

	<b>Guideline:</b> IRB Conflicts of Interest in Research	
	<b>Department Responsible:</b> SW-IRB Research	<b>Date Approved:</b> 09/11/2020
	<b>Effective Date:</b> 09/11/2020	<b>Next Review Date:</b> 09/11/2023

**PURPOSE:**

To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research is free from bias resulting from researcher financial conflicts of interest (FCOI). Research-related conflicts of interest (COI) occur when an institution or an individual, including his or her immediate family, enters into any type of relationship that interferes with or compromises, or gives appearance of compromising, the professional judgment or research obligations of the institution or individual.

**DEFINITIONS:**

- **Investigator:** A principal investigator, project director, co-investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of sponsored research (project) results, including collaborators and consultants.
- **Conflict of interest official (COI official):** The human protections administrator as specified in Cone Health’s Federal Wide Assurance (FWA) or such other individual as may be appointed by the Institutional Official of Cone Health. The COI official may assign, in writing or by electronic mail, some or all of their obligations under this policy to one or more designees.
- **Financial Interest:** An interest in a business consisting of (1) any stock, stock option, or similar ownership interest in such business, but excluding any interest arising solely by reason of investment in such business by a mutual, pension, or other institutional investment fund over which the faculty member does not exercise control; or (2) receipt of, or the right or expectation to receive, any income from such business (or from an agent or other representative of such business), whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology, technology transfer, patents, gifts, rent, capital gain, real or personal property, or any other form of compensation.
- **Significant financial interest (SFI):** A financial interest held by an investigator, or the investigator’s spouse or dependent children that reasonably appear to be related to the investigator’s institutional responsibilities and that consists of one or more of the following:
  - Remuneration including, but not limited to salary, consulting fees, honoraria, and paid authorship received from a publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, and/or an equity interest (e.g., stock, stock options, or other ownership interest) held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the equity interest as of the date of disclosure for studies; or
  - Remuneration (including, but not limited to, salary, consulting fees, honoraria, and paid authorship) received from a non-publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds the amount stated above, or there is specific permission granted

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to use another triggering amount from the Cone Health SW IRB – Research office associate director; or

- Any equity interest in a non-publicly traded company or business, regardless of value; or
- Intellectual property rights and interests (e.g., patents and copyrights), upon receipt of income related to such rights and interests.
- Any reimbursed travel or travel expenses paid on an Investigator's behalf related to his/her institutional responsibilities, including circumstances when the exact monetary value of the travel is not readily available. This requirement does not apply to travel that is reimbursed by a federal, state, or local government; an institution of higher education; an academic medical center; or a research institute that is affiliated with an institution of higher education.

Significant financial interest does not include:

- An employee's salary or royalties received from Cone Health; or
  - Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency or an institution of higher education; or
  - Income from service on panels for a federal, state, or local government agency or institution of higher education.
- **Related to the research:** A researcher's financial interest is considered to be related to the research when the researcher is engaged in the research (interacting or intervening with participants, obtaining consent, conducting analysis of data, collaborating/consulting with or for an external entity involved in the study in any way including a subcontractor or award subrecipient). A person's financial interests are not related to research when they are not engaged in research. For example, providing advice about the design of studies, conducting analysis of deidentified information, or providing information about research (where a clinician does not recruit or obtain consent) are examples where a person is not engaged in research. When a person has a financial interest but is not engaged in PHS-funded research, that interest is not considered related to PHS-funded research for purposes of compliance with PHS funded research conflict of interest requirements.
  - **Organizational conflict of interest (COI):** An organizational conflict of interest may exist when Cone Health has a financial interest(s) in research that could cause a conflict with clinical care. Organizational conflicts of interest may include Cone Health's interests in the following:
    - Licensing, technology transfer, and patents, when Cone Health owns the intellectual property.
    - Investments of Cone Health, in excess of \$100,000 (exception: Mutual funds and fiduciary-managed funds: interests of any amount in publicly-traded, diversified mutual funds or in funds in which the investment decision making is made by fiduciary managers appointed by Cone Health but not otherwise affiliated with Cone Health are not institutional financial interests).
    - Gifts, when the donor has an interest in the research.
    - Financial interests of senior administrators except that having equity or royalties up to \$10,000 from a publicly traded sponsor is not an institutional financial interest if the senior administrator is not participating in the research.
    - Other financial interests that are determined to be a conflict of interest.

When organizational conflicts of interest are identified, they are managed by the office of Corporate Compliance, which may develop a management plan when appropriate.

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- **Public Health Service (PHS):** “Public Health Service” (PHS) means the section of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration. Funding overseen by the financial conflict of interest regulations is issued by the Department of Health and Human Services (DHHS) and administered by the National Institute of Health (NIH).

### **TRAINING:**

The institution has the responsibility to educate investigators and research staff about disclosures and responsibilities related to financial conflict of interest. This requirement must be accomplished by completing the COI modules within CITI Program ([www.citiprogram.org](http://www.citiprogram.org)). Funding for any sponsored project may not proceed until all the investigators involved in research activities have completed the COI training.

- Education is required of each individual prior to engaging in research, and at least every four years.
- Education is required immediately when:
  - Financial conflict of interest policies is revised in a manner that changes investigator requirements.
  - An investigator is new to the organization.
  - An investigator is non-compliant with financial conflict of interest policies and procedures.

### **DISCLOSURE:**

A significant financial interest is an interest held by the investigator in which the value of the interest could directly or significantly affect the design, conduct, or reporting of the research; a proprietary interest in the tested product, including but not limited to, a patent, trademark, copyright, or licensing agreement; any equity interest in the sponsor of a covered study (i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices); or any arrangement where the value of the ownership interests would be affected by the outcome of the research or ownership interests that exceeds \$0.00 in any one single entity when aggregated for the immediate family.

This requirement applies to all covered studies, whether ongoing or completed; any equity interest in a publicly held entity or non-publicly held entity that exceeds \$0.00 in value. The requirement applies to interests held during the time the clinical investigator is carrying out the study and for 1 year following completion of the study; and significant payments of other sorts, which are payments that have a cumulative monetary value of more than \$0.00 made by the sponsor of a covered study to the investigator or the investigator’s institution to support activities of the investigator exclusive of the costs of conducting the clinical study or other clinical studies (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for 1 year following completion of the study.

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Financial Conflict of Interest Disclosures (FCOI) must be completed by Investigators:

- No later than at the time of application for PHS-funded research
- At least annually (during the period of the award, if applicable)
- Within 30 days of discovering or acquiring a new SFI

Conflict of Interest forms are available through the Cone Health SW IRB-Research office.

**Table 1: Comparison of Cone Health Policy with Federal COI Regulations:**

<b>TOPIC</b>	<b>2011 Final Rule 42 CFR Part 50 Subpart F</b>	<b>CONE HEALTH POLICY (Revised 2020)</b>
Significant Financial Interest (SFI)	Compensation ≥\$5,000. Ownership interests >0% for non-publicly traded entities. Income from patents/copyrights.	FULL disclosure – all compensated (any dollar amount) and uncompensated relationships with any entity.
Which SFIs Need to Be Disclosed to Cone Health?	ALL SFI related to Investigator’s institutional responsibilities	Investigator reports ANY Financial interest to Cone Health.
Types of SFI Excluded	Mutual funds and trusts. Investigator cannot directly control investment decisions.	Mutual funds and trusts. Investigator cannot directly control investment decisions.
Travel*	Disclose to institution any reimbursed or sponsored travel related to institutional duties.	New regulation will only apply to PHS funded investigators.
Authorship* Including Textbooks	Disclose to institution any paid authorship activity, including textbooks, and resulting income.	New regulation will only apply to PHS funded investigators.
Public Accessibility*	FCOIs held by personnel listed on a public website OR written response to any requestor within 5 business days. (Name, research role, entity, nature of SFI, dollar range.)	New regulation will only apply to PHS funded investigators.
FCOI Training	Investigator must complete training prior to engaging in research and every four years thereafter.	All individuals must complete COI training and every four years thereafter

\*Travel, Authorship, and Public Accessibility Requirements: At Cone Health these requirements will apply ONLY to investigators with PHS funding.

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### **SUBRECIPIENT:**

If Cone Health conducts research funded by PHS, or other federal entities, through subrecipients or contractors, Cone Health will take appropriate steps to ensure that investigators from collaborating institutions meet federal conflict of interest requirements by either 1) complying with this policy or 2) the collaborating institution must demonstrate their own written policy complies with the federal requirements on financial conflict of interest.

If the subrecipient provides assurance of its own policy, the subrecipient shall report to the IRB-Research Office the following information for any FCOI of subrecipient investigators: (a) subrecipient contract number; (b) name of the subrecipient investigator with the FCOI; (c) name of the entity with which the investigator has a FCOI; (d) nature of the financial interest (e.g., equity, consulting, etc.); (e) value of the financial interest; (f) a description of how the financial interest relates to the PHS-funded research and the basis for the subrecipient's determination that the financial interest conflicts with the PHS funded research; and (g) a description of the management plan.

If the subrecipient chooses to comply with the IRB-Research Office, then a statement to this effect should be included in the letter of intent and will be included in the subaward contract. All subrecipient investigators known at the time of application must be identified and complete the necessary disclosure process and applicable training as detailed in this guideline.

### **MANAGEMENT OF CONFLICTS OF INTEREST:**

The human protections administrator will appoint a Conflict of Interest Committee (COIC) that will review disclosures and relevant features of the sponsored project(s), recommend to the investigator any modifications necessary to manage, reduce or eliminate any financial conflicts of interests related to the project, and develop management plans as needed. In addition, the COIC will implement a management plan within sixty days whenever the institution identifies an SFI that was not disclosed timely by an investigator or not previously reviewed by the institution.

The COIC will consist of at least three (3) voting committee members with the following qualifications:

- At least one Cone Health Legal Department or Cone Health Corporate Compliance Department employee with regulatory, compliance, or ethics experience.
- At least one Cone Health employee that is not part of the Cone Health SW IRB – Research office or affiliated with the Cone Health facility performing the research.
- At least one Cone Health employee with research ethics experience.

The human protections administrator may appoint additional voting members where such appointment(s) will enhance Cone Health COIC's quality of review and/or efficiency.

The convened IRB will review the proposed management plan developed by the COIC. The Cone Health IRB is responsible for reviewing and approving all management plans regardless of the IRB of record.

Examples of management plans include, but are not limited to:

- Prohibiting the conduct of the research at Cone Health if the conflict cannot be managed.

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- Requiring another researcher to conduct the research or conduct parts of the research such as recruitment and obtaining consent.
- Requiring monitoring of the research, or parts of the research such as the consent process.
- Management may include a retrospective review and a mitigation report if necessary.
- Other management activities as determined by the Cone Health COIC.

If the COIC develops a COI management plan, and the Cone Health IRB has oversight over the research, the Conflict of Interest Disclosure Form and COI management plan must be submitted to the IRB for consideration prior to final research approval. The investigator shall assure that research is not initiated prior to the IRB's consideration of the COI Disclosure Form and COI management plan. Where IRB approval has already occurred, the foregoing documents will be submitted to the IRB and the IRB may reevaluated its approval. The Conflict of Interest Disclosure Form is available through the Cone Health SW IRB-Research office.

If the IRB disagrees with the COI management plan, the IRB may decline to approve the research (e.g., the IRB may decline to approve the research if the IRB finds the COI management plan to be insufficient to adequately protect the research subjects, fails to maintain the integrity of the research, or fails to meet any approval criteria of the IRB). Changes to the COI management plan may be suggested by the IRB to the COIC, though such suggestions will not be prescriptive upon the COIC. The IRB remains free to make all determinations and decisions as specified by law or regulation. The COIC remains free to set a COI management plan under the auspices of Cone Health.

The IRB should evaluate the COI materials presented and should consider implementing the most effective means of informing research subjects of the COI. The IRB should review the COI materials presuming that any COI should be disclosed to the research subject in the Informed Consent Form (ICF) and/or in a medium most conducive to the research subject's understanding of the COI.

### **REPORTING REQUIREMENTS:**

The Cone Health IRB-Research office will submit reports to federal sponsors as required under applicable federal regulations. Reports on FCOIs for those investigators with PHS funding shall be submitted to the PHS awarding component as required ("FCOI Reports"). FCOI Reports shall be submitted:

- Prior to the expenditure of funds.
- Within 60 days of identification for an investigator who is newly participating in the project.
- Within 60 days for new, or newly identified, FCOIs for existing investigators.
- At least annually (at the same time as when the institution is required to submit the annual progress report, multiyear progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- Following a retrospective review to update a previously submitted report, if appropriate.

The following required details will report provided in the reporting:

1. The covered individual's name;
2. The covered individual's title and role with respect to the research;
3. The name of the entity in which the significant financial interest is held;

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4. The nature of the significant financial interest that constitutes a financial conflict of interest; and
5. The approximate value of the significant financial interest by range or, if the dollar value cannot be determined by reference to public prices or other reasonable measures of fair market value, a statement to that effect.

The Cone Health IRB-Research office will notify the NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and will comply with the requirement to submit a mitigation report in accordance with the federal regulation.

The Cone Health IRB-Research office will notify NIH promptly if an investigator fails to comply with the institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

**WEB POSTING OF FINANCIAL CONFLICT OF INTEREST INFORMATION:**

This policy and each update of this policy will be accessible through the Internet.

1. For each financial conflict of interest that is found to exist by the Cone Health Conflict of Interest Committee, the institution will make the following information available in regard to each covered individual who contributes to the scientific development or execution of the research project in a substantive, measurable way, including a covered individual who is the project director or principal investigator;
  - a. The covered individual's name;
  - b. The covered individual's title and role with respect to the research;
  - c. The name of the entity in which the significant financial interest is held;
  - d. The nature of the significant financial interest that constitutes a financial conflict of interest; and
  - e. The approximate value of the significant financial interest by range or, if the dollar value cannot be determined by reference to public prices or other reasonable measures of fair market value, a statement to that effect.
2. The approximate dollar value of the significant financial interest shall be provided within the following ranges if it can be determined by public access or other reasonable measures of fair market value:
  - a. \$0 - \$4,999
  - b. \$5,000 - \$9,999
  - c. \$10,000 - \$19,999
  - d. Amounts between \$20,000 - \$100,000 by increments of \$20,000; or
  - e. Amounts above \$100,000 by increments of \$50,000.
3. The institution will update the information required by this section annually. In addition, for any financial conflict of interest of a covered individual whose information must be available under this section and for which the information was not previously available, the institution will make the information required by this section available not later than the 60th day after the financial conflict of interest is identified.
4. The information must note that it is current as of the date listed and is subject to updates.
5. The information required by this section must remain available for five years after its most recent update.

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6. For PHS-funded research, in regard to project directors, principal investigators, and other senior or key personnel, this information must be available BEFORE expending PHS funds.

### **SANCTIONS:**

All individuals are expected to comply fully and promptly with all requirements of this guideline. Failure to comply with this guideline will be grounds for disciplinary action. The COI Committee is responsible for investigating instances of noncompliance and determining whether to impose sanctions and what sanctions will be applied.

If the COI Committee determines that research was conducted on a PHS award during a timeframe when a COI was not identified or managed, or if the investigator was noncompliant with the management plan, Cone Health must conduct a retrospective review within 120 days, implement a mitigation plan to ensure that research was not biased during that period, and report to the PHS agency. In the instance of COI noncompliance that was not managed or reported by Cone Health as required by regulation, Cone Health will require the investigator to disclose the COI in each public presentation of results of the research and request an addendum to previously published presentations. In addition, federal regulations may require reports to the federal sponsor of any information which may show a violation of Cone Health policy/guideline.

Cone Health may require mandatory education, monitoring of research, suspension of research privileges, suspension or termination of research, or other sanctions as appropriate. In addition, sponsors may suspend or terminate the award and/or debar an investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of significant financial interests related to federally sponsored projects.

### **RECORD RETENTION:**

All conflict of interest records, including disclosure forms, management plans, and all other related documents, will be maintained for at least three (3) years from the date of submission of the final expenditures report, or as required by applicable government regulation, whichever is greater.

### **REFERENCES:**

- CITI Program. (n.d.). CITI Program. Retrieved September 11, 2020, from <https://about.citiprogram.org/en/homepage/>
- Cone Health. (n.d.). Office of Research Support. Retrieved September 11, 2020, from <https://www.conehealth.com/services/research-and-clinical-trials/office-of-research-support/>
- National Institutes of Health. (2020, January 10). *Financial Conflict of Interest*. Retrieved September 11, 2020, from NIH Grants & Funding: <https://grants.nih.gov/grants/policy/coi/index.htm>