

FINANCIAL CONFLICTS OF INTEREST POLICY FOR INVESTIGATORS

SUBJECT: Investigator Financial Conflicts of Interest	PREPARED BY: Compliance Services	EFFECTIVE DATE: March 11, 2019	POLICY NUMBER: CNE-FIN-211
PAGE: 1 of 19	APPROVED BY: Joseph Iannoni, Senior Vice President, Chief Financial Officer		REPLACES: Women & Infants Hospital: Disclosure of Financial Interest in Research Butler Hospital: Conflict of Interest Policy for Investigators (PPM 730.030)A-20)

- I. Purpose.** Care New England Health System (the “CNE”) is committed to maintaining the highest standards of integrity, honesty and ethical responsibility in all aspects of our operations and professional and business conduct. Accordingly, CNE has developed this Financial Conflicts of Interest Policy for Investigators (the “Policy”) to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting related to research, whether unfunded or funded (by means of a grant or cooperative agreement or other contract) (the “Funded/Unfunded Research”) will be free from any bias as a result of a Financial Conflict of Interest of any Investigator (each as defined in this Policy). Additionally The Department of Health and Human Services amended its regulations related to financial disclosure on 8/25/2011. All institutions applying for U.S. Public Health Service (PHS) funding for research are required to have a policy that complies with these amended regulations; this Policy which include the PHS/NIH Conflict of Interest in Research regulations is designed to comply with the federal regulations and hereby incorporates by reference 42 CFR chapter I, subchapter D, part 50.
- II. Scope.** This Policy applies to (a) Care New England (“CNE”) , all Care New England hospitals, and other Care New England health care entities, that are a direct or indirect subsidiary of Care New England (each a “CNE Affiliate”) that engages in any Funded/Unfunded Research. (Note: Each Affiliate engaged in research may be referred to as the “Institution”); and (b) any Investigator who is planning to participate in, or is participating in any Funded/Unfunded Research with a CNE Institution. CNE expects that each Institution and Investigator will become familiar with this Policy and with the Public Health Service (PHS) Regulations which include *Responsibility of Applicants for Promoting Objectivity in Research* (42 C.F.R. Part 50, Subpart F) (the “PHS Funding Regulations”) and the PHS regulations for *Responsible Prospective Contractors* (45 C.F.R. Part 94) (the “PHS Contract Regulations”). In the event this Policy is more restrictive with respect to any subject matter that is addressed in the PHS Regulations or by any other responsible awarding agency, the more restrictive provisions in this Policy will prevail and any FCOI Reports to the PHS Awarding Component (each as defined in this Policy) or any other responsible awarding agency regarding identified Financial Conflicts of Interest will be reported in accordance with this Policy within the timeframes prescribed by the applicable PHS Regulations or other responsible awarding agency.
- III. Policy.** It is the policy of CNE that employees, medical staff members and all external investigators conducting research at a CNE Affiliate will identify, disclose and address financial conflicts of interest including but not limited to conflicts related to PHS funded research. All Disclosures of Significant Financial Interests (SFIS) will be made on an ongoing basis.

IV. Definitions.

- a) **Academic Institution** means 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) **CNE Assurance of Compliance** means the form that will be completed and signed annually by each Investigator as the disclosure of Significant Financial Interests.
- c) **CNE Investigator Statement of Financial Interests** means the form that will be completed and signed for each new project by each Investigator who is planning to participate, or is participating, in Funded/Unfunded Research.
- d) **CNE designee** is the equivalent of Institutional Official.
- e) **Equity Interest** includes any stock, stock option, or other ownership interest, the value of which may be determined through reference to public prices or other reasonable measures of fair market value.
- f) **Family Member** includes the individual's spouse/civil partner, siblings, parents, lineal descendants (i.e., children and grandchildren), and the spouses of the parents, siblings, and lineal descendants, and anyone who has the same residence. This definition includes such individuals that are related by whole or half blood, adoption, or marriage.
- g) **Financial conflict of interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- h) **Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.
- i) **FCOI Report** means an Institution's report of a Financial Conflict of Interest to a PHS Awarding Component or other responsible awarding entity.
- j) **HHS** means the United States Department of Health and Human Services, and any components of the United States Department of Health and Human Services to which the authority involved may be delegated.
- k) **Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of an Institution which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as IRBs or data and safety monitoring boards.
- l) **Investigator** means the Project Director (PD) or Principal Investigator (PI), any senior/key personnel as determined by an Institution (including, those identified in a grant application, progress report, contract proposal and contract or any other report submitted to PHS or other responsible awarding entity) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of any Funded/Unfunded Research, or Research for which PHS funding or other funding is or will be sought (e.g. collaborators, consultants).
- m) **Manage** means taking action to address a Financial Conflict of Interest which may include reducing or eliminating the Financial Conflict of Interest to ensure, to the extent possible, that the design, conduct, and reporting of any Funded/Unfunded Research will be free from bias.
- n) **PHS** means the Public Health Service of the United States Department of Health and Human Services, and any components of the Public Health Service of the United States Department of Health and Human

Services to which the authority involved may be delegated, including the National Institutes of Health (NIH).

o) **Research** means 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. For purposes of this Policy, Research will include basic and applied research (e.g. a published article, book or book chapter), product development (e.g. a diagnostic test or drug), and any activity for which funding is available from a PHS Awarding Component through a PHS grant or cooperative agreement or through a PHS 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.

p) **Significant Financial Interest (SFI)** means a Financial Interest(s) consisting of one or more of the following interests of an Investigator (and those of the Investigator's Family Members) that reasonably appears to be related to such Investigator's Institutional Responsibilities or professional expertise:

- i. Remuneration (any monetary or other financial benefit such as salary, consulting fees, honoraria or paid authorship) from any External Entity that is related to the Investigator's PHS-funded or other research activities and exceeds \$5,000 during the 12- months prior to the disclosure 'when aggregated for the Investigator and their Family Members;
- ii. with regard to any publicly traded entity, a SFI exists if the value of any Remuneration received from the entity in the 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.
- iii. with regard to any non-publicly traded entity, a SFI exists if the value of any Remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's Family Member) holds any Equity Interest.
- iv. intellectual property rights and interests (e.g. patents, copyrights, and pending patents) upon receipt of income related to such rights and interests.
- v. any reimbursed or sponsored travel (i.e. that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities or professional expertise (details related to this disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration).
- vi. any compensation from an entity (e.g. receipt of gifts or other items each having a value of twenty-five dollars (\$25) or more (or having a value of twenty-five dollars (\$25) or less but exceeding an annual aggregate (in the 12 months preceding disclosure) of two hundred dollars (\$200)), or acceptance of meals or entertainment having a value of seventy-five dollars (\$75) or more (or having a value of seventy-five dollars (\$75) or less but exceeding an annual aggregate (in the 12 months preceding disclosure) of two hundred dollars (\$200)).

q) **Significant Financial Interest Exclusions** mean the following types of Financial Interests:

- i. salary, royalties, or other Remuneration paid by an Institution to an Investigator if the Investigator is currently employed or otherwise appointed by the Institution paying such

salary, royalties or other remuneration, including intellectual property rights assigned to such Institution and agrees to share in royalties related to such rights;

- ii. 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;
- iii.
- iv. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, or an Academic Institution;
- v.
- vi. income from service on advisory committees or review panels for a federal, state, or local government agency, or an Academic Institution; and
- vii.
- viii. travel reimbursed or sponsored by a federal, state, or local government agency, or an Academic Institution.
- ix.
- x. This Policy does not apply to SFI Exclusions.

r) **Sub recipient Investigator** means a project director or principal investigator, any senior/key personnel and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Funded/Unfunded Research, or Research for which PHS funding or other funding is or will be sought and who is a subrecipient of an Institution (as an awardee Institution).

V. Institution and Investigator Responsibilities Regarding Investigator Financial Conflicts of Interest.

CNE and/or each Institution and (where applicable the Investigator) will have the following responsibilities with respect to Investigator Financial Conflicts of Interest:

- a) CNE will maintain this Policy consistent with the PHS Regulations and will make this Policy available on the internal and external CNE website.
- b) Each Institution will inform each of its Investigators of this Policy, the Investigator's responsibilities regarding Disclosure of SFIs, and the PHS Regulations.
- c) Prior to an Investigator engaging in any Research (and at least every four years thereafter), the applicable Institution will require such Investigator to complete training regarding this Policy, inform such of the Investigator's responsibilities regarding Disclosure of SFIs as well as the PHS Regulations. The investigator will do what the Institution requires concerning training and form completion. Also, the mentioned training will be immediately required when any of the following circumstances apply:
 - i. CNE revises this Policy and/or CNE or an applicable Institution revises any procedures related to this Policy in any manner that affects the requirements of Investigators;
 - ii. An Investigator is new to an Institution; or
 - iii. CNE and/or an Institution determine that an Investigator is not in compliance with this Policy or any management plan applicable to such Investigator.
- d) Any Institution that carries out any Funded/Unfunded Research through a subrecipient (*e.g.* entities with which an Institution may subcontract) will take reasonable steps to ensure that any Subrecipient Investigator complies with the following:

- i. incorporating as part of a written agreement with the subrecipient terms that establish whether this Policy or that of the subrecipient will apply to the Subrecipient's Investigators.
 - ii. If the Subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient will certify as part of the written agreement with the Institution that the subrecipient's policy complies with the PHS Funding Regulations, the PHS Contract Regulations or any requirements of any other responsible awarding entity, as applicable (if the subrecipient cannot provide such certification, the written agreement will state that the Subrecipient's Investigators are subject to this Policy for Disclosure of SFIs that are directly related to the subrecipient's work for such Institution);
 - iii. If the Subrecipient's Investigators must comply with the subrecipient's FCOI policy, the written agreement will specify time period(s) for the subrecipient to report all identified Financial Conflicts of Interest (as defined in subrecipient's FCOI policy) to the Institution (such time period(s) must be sufficient to enable the Institution to provide timely FCOI Reports to PHS with respect to any PHS Funded Research, as necessary and as required by the PHS Funding Regulations or the PHS Contract Regulations, as applicable, and any other FCOI Reports to any other responsible awarding entity as may be required by such other responsible awarding entity);
 - iv. If the Subrecipient's Investigators must comply with this Policy, the written agreement will specify time period(s) for the subrecipient to submit to the Institution all Subrecipient Investor Disclosures of SFIs (such time period(s) must be sufficient to enable the Institution to comply timely with its review, management, and reporting obligations with respect to any PHS Funded Research, as required by the applicable PHS Regulations, and any other Funded/Unfunded Research, as may be required by any other responsible awarding entity).
 - v. providing FCOI Reports to the PHS Awarding Component or any other responsible awarding entity regarding all Financial Conflicts of Interest in connection with any Funded/Unfunded Research for all Subrecipient Investigators prior to expenditure of funds and within 60 days of any subsequently identified FCOI.
- e) Each Institution will designate an Institution official(s) or a CNE designee (determined by the same process the Institution uses to designate the Institutional Official) (each an **Institutional Official**) to solicit and review Disclosures of SFIs whether disclosed on a CNE Assurance of Compliance or on a CNE Conflict of Interest Disclosure from their respective Investigators who are planning to participate, or are participating, in any Funded/Unfunded Research (which includes the SFIs of such Investigator's Family Members).
 - f) Each Institution will require its Investigators who are planning to participate, or are participating, in any Funded/Unfunded Research to and the Investigators will comply by providing:
 - i. A CNE Assurance of Compliance (AOC) - on such date as determined by the applicable Institutional Officials CNE AOC wherein the Investigator will certify that he or she has read and understands this Policy, understands his or her responsibilities regarding Disclosure of SFIs, and the applicability of the PHS Regulations to any PHS Funded Research will make a Disclosure of SFIs. Exceptions to completing the AOC may be made if there is a reasonable substitute (such as, but not limited to, a recent FCOI survey) approved by the Institutional Official ;
 - ii. A CNE Investigator Statement of Financial Interests - no later than (A) the time of application for the PHS Funded Research under a PHS grant or cooperative agreement for which such Investigator is planning to participate or is participating; (B) the date of submission of the Institution's proposal for PHS Funded Research under a PHS contract for which such Investigator

is planning to participate or is participating; or (C) prior to participating in any Funded/Unfunded Research project for which such Investigator is planning to participate or is participating, as applicable, provide to the applicable Institutional Official a CNE Investigator Statement of Financial Interests disclosing any SFIs (and those of Family Members)

- iii. Updates – disclosure, as necessary, to the applicable Institutional Official any updates to such Investigator’s previously disclosed SFIs on a CNE Assurance of Compliance, CNE Conflict of Interest Disclosure or otherwise, including those that may (A) have occurred during the period of the award related to PHS Funded Research for which such Investigator is planning to participate or is participating; (B) have occurred during the duration of the Funded/Unfunded Research project for which such Investigator is participating; (C) be related to a new Funded/Unfunded Research project for which such Investigator is planning to participate or is participating, as applicable. Such disclosure will include any relevant information that was not disclosed initially to the Institution (*e.g.* any financial conflict of interest identified on a research project that was transferred from another institution), and will also include updated information regarding any previous Disclosure of SFIs (*e.g.* updated value of a previously disclosed Equity Interest); and
- iv. Any New Disclosures – within 30 days of an Investigator discovering a new SFI, disclosure to the applicable Institutional Official any such new SFIs (*e.g.* through purchase, marriage or inheritance).

- g) Each Institution will assure that its Institutional Official will (in conjunction with the Review Committee on an as needed basis) review all Disclosures of SFI by an Investigator and determine whether such SFI is Financial Conflict of Interest in accord with Section VIII Management of Financial Conflicts of Interest of this policy.
- h) The Investigator may be involved in the determination of whether such Investigator’s SFI is related to the Funded/Unfunded Research project. Notwithstanding the foregoing, in the event CNE designates, and delegates any of the duties in Section V m to a CNE Research Council, such review and determination may be conducted by the CNE Research Council.
- i) Each Institution will take such actions as necessary to manage Financial Conflicts of Interest, including any Financial Conflicts of Interest of a Subrecipient Investigator, consistent with Policy. Management of an identified Financial Conflict of Interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report consistent with this Policy.
- j) Each Institution will provide initial, ongoing and revised FCOI Reports to the PHS Awarding Component with respect to PHS Funded Research and all such FCOI Reports will be consistent with the requirements set forth in §50.605(b) of the PHS Funding Regulations or §94.5(b) of the PHS Contract Regulations, as applicable. Each Institution will provide FCOI Reports to all other responsible awarding entities as required by such awarding entities with respect to any Funded/Unfunded Research.
- k) Each Institution will maintain records, at its principal office or such other location as such Institution’s administration designates, relating to all Investigator Disclosures of SFIs and such Institution’s (or its Institutional Official’s) review of, and response to, such Disclosures of SFI
- l) s (whether or not a Disclosure of a SFI resulted in a determination of a Financial Conflict of Interest) and all actions taken pursuant to this Policy or retrospective review, if applicable (A) for PHS Funded Research under a PHS grant or cooperative agreement, six years after research is completed, or where applicable, from other dates specified in 45 C.F.R. § 74.53(b) and 92.42(b) for different situations;

(B) for PHS Funded Research under a PHS contract, six years after research is completed or, where applicable, for the time periods specified in 48 C.F.R. Part 4, Subpart 4.7; or (C) for any other Funded/Unfunded Research, six years after research is completed.

- m) Each Institution will establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
 - i. With respect to PHS Funded Research, each Institution will certify, as required by each application or contract proposal for PHS Funded Research, that such Institution:
 - a. has in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest with respect to all research projects for which funding is sought or received from PHS;
 - b. will promote and enforce Investigator compliance with this Policy's requirements, including those pertaining to Disclosure of SFIs;
 - c. will manage Financial Conflicts of Interest and provide initial, ongoing and revised FCOI Reports to the PHS Awarding Component as required by the applicable PHS Regulations;
 - d. agrees to make information available, promptly upon request, to the HHS relating to any Investigator Disclosure of SFIs and such Institution's review of, and response to, such Disclosure of SFIs, whether or not such Disclosure of SFIs resulted in a determination of a Financial Conflict of Interest; and
 - e. will fully comply with the requirements of the applicable PHS Regulations.
 - n) CNE's Chief Financial Officer may, as deemed necessary, designate a CNE Research Council. The number and composition of which will be determined by CNE CFO. If created, there will be equal representation from each Institution in the CNE Research Council. The duties and obligations, if any, delegated to the CNE Research Council from the Chief Financial Officer may include oversight of the Institutional Officials, determinations of whether SFI is a Financial Conflict of Interest and establishment of any Review Committees (as defined and described in Section VIII.b)).

VI. Additional Duties and Responsibilities of Investigators not detailed in Section V of this policy.

- a) Each Investigator is prohibited from:
 - i. soliciting for personal benefit gratuities, favors or anything of monetary value from students, vendors, or contractors of CNE or any Institution;
 - ii. investing personally or owning stock in any privately held business ventures of current students of the Institution that the Investigator is currently employed or otherwise appointed by and that the Investigator directly or indirectly supervises; and
 - iii. using, for personal gain, any confidential and/or proprietary information that may be disclosed or available to such Investigator as a result of his or her position with an Institution or the performance of any Research.

VII. Institution and Investigator Responsibilities Regarding Research Involving Other Academic Institutions.

- a) Each Institution engaging in Research that involves an Academic Institution will take reasonable steps to ensure that the undergraduates, graduates, medical students and/or employees who are supervised by such Institution (**Affiliated Individuals**) will be subject to, through a written agreement with the Academic Institution, this Policy or the Academic Institution's FCOI policy; provided, however that if the terms of this Policy are more restrictive than that of an Academic Institution's FCOI policy, the Institution will ensure that the terms of this Policy are incorporated in the written agreement with the Academic Institution.
- b) Each Institution engaging in Research that involves an Academic Institution's Affiliated Individuals will notify such Academic Institution, through such Academic Institution's designated representative, of any meetings scheduled to review any potential Financial Conflicts of Interests (as defined by this Policy or the Academic Institution's FCOI policy, as applicable) concerning any of such Academic Institution's Affiliated Individuals.
- c) Each Investigator involved in Research that involves an Academic Institution is prohibited from the same solicitations, investments and use of confidential information as in Section VI Additional Duties and Responsibilities of Investigators.

VIII. Management of Financial Conflicts of Interest.

- a) Prior to an Institution's expenditure of any funds with respect to any PHS Funded Research or prior to commencement of any other Funded/Unfunded Research, the applicable Institutional Official (or CNE Research Council, if any, and as authority is delegated), in conjunction with the applicable Review Committee consistent with this Policy and the PHS Regulations (as applicable), will:
 - i. review all Disclosures of SFIs by Investigators;
 - ii. determine whether any SFI is (1) related to the Funded/Unfunded Research project; and (2) if so related, whether the SFI is a Financial Conflict of Interest (in accordance with Section V g); and
 - iii. if it determined that a Financial Conflict of Interest exists, develop (subject to review by the Review Committee, if any), and implement a management plan that will specify the conditions and/or restrictions that will be taken to manage such Financial Conflict of Interest, which conditions and/or restrictions may include, but are not limited to:
 - 1. public disclosure of such Financial Conflict of Interest (*e.g.* when presenting or publishing the Research);
 - 2. for Research involving human subjects, disclosure of such Financial Conflict of Interest directly to participants;
 - 3. appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from such Financial Conflict of Interest;
 - 4. modification of the Research plan;
 - 5. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
 - 6. reduction or elimination of such Financial Interest(s) (*e.g.* sale of an Equity Interest); or
 - 7. severance of relationship(s) that create such Financial Conflicts of Interest.
- b) Upon receipt and an initial review of Disclosures of SFIs from its respective Investigators, the applicable Institutional Official (or CNE Research Council, if any and as authority is delegated) will refer any potential Financial Conflict of Interest to an appropriately-constituted review

committee (the **Review Committee**). Each Institution's Review Committee will consist of such Institution's Institutional Official, at least one individual representing the finance department of the applicable Institution and additional designees appointed in consultation with the executive leadership of the applicable Institution. Any individual appointed to a Review Committee should possess the academic, professional and administrative competence and expertise necessary to review the subject matter of the proposed Research.

- i. The Review Committee may independently determine whether any SFI is (1) related to the Funded/Unfunded Research project; and (2) if so related, whether the SFI is a Financial Conflict of Interest (in accordance with Section V g). Then, if the Review Committee finds that the SFI is a Financial Conflict of Interest, the Management Plan the Institutional Officer (if there is one prepared) will be reviewed.
 - ii. The Review Committee will also be responsible for (1) reviewing the Financial Conflict of Interest in conjunction with the applicable Funded/Unfunded Research project, and on the basis of such review, making recommendations to the applicable Institution (or CNE Research Council, if any) regarding whether any modifications or conditions are necessary prior to engaging in the applicable Funded/Unfunded Research project, and (2) taking such actions as necessary to ensure the management of Financial Conflicts of Interest, maintenance of records of all identified Financial Conflicts of Interest and enforcement of this Policy. In furtherance of these responsibilities, the Review Committee may:
 1. consult with Principal Investigators, department chairs, administrators, attorneys, faculty and others involved in the research and review process or the academic discipline in question;
 2. request Principal Investigator(s) or department chair(s) to provide any relevant information; and
 3. request the assistance of individuals with competence in special areas in a review that requires expertise beyond, or in addition to, the expertise available to the Review Committee.
 - iii. Any Review Committee reviews will be completed in a timely manner in order to assure that commitments are not inadvertently made to the PHS Awarding Component or other responsible awarding entity.
 - vi. Any Research Review Committee will be conducted in a manner that is consistent with this Policy and that addresses any requirements, policies or procedures set forth in the PHS Regulations and any applicable requirements, policies or procedures of the applicable awarding entity.
 - vii. All Review Committee reviews will be documented in writing and any recommendations regarding whether any modifications or conditions are necessary or recommendations with respect to management of a Financial Conflict of Interest as a result of such review should be clearly established in such documentation.
- c) If, during the course of any Funded/Unfunded Research, an Investigator new to such Funded/Unfunded Research discloses a SFI or an existing Investigator of such Funded/Unfunded Research discloses an updated and/or new SFI to the applicable Institutional Official, such Institutional Official (or CNE Research Council, if any and as authority is delegated), consistent with this Policy and the PHS Regulations (as applicable), will (in conjunction with the Review Committee established by the Institutional Official), within 60 days of such disclosure do the following:

1. review the Disclosure of SFI;
 2. determine whether such SFI is (1) related to the Funded/Unfunded Research project; and (2) if so related, whether the SFI is a Financial Conflict of Interest (in accordance with Section V.f)iv (depending on the nature of such SFI, the applicable Institutional Official or designee may determine that interim management measures are necessary with regard to such Investigator's participation in the Funded/Unfunded Research between the date of disclosure and the completion of review by such Institutional Official of the SFI);
 3. if it determined that a Financial Conflict of Interest exists, develop and implement (on at least an interim basis) a management plan that will specify the conditions and/or restrictions that have been, and will be, taken to manage such Financial Conflict of Interest; and
 4. will notify the chairperson of the applicable IRB of the Financial Conflict of Interest and the management plan implemented in connection with such Financial Conflict of Interest to allow such applicable IRB to consider the impact on any previously approved IRB project and to take any action related to such Financial Conflict of Interest.
- d) If a CNE, an Institution, an Institutional Official or designee, the CNE Research Council, if any, or Review Committee, if any, identifies a SFI of an Investigator that was not timely disclosed by such Investigator or, for whatever reason, was not previously reviewed by the applicable Institutional Official (*e.g.* was not timely reviewed or reported by a subrecipient), such Institutional Official (or CNE Research Council, if any and as authority is delegated), consistent with this Policy and the PHS Regulations (as applicable), will (in conjunction with the Review Committee established by the Institution Official), within 60 days of such identification:
1. review such SFI;
 2. determine whether such SFI is (1) related to the Funded/Unfunded Research project; and (2) if so related, whether the SFI is a Financial Conflict of Interest (in accordance with Section V.f)iv) (depending on the nature of such SFI, the applicable Institution Official may determine that interim management measures are necessary with regard to such Investigator's participation in the Funded/Unfunded Research between the date of disclosure and the completion of review by such Institutional Official);
 3. if it determined that a Financial Conflict of Interest exists, develop and implement (on at least an interim basis) a management plan that will specify the conditions and/or restrictions that have been, and will be, taken to manage such Financial Conflict of Interest; and
 4. will notify the chairperson of the applicable IRB of the Financial Conflict of Interest and the management plan implemented in connection with such Financial Conflict of Interest to allow such applicable IRB to consider the impact on any previously approved IRB project and to take any action related to such Financial Conflict of Interest.

- e) If a Financial Conflict of Interest of an Investigator is not identified or managed by an Institution in a timely manner, including due to (1) failure by an Investigator to disclose a SFI; (2) failure by such Institution or its Institutional Official to review such SFI or manage the resulting Financial Conflict of Interest; or (3) failure by such Investigator to comply with a management plan related to such Financial Conflict of Interest, the applicable Institutional Official (or CNE Research Council, if any and as authority is delegated), consistent with this Policy and the PHS Regulations (as applicable), will (in conjunction with the Review Committee established by the Institution Official), within 120 days of such Institution's determination of non-compliance:
1. complete a retrospective review of such Investigator's activities and the Funded/Unfunded Research project, to determine whether any Research (or portion thereof), conducted during the time period of non-compliance was biased in design, conduct, or reporting of such Research;
 2. document such retrospective review, which documentation will include, but not be limited to (and as applicable), all of 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 Financial Conflict of Interest;
 - e. name of the entity or the nature of the conflict 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.
 3. Based on the results of a retrospective review conducted in accordance with this Section VIII (e)) (1-2), if appropriate, the Institution will update any previously submitted FCOI Report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, such Institution will notify the PHS Awarding Component or other responsible awarding entity promptly and submit to it a mitigation report. Such mitigation report must include, at a minimum, (1) the key elements documented in the retrospective review; (2) a description of the impact of the bias on the Research; and (3) such Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (*e.g.* impact on the Research; extent of harm done, (including any qualitative and quantitative data to support any actual or future harm) and analysis of whether the Research is salvageable). Thereafter, such Institution will submit FCOI Reports annually or as otherwise required.
- f) Any management plan for an Investigator implemented by an Institution (or its Institutional Official) in accordance with this Policy, will be monitored by the applicable Institutional Official (or CNE Research Council, if any and as authority is delegated), in conjunction with any Review Committee established by the Institution Official, to ensure Investigator compliance with such management plan on an ongoing basis until the completion of the applicable Funded/Unfunded Research.

g) In the event an Institutional Official (or CNE Research Council, if any and as authority is delegated), in conjunction with the Review Committee, determines that a Financial Conflict of Interest exists, then the Investigator with such Financial Conflict of Interest will be notified of such determination and given the right to appeal using the following appeal process:

1. Notify the Institutional Official (or CNE Research Council, if any and as authority is delegated) and/or the Review Committee of his or her desire to initiate an appeal;
2. The Institution's administration will schedule an appeal to be heard by the Review Committee of the applicable Institution;
3. On the scheduled appeal date, the Principal Investigator will be given the opportunity to present his or her position on the Financial Conflict of Interest and may do so in writing or in-person; and
4. On the scheduled appeal date and after the investigator has entered the facts into the record, the Review Committee of the applicable Institution will take final action on the appeal.

IX. Public Accessibility of Financial Conflicts of Interest Related to PHS Funded Research.

a) Prior to any Institution's expenditure of any funds with respect to any PHS Funded Research, CNE will provide the public with access to, through the CNE website or a written response to any requestor within five days of a request, information concerning any SFI disclosed to such Institution and that meets the following criteria:

1. the SFI was disclosed and is still held by the Investigator;
2. the applicable Institutional Official (or CNE Research Council, if any and as authority is delegated), in conjunction with the Review Committee, determines that such SFI is related to PHS Funded Research; and
3. the applicable Institutional Official (or CNE Research Council, if any and as authority is delegated), in conjunction with the Review Committee, has determined that such SFI is a Financial Conflict of Interest.
4. The information made available to the public by an Institution through the CNE website or a written response to any requestor within five days of a request will include, at a minimum:
 - a. the Investigator's name;
 - b. the Investigator's title and role with respect to the PHS Funded Research;
 - c. the name of the entity in which the SFI is held by such Investigator;
 - d. the nature of such SFI and the approximate dollar value (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; and amounts above \$100,000 by increments of \$50,000) or a statement that the SFI is one

whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

- b) If CNE makes information available to the public through the CNE website, then:
1. will be updated no less than annually;
 2. will be updated within 60 days of any Institution's receipt or identification of information concerning any additional SFI of an Investigator of PHS Funded Research that was not previously disclosed, or upon the disclosure of a SFI of an Investigator new to the PHS Funded Research, if an applicable Institutional Official (or CNE Research Council, if any and as authority is delegated), in conjunction with the Review Committee, determines that such SFI is related to the PHS Funded Research and is a Financial Conflict of Interest;
 3. will note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of such Institution's identification of a new Financial Conflict of Interest.
 4. Information concerning a SFI of an Investigator that is subject to Section IX will remain available, for response to written requests or for posting via the CNE website for at least three years from the date that the information was most recently updated.

X. Reporting of Financial Conflicts of Interest.

- a) Prior to an Institution's expenditure of any funds with respect to any Funded/Unfunded Research, such Institution will (1) provide to the PHS Awarding Component or other responsible awarding entity, as applicable, an FCOI Report regarding any Investigator's SFI that the applicable Institutional Official has determined is related to such Funded/Unfunded Research and that such Institutional Official (or CNE Research Council, if any and as authority is delegated), in conjunction with the Review Committee, has determined that such SFI is a Financial Conflict of Interest; and (2) ensure that such Institution has implemented a management plan in accordance with this Policy and consistent with the PHS Regulations, as applicable.
- b) In the event an Institutional Official (or CNE Research Council, if any and as authority is delegated) identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of any funds, such Institution will not be required to submit an FCOI Report to the PHS Awarding Component or other responsible awarding entity, as applicable.
- c) If an Institutional Official (or CNE Research Council, if any and as authority is delegated) or Review Committee identifies a Financial Conflict of Interest subsequent to such Institution's initial FCOI Report during an ongoing Funded/Unfunded Research project (*e.g.* upon the participation of an Investigator who is new to such Funded/Unfunded Research, or an existing Investigator of such Funded/Unfunded Research discloses an updated and/or new SFI to the Institution), the Institution will provide to the PHS Awarding Component or other responsible awarding entity, as applicable, within 60 days of such identification, (1) an FCOI Report regarding such Financial Conflict of Interest; and (2) ensure that such Institution has implemented a management plan in accordance with this Policy and consistent with the PHS Regulations, as applicable.

- d) If an FCOI Report involves a Financial Conflict of Interest, the applicable Institutional Official or designee (or CNE Research Council, if any and as authority is delegated) will conduct a retrospective review and, as necessary, such Institution will submit it to a mitigation report with the information outlined in Section VIII.e).
- e) All FCOI Reports will include sufficient information to enable the PHS Awarding Component or other responsible awarding entity to understand the nature and extent of the Financial Conflict of Interest, and to assess the appropriateness of the reporting Institution's management plan. All FCOI Reports will include, but are not limited to, the following information:
1. project number;
 2. PD/PI or contact PD/PI if a multiple PD/PI model is used;
 3. name of the Investigator with the Financial Conflict of Interest;
 4. name of the entity with which the Investigator has a Financial Conflict of Interest;
 5. nature of the Financial Conflict of Interest (*e.g.* equity, consulting fee, travel reimbursement, honorarium);
 6. value of the Financial Conflict of 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; and amounts above \$100,000 by increments of \$50,000) or a statement that the Financial Conflict of Interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
 7. a description of how the Financial Conflict of Interest relates to the Funded/Unfunded Research project and the basis for the Institution's determination that the SFI is a Financial Conflict of Interest with such Funded/Unfunded Research project; and
 8. a description of the key elements of the Institution's management plan for the Financial Conflict of Interest, including:
 - a. role and principle duties of the conflicted Investigator involved in the Research;
 - b. conditions of the management plan;
 - c. how the management plan is designed to safeguard objectivity in the Research;
 - d. confirmation of the Investigator's agreement to the management plan;
 - e. how the management plan will be monitored to ensure Investigator compliance; and
 - f. other information as necessary.
- f) For any Financial Conflict of Interest previously reported by an Institution with regard to an ongoing Funded/Unfunded Research project, such Institution will provide to the PHS Awarding Component or other responsible awarding entity, as applicable, an annual FCOI Report that addresses the status of such Financial Conflict of Interest and any changes to the management plan for such Financial Conflict of Interest for the duration of such Funded/Unfunded Research project. Such annual FCOI Report will specify whether the Financial Conflict of Interest is still

being managed or explain why the Financial Conflict of Interest no longer exists. Each Institution will provide annual FCOI reports to the PHS Awarding Component or other responsible awarding entity, as applicable, for the duration of a Funded/Unfunded Research project (including extensions with or without funds) and in the time and manner specified by the PHS Awarding Component or such other responsible awarding entity, as applicable.

XI. Failure to Comply with this Policy by an Investigator; Failure to Report Financial Conflicts of Interest by an Institution.

a) *Failure to Comply with this Policy by an Investigator.* Investigators who fail to disclose SFIs or who otherwise fail to comply with this Policy (or any management plan related to such Investigator) will be reported to the applicable Institutional Official (or CNE Research Council, if any and as authority is delegated) and will be subject to appropriate disciplinary action as determined by (i) the applicable Institution; (ii) a committee of the applicable Institution which has been delegated with such authority (which committee may be a standing committee or an ad hoc committee, the composition of which will be determined by the applicable Institution); or (iii) the CNE Research Council, if any and as authority is delegated. Such disciplinary action will vary according to the severity of the non-compliance but may include formal reprimand, termination of the Research, suspension, termination of employment or such other disciplinary actions.

b) *Failure to Report Financial Conflicts of Interests or Other Non-Compliance by an Institution.*

1. If the failure of an Investigator to comply with this Policy or a Financial Conflict of Interest management plan of an Institution appears to have biased the design, conduct, or reporting of Funded/Unfunded Research, such Institution must promptly notify the PHS Awarding Component or other responsible awarding entity, as applicable, of the corrective action taken or to be taken and such Institution will be required to take any further action as determined necessary by the PHS Awarding Component or such other responsible awarding entity, as applicable.
2. Pursuant to applicable PHS Regulations related to PHS Funded Research, the PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator Disclosure of SFIs and an Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in an Institution's determination of a Financial Conflict of Interest. Each Institution is required to submit, or permit on site review of, all records pertinent to compliance with such PHS Regulations. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular Financial Conflict of Interest will bias the objectivity of the PHS Funded Research to such an extent that further corrective action is needed or that the Institution has not managed the Financial Conflict of Interest in accordance with applicable PHS Regulations. For PHS Funded Research under a PHS grant or cooperative, the PHS Awarding Component may determine that imposition of special award conditions under 45 CFR §§ 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR §§ 74.62 and 92.43, is necessary until the matter is resolved. For PHS Funded Research under a PHS contract, the PHS Awarding Component may determine that issuance of a stop work order by the contracting officer or other enforcement action is necessary until the matter is resolved.

3. In any case in which the HHS determines that a PHS Funded Research of clinical research 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 Financial Conflict of Interest that was not managed or reported by an Institution as required by applicable PHS Regulations, such Institution will require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

XII. References:

- Care New England Conflicts of Interest and Confidentiality Policy CNE-GC-003
- Care New England Code of Conduct
- 21 CFR 46.103, 107
- 21 CFR 56.107
- 21 CFR 54
- 42 CFR Part 50 subpart F
- 45 CFR Part 94
- 45 CFR 74.14, 74.62 and 92.43
- FDA Information Sheets, FAQ's Section II, question 12
- OHRP Guidance on Financial Relationships
- CITI Financial Conflict of Interest: Overview of Investigator Responsibilities and COI Rules
- NIH Financial Conflict of interest <http://grants.nih.gov/grants/policy/coi/>
- FDA Financial Disclosure by Clinical Investigators Guidance for Industry <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm>
- National Institute of Health Financial Conflict of Interest Online Research Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial/fcoi.html>

REVISION AND APPROVAL HISTORY:

Initial Version 7.26.12

Amended: as of 1.28.19

Care New England Investigator Statement of Financial Interests (there is also an alternative electronic survey)*

Under CNE Policy CNE-FIN-211, the Principal Investigator and all other Investigators who are responsible for the design conduct or reporting of any Funded/Unfunded Research must report their personal financial interests in any organization(s) that reasonably appears to be related to the Investigator’s institutional responsibilities. Each Investigator planning to participate, or participating, in any Funded/Unfunded Research must comply with the Policy and is required (i) on at least an annual basis to provide a CNE Assurance of Compliance according to policy; (ii) to provide this Statement of Financial Interests form with each new protocol submission to the Institutional Review Board, and; (iii) to disclose any updates to any previously disclosed Significant Financial Interests (SFI (as defined below)); and (iv) to disclose any new SFIs. Each Investigator understands that if a review of any disclosure of a SFI indicates that such SFI potentially gives rise to a Financial Conflict of Interest, an additional investigation may be conducted and measures to manage, reduce or eliminate any such Financial Conflict of Interest may be implemented. Each Investigator further understands that a failure to disclose a SFI or otherwise fail to comply with the Policy will be reported and may subject such Investigator to disciplinary action which may vary according to the severity of the non-compliance but may include formal reprimand, termination of affected research project, suspension, termination of employment or such other disciplinary actions. See specifically Section V, Section VII and Section X(a) of the Policy.

Investigator Name: _____

If this submission is for a grant application, please provide the title: _____

Any potential Financial Conflicts of Interest must be resolved prior to the commencement of the affected Funded/Unfunded Research. To make possible the processing of a grant application/award or IRB application, all proposed Investigators in the applicable Funded/Unfunded Research must complete this CNE Investigator Statement of Financial Interests.

By executing this CNE Investigator Statement of Financial Interests, I certify that I (and Family Member as defined in CNE-FIN-211 as applicable) have [CHECK ONE]:

- No Significant Financial Interests.
- Significant Financial Interests as described on the attached written statement detailing such Significant Financial Interest(s).

For purposes of this CNE Investigator Statement of Financial Interests and the Policy, an SFI consists of one or more of the following interests of an Investigator (and those of Investigator’s Family Members): :

- with regard to any publicly traded entity, a SFI exists if the value of any Remuneration (including salary and any payment for services not otherwise identified as salary) **received from the entity in the 12 months preceding the disclosure** and the value of any equity interest (includes stock, stock option, or other ownership interest) in the entity as of the date of disclosure, when aggregated, exceeds **\$5,000**;
- with regard to any non-publicly traded entity, a SFI exists if the value of any Remuneration **received from the entity in the 12 months preceding the disclosure**, when aggregated, exceeds **\$5,000**, or when the Investigator (or the Investigator’s Family Member) holds any Equity Interest;
- intellectual property rights and interests (e.g. patents, copyrights, pending patents) upon receipt of income related to such rights and interests;
- any reimbursed or sponsored travel (i.e. that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to such Investigator’s responsibility to an entity of CNE or professional expertise (details related to this disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration); and
- any compensation from an entity (e.g. receipt of gifts or other items each having a value of **twenty-five dollars (\$25)** or more (or having a value of twenty-five dollars (\$25) or less but exceeding an annual aggregate (**in the 12 months preceding disclosure**) of **two hundred dollars (\$200)**), or acceptance of meals or entertainment having a value of **seventy-five dollars (\$75)** or more (or having a value of seventy-five dollars (\$75) or less but exceeding an annual aggregate (in the 12 months preceding disclosure) of **two hundred dollars (\$200)**).
- **EXCLUSIONS TO SIGNIFICANT FINANCIAL INTERESTS ARE ON THE REVERSE SIDE**

Please sign, date and return this form (along with any written statement detailing any Significant Financial Interest(s) in a sealed envelope to the Institutional Official when there is a Significant Financial Interest disclosure:

Signature Date: _____

Reviewed by (initials) _____ (as required by policy) Date: _____

*This form is a sample that may be modified from time to time with the CNE SVP CFO’s approval without a change to FCOI policy.

For purposes of this CNE Investigator Statement of Financial Interest and the Policy, an SFI DOES NOT include any of the following:

- a. Salary, royalties or other remuneration paid by CNE to the Investigator and intellectual property rights assigned to CNE;
- b. Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001.
- c. Income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001.
- d. 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.
- e. Travel 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

Summary of FCOI Noncompliance and FCOI Reporting	
FCOI Report (within 60 days of identification)	Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.
Retrospective Review (to determine bias)	If an FCOI exists, complete and document a retrospective review within 120 days of the Institution's determination of noncompliance. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.
Update/Revise FCOI Report (following retrospective review)	If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report.
Mitigation Report (promptly after retrospective review)	If bias is found, <ul style="list-style-type: none"> • Notify NIH promptly • Submit mitigation report through FCOI Module
Annual FCOI Report	Submit annual FCOI report thereafter through FCOI Module