

Policy Title: Research – Conflicts of Interest

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Policy:

Because conflict of interest situations create the risk of undue influence on research integrity and raise concern about the protection of human subjects who participate in research, it is the policy of ChristianaCare Health System (CCHS) that researchers should make reasonable efforts to avoid the occurrence of conflict of interest situations and that such circumstances be fully disclosed and appropriately evaluated, managed, reduced, or eliminated.

Purpose:

The scientific credibility and general acceptance regarding the results of research depend on the integrity and objectivity of the professional judgments of the individuals involved in the research.

Situations may arise in which a researcher has financial interests that may create a risk of undue influence and bias in the design, conduct, and reporting of research. This policy is established to address these situations.

Scope:

This policy applies to all individuals identified as researchers (investigators) at ChristianaCare Health System, Inc. and its subsidiaries.

Select applicable:

- Christiana Care Health Services and the Medical Dental Staff**
 - Christiana Hospital
 - Wilmington Hospital
 - Union Hospital
- Christiana Care Home Health and Community Services**
- Christiana Care Health Initiatives**

Definitions:

For purposes of this policy, the following definitions apply:

COI Smart Database:

Electronic database maintained by the Corporate Compliance Department that is used to track, monitor, evaluate, and maintain conflict of interest disclosures, as well as facilitate practitioner requests to participate in outside activities.

Conflict of Interest (COI) Steer Committee:

The Committee is responsible for reviewing any potential financial conflicts of interest (FCOI), as identified by the Research COI Team. The Committee will be led by Corporate Compliance and chaired the Chief Physician Executive or his/her designee and consist of various individuals from the institution who are appointed by the Chief Physician Executive.

Financial Conflict of Interest:

When the institution through its designated official(s) reasonably determines that an investigator's significant financial interest is related to a funding type (e.g., federal, industry, foundation, state) and could directly and significantly affect the design, conduct or reporting of research.

Financial Interest:

Anything that has monetary value, whether the value is readily ascertainable. Value of stocks, stock options or other ownership interests is to be determined through reference to public prices or other reasonable measures of fair market value.

Immediate Family Members:

Spouse and dependent children.

Institutional Responsibilities:

An investigator's responsibilities on behalf of the institution and as defined by the organization in its policy on financial conflicts of interest which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels including but not limited to Institutional Review Boards (IRBs) or Data and Safety Monitoring Boards (DSMBs).

Public Health Service (PHS):

The Public Health Service (PHS) of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

Researcher (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 regardless of funding type (e.g., federal, industry, foundation, state) or proposed for such funding, which may include contractors, collaborators, or consultants. [Clinical Investigator](#) also includes the spouse and each dependent child of the investigator.

Research Conflicts of Interest (COI) Team:

A team comprised of members from the Office of Sponsored Programs (OSP), Corporate Compliance, Legal, and the IRB. The team will meet to review all new potential conflicts of

interest and to ensure investigators/researchers comply with internal/external management plans that may be established.

Senior/Key Personnel:

The Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by an institution within the grant application, progress report, or any other report submitted to PHS by the institution under the regulation.

Significant Financial Interest:

- A. A financial interest consisting of one or more of the following interests of the researcher (and those of the researcher's spouse and dependent children that reasonably appears to be related to the researcher's institutional responsibilities:
1. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the equity **in the twelve months preceding the disclosure** and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds **\$5,000**.
 - a) For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option(s), or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 2. Regarding any non-publicly traded entity, a *significant financial interest* exists if
 - a) The value of any remuneration received from the entity **in the twelve months preceding the disclosure**, when aggregated, exceeds **\$5,000**, or
 - b) The researcher (or the researcher's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests where such income received **in the twelve months preceding disclosure**, when aggregated, exceeds **\$5,000**.
 4. Researchers also must disclose the occurrence of any reimbursed or sponsored travel if the value of any remuneration received per reimbursing or sponsoring entity **in the twelve months preceding the disclosure**, when aggregated, exceeds **\$5,000**
 - a) (e.g., that which is paid on behalf of the researcher and not reimbursed to the researcher so the exact monetary value may not be readily available), related to his/her institutional responsibilities; provided, however, that this does not apply to travel that is reimbursed or

sponsored by CCHS, or 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.

- B. *Significant financial interest* does not include the following types of financial interests:
1. Salary, royalties, or other remuneration paid by CCHS to the researcher if the researcher is currently employed or otherwise appointed by CCHS, including intellectual property rights assigned to CCHS and agreements to share in royalties related to such rights income from investment vehicles, such as mutual funds and retirement accounts as long as the researcher does not directly control the investment decisions made in these vehicles;
 2. Income from seminars, lectures, or teaching engagements 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; or
 3. Income from service on advisory committees or review panels for 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.

Procedure:

- I. All researchers shall complete on an annual basis a Research Conflicts of Interest Disclosure Statement which shall require a detailed description of significant financial interests, as described above that reasonably appear to be related to the researcher's institutional responsibilities.
 - A. The Annual Disclosure Statement(s) shall be completed via the COI Smart system and reviewed by the Research Education and Compliance Manager in the Office of Sponsored Programs.
 - B. It is the responsibility of the researcher to file a revised Annual Disclosure Statement [within thirty \(30\) calendar days](#) of acquiring or discovering a new significant financial interest required to be disclosed.
 - C. If a researcher is in doubt about a situation, it should be fully disclosed. This disclosure requirement includes proposals to the Public Health Service (PHS), including the National Institutes of Health ([NIH](#)), and the National Science Foundation ([NSF](#)).
- II. The Director of the OSP or his/her designee shall provide training to all researchers regarding this Conflict of Interest in Research Policy and its disclosure requirements.
 - A. Each researcher shall complete such training prior to the earlier of:

1. Engaging in PHS funded grants, cooperative agreements, or contracts with an issue date of the Notice of Award or contract effective date (including noncompeting continuations) on or after October 1, 2020; or
 2. The next Annual CCHS Conflicts of Interest Disclosure Statement Campaign.
 3. Thereafter, each researcher shall again complete training at least every four (4) years.
- B. The Director of the OSP or his/her designee shall expeditiously provide training if:
1. This policy is changed in a manner that affects researcher requirements;
 2. A researcher is new to CCHS; or
 3. It is determined by the Research Conflicts of Interest Team that a researcher is not in compliance with this policy or a management plan imposed by the Committee.
- III.** In reviewing disclosure statements if the Research Conflicts of Interest Team deems it appropriate, the Team may request additional information and documentation from the researcher, who shall be required to comply with any such requests.
- A. Examples of additional information include the disclosure or determination of the monetary value of reimbursed or sponsored travel.
- B. Whenever, in the course of an ongoing PHS-funded research project, an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator discloses a new significant financial interest to the institution, the Research Conflicts of Interest Team shall, within 60 days, review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest.
- C. Whenever an institution identifies a significant financial interest that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed by the institution during an ongoing PHS-funded research project, the Research Conflicts of Interest Team shall, within 60- days, review the significant financial interest, determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists, and if so, implement a management plan.
- D. The Research Conflicts of Interest Team may, if deemed appropriate, consult with the appropriate department chair.
- E. After reviewing the disclosure statements and any additional information and documentation and consultation, the Research Conflicts of Interest Team shall reasonably determine if any disclosed significant financial interests relate to research being conducted or proposed by the researcher and, if so, whether such research is PHS-funded research or NSF-funded.

- F. In making such determinations, a significant financial interest relates to research being conducted or proposed if such interest could be affected by the research or is in an entity whose financial interest could be affected by the research.
- IV.** In the situation where the research is PHS-funded, the Research Conflicts of Interest Team shall reasonably determine if the researcher is considered Senior/Key Personnel.
- A. In making such determination, a researcher is considered Senior/Key Personnel if he/she is the Project Director or Principal Investigator or any other person identified as such in a PHS grant application, progress report, or any other report submitted to the PHS or in a contract proposal or contract providing PHS research funding.
- V.** If the Research Conflicts of Interest Team after reviewing a disclosure statement and any additional information, documentation, and consultation, determines that any significant financial interest disclosed relates to research being conducted or proposed by the researcher, the Research Conflicts of Interest Team shall refer the disclosure statement with the additional information and documentation to the Chair of the Conflicts of Interest Steer Committee.
- A. In making such referral, the Research Conflicts of Interest Team shall specify whether the significant financial interest relates to PHS-funded research or NSF-funded research and if PHS-funded, whether the researcher is considered Senior/Key Personnel.
- VI.** The Chief Physician Executive shall serve as the Chair of the Conflicts of Interest Steer Committee.
- A. If the Chair deems it appropriate, he/she may consult with individuals beyond those on the Committee to assist in deliberations.
- VII.** The Conflicts of Interest Steer Committee shall reasonably determine whether the disclosed significant financial interest found relates to the research being conducted or proposed by the researcher and constitutes a financial conflict of interest.
- A. In making such determination, a significant financial interest is a financial conflict of interest in that financial interest could directly and significantly affect the design, conduct, or reporting of the research.
- VIII.** The Conflict of Interest Steer Committee shall further determine if the financial conflict of interest shall be managed, reduced, or eliminated.
- A. In making such determination, the Committee shall consider both the likelihood that the researcher's decisions made under the relevant circumstances would be unduly influenced and biased as well as the seriousness of the harm or wrong that could result.

- B. The probability of undue influence and bias is affected by the value of the financial interests and the extent of the discretion that the researcher has in making important decisions regarding the research.
 - C. The Committee may consider the uniqueness of the researcher's position with respect to the research (e.g., whether safety or other factors will be diminished if the researcher does not participate).
 - D. The Committee may determine that the risk of undue influence is not significant and permit the researcher to participate in the research.
 - E. The Committee may determine that the risk of undue influence is significant and prohibit the researcher from participating at all in the research.
 - F. Alternatively, the Committee may prohibit a researcher from participating in certain aspects of the research, but allow the researcher to participate in other aspects, or allow the researcher to participate in a manner and subject to such conditions that the Committee determines appropriate under the circumstances to mitigate any effects of the financial conflict of interest. Such conditions generally should include, but not be limited to:
 - 1. Requiring disclosure of the financial conflict of interest to the study participants, on presentations and publications of the data emanating from the study, and to all other researchers engaged in the research.
 - 2. Where warranted by the circumstances, such as deliberate failure to disclose a significant financial interest or failure to comply with an accepted management plan, the Committee may impose appropriate sanctions on a researcher including, but not limited to, prohibiting the pursuit of further research at CCHS by the researcher. The Committee Chair shall communicate the Committee's determination to the researcher.
- IX.** In those situations where the Conflicts of Interest Steer Committee determines that the researcher may participate in the research subject to certain conditions.
- A. A plan for managing the financial conflicts of interest setting forth the conditions shall be outlined in a letter agreement forwarded to the researcher for his/her signature from the Committee Chair.
 - B. Once the researcher executes the management plan letter expressing his/her commitment to its terms, and the executed letter is returned to the Committee Chair, the research may move forward.
 - C. The fully-executed letter agreement embodying the management plan conditions shall be forwarded by the Committee Chair to the Director of the OSP or his/her designee who shall keep the executed letter agreement with a copy in the research project file.
 - D. The Director of the OSP or his/her designee shall be responsible for monitoring compliance with the management plan by the researcher and enforcing the conditions imposed by the management plan on an ongoing basis.

- E. The researcher shall notify the Committee Chair, with a copy to the Director of the OSP or his/her designee of any changes in the researcher's significant financial interests, so it can be determined whether further management is appropriate.

- X. The Director of the OSP shall submit any required reports to the PHS or NSF. The Director of the OSP, or his/her designee shall also make:
 - A. This Conflicts of Interest in Research policy publicly accessible by posting on CCHS' website; and
 - B. Make publicly accessible information concerning financial conflicts of interests disclosed and still held by Senior/Key Personnel relating to those individuals' PHS financial research through the website or by written response to any requestor within five (5) business days of receipt of written request.

- XI. In instances where CCHS carries out PHS-funded research through a subrecipient (e.g., subcontractor or consortium member) CCHS shall:
 - A. Require such subrecipient researcher either to comply with this Conflicts of Interest in Research Policy or
 - B. Require the subrecipient to:
 - 1. Certify that its Financial Conflicts of Interest Policy complies with applicable federal requirements.
 - 2. Require subrecipient researcher to comply therewith, and
 - 3. Agree to submit to CCHS disclosures of significant financial interests in specified time periods to enable CCHS to comply with its review, management, and reporting obligations.
 - 4. If applicable, obtain a certification from the subrecipient that its FCOI policy complies with the regulation.
 - 5. If applicable, include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its investigators in a time frame that allows CCHS to report identified FCOIs to the NIH as required by the regulation.
 - 6. If applicable, include in the written agreement a requirement to solicit and review subrecipient investigator disclosures that enable CCHS to identify, manage, and report identified FCOIs to the NIH.

- XII. No individual person should be involved in considering whether significant financial interests are related to research, including PHS-funded research, whether financial conflicts of interest exist, or the management or oversight of a financial conflict of interest if that person is a party to the interest or conflict.

- XIII. All records relating to financial disclosures and actions taken to review and respond to such disclosures (whether or not a disclosure resulted in a determination of financial

conflict of interest) and all actions taken under this Conflicts of Interest in Research Policy shall be retained for at least three (3) years after the later of:

- A. The date of the final expenditure report is submitted for the PHS or NSF award to which it relates or the date of final payment on a PHS or NSF-funded research contract or other date of final payment,
- B. The resolution of any government action involving those records, or
- C. Longer as required by other CCHS policies, research sponsors or other applicable legal requirements.

The Conflicts of Interest in Research Policy, including the requirements set forth herein are believed to comply with PHS and NSF requirements. To the extent it does not wholly comply, this policy is to be interpreted to assure compliance.

Penalties and Enforcement:

- I. ChristianaCare has broad power under this Conflict of Interest in Research Policy to require the disclosure of significant financial interests, determine if such significant financial interests relate to research and federally-funded research, determine financial conflicts of interest, and subject financial conflicts of interest to appropriate management and oversight as well as to impose sanctions on researchers.
 - A. Management and oversight include the imposition of conditions or restrictions intended to manage, reduce or eliminate such financial conflicts of interests.
 - B. Individuals violating this policy may be subject to disciplinary action up to and including prohibition from participating in research and/or termination of employment and other sanctions as appropriate.

References:

ChristianaCare Policy: Research - [Compliance with Federal and Institutional Requirements](#)

Code of Federal Regulations [21 CFR 54.2](#), *Financial Disclosure by Clinical Investigators*

Code of Federal Regulations [42 CFR 50.603, Subpart E](#), *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*

Code of Federal Regulations [45 CFR 94\(a\)](#), *Responsible Prospective Contractors*

[National Institutes of Health](#), *Checklist for FCOI Policy Development*

National Institutes of Health, [NIH Grants Policy Statement, Financial Conflict of Interest](#)

National Institutes of Health, [NOT-OD-21-002](#), *Required Submission of Financial Conflict of Interest Policy into the eRA Commons Institution Profile (IPF) Module*

[National Science Foundation](#), *Conflict of Interest Policies*

[42 U.S.C. § 1320a-7b\(b\)](#), *The Federal Anti-Kickback Statute, Guidance regarding application of health care fraud and abuse sanctions*

[42 U.S.C. § 1395nn](#), *The Stark Act, Limitation on certain physician referrals*