOI.[15]

The information that D-H makes available via written response to any requestor within five (5) business days of a request includes, at a minimum, the following:

(1) the Investigator's name;
(2) the Investigator's title and role with respect to the applicable research project;
(3) the name of the entity in which the SFI is held;
(4) the nature of the SFI; and the approximate dollar value of the SFI (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.[16]

D-H shall note in its written response D-H's determination 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 sixty (60) days of D-H's identification of a new FCOI, which should be requested subsequently by the requestor.[17]

Information concerning SFIs shall remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated.[18]

K. Record Retention

Records of all Financial Interest disclosures (whether or not a disclosure resulted in D-H's determination of an FCOI) and any actions taken by D-H with respect to COIs shall be retained electronically and managed by D-H for at least three (3) years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 C.F.R. 75.361.

L. Other Considerations

Students/Trainees: An important part of training of graduate students and postdoctoral fellows is research mentoring. D-H and the staff who oversee student research must ensure that the educational interests of these trainees are not compromised by FCOIs. Care must be taken to ensure that the source of research funding does not cause a change in the training experience. Students and fellows should not be placed in a situation where the financial interests of D-H or the mentor shall influence the direction of the research project. Furthermore, agreements with sponsors should not compromise the rights of students to publicly present and publish dissertations and manuscripts reporting their research.

M. Regulatory Compliance

The review of all financial conflicts shall be conducted according to this policy regardless of the funding source. D-H shall comply with all applicable federal, state, and institutional regulations, standards, and requirements including those of Public Health Service (PHS) agencies, the National Science Foundation (NSF), and the Department of Defense (DoD).

[15] 42 C.F.R. §50.605(a)(5)(i).
[16] 42 C.F.R. §50.605(a)(5)(ii).
[17] 42 C.F.R. §50.605(a)(5)(iii).
[18] 42 C.F.R. §50.605(a)(5)(iv).

V. References

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, 76 Fed. Reg. 53,256 (Aug. 25, 2011) (codified at 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94).

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 C.F.R. 75 (Dec. 19, 2014).

Uniform Administrative Requirements, Cost Principles, and Audit Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 C.F.R. Part 200 (Dec. 26, 2014).

Food and Drug Administration – Financial Disclosure by Clinical Investigators, 63 Fed. Reg. 5,250 (Feb. 2, 1998) (codified at 21 C.F.R. Part 54).

Responsible Owner:	Compliance and Audit Services	**Contact(s): email**	Claire Nerenz
Approved By:	Chief Officer - Nursing Executive D-HH; Office of Policy Support - Organizational Policies Only; Organizational Ethics Committee; Burgess, Leigh	**Version #**	1
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Related Polices & Procedures:	Conflict of Interest (COI) in General and Business Affairs Policy-D-H Conflict of Interest (COI) Management Action Plan (MAP) Procedure Conflict of Interest (COI) Consulting and Vendor Sponsored Activities Policy-D-H Conflict of Interest Policy (COI) - Personal Gifts including Meals, Travel, and Education-D-H Code of Ethical Conduct-D-H		
Related Job Aids:	Conflict of Interest (COI) Frequently Asked Questions Job Aid Conflict of Interest (COI) Speakers Bureaus Frequently Asked Questions Job Aid		