



ADMINISTRATIVE POLICY AND PROCEDURE

TITLE: POLICY ON RESEARCH-RELATED CONFLICTS OF INTEREST

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Policy:

Chester County Hospital (“CCH” or the “Hospital”) prides itself on maintaining the highest ethical standards when conducting clinical research, including but not limited to ensuring that all Investigators conducting such research are and remain free from substantive Financial Conflicts of Interest. Therefore, Financial Conflicts of Interest involving Investigators conducting research at CCH must be disclosed and effectively managed or eliminated. It is the policy of CCH that all Investigators disclose Significant Financial Interests at the time new research is proposed, on an annual basis, when new Significant Financial Interests emerge, when requested by the University or CCH, and when required by law or a research funder or research contract.

Purpose:

The purpose of this policy is to set forth and establish the framework and mechanisms for identifying, evaluating, and managing Financial Conflict of Interests related to research activities, to minimize their ability to create bias, and to maintain integrity, credibility, and respect for the work of CCH researchers.

Applicability/Scope/Exclusions:

This Policy applies to all Investigators who are planning to participate or are participating in research at CCH and any other facility owned by or operated as part of the Chester County Hospital and Health System in which The Trustees of the University of Pennsylvania, through its operating division Penn Medicine (the “University”), owns any interest (collectively, “CCH”).

Definitions:

1. “Outside Organization” means any organization other than Chester County Hospital and Health System, the University Of Pennsylvania, the University of Pennsylvania Health System and its corporately-owned entities (e.g., Clinical Care Associates and Clinical Practices of the University of Pennsylvania), Lancaster General Health and its wholly-owned entities (e.g., Lancaster General Hospital), or any federal, state, or local government agency, a US institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

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2. "Investigator" means the principal investigator, co- investigator, collaborator, project director, and any other person who is responsible for the design, conduct, reporting of the protocol, or is otherwise responsible for accomplishing protocol objectives.
3. "Financial Conflict of Interest" means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of the research.
4. Senior/key personnel means the project director or principal investigator and any other person identified as Senior/key personnel by CCH in a grant application, progress report, Institutional Review Board (IRB) protocol, or any other report submitted to the sponsor related to the research.
5. "Significant Financial Interest" means any financial interest that an Investigator (or his/her spouse or dependent children) might have that would reasonably appear to be related to the Investigator's institutional responsibilities (*i.e.*, an Investigator's responsibilities on behalf of CCH, such as research, professional practice, teaching, and CCH committee membership).
 - a. Significant Financial Interest includes the following:
 - i. Consulting fees, honoraria (including honoraria from a third party, gifts or other "in kind" compensation, whether for consulting, lecturing, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the prior twelve (12) months exceeded \$5,000.
 - ii. Equity interests, including stock options, of any amount in a non-publicly-traded Outside Organization.
 - iii. Equity interests (or entitlement to the same) in a publicly-traded outside organization that when aggregated with any payments from that Outside Organization for the prior twelve (12) months exceed \$5,000 (when valued in reference to current public prices or using accepted valuation methods).
 - iv. Royalty income for the prior twelve (12) months or the right to receive future royalties under a patent license, copyright, or other agreement where the research is directly related to the licensed technology or work.
 - v. Any non-royalty payments for the prior twelve (12) months or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement). This includes any bonus or milestone payments to the investigators in excess of reasonable costs incurred.
 - vi. Service as an officer, director, or in any other executive position for an Outside Organization whether or not remuneration is received for such service.

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- vii. With respect to research funded by the Public Health Service only, any reimbursed or sponsored travel (*i.e.*, travel which is paid on behalf of an Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily known) during the previous twelve (12) months. However, sponsored or reimbursed travel from 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 need not be disclosed.
- b. Significant Financial Interests *do not* include the following:
 - i. Interests of any amount in publicly traded, diversified mutual funds in which the Investigator does not exercise management of fund investment;
 - ii. Payments to the University or CCH or the Investigator that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the institution;
 - iii. 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 affiliated with an institution of higher education;
 - iv. 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 affiliated with an institution of higher education; and
 - v. Salary, royalties, or other remuneration paid by CCH or the University to the Investigator if the Investigator is employed by CCH or the University.

Procedure:

1. Disclosure of Significant Financial Interests

- a. On an annual basis, each Investigator must disclose all Significant Financial Interests on the Conflict of Interest Disclosure Statement that is distributed by the CCH Director of Research, IRB Administrator, or one of their designees. An annual Conflict of Interest Disclosure Statement is required even if the Investigator has no Significant Financial Interests to disclose.
- b. Each Investigator also must update his or her Conflict of Interest Disclosure Statement within thirty (30) days of discovering or acquiring a new Significant Financial Interest, and within thirty (30) days of receiving a written request from the CCH Director of Research, IRB Administrator, or their designees.

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- c. Upon submission of a grant proposal, submission of a protocol to the IRB or upon being added as an Investigator on a current research protocol, an Investigator must update his or her Conflict of Interest Disclosure Statement or attest that it remains accurate and complete a Research Certification.

2. Disclosure of Travel

Investigators who are funded or proposed to be funded by the Public Health Service must also disclose the occurrence of any reimbursed or sponsored travel, related to the Investigator's institutional responsibilities, during the previous twelve (12) months, except for travel paid or reimbursed by CCH, the University, government agencies, U.S. institutions of higher education, or their affiliated teaching hospitals, medical centers or research institutions. "Sponsored travel" means travel which is paid on behalf of the Investigator, and not reimbursed to the Investigator, so that the exact monetary value may not be readily determinable. In addition, CCH may request other information about the trip as necessary to evaluate whether the travel may constitute a Financial Conflict of Interest.

3. Review of Significant Financial Interests

- a. The CCH IRB is responsible for reviewing all Conflict of Interest Disclosure Statements and Research Certifications. The CCH Institutional Official is responsible for determining whether any Significant Financial Interest is related to the research and constitutes a Financial Conflict of Interest.
- b. At the time the CCH IRB reviews a new protocol, or an amendment to a protocol where a new Investigator is added, the CCH IRB will review all Financial Conflicts of Interest for all Investigators participating in the reviewed research and make a recommendation to the CCH Institutional Official regarding management of any Financial Conflict of Interest identified.

4. Management and Reporting of Financial Conflicts of Interest

- a. If the CCH IRB determines that a Significant Financial Interest constitutes a Financial Conflict of Interest, the CCH IRB may recommend that the Investigator eliminate the Financial Conflict of Interest or that the Financial Conflict of Interest be managed. Factors to consider when determining management of a Financial Conflict of Interest instead of elimination include, but are not limited to:
 - The magnitude and nature of the Financial Conflict of Interest
 - The uniqueness of the Investigator's position with respect to the study
 - The extent to which the Significant Financial Interest could be influenced by research
 - The degree of risk to human subjects
 - The role of the Investigator in the research such as recruitment, data analysis, or research design

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- b. If the CCH IRB determines that a Financial Conflict of Interest can be managed, in consultation with the Investigator, the CCH IRB will develop a management plan. Components of the management plan may consist of: (i) public disclosure of the Financial Conflict of Interest; (ii) disclosure of the Financial Conflict of Interest to research participants; (iii) appointment of an independent monitor to oversee the conduct of the research; (iv) modification of the research plan; or (v) change in personnel responsible for the research. The management plan must also detail responsibilities and methods to monitor compliance with the management plan throughout the duration of the research.
- c. The recommendation of the CCH IRB for elimination or management of Financial Conflicts of Interest will be sent to the CCH Institutional Official for review, and the CCH Institutional Official may either approve, reject, or revise the recommendation. For Financial Conflicts of Interest identified during the process of initial submission of a protocol to the IRB or at submission for continuing review, the CCH IRB will make reasonable efforts to provide its recommendations for review by the CCH Institutional Official at the same time as the protocol submission.
- d. An Investigator must indicate in writing acceptance of the management plan and comply with all terms and conditions approved by the CCH Institutional Official. If an Investigator objects to the management plan, the Investigator can request in writing that the CCH Institutional Official reevaluate the management plan. The Investigator's written request must include reasons for objecting to the management plan and, if appropriate, alternative methods to manage the Financial Conflict of Interest. Any revisions to the management plan must then be submitted to the CCH Institutional Official for review, and then approval, rejection or modification. The University's Research Integrity Officer is available as a resource to make recommendations to the CCH Institutional Official. The Institutional Official's determination shall be final.
- e. IRB approval (initial or continuing) of a protocol cannot be granted until any Financial Conflicts of Interest have been addressed to the satisfaction of the CCH Institutional Official, including Investigator's written acceptance of the management plan.
- f. Prior to expenditure of funds, prior to commencing the research, when new Financial Conflicts of Interest are identified during the conduct of research, and on an annual basis, to the extent required by the applicable research sponsor or government agency, the CCH IRB Administrator, CCH Director of Research, or their designee, will report an Investigator's Financial Conflict of Interest and the management plan to the applicable research sponsor or government agency. The report will contain information as required by law or otherwise by the sponsor.
- g. At any time, the CCH IRB or the CCH Institutional Officer may seek the advice and guidance of the University's Research Integrity Office with regard to the development of a management plan or assessment of whether a Significant Financial Interest may present a Financial Conflict of Interest.



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5. Miscellaneous

- a. **Training:** All Investigators must receive training related to this Policy and Financial Conflicts of Interest prior to their initial participation in research at CCH and at least every four (4) years thereafter. Investigators must also receive training within a reasonable period of time following any substantive changes to this Policy or in the event an Investigator is found to be non-compliant with this Policy. The CCH IRB, CCH Institutional Official, CCH Director of Research, or CCH Chief Medical Officer may also require an Investigator to undergo training at any time, in their respective reasonable discretion.
- b. **Public Notice:** This Policy will be posted publicly on the CCH website. In addition, to the extent required by law, CCH will make available to the public, upon written request to the CCH IRB Administrator, certain information regarding Financial Conflicts of Interest of Senior /key personnel with respect to research conducted at CCH. Within five (5) days of a written request, CCH will provide the following information: (i) Investigator's name, title, and role with respect to research; (ii) the name of the entity in which a Significant Financial Interest is held; (iii) the nature of the Significant Financial Interest; and (iv) the approximate value of the Significant Financial Interest. CCH may choose to disclose the approximate value of the Significant Financial Interest in the following ranges (\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; and amounts above \$100,000 by increments of \$50,000).
- c. **Non-Compliance:** In the event CCH or the University becomes aware of an instance in which a Significant Financial Interest was not timely disclosed by an Investigator or was not timely reviewed by CCH, CCH will:
- As soon as reasonably possible, but in no event later than sixty (60) days, review and evaluate the Significant Financial Interest and determine whether it constitutes a Financial Conflict of Interest;
 - Develop a management plan if the Significant Financial Interest constitutes a Financial Conflict of Interest.

In addition, whenever a Financial Conflict of interest is not identified or managed in a timely manner (e.g. due to failure of an Investigator to timely disclose a Significant Financial Interest that is determined to constitute a Financial Conflict of Interest; failure by the Investigator to comply with the management plan, or CCH's failure to review or manage a Financial Conflict of Interest), the CCH IRB will perform a retrospective review of the research to determine if, during the period of non-compliance, the research was biased in the design, conduct, or reporting of such research. Such retrospective review must be documented and performed within 120 days of the identification of non-compliance. CCH will update any Financial Conflict of Interest report previously submitted to the sponsor or applicable government agency. If bias is found, CCH will immediately notify the sponsor or appropriate government agency and submit a mitigation report as required by the sponsor or government agency.

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d. **Subrecipients:** To the extent applicable, if any research is conducted by another party through a sub award or subcontract, the written agreement between CCH and the subrecipient must require the subrecipient to maintain a Financial Conflict of Interest Policy that meets the requirements of the applicable sponsor or government agency. The written agreement will require the subrecipient to certify that its established policy complies with the requirements of the applicable sponsor or government agency. The written agreement will also contain appropriate timeframes for the subrecipient to report to CCH any sub-investigator Financial Conflicts of Interest to allow CCH to comply with any applicable reporting requirements.

e. **Retention of Records:** All Financial Conflict of Interest Disclosure Statement, management plans, and other documents related to Financial Conflicts of Interest will be retained for the longer of: (i) three (3) years following the date that the final research expenditure report has been submitted to the research sponsor; (ii) as specified by any government agency or in a research contract with a funder or sponsor; or (iii) as required by a CCH or University policy. Upon notification from the University General Counsel's Office, CCH will suspend any destruction of records eligible for destruction pursuant to this policy, until notified otherwise in writing by the University General Counsel's Office.

f. **Sanctions for Violation:** If it is suspected that an Investigator has violated this policy, the CCH Institutional Official will make appropriate inquiry regarding the matter and if a violation is found, institute suitable corrective action. In the event that the Department of Health and Human Services determines that a clinical research project funded by the Public Health Service with the purpose of evaluating the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by CCH as required by Federal regulations, CCH shall among other things require the Investigator involved to disclose the Financial Conflicts of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.



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Approvals:

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Institutional Official

Committee Approval (if applicable):

Committee Name: Policy & Procedure Taskforce **Date:** October 4, 2016

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