



Entities: (check all that apply) <input checked="" type="checkbox"/> Cottage Health <input checked="" type="checkbox"/> SBCH <input checked="" type="checkbox"/> GVCH <input checked="" type="checkbox"/> SYVCH <input checked="" type="checkbox"/> PDL <input checked="" type="checkbox"/> GPC <input checked="" type="checkbox"/> CSC			
Policy Title:	Financial Conflict of Interest in PHS Funded Research		
Policy Number:	8013-IRB25	Original Policy Effective Date:	10/2012
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Owner Title:	VP, Research & CRO	Owner Approval Date:	08/2018
Committee Approval:		Committee Approval Dates:	
VP Approval:	Richard Beswick, PhD, MBA	VP Approval Date:	08/2018
Departments Affected:	Cottage Health Research Institute, Institutional Review Board		

GOALS

The goal of this policy is to assure the objectivity in Public Health Service (PHS) funded research by establishing standards to ensure that the design, conduct, and reporting of such research will not be biased and/or influenced by financial conflicts of interest of an investigator. This policy implements federal disclosure requirements pertaining to objectivity in research promulgated by the U.S. Public Health Service (PHS) in 42 CFR Part 50 and 45 CFR Part 94.

This policy is intended to supplement, but not replace, CH IRB policy, Conflicts of Interest in Research (8013-IRB25).

POLICY

This policy applies to all personnel who conduct research, or assist in the performance of such research activities, where that research is performed at or under the auspices of any Cottage Health facility or subsidiary organization covered by Cottage Health's Federalwide Assurance (FWA) for the protection of Human Subjects (FWA00000147).

This policy applies only to research projects for which an institution, under Cottage Health's FWA submits a proposal to, or receives research funding (directly or indirectly) from, the Public Health Service (PHS). This policy sets forth requirements that each investigator who is planning to participate in, or is participating in, such as research, must follow; however, this policy does not apply to SBIR (Small Business Innovation Research) Program Phase I applications.

DEFINITIONS

CH IRB: Cottage Health Institutional Review Board

CHRI: Cottage Health Research Institute

Clinical Research: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product/s, and/or to

identify any adverse reactions to an investigational product/s, and/or to study absorption, distribution, metabolism, and excretion of an investigational product/s with the object of ascertaining its safety and/or efficacy. A specific clinical research project is referred to as a study.

Conflict of Interest Officer: The individual designated to review the significant financial interests of investigators in order to determine possible financial conflict of interest on behalf of Cottage Health. Appropriately designated officials within Cottage Health may assist the Conflict of Interest Officer regarding the resolution of the financial conflict of interest.

CH COIR: the Cottage Health Conflict of Interest in Research Committee. The CH COIR is charged with reviewing Physician Payment Sunshine Act disclosures and conflict of interest disclosures that have been determined to disclose significant conflicts of interest and formulating recommendations to manage, reduce, or eliminate conflicts of interest.

CRC: The primary Clinical Research Coordinator acts as the point of contact for all study related matters, both from the Sponsor and from clinicians. The CRC will be familiar with the study requirements, relevant regulations and study documentation including the study protocol, CRFs and any other relevant study specific documentation.

Disclosure of Significant Financial Interests: an investigator's disclosure of significant financial interests to Cottage Health.

Financial Conflict of Interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI Report: Cottage Health's report of a financial conflict of interest to a PHS Awarding Component.

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

HHS: the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution: any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding under Cottage Health's FWA.

Institutional Responsibilities: an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator: the project director or principal Investigator and any other person, regardless of title or position, who is responsible for (as opposed to simply assisting with) the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Key Research Personnel: Principal Investigator, Sub-Investigator, Study Coordinator and any individual performing various tasks related to the conduct of human subjects research activities. Such involvement would include:

- Obtaining information about living individuals by intervening or interacting with them for research purposes;
- Obtaining identifiable private information about individuals for research purposes;

- Obtaining the voluntary informed consent of individuals to be subjects in research; and
- Studying, interpreting, or analyzing identifiable, private information or data for research purposes

Management Plan: An action(s) to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias and/or the appearance of a FCOI.

PD/PI: a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this policy.

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

PHS Awarding Component: the organizational unit of the PHS that funds the research that is subject to this policy.

Principal Investigator (PI): The person responsible for the conduct of a Clinical Research study at the study site. The Principal Investigator is the responsible leader of the team.

Public Health Service Act or PHS Act: the statute codified at 42 U.S.C. 201 et seq.

Regulatory Coordinator: The primary point of contact between the Sponsor and/or CRO and CH IRB. The Regulatory Coordinator's primary concerns are with regulatory documents and submissions to CH IRB.

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. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, 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. For the purposes of this policy, "Research" also includes educational activities funded by the National Science Foundation (NSF).

Senior/Key Personnel: the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant Financial Interest or SFI: a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity 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. 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, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

The term significant financial interest does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- 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.

Small Business Innovation Research (SBIR) Program: the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

Sponsor: An individual, company, institution, or organization, which takes responsibility for the initiation, management, and/or financing of a Clinical Research study.

Sub-Investigator (Sub-I): any Key Research Personnel who plays a significant role in the conduct of the Clinical Research study.

PROCEDURE

I. Investigator Responsibilities

A. Training

Prior to engaging in PHS-funded research, each Investigator must complete the Cottage Health-designated training program with regard to the PHS FCOI regulations. This training will include information regarding this policy, the Investigator's responsibilities regarding disclosure of SFI, and the Federal FCOI regulations. Training must be repeated at least every four (4) years thereafter, and within thirty (30) days of the following triggering events:

- When this Policy, the Significant Financial Interest Disclosure Form, or Cottage Health procedures related to this Policy are revised in any manner that affects the Investigator's responsibilities thereto;
- an Investigator is newly hired, is appointed by, or receives approval of medical staff privileges from, Cottage Health; or

- an Investigator is found not to be in compliance with this Policy or a management plan.

B. Disclosure

When an Investigator has an SFI, a written Significant Financial Interest Disclosure Form detailing that interest is required to be submitted to Cottage Health's designated Reviewing Official. This SFI Disclosure Form must be filed no later than at the time of application for PHS funded research. The lead principal investigator on a proposed application for PHS funding is responsible for ensuring submission of a SFI Disclosure Form for all participating Investigators. Each investigator must update his or her SFI disclosures by completing a new SFI Disclosure Form. Throughout the period of the award, this update must occur at least annually, as well as within thirty (30) days of a new SFI being discovered or acquired. One annual disclosure will be sufficient to cover all on-going PHS-funded research.

The Investigator must cooperate with all requests from the applicable PHS Awarding Component and/or the Cottage Health for additional information as needed. All such internal disclosures will be treated as confidential personal information.

II. Cottage Health Responsibilities

A. Review of Disclosures and Management of FCOI

1. Initial review and management:

Prior to Cottage Health's expenditure of any funds under a PHS-funded research project, CHRI will follow the multi-level review process outlined in CH IRB's policy, Conflicts of Interest in Research (8013-IRB25). This includes an internal review by CHRI, a CH COIR annual and ad hoc review, and a CH IRB review at initial, continuing and ad hoc. The CH COIR is Cottage Health's designated Institutional Official ("IO") for purposes of complying with the requirements of 42 CFR Part 50 Subpart F (Promoting Objectivity in Research) and 45 CFR Part 94 (Responsible Prospective Contractors) and is chaired by the Conflict of Interest Officer. The CH COIR is therefore also responsible for all reporting required under these requirements. This process will include the review all Investigators' SFI Disclosure Forms; determine whether any Significant Financial Interests relate to PHS-funded research; determine whether a FCOI exists; and, if so, develop and implement a management plan that specifies the actions that have been and will be taken to manage such FCOI.

2. Review and management in the course of a PHS-funded research project:

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a SFI; an existing Investigator discloses a new SFI; or Cottage Health identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by Cottage Health during an ongoing PHS funded research project, CHRI will, within sixty (60) days institute the review process to: review the disclosure of the Significant Financial Interest; determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that specifies the actions that have been and will be taken to manage such FCOI. Depending on the nature of the SFI, Cottage Health may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Cottage Health's review.

Examples of conditions or restrictions that may be imposed to manage an FCOI include, but are not limited to:

- Public disclosure of the FCOI;
- For research projects involving human subjects, disclosure of the FCOI directly to participants;

- 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest; or
- Severance of relationships that create financial conflicts.

3. Requirements for retrospective review:

In addition to the above requirements, whenever an FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose an SFI that is determined by Cottage Health to constitute an FCOI; failure by Cottage Health to review or manage such an FCOI; or failure by the Investigator to comply with an FCOI management plan, Cottage Health will, within 120 days of Cottage Health's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Cottage Health is required to document the retrospective review, including all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

4. Monitoring:

Whenever Cottage Health implements a management plan, Cottage Health will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS funded research project.

B. Reporting of Financial Conflicts of Interest

1. Initial FCOI Report:

Prior to Cottage Health's expenditure of any funds under a PHS-funded research project, Cottage Health will provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by Cottage Health to be an FCOI and ensure that Cottage Health has implemented a management plan in accordance with this Policy. In cases in which Cottage Health identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, Cottage Health does not need to submit an FCOI report to the PHS Awarding Component.

Based on the results of a retrospective review, if appropriate, Cottage Health will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Cottage Health will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and Cottage Health's plan of action or actions taken 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). Thereafter, Cottage Health will

submit FCOI reports annually. Depending on the nature of the FCOI, Cottage Health may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of Cottage Health's retrospective review.

2. Subsequent FCOI Reports:

For any SFI that Cottage Health identifies as conflicting after Cottage Health's initial FCOI report during an ongoing PHS-funded research project, Cottage Health will provide to the PHS Awarding Component, within sixty (60) days, an FCOI report regarding the FCOI and ensure that Cottage Health has implemented a management plan in accordance with this Policy and, if required, a retrospective review and a mitigation report according to this Policy.

3. Contents of an FCOI report:

Any FCOI report required under this Policy will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Cottage Health's management plan. Elements of the FCOI report will include, but are not necessarily limited to the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 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 readily be determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the PHS-funded research and the basis for Cottage Health's determination that the financial interest conflicts with such research; and
- A description of the key elements of Cottage Health's management plan, including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.

4. Annual FCOI Report:

For any FCOI previously reported by Cottage Health with regard to an ongoing PHS-funded research project, Cottage Health will 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 will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Cottage Health will 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.

C. Enforcement

Failure to comply with this Policy, including failure to file a complete or timely SFI Disclosure Form or update or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy, including a management plan, will be grounds for discipline up to and including termination of employment, appointment, and/or corrective action pursuant to provisions of the Medical Staff Bylaws with regard to medical staff privileges.

In addition, if the failure of an Investigator to comply with this Policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, Cottage Health is required to promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Cottage Health for further action, which may include directions to Cottage Health on how to maintain appropriate objectivity in the PHS funded research project. In addition, federal regulations may require reports to the federal sponsor of any information which may show a violation of Cottage Health policy. Sponsors may impose special award conditions or may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of Significant Financial Interests related to federally sponsored projects.

D. Records

Records regarding SFI Disclosure Forms, the determinations as a result of the review process and Cottage Health's actions regarding management of an FCOI will be retained by Cottage Health for three years beyond the date of the final expenditure report submitted to PHS under an award.

E. Public Accessibility

In compliance with Federal regulations, this Policy will be made publicly accessible through the Cottage Health Web site. Information (including, at least, the minimum elements as provided in the regulation) regarding FCOIs identified under this Policy held by senior/key personnel (as defined by the regulation), shall be provided to a requestor within five (5) calendar days of a written request.

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Superseded:			
Regulations/ Standards References:	<ul style="list-style-type: none">• Title 42 Public Health, Part 50 – Policies of General Applicability, Subpart F – Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought (42 CFR 50, Subpart F)• Title 45 Public Welfare, Part 94 – Responsible Prospective Contractors (45 CFR 94)		