



Financial Conflict of Interest and Commitment for Investigators

PREPARED BY: Gail Brewer, Associate Research Compliance Officer	PAGE: 1 of 12	EFFECTIVE DATE: October 20, 2022	POLICY NUMBER: CNE-CC-018
REVIEWED BY: Susan Elmore, Senior Director, Research Administration	REVIEWED BY: Paari Gopalakrishnan, MD, President & COO (KH)	REVIEWED BY: Jill Maron, MD, Chief of Pediatrics (WIH)	REVIEWED BY: Methodius Tuuli, MD, Chief of OB-GYN (WIH)
REVIEWED BY: Lisa Uebelacker, Director of Research (BH)	REVIEWED BY: Audrey Tyrka, MD Chief Scientific Officer	REVIEWED BY:	APPROVED BY: Jennie Henriques, VP, Chief Compliance and Privacy Officer

- I. **Purpose.** The purpose of this *Financial Conflict of Interest and Commitment for Investigators* (this “Policy”) policy is to maintain the integrity of research conducted at Care New England and the CNE Affiliates, outline the compliance framework for ensuring transparency with respect to external relationships and objectivity in the conduct of research, ensure consistency with federal and state law and Public Health Service (PHS) regulations, and establish boundaries on financial conflicts of interest and conflicts of commitment held by Investigators.

- II. **Scope.** This Policy applies to Investigators conducting Research at or under the auspices of their affiliation with Care New England (“CNE”), any Care New England hospital or healthcare entity or any other Care New England entity that is a direct or indirect subsidiary of Care New England (each a “CNE Affiliate” and collectively, “CNE Affiliates”).

- III. **Policy.** It is the policy of Care New England and each CNE Affiliate that Investigators must identify and disclose any significant personal and financial interests as well as outside activities to CNE and the CNE Affiliates so that they may manage, reduce or eliminate any potential or real financial conflicts of interest or commitment that might risk the integrity of research conducted at or under the auspices of CNE and the CNE Affiliates or damage the public’s trust in the organization. Investigators are responsible for becoming familiar with and following this policy, completing any training required by the organization, and reporting any violations of the policy to the organization.

- IV. **Procedure.**
 - (a) Conflict of Interest Disclosures - Investigators are required to report to CNE and the CNE Affiliates via Compliance Services their financial interests, outside professional activities and any other interests or activities, as requested, that could affect or appear to affect their Research, including their Significant Financial Interests (SFIs) that reasonably appear to be related to their professional expertise and organizational responsibilities. Conflict of Interest (COI) reporting is completed annually and at various milestones as outlined further below. Investigators will be asked to certify their understanding and compliance with this Policy and to the accuracy of their submission each time a COI Reporting form is submitted. Note that Compliance Services may

utilize CMS Open Payments and other publicly available data to validate Investigator disclosures.

- (1) Annual Reporting: On an annual basis, Investigators must submit a (Annual COI Reporting Form) in accordance with CNE and CNE Affiliates' reporting procedures and time frames. This form is in addition to any general CNE Conflict of Interest Disclosures made to satisfy IRS regulatory reporting or other internal CNE or CNE Affiliate business purposes.
 - (2) Transactional Reporting: In addition to the annual submission of a COI Reporting Form, Investigators must also submit updates to the ([FCOI and Commitment long form](#)) or certify the accuracy and completeness of the last submission ([FCOI and Commitment short form](#)), in accordance with CNE and CNE Affiliates' reporting procedures and time frames. Transactional COI reporting includes, but is not limited to, submitting an updated COI Reporting Form or certifying the accuracy of the most recently submitted COI Reporting Form upon the occurrence of any of the following:
 - i. Applying to participate as an Investigator on a new sponsored research proposal, submission of a Just-In-Time filing or upon acceptance of a sponsored research award
 - ii. Participating as an Investigator on a new human subject research study or being added to a study via an amendment to an existing human subject research study
 - iii. Being added as a new Investigator to an ongoing Research project
 - iv. A significant change in circumstances such as the acquisition of a SFI due to marriage, inheritance or purchase
 - v. Upon the request of Research Administration, the General Counsel or the Chief Compliance Officer
 - (3) Additional PHS Award Reporting: Investigators on PHS funded awards or foundation awards that follow PHS must adhere to additional reporting requirements as set forth in Section IV(d), below.
 - (4) Encouraged Disclosure of Proposed Financial Interests and Relationships – CNE and CNE Affiliates actively encourage the disclosure of proposed or anticipated financial interests or relationships before they become effective. Preemptive disclosure assists all parties in managing potential of actual FCOIs effectively and with the least disruption to Research.
- (b) Conflict of Interest Review – Compliance Services (in conjunction with the COI Review Committee as needed) has the authority to and is responsible for the following:
- (1) Administering the COI Reporting Form and review process for Investigators
 - (2) Reviewing reported Financial Interests and Outside Activities (with the COI Review Committee as needed), including Significant Financial Interests, that reasonably appear to be related to the Investigator's Institutional Responsibilities

- (3) Conducting COI reviews in accordance with standards set forth in the federal PHS COI regulations, 42 CFR 50 Subpart F, and the DoE interim COI Policy, including:
 - i. Determining whether any reported Significant Financial Interest is related to any of the Investigator's Research, and
 - ii. Determining whether any reported related Significant Financial Interest constitutes a FCOI.
 - (4) Evaluating and resolving identified Financial Conflicts of Interest, including how identified Financial Conflicts of Interest must be managed, reduced, or eliminated
 - (5) Providing appropriate oversight of identified Financial Conflicts of Interest and any related management plans with CNE or CNE Affiliate officials and offices as circumstances require
 - (6) Evaluating Financial Interests, Outside Activities, and any other reported interests that do not constitute SFIs and do not constitute Financial Conflicts of Interest, but where it is determined that there are other conflict of interest concerns and/or action is needed to preserve the integrity of the research
 - (7) Maintaining records, at its principal office, relating to all Investigator disclosures of SFIs, the review of such SFIs and any management plans, retrospective reviews, or other funding agency disclosures. Unless otherwise required by law, such records shall be maintained for at least six (6) years after the Research is completed, or where applicable, for such time periods as specified in 45 C.F.R. § 74.53(b) and 92.42(b), or 48 C.F.R. Part 4, Subpart 4.7.
- (c) Conflict of Interest Management - When a FCOI is determined to exist, CNE or the relevant CNE Affiliate must develop and implement a management plan that specifies actions that have been taken and/or will be taken to manage the FCOI.
- (1) Generally Required Conflict Management Steps: In many cases, a FCOI may be managed successfully through full and open disclosure of the Significant Financial Interest or Fiduciary Role to all students and trainees and other personnel who are directly supervised by the Investigator or who work in the Investigator's lab; in all publications and presentations of Research related to the Significant Financial Interest; and to human subjects participating in a study via a written statement in the informed consent or provided orally, as approved by the Institutional Review Board (IRB).
 - (2) Additional Conflict Management Actions – In some cases, federal or state law or regulations, or project funding requirements will require additional actions to manage a FCOI. CNE or a CNE Affiliate may also develop a management plan in situations that do not constitute Financial Conflicts of Interest, but where it is determined that there are other Conflict of Interest concerns and/or action is needed to preserve the integrity of the Research. Such actions may include, but are not limited to the following:
 - i. Periodic review of the Research, the Significant Financial Interest, and related activities in the lab by a neutral party or committee
 - ii. Disclosure of the SFI to the relevant research team and provision of measures to protect members of the research team (e.g., where a power differential may exist)

- iii. Modification of the research plan to ensure the integrity of the Research
- iv. Independent oversight of the Research, including appointment of an independent monitor
- v. Involvement of an independent statistician to review research results, data analysis and interpretation
- vi. Change of personnel responsibilities
- vii. Prohibition to participate in the Research
- viii. Divestiture of the Significant Financial Interest that creates the FCOI
- ix. Severance of the relationship(s) that creates the FCOI.

(3) Presumptively Prohibited Conflicts/Activities

- i. Research Involving Human Subjects - To protect research participants and preserve the integrity of the research study and data, CNE and the CNE Affiliates have a presumptive prohibition against participation in human subject research by an Investigator in the following situations:
 - a. The human subject research is funded by an Outside Entity in which the Investigator has a SFI;
 - b. The human subject research involves a product or intellectual property from an Outside Entity in which the Investigator has a SFI; and
 - c. The human subject research is funded by an Outside Entity for which the Investigator serves in a Fiduciary Role (e.g., Board of Directors, Chief Executive Officer).

Exceptions to the presumptively prohibited activities may be made in compelling circumstances on a study-by-study basis. Compelling circumstances could include the nature of the Research, the risk level of the study (minimal risk vs. more than minimal risk, as defined at 45 C.F.R. 46.102(j)), the nature of the SFI, how closely the SFI relates to the proposed Research, and the degree to which the interest may be affected by the proposed Research.

Investigators wishing to participate in a presumptively prohibited human subject research activity must present a written request for an exception to the COI Review Committee and CNE's or the relevant CNE Affiliates' Institutional Review Board(s) (IRB(s)). This request must include a list of compelling circumstances, and a proposal on how the conflict of interest could be effectively managed.

- ii. Research Involving Sponsorship and/or Support from a Privately Held Entity - An Investigator wishing to conduct Research activities that involve sponsorship, including but not limited to funding or in-kind support, or products/intellectual property from a privately held Outside Entity, including a start-up, in which the Investigator has a SFI, should be aware that these situations may create conflicts of interest that can impact the scientific integrity of the Research. The following activities/situations are presumptively prohibited as they create, in almost all

circumstances, conflicts of interest that cannot be effectively managed.

- a. An Investigator's Research at CNE or a CNE Affiliate is sponsored by a privately held Outside Entity, including a start-up, in which the Investigator has a Significant Financial Interest or otherwise holds a Fiduciary Role or executive-level position.
- b. An Investigator's Research at CNE or a CNE Affiliate is sponsored by a privately held Outside Entity, including a start-up, in which the Investigator's current research staff, trainees, students, or others over which the Investigator has supervisory authority have a Significant Financial Interest or otherwise hold a Fiduciary Role or executive-level position.

The COI Review Committee may make exceptions in compelling circumstances, which will depend in each case upon the nature of the Research, the status of the Outside Entity, the nature of the Significant Financial Interest, how closely the Significant Financial Interest is related to the proposed Research, and the degree to which the interest may be affected by the proposed Research. The COI Review Committee may, within its discretion, consult other offices as necessary and appropriate in its evaluation of the compelling circumstances or it may refer a case to CNE leadership for adjudication.

Investigators wishing to engage in a presumptively prohibited activity must present a written request for exception to the COI Review Committee. This request must include a list of compelling circumstances, and a proposal on how the conflict of interest could be effectively managed.

- iii. Self-Funded Research - Investigators are presumptively prohibited from using their own personal funds or receiving funding from a Family Member or a family trust to support research efforts they are directing or conducting under the auspices of CNE or a CNE Affiliate, including efforts that involve research personnel. Self-funded research can blur the boundary between funder and researcher, and may give rise to concerns regarding appropriate oversight, accountability, and conflict of interest. As an exception to this presumptive prohibition, an Investigator may, in the normal course of conducting research, use personal funds to purchase low-cost, routine research-related items or to supplement travel. Review and prior approval by Research Administration, the General Counsel and Chief Compliance Officer is required if an Investigator wishes to use personal funds to purchase major or capital research items or equipment. Investigators and their Family Members wishing to support research projects at CNE or a CNE Affiliate may donate in accordance with CNE's donation guidelines and policies. However, Investigators cannot donate to a research account over which they or someone they directly supervise has spending authority.

- (4) Appeals of Conflict Management or Elimination Decisions - In the event Compliance Services, in conjunction with the COI Review Committee, determines that a FCOI exists, then the Investigator will be notified and given the right to appeal using the following appeal process:

- i. Notify Compliance Services in writing of the desire to initiate an appeal;
- ii. CNE or the relevant CNE Affiliate will schedule an appeal to be heard (in person or virtually) by the COI Review Committee of the CNE Affiliate within 30 days;
- iii. On the scheduled appeal date, the Investigator will be given the opportunity to present his or her position on the FCOI and may do so in writing or in-person; and
- iv. The relevant COI Review Committee shall take final action and provide written notice of its decision to the Investigator within 60 days of the appeal being heard.

(d) Special Requirements for PHS-Funded Research or Entities Following PHS COI

Requirements – For any Investigators on research awards funded by PHS or an entity that has adopted PHS COI Requirements, special requirements shall be put in place to ensure compliance with 42 C.F.R. Part 50, Subpart F (the “PHS COI Regulations”). These special requirements shall include, unless the PHS COI Regulations create an exception, the following:

- (1) FCOI Training - Investigators must complete FCOI training prior to engaging in PHS-Funded Research. Investigators must be re-trained every four years and whenever there is a substantive change to this Policy. CNE and CNE Affiliates must also re-train any Investigator who has been found to be non-compliant with the PHS COI regulations or this Policy.
- (2) Reporting of New SFIs Within Thirty (30) Days of Acquisition/Receipt - Investigators participating in PHS-Funded Research or Research funded by entities following PHS COI Requirements must submit an updated COI Reporting Form to CNE within thirty (30) days of discovering or acquiring a new SFI.
- (3) Reporting of Sponsored or Reimbursed Travel- Investigators participating in PHS-Funded Research are required to report on their annual COI Reporting Form the occurrence of any Reportable Travel. The internal threshold for reporting and reviewing travel is \$5,000 for any 12-month period from any one entity. Exceptions to this reporting requirement are set forth in PHS COI Regulations and include when travel is reimbursed or sponsored by (1) a U.S. federal, state, or local government agency; (2) a U.S. institution of higher education as defined at 20 U.S.C. 1001 (a); (3) a U.S. academic teaching hospital; (4) a medical center; or (5) a U.S. research institution that is affiliated with a U.S. institution of higher education. Investigators must provide information on the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration and the amount of the Reportable Travel.
- (4) Institutional Reporting Requirements of Conflicts/Conflict Management - Prior to the expenditure of any funds under PHS-Funded Research, CNE or a CNE Affiliate, acting through its designated Institutional Officials and the COI Review Committee shall:
 - i. Develop and ensure the implementation of a management plan that specifies how an identified FCOI will be managed;
 - ii. Ensure that any FCOI is managed, mitigated, or eliminated; and

- iii. Notify the PHS awarding agency of the existence of any FCOI in accordance with PHS requirements.
 - iv. For any FCOI that CNE or a CNE Affiliate identifies after PHS funding for the research at the organization has commenced, CNE or the relevant CNE Affiliate shall, within sixty (60) days of identification:
 - a. Ensure that any impermissible FCOIs are eliminated;
 - b. Ensure that any other identified FCOIs are managed, a management plan has been implemented, and interim measures deemed necessary are implemented while the management plan is being finalized; and
 - c. Notify the PHS awarding agency of the FCOI in accordance with PHS requirements.
- (5) Public Accessibility - Under PHS COI Regulations, CNE and CNE Affiliates are required to make specific information available to the public, upon request, regarding FCOIs identified for Investigators conducting PHS-Funded Research. CNE and CNE Affiliates will provide the required information to a requestor within five business days of receiving the request.
- (6) Managing Subrecipients - When proposed PHS-Funded Research is to be carried out through a subrecipient, CNE or the relevant CNE Affiliate will:
- i. Establish, at the time of proposal submission, whether the subrecipient on PHS-funded Research has a COI policy that is compliant with 42 CFR 50 Subpart F;
 - ii. Establish, in cases where the subrecipient does not have a COI policy that is compliant with 42 CFR 50 Subpart F whether the subrecipient will implement a compliant policy prior to accepting funding or follow this Policy for the duration of the PHS-Funded Research activity (if the latter, subrecipient's Investigators must adhere to procedures and time frames outlined in the Policy or any related internal COI procedures document); and
 - iii. In cases where the subrecipient has a compliant COI policy, incorporate terms into the subrecipient agreement that establish obligations of the subrecipient relative to conflict of interest, including specific time periods for providing FCOI reports.
- (7) Managing Non-Compliance with PHS COI Requirements - In the event of non-compliance with PHS COI Requirements, CNE or the relevant CNE Affiliate shall engage Compliance Services to conduct a retrospective review of the Investigator's activities to determine whether any PHS- Funded Research, or any portion thereof, conducted during the time of non-compliance, was biased in its design, conduct, or reporting. To the extent required by federal regulations or policy, CNE or the CNE Affiliate shall then submit a mitigation report to PHS. Non-compliance with special requirements includes the following:
- i. An Investigator fails to report a new SFI within the required time frame or CNE or a CNE Affiliate fails to review a new SFI within the required time frame, and that SFI is determined to constitute a FCOI related to PHS-Funded Research;

- ii. A FCOI is not identified or managed in a timely manner; and
- iii. An Investigator fails to comply with a FCOI management plan.

(e) Conflicts of Commitment

- (1) Use of Office/Laboratory Space and Other Resources - Investigators may only use CNE or CNE Affiliate facilities and resources for CNE or CNE Affiliate business. Use of CNE or CNE Affiliate space for Research by an Outside Entity is permitted under special conditions and only with an agreement formally approved by and signed by CNE or the CNE Affiliate. Use of CNE or CNE Affiliate space for research by an Outside Entity in which an Investigator has a Significant Financial Interest or Fiduciary Role, must be reviewed, in advance, by the COI Review Committee to determine if it is allowable and, if allowable, what management, if any, should be implemented.
- (2) Use of Students/Trainees - Any students, trainees, or other personnel whom an Investigator actively or directly supervises or advises cannot be involved in work at a privately owned Outside Entity in which that Investigator has a Significant Financial Interest or a Fiduciary Role. In exceptional circumstances, approval may be granted by the COI Review Committee if the Committee, General Counsel and Chief Compliance Officer are in agreement.
- (3) Participation in Certain Foreign Government Sponsored Talent Programs – Given the high potential to constitute a conflict of commitment, Investigators may not participate in Foreign Government Sponsored Talent Programs where prohibited by law or without the prior written approval of the General Counsel, Research Administration and Chief Compliance Officer.

(f) Training

- (1) Investigators shall complete training on this Policy before engaging in any Research (and at least every four years thereafter) and at such other times as CNE may revise the Policy or related procedures in a way that impacts Investigator obligations.
- (2) Remedial training may be required in the event that CNE or a CNE Affiliate determines that an Investigator has not complied with the Policy or a management plan applicable to the Investigator.

(g) Confidentiality - Access to COI Reporting Forms submitted to Compliance Services is limited to authorized individuals in the conduct of their official CNE or CNE Affiliate responsibilities. Information will not be shared with any individual, organization, or entity outside of the organization except where required contractually or by law, such as in cases of federal audits or investigations, when FCOI notifications are sent to outside research sponsors, or to assist CNE or a CNE Affiliate with satisfying its institutional obligations (e.g., sharing with CNE or CNE Affiliate counsel, auditors or financial advisers).

(h) Consequences for Policy Violations – Failure to comply with this policy may subject an Investigator to disciplinary action, up to and including suspension without pay, suspension or termination of Research, termination of employment, or termination of staff privileges (subject to completion of any required professional staff administrative process). Compliance Services, in cooperation with Research Administration and the relevant Chief Medical

Officers, will establish appropriate sanctions or administrative actions to ensure compliance as appropriate.

V. Definitions. Terms not already defined in this Policy have the following meanings:

- (a) **COI Reporting Form:** The COI Reporting Form is a form that is collected electronically annually and at various transaction points from Investigators who are subject to this Policy. It requires Investigators to report their financial interests, Outside Professional Activities, and any other interests that could affect or appear to affect their Research, including reporting SFIs that reasonably appear to be related to their professional expertise and organizational responsibilities. The SFIs and Outside Professional Activities of an Investigator's immediate family (spouse and dependent children) must also be reported if they are related to the Investigator's institutional responsibilities. The investigator should also report SFIs and Outside Professional Activities of their extended family members, to the best of their knowledge.
- (b) **Conflict of Interest Review Committee (COI Review Committee):** The COI Review Committee is comprised of the Designated Institutional Official (Chief Medical Officer) from the Operating Unit unless Compliance Services is their designee, Operating Unit IRB Administration personnel, Senior Director of Research Administration, and other appropriate personnel. These individuals are responsible for reviewing submitted COI Reporting Forms and for conducting COI reviews in accordance with standards set forth in the federal PHS COI regulations: 42 CFR 50 Subpart F. For all identified Financial Conflicts of Interest, the COI Review Board determines whether the FCOI needs to be managed, reduced, or eliminated.
- (c) **Conflict of Commitment:** A Conflict of Commitment is any situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities such that the individual cannot satisfy their institutional responsibilities to CNE or a CNE Affiliate or the situation puts CNE or CNE Affiliates' reputation at risk.
- (d) **Equity Interest:** An 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.
- (e) **Immediate family member** refers to the individual's spouse and dependent children.
- (f) **Extended Family Member:** Extended Family Member includes an individual's spouse, domestic partner, parent, child, sibling, grandparent, grandchild, parents-in-law, brothers- and sisters-in-law, stepparent, stepchild, stepsibling, step grandchild, guardian, ward, or member of one's household.
- (g) **Fiduciary Role:** A Fiduciary Role is a position in which one has a legal responsibility of care for the assets or rights of another entity or person. Fiduciary roles include serving as a member of a company's board of directors, or a position such as an officer or executive of a company (e.g., Chief Executive Officer, Chief Operating Officer) that requires high-level responsibility for the day-to-day management of the business.
- (h) **Financial Conflict of Interest (FCOI):** Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.

- (i) **Financial Interest:** Financial Interest generally refers to any pecuniary interests in and from Outside Entities. The term includes salary, honoraria, or other payments for services, equity and ownership interests like stocks and stock options, as well as intellectual property rights and royalty payments.
- (j) **Foreign Government Sponsored Talent Program:** (Conflict of Commitment) An effort, directly or indirectly organized, managed, or funded by a foreign government or institution to recruit science and technology professionals or students (regardless of citizenship or national origin and whether having a full time or part time position).
- (k) **Gifts:** Gifts are contributions received for either restricted or unrestricted purposes in support of the organization and for which the institution has made no commitment of resources or services other than, possibly, committing to use the gifts as the donor specifies.
- (l) **Institutional Official:** The Institutional Official (IO) is an individual who is legally authorized by CNE or a CNE Affiliate to obligate the relevant organization with respect to any Research.
- (m) **Investigator:** Investigator means the project director (PD) or principal investigator (PI) and 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 and consultants. “Design, conduct, or reporting” includes, but is not limited to, the following:
- Designing, conducting, and/or directing Research;
 - Enrolling research subjects (including obtaining informed consent, if applicable) or making decisions related to eligibility for enrollment; and
 - Analyzing, reporting, presenting, or publishing research data.
- (n) **Organizational Responsibilities:** Organizational Responsibilities mean an Investigator’s professional responsibilities on behalf of CNE or a CNE Affiliate including research, education, clinical care, administrative, and other CNE or CNE Affiliate activities and services.
- (o) **Outside Entity:** Outside Entity means any for-profit or non-profit corporation, foundation, or other organization, including any governmental entity that is not a CNE-affiliated institution.
- (p) **Outside Professional Activity:** An Outside Professional Activity is generally an engagement in specific work or services for an entity that is not part of, or affiliated with, CNE or a CNE Affiliate. Outside Professional Activities can be compensated or uncompensated, and are generally related to the professional expertise of the Researcher. Outside Professional Activities may include private consulting activities, service on advisory boards, and engaging in business activities.
- (q) **PHS-Funded Research:** PHS-Funded Research means Research funded by the Public Health Service (e.g., NIH).
- (r) **Reportable Travel:** Reportable Travel means travel that is either reimbursed or sponsored by a third party, and that is related to the Investigator’s Organizational Responsibilities. Reimbursed travel is travel for which the investigator is directly reimbursed by the

sponsoring entity. Sponsored travel is travel that is paid directly by the sponsoring entity and is not reimbursed to the Investigator.

- (s) **Research:** Research means any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research (*e.g.*, a published article, book or book chapter) and product development (*e.g.*, a diagnostic test, drug or device), and non-research projects such as training, clinical services, educational conferences, exhibitions, performances, archives, workshops, and library projects for which external funding is received. Research also includes any such activity for which a proposal is submitted for funding from external sources through a grant, contract, or agreement, including, but not limited to, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects and research resources awards. Research also includes projects that are internally funded (*i.e.*, funded by CNE or a CNE Affiliate), as well as research for which approval of an IRB (or IRB exemption) or Institutional Animal Care and Use Committee (IACUC) is required.
- (t) **Significant Financial Interest (SFI):** A Significant Financial Interest (SFI) means the receipt by an Investigator or an Investigator's Immediate Family of any of the following, to the extent reasonably related to the Investigator's Institutional Responsibilities:
- Income that exceeds \$5,000 from any individual Outside Entity, measured on a 12-month basis.
 - Acquisition of equity in a public company that exceeds \$5,000 in value;
 - Aggregated income and equity/ownership interest from a public company that exceeds \$5,000, as measured on a 12-month basis;
 - Any equity/ownership interest in a privately-held company; and
 - Any income received from rights in intellectual property (*e.g.*, patents, copyrights, pending patents, royalties), as measured on a 12-month basis.
 - SFI also includes the receipt by the Investigator's extended family of any of the above, to the best of the Investigator's knowledge.
- (u) Excluded from this definition are payments (including travel) received from or through CNE or a CNE Affiliate and income from investment vehicles over which the Investigator or Investigator's Family Member does not exercise control (*e.g.*, mutual funds and retirement accounts). Also excluded from this definition are payments received from any of the following entities, provided these payments are received for teaching engagements, lectures, seminars, or service on advisory committees or review panels:
- U.S. Federal, State or Local Government agencies;
 - U.S. institutions of higher education and research institutes affiliated with them;
 - U.S. academic teaching hospitals; and
 - Medical centers

REFERENCES:

CNE Conflict of Interest and Confidentiality Policy; CNE 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 PI/PD or KSP Responsibilities and COI Rules; NIH Financial Conflict of interest; FDA Financial Disclosure by Clinical PI/PD and KSPs Guidance for Industry; National Institute of Health Financial Conflict of Interest Online Research Tutorial

APPROVAL/REVISION:

04/30/2022: Initial Version of Policy approved

REPLACES:

Financial Conflicts of Interest Policy for PI/PD or KSPs CNE-FIN-211