COOK COUNTY HEALTH	Category: **CCH SYSTEM WIDE**	
Subject: **Corporate Compliance**	Page **1 of 11**	Policy #: **CC.007.02**
Title: **Financial Conflict of Interest Policy**	Approval Date: **6/20/24**	Posting Date: **6/20/24**

PURPOSE

Federal regulations on promoting objectivity in research apply to all research and sponsored programs conducted by or at Cook County Health (CCH). The purpose of this policy is to set forth the requirements for disclosure of and management of Financial Conflicts of Interest (FCOI) in research conducted by or for CCH in order to ensure that all research is free from bias that may result from a FCOI. This policy is intended to supplement and not circumvent other CCH policies.

AFFECTED AREAS

This policy applies to Investigators and any other person responsible for the design, conduct or reporting of all research and sponsored programs, regardless of title or position. This includes scientists, trainees, technicians, students, fellows, volunteers, guest researchers and collaborators on research projects in which County employed personnel or contractors are designated key personnel, subcontractors, principal investigators, co- investigators, study coordinators and research assistants.

POLICY

It is CCH policy to promote scientific integrity, patient safety and investigator objectivity in sponsored research. Any conflict of interest on the part of Investigators or other members of the research team that has the potential to compromise or can appear to compromise the safety and well-being of human subjects and the integrity of study data and results must be reported and addressed by the CCH Conflict of Interest (COI) Committee. The policy applies at the onset of a proposal, award, or study (via Internal Review Board (IRB) or Sponsored Program application) and remains applicable through the life of the funding award or study, whichever is longer.

Anyone planning to conduct or conducting research and/or sponsored programs at CCH, including Investigators and key study personnel, must disclose financial interests within the initial CCH IRB or Sponsored Program application, including the financial interests of their spouse, domestic partner, and/or dependent child(ren). Investigators and key study personnel must also update the CCH IRB or disclosure within thirty (30) days of discovering or acquiring a new financial interest or revising an already reported financial interest. Updates to financial interest disclosures must also be made annually as part of the Dual Employment survey.

Financial interests disclosed will be reviewed by the CCH COI Committee in order to determine whether a financial conflict of interest (FCOI) exists. The CCH COI Committee will implement a Management Plan for any identified FCOI, as appropriate. As applicable, the CCH Research Compliance Officer will provide a FCOI Report to the relevant PHS Awarding Component regarding any financial interest found to constitute a FCOI, including details of the management plan.

Any failure to disclose a potential financial conflict of interest for review to the COI Committee will be considered a violation of this policy.

DEFINITIONS

A. *Conflict of Interest (COI) Committee:* Committee of Cook County Health faculty and stakeholders tasked with advising and assisting CCH Research Compliance Officer in the development, implementation, and oversight of CCH's Research Compliance Program. The COI Committee may include the Research Compliance Committee and/or the IRB Committee.

B. *Financial Conflict of Interest (FCOI):* PHS defines this as a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of a sponsored program or PHS-funded research.

C. *Financial Conflict of Interest (FCOI) Report:* A report of a FCOI that is made to a research sponsor (i.e., PHS awarding Component).

D. *Financial Interest:* Anything of monetary value, whether or not the value is readily ascertainable. Financial interests may include but are not limited to remuneration, compensation, and/or payments for services (e.g., consulting, speaking), royalties, equity interests, intellectual property rights and interests and industry sponsored or reimbursed travel.

E. *Institutional Responsibilities:* An Investigator's professional responsibilities on behalf of CCH including, but is not limited to, activities such as research, sponsored programs as defined by CCH, teaching, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards or Data Safety Monitoring Boards.

F. *Institutional Review Board (IRB):* An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.

G. *Investigator:* For the purpose of this policy, the PHS defines Investigator as the Project Director or Principal Investigator (PD/PI) as well as any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include, for example, collaborators or consultants.

H. *Key personnel*: In parallel to the use of the term "senior/key personnel" in making FCOI information publicly accessible for research grants and cooperative agreements under 42 CFR 50.605, the term "key personnel" is used for research contracts under 45 CFR 94.5. PHS defines Key personnel as the PD/PI and any other personnel considered to be essential to work performance in accordance with HHSAR (HHS Acquisition Regulations) subpart 352.242-70 and identified as key personnel in the contract proposal and contract.

I. *Management Plan:* A Management Plan is implemented when a Financial Interest is determined to constitute a Financial Conflict of Interest. The CCH COI Committee approves and monitors the Management Plan.

J. *PD/PI:* A Project Director or Principal Investigator.

K. *Public Health Service (PHS) agency:* Includes the Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Office of the Assistant Secretary for Health (OASH), Office of the Assistant Secretary for Preparedness and Response (ASPR), Office of Global Affairs (OG), and Substance Abuse and Mental Health Services Administration (SAMHSA). Other organizations that follow PHS regulations may include; Alliance for Lupus Research, Alpha-1 Foundation, American Asthma Society, American Heart Association, American Lung Association, American Lung Association of Michigan, Arthritis Foundation, CurePSP (Progressive Supranuclear Palsy), Juvenile Diabetes Research

Foundation (JDRF), Lupus Foundation of America, Patient-Centered Outcomes Research Institute (PCORI), and Susan G. Komen Foundation.

L. *Research:* Is any activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. The PHS notes that PHS funds a wide variety of award types and there may be some research components within award types that are not specifically labeled "research" awards. CCH applies this policy to all sponsored programs.

M. *Research Compliance Officer:* The Chair of the Cook County Research Compliance Committee.

N. *Retrospective Review:* A process utilized to determine (1) if a financial conflict of interest exists in the event of an Investigator's failure to disclose a financial interest; (2) which is subsequently deemed a FCOI, CCH's failure to review or manage an identified FCOI, or an Investigator's failure to comply with a management plan.

O. *Significant Financial Interest (SFI):* Per the HHS and FDA requirements for PHS studies, a financial interest that consists of one or more of the following interests of the Investigator (or those of the Investigator's spouse, domestic partner, and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities with regard to:

1. A publicly traded entity
   Remuneration received as of the date of disclosure and 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 $5,000. Remuneration includes salary, equity interests, royalties and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). Equity interests include any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
2. A non-publicly traded (private) entity outside organization:
   Remuneration received from the entity as of the date of disclosure and in the twelve (12) months preceding the disclosure, when aggregated, exceeds $5,000, or the Investigator (or the Investigator's spouse of dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
3. Intellectual property rights and interests (e.g., patents, patent applications, copyrights) upon receipt of any income related to such rights and interest not assigned to CCH.
4. Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities.
5. Any Clinical trial intellectual property rights not assigned to CCH.
6. Any Fiduciary Role.
7. Significant Financial Interest does **not** include the following:
   a. Salary, royalties, or other remuneration paid by CCH to the Investigator if the Investigator is currently employed or otherwise appointed by CCH, including intellectual property rights assigned to CCH 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 or manage the investment decisions made in these vehicles;
   c. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local 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;

d. Income from service on advisory committees or review panels sponsored by a Federal, state, or local 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;
e. Travel that is reimbursed or sponsored by a Federal, state, or local 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/PROCESS

A. *Disclosure of Financial Interests to the CCH COI Committee*

1. All Investigators and key study personnel must disclose their SFI at the time of proposal submissions, annually through the Dual Employment Survey, when added as an Investigator to an ongoing Public Health Service (PHS) project, and prior to participation in any PHS funded research whether they (or their spouse, domestic partner, or dependent child(ren)) have a financial interest in any external entity related to the research conducted or their Institutional Responsibilities.
2. Investigators and key study personnel must disclose the following Significant Financial Interests (SFI) (and those of his/her Family members) that reasonably appear to be related to the Investigator's Institutional Responsibilities:
   a. For a public outside organization: remuneration received from an entity in the twelve months preceding the disclosure (including non-CCH-sponsored seminar or lecture income);
   b. For a non-publicly traded outside organization: any equity (regardless of value) and remuneration for the 12 months preceding the date of the disclosure.
   c. Any equity or proprietary interest;
   d. Intellectual property rights and interests to CCH; and
   e. Sponsored or reimbursed travel costs, including information regarding the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
   f. Any Fiduciary role.
3. Investigators and key study personnel must initially disclose all relevant financial interests, including those of their spouse, domestic partner, and/or dependent child(ren), to the CCH COI Committee as part of the initial IRB or Sponsored Program application for the research study.
4. Investigators are required to timely update (within 30 days) their disclosures in the event of acquiring new SFIs or changes in their previously reported SFIs.
5. Where an Investigator and/or key study personnel discover or acquire a new financial interest related to the study, a timely update (within 30 days) must be provided to the CCH COI Committee within 30 days. Investigators and key study personnel may also submit annual updates related to their relevant financial interests, as required by the CCH COI Committee (i.e., as part of the Progress Report Form / Continuing Review process).
6. Investigators and key study personnel may also need to report their financial interest as part of the institutional CCH Dual Employment Survey process (See HR.001.03 Dual Employment), as required by the CCH Conflict of Interest policy (See CC.007.01, Conflict of Interest policy), and as part of their annual county ethics filing (Cook County Disclosure of Economic Interests). The annual Dual Employment Survey is open from October 1st to December 31st for every fiscal year. All CCH employees are required to complete their attestations and submit for manager review on or by December 31st. After this initial timeframe, employees will have an additional 90 days, or until March 31st, to provide any edits to the previous year's survey that may have been entered in error.

B. *CCH COI Committee Review of Reported Financial Interests*

1. The COI Committee shall solicit and review disclosures of financial interests from each Investigator and/or study personnel who is planning to conduct or is conducting research. For each financial interest disclosed, the COI Committee shall review and consider the following information when determining whether a financial conflict of interest (FCOI) exists:
   a. The value of the financial interest disclosed, including whether the financial interest disclosed meets the definition of a significant financial interest (SFI), as defined by federal HHS and FDA regulations.
   b. Whether the disclosed financial interest could reasonably appear to directly and significantly affect the design, conduct, or reporting of a research project;
   c. Whether the financial interest could reasonably appear to affect the rights and welfare of the human research participants;
   d. Whether the research is consistent with the core mission and values of CCH;
   e. Whether the potential benefit of the research outweighs the inherent risk of attempting to manage the financial interest; and
   f. Whether the financial interest can be managed in a way that ensures the integrity of the research and safety of CCH patients and protects the reputation of CCH and its staff.
2. The COI Committee review will take into account the nature and extent of the individual's role on a project, the nature and extent of their financial interests, and the nature of the research activity under review. The COI Committee may involve the Investigator and/or study personnel, if needed, in the determination of whether a financial interest is related to the research conducted. The COI Committee will also consider the following when reviewing whether a financial interest is considered an FCOI:
   a. FCOIs are per se inevitable, as CCH recognizes that Investigator participation in outside professional and commercial activities makes important direct and indirect contributions to the vitality and strength of the organization;
   b. A financial interest may still be considered a FCOI if it does not meet the disclosure thresholds outlined within the SFI definition; and
   c. FCOIs do not necessarily represent any impropriety when disclosed in advance.
3. The COI Committee may consult with CCH Compliance and/or Legal (or other CCH Executive Leadership, as needed) when determining whether the financial interest is a FCOI.
4. Where the COI Committee determines that the interest reported by the Investigator or key study personnel is a FCOI, the COI Committee will develop and implement a Management Plan that specifies the actions that have been, and will be, taken to manage the FCOI, as detailed in Section C below.
5. For financial interests disclosed as part of the initial IRB or Sponsored Program application, the review and determinization by the CCH COI Committee of whether the interest is a FCOI must be made prior to expenditure of funds for the study.
6. For newly disclosed financial interests made by existing Investigators for an existing study (i.e., after submission of IRB or Sponsored Program Application or Award), the review and determinization by the CCH COI Committee of whether the interest is a FCOI must be made within sixty (60) days of disclosure.
7. For disclosed financial interests by new Investigators for an existing study (i.e., after submission of IRB or Sponsored Program Application or Award), the review and determinization by the CCH COI Committee of whether the interest is a FCOI must be made within sixty (60) days of disclosure.
8. If it is identified that a financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during an ongoing research project (e.g., was not timely reviewed or reported by a subrecipient), the IRB shall, within 60 days:

a. Review the disclosure of the financial interest;
b. Determine whether a FCOI exists;
c. Implement, on at least an interim basis, a management plan; and
d. Determine whether the conflict information needs to be reported to the relevant PHS agency.

C. *Management of Determined FCOIs*

1. If the CCH COI Committee determines that a FCOI exists, a Management Plan must be developed, specifying the actions that must be taken to manage such FCOI. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:
   a. Public disclosure of FCOI (e.g., when presenting or publishing the research);
   b. For research projects involving human subjects research, disclosure of FCOI directly to participants;
   c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
   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
   g. Severance of relationships that create FCOI.
2. Depending on the nature of the financial interest, the COI Committee may determine that additional interim measures are necessary with regard to the Investigator or study personnel's participation in the research project between the date of disclosure and the completion of the review.
3. The COI Committee may consult with CCH Compliance and/or Legal (or other CCH Executive Leadership, as needed) when designing an appropriate Management Plan. The Management Plan must include the following:
   a. Signed Agreement - The Investigator and/or study personnel must accept the plan in writing. Final COI approval of the study is contingent upon receipt of this signed agreement.
   b. Assurance of Continued Compliance - The COI Committee must monitor compliance with the Management Plan until the research is completed.
   c. Notification of Changes - The Investigator and/or study personnel must agree to notify the COI Committee of any changes, in a timely manner, of financial interests or relationships to determine whether additional oversight is necessary.
4. The COI Committee must monitor compliance with the Management Plan by the Investigator and/or study personnel on an ongoing basis until the completion of the research project. COI monitoring of compliance with the Management Plan must be documented.
5. The COI Committee shall provide regular reports on compliance with the progress of Management Plans to the Research Compliance Officer, as determined necessary.

D. *Investigator Appeal of Determined FCOI*

1. If an Investigator or study personnel has been determined to have a FCOI by the COI Committee, they may contact the Research Compliance Officer to request an appeal. The Research Compliance Officer will coordinate with the Investigator and/or study personnel and the COI Committee to receive all pertinent documentation and information regarding the FCOI decision and appeal.
2. The Investigator or study personnel shall then appear before the Research Compliance Committee to answer questions and/or to provide additional information.

3. The Research Compliance Committee shall make the final determination as to whether an actual FCOI exists, based on the information provided. The final determination shall be based on the decision of a majority of the Committee.

E. *Reporting of Determined Conflicts to the Research Compliance Officer*
   1. Where the CCH COI Committee determines that the financial interest reported by the Investigator or key study personnel is a FCOI, the COI Committee will provide all relevant information regarding the identified FCOI to the CCH Research Compliance Officer, including details regarding the Management Plan.
   2. The Research Compliance Officer will review the FCOI and the study information provided to determine whether the conflict is related to PHS-funded research.
   3. The Research Compliance Officer will coordinate with designated officials within CCH to ensure that any required FCOI Report is submitted to the study sponsor or PHS Awarding Component, as required pursuant to the study agreement or contract.

F. *Reporting of Determined Conflicts for PHS Funded Research*
   1. Where necessary, the Research Compliance Officer will coordinate with designated officials within CCH to ensure that the required FCOI Report is submitted to the PHS Awarding Component, prior to the expenditure of any funds under the research project. The FCOI Report shall include at least the following:
      a. Project number;
      b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
      c. Name of the Investigator with the FCOI;
      d. Name of the entity with which the investigator has a FCOI;
      e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
      f. Value of the financial interest (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;
      g. A description of how the financial interest relates to the PHS-funded research and the basis for the determination that the financial interest conflicts with such research; and
      h. A description of the key elements of the management plan, including:
         1) Role and principal duties of the conflicted investigator in the research project;
         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; and
         6) Other information as needed.
   2. In cases in which CCH identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, CCH is not required to submit an FCOI Report to the PHS Awarding Component.
   3. For any FCOI that is identified after submission of the initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an investigator who is new to the research project), CCH shall provide to the PHS Awarding Component, within 60 days, a revised FCOI Report regarding the FCOI and ensure that CCH has implemented a management plan.

4. For any FCOI previously reported by CCH with regard to an ongoing PHS-funded research project, CCH shall provide to the PHS Awarding Component an annual FCOI Report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists.
5. CCH shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.
6. In any case in which the HHS determines that a PHS-funded project 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 CCH as required by this subpart, CCH 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.

G. *Retrospective Review of FCOI*

1. Whenever a FCOI for a study is not identified or managed in a timely manner, the CCH COI Committee must conduct a retrospective review of the Investigator or study personnel's research activities to determine if there is bias in the design, conduct, or reporting of the research resulting from the FCOI. Examples of scenarios that would require a retrospective review include:
   a. Failure by the investigator to disclose a financial interest that is determined to constitute a FCOI;
   b. Failure by CCH to review or manage the FCOI; or
   c. Failure by the Investigator to comply with the Management Plan.
2. The retrospective review must be completed within 120 days of determination of the FCOI. The review must include implementing a Management Plan that specifies the actions that have been and will be taken to manage the FCOI moving forward.
3. Documentation of the retrospective review must include, but is not limited to the following key elements:
   a. Project number;
   b. Project title;
   c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
   d. Name of the Investigator with the FCOI;
   e. Name of the entity with which the Investigator has a financial conflict of interest;
   f. Reason(s) for the retrospective review;
   g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
   h. Findings of the review; and
   i. Conclusions of the review.
4. Completion of a retrospective review of the Investigator or study personnel's activities and research will determine whether any portion of a funded research conducted during a period of noncompliance was biased.
5. The findings of each retrospective review must be reported to the Research Compliance Officer who will determine whether notification needs to be made to a PHS Awarding Component.
6. The Research Compliance Officer will facilitate prompt notification to the PHS Awarding Component, including the submission of a mitigation report, as necessary.
7. The mitigation report must include, at a minimum: the key elements documented in the retrospective review; a description of the impact of the bias on the research project; actions taken by CCH to

eliminate or mitigate the effect of the bias (e.g., impact on the research project); extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable.

8. If appropriate based on the results of the retrospective review, the Research Compliance Officer, in collaboration with designated officials within CCH, shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. Thereafter, CCH will submit FCOI reports annually.
9. Depending on the nature of the FCOI, CCH may determine that additional interim measures are necessary regarding the Investigator's participation in the research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

H. *Public Accessibility of FCOI Policy and Disclosed Financial Interests for PHS Awards or Studies*

1. CCH will post this policy on its website.
2. Upon written request from the public, CCH will make available to the public within five (5) business days certain information related to a FCOI held by an Investigator or study personnel for a PHS award or study. The information will include:
   a. The investigator's name, title, and role regarding the research project;
   b. Name of the entity in which the financial interest is held;
   c. Nature of the financial interest; and
   d. Approximate dollar value of the financial interest (dollar ranges are permissible) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.
3. CCH shall note that the information provided is current as of the date sent and is subject to updates, on at least an annual basis and within 60 days of CCH's identification of a new FCOI.
4. The Research Compliance Officer shall coordinate requests received from the public and responses, in collaboration with the CCH COI Committee, the Investigator or study personnel, and other CCH institutional officials (as needed).

I. *Sub-Recipient Responsibilities*

If CCH carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), CCH must take reasonable steps to ensure that any subrecipient Investigator complies with the applicable federal FCOI requirements by:

1. Incorporating as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of CCH or that of the subrecipient will apply to any subrecipient Investigator and study personnel. If the subrecipient's FCOI policy will apply:
   a. CCH must receive certification, as part of the agreement referenced above, that the subrecipient policy complies with federal FCOI requirements (42 CFR Part 50, Subpart F and 21 CFR Part 54). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient investigators and study personnel are subject to the CCH Research Financial Conflict of Interest Policy for disclosing financial interests that are directly related to the subrecipient's work for CCH.
   b. CCH must specify in the agreement the time period(s) for the subrecipient to report all identified FCOI to the CCH Research Compliance Officer and the CCH COI Committee, which shall be sufficient to enable CCH to provide timely FCOI reports, as necessary, to the PHS Awarding Component;

2. If the CCH Research Financial Conflict of Interest Policy will apply, the agreement shall specify time period(s) for the subrecipient to submit all disclosures of financial interests to the CCH COI Committee, which shall be sufficient to enable CCH to comply timely with its review, management, and reporting obligations.

J. *Record Keeping*
1. The CCH COI Committee will maintain records of all disclosures of financial interests and the IRB's review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a FCOI) for:
   a. Three (3) years from the date of submission of the final expenditures report (in the case of grants and cooperative agreements); or
   b. Three (3) years from the final payment (in the case of research contracts), or
   c. Resolution of any government action involving the records, or
   d. As otherwise required by law.
2. CCH will submit, or permit on site review of, all records pertinent to demonstrate compliance with financial conflict of interest requirements related to research by the sponsor agency.

K. *Training*
1. All Investigators and key study personnel must complete CCH-approved Conflict of Interest training (i.e., CITI Conflict of Interest training) prior to engaging in research and on a periodic basis (at least every four (4) years) after, as required by the IRB and Sponsored Program Office.
2. Investigators and key study personnel must also complete CCH-approved Conflicts of Interest training within thirty (30) days of:
   a. Implementation of this policy;
   b. Revisions to this policy in any manner that impacts the Investigator or study personnel related requirements;
   c. An Investigator or study personnel's employment by CCH; or
   d. A CCH determination that an Investigator or study personnel is not in compliance with this policy.

L. *Sanctions and Related Reporting Responsibilities.*
1. A failure to disclose a financial interest in accordance with this policy shall lead to discipline, up to and including potential termination.
2. If the failure of an Investigator or study personnel to comply with this policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, CCH shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

M. *Confidentiality*.
Access to information collected in connection with this policy will be limited to those who have a "need to know" and will be shared in accordance with CCH policy and other legal requirements.

CROSS REFERENCES
CCH Code of Ethics
Conflict of Interest Policy (CC.007.01)

REGULATORY REFERENCES
21 CFR part 54, Financial Disclosure by Clinical Investigators
42 CFR Part 50, Subpart F, Promoting Objectivity in Research

ATTACHMENT(S)/APPENDIX(CIES)
None

POLICY UPDATE SCHEDULE
This policy shall be reviewed and/or updated at least every three (3) years, or more often as appropriate.

POLICY LEAD	Nicole Almiro, JD Chief Compliance and Privacy Officer, CCH
REVIEWER(S)	Jeffery McCutchan, JD General Counsel, CCH
	Betty Donoval Director Research and Regulatory Affairs
APPROVAL PARTY(IES)	Erik Mikaitis Interim Chief Executive Officer, CCH Electronically Approved

POLICY HISTORY

Written: June 2022	Approved: 07/27/22	Posted: 07/28/22
Policy Name: Financial Conflicts of Interest in Research		
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