

## UNOS Policy

### Policy and Procedures on Financial Conflict of Interest to Promote Objectivity in Public Health Service-Funded Research

***Approved: March 7, 2023***

## Purpose

United Network for Organ Sharing ("UNOS") adopts this Policy to promote objectivity in PHS-Funded Research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of such PHS-Funded Research are free from bias resulting from Investigators' Financial Conflicts of Interest. UNOS adopts this Policy as required to implement and to comply with U.S. Public Health Service ("PHS") regulations promoting objectivity in research.

## Policy Statement

### 1. Designation of Conflict of Interest Officer

The COI Officer is designated as UNOS's institutional official to solicit and review disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, PHS-Funded Research. The COI Officer shall coordinate such efforts with UNOS's Sponsored Research Programs Administration in the Office of Research and Development.

### 2. Training

- a. Each Investigator who is planning to participate in, or is participating in, PHS-Funded Research must complete training related to financial conflicts of interest (regardless of whether or not a Financial Conflict of Interest exists).
- b. Such training must be completed:
  - i. Prior to engaging in PHS-Funded Research;
  - ii. At least every four (4) years;
  - iii. If the Investigator is new to UNOS, within sixty (60) days of the commencement of employment (but not later than the beginning of PHS-Funded Research by the Investigator);
  - iv. Whenever UNOS revises this Policy in a manner that affects the requirements of Investigators; and/or
  - v. When so directed as a result of an Investigator's non-compliance with this Policy or any Management Plan.
- c. Training, or access to training, shall be provided by UNOS and shall consist at a minimum of a curriculum including this Policy and the Investigator's responsibilities under this Policy and the

PHS Regulations to disclose Significant Financial Interests of the Investigator (and the Investigator's spouse and dependent children).

### **3. Disclosure of Significant Financial Interests**

- a. Each Investigator who is planning to participate in, or who is participating in, PHS-Funded Research shall disclose any Significant Financial Interest (and/or of the Investigator's spouse and dependent children) to the COI Officer if it reasonably appears that a Significant Financial Interest is related to the Investigator's Institutional Responsibilities. Alternatively, if no such Significant Financial Interest exists, the Investigator shall so certify to the COI Officer.
- b. Disclosures of Significant Financial Interests (or certifications that no such Significant Financial Interests exist) shall be made by each Investigator as follows:
  - i. At or before the time of submission of an application for PHS-Funded Research;
  - ii. At least annually during the period of the PHS-Funded Research award, no later than sixty (60) days prior to the beginning of each fiscal year of such award.
    - A. The annual disclosure shall include: (a) any new information that was not disclosed to the COI Officer either initially or subsequently (e.g. any Financial Conflict of Interest identified on a PHS-Funded Research project that was transferred from another institution); and (b) updated information regarding any previously disclosed Significant Financial Interest (e.g. the updated value of a previously disclosed equity interest);
    - B. Annual updates shall be required of all Investigators participating in a PHS-Funded Research project, regardless of whether or not a Significant Financial Interest was previously disclosed.
  - iii. If the Investigator discovers or acquires (e.g. through purchase, marriage, or inheritance) a new Significant Financial Interest: within thirty (30) days of the discovery or acquisition.
- c. The disclosure shall include without limitation the following information:
  - i. The amount of remuneration received from any entity in the twelve (12) months preceding the disclosure;
  - ii. If there is an equity interest in the entity, any value as of the date of disclosure; and
  - iii. With respect to reimbursed or reimbursable travel expenses that require disclosure: the purpose of the trip; the identity of the sponsor/organizer; the destination; and the duration of the travel.
- d. The COI Officer shall determine if further information is needed, including without limitation a determination or disclosure of monetary value, in order to decide whether the disclosed Significant Financial Interest constitutes a Financial Conflict of Interest with the PHS-Funded Research.

### **4. Determination of the Existence of Financial Conflicts of Interest**

- a. Prior to UNOS's expenditure of any funds under a PHS-Funded Research project, the COI Officer shall, consistent with this Policy and the PHS Regulations review all Investigator disclosures of Significant Financial Interests, and, if applicable, make the determinations set forth in this Section.

- b. The COI Officer, in his reasonable discretion, shall determine whether any Significant Financial Interest is related to PHS-Funded Research.
  - i. A Significant Financial Interest is related to PHS-Funded Research if (as reasonably determined by the COI Officer): (i) the Significant Financial Interest could be affected by the PHS-Funded Research; and/or (ii) the Significant Financial Interest is in an entity whose financial interest could be affected by the PHS-Funded Research.
  - ii. The COI Officer may involve the Investigator in the determination of whether a Significant Financial Interest is related to PHS-Funded Research.
- c. If the Significant Financial Interest is related to PHS-Funded Research, the COI Officer, in his reasonable discretion, shall then determine whether a Financial Conflict of Interest exists.
  - i. A Financial Conflict of Interest exists if the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-Funded Research.
- d. If it is determined that (a) Significant Financial Interest is related to PHS-Funded Research and (b) a Financial Conflict of Interest exists, the COI Officer shall communicate the determination to the Investigator and the Investigator's department chair (or Dean or designee, if the Investigator's school does not have departments).

**5. Management of Financial Conflicts of Interest / Management Plan**

- a. If it is determined that a Financial Conflict of Interest exists, the COI Officer shall work with the Investigator to develop and implement a Management Plan. The purpose of the Management Plan is to establish rules and procedures that provide a reasonable expectation that the PHS-Funded Research associated with the Investigator's Financial Conflict of Interest will be free from bias. The Management Plan shall specify the actions that have been, and shall be, taken to Manage such Financial Conflict of Interest in accordance with this Policy and the PHS Regulations.
- b. Actions, conditions, or restrictions that may be required under the Management Plan shall be determined by the COI Officer, and may vary depending upon the nature and extent of the Financial Conflict of Interest. Examples of actions, conditions, or restrictions that might be imposed to Manage a Financial Conflict of Interest include but are not limited to:
  - i. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the Research);
  - ii. For Research projects involving human subjects, disclosure of financial conflicts of interest directly to participants;
  - iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the Financial Conflict of Interest;
  - iv. Modification of the Research plan;
  - v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;

- vi. Reduction or elimination of the Significant Financial Interest (e.g., sale of an equity interest); and/or Reduction or elimination of the Significant Financial Interest (e.g., sale of an equity interest); and/or
- vii. Severance of relationships that create financial conflicts.
- c. The Management Plan shall be presented for review and comment to the Investigator's supervisor and the Investigator's department chair (or Dean or designee, if the Investigator's school does not have departments).
- d. The Management Plan is subject to approval by the Chief Academic and Research Officer or designee
- e. The Investigator's department chair (or Dean or designee, if the Investigator's school does not have departments) is responsible for: (a) ensuring that steps set forth in the Management Plan are implemented; and (b) taking reasonable steps to ensure the Investigator's compliance with the Management Plan.

#### **6. Reporting of Financial Conflicts of Interest**

- a. The COI Officer shall be responsible for ensuring that all Financial Conflict of Interest reports and other information are submitted to the PHS Unit, as required by the PHS Regulations.
- b. Such reports must be filed by the COI Officer:
  - i. Prior to UNOS's expenditure of funds under a PHS-Funded Research project;
  - ii. Within sixty (60) days, with respect to any Significant Financial Interest that the COI Officer identifies as conflicting subsequent to the initial Financial Conflict of Interest report during an ongoing PHS-Funded Research project (e.g. upon the participation of an Investigator who is new to the PHS-Funded Research project); and
  - iii. Annually with respect to any Financial Conflict of Interest previously reported with regard to an ongoing PHS-Funded Research project.

#### **7. New Significant Financial Interests during Ongoing PHS-Funded Research**

- a. This Section 7.G applies: (a) whenever an Investigator discloses a Significant Financial Interest that was developed or acquired after Research under a PHS-funded award had begun; or (b) whenever, in the course of an ongoing PHS-Funded Research project, an Investigator who is new to participating in the Research project discloses a Significant Financial Interest.
- b. In any such event, within sixty (60) days of the disclosure, the COI Officer shall: (a) review the disclosed interest; (b) determine whether it is related to the PHS-Funded Research; and (c) if so, determine whether a Financial Conflict of Interest exists.
- c. If a Financial Conflict of Interest exists, the COI Officer shall implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to Manage such Financial Conflict of Interest going forward. The COI Officer shall report to the PHS Unit as required by the PHS Regulations.
- d. Depending on the nature of the disclosed interest, additional interim measures may be taken with regard to the Investigator's participation in the PHS-Funded Research between the date of disclosure and the completion of the review by the COI Officer.

## 8. Retrospective Review and Mitigation Report

- a. If a Significant Financial Interest is not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by UNOS during an ongoing PHS-Funded Research project (e.g., was not timely reviewed or reported by a subrecipient), the COI Officer shall, within sixty (60) days of the disclosure: (a) review the disclosed interest; (b) determine whether it is related to the PHS-Funded Research; and (c) if so, determine whether a Financial Conflict of Interest exists.
- i. If a Financial Conflict of Interest exists, the COI Officer shall implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to Manage such Financial Conflict of Interest going forward. The COI Officer shall report to the PHS Unit as required by the PHS Regulations.
- b. In addition, whenever a Financial Conflict of Interest is not identified or Managed in a timely manner (including failure by the Investigator to disclose a Significant Financial Interest that is determined by the COI Officer to constitute a Financial Conflict of Interest; failure by the COI Officer to review or Manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a Management Plan), the COI Officer shall, within one hundred twenty (120) days of the determination of non-compliance: (a) complete a retrospective review of the Investigator's activities and the PHS-Funded Research, or portion thereof, conducted during the time period of the non-compliance; and (b) determine whether or not there was bias in the design, conduct, or reporting of the PHS-Funded Research. The COI Officer shall document the retrospective review as required by the PHS Regulations.
- i. Based on the results of the retrospective review, if appropriate, the COI Officer shall update the previously submitted Financial Conflict of Interest report, specifying the actions that will be taken to Manage the Financial Conflict of Interest going forward. If bias is found, the COI Officer shall notify the PHS Unit promptly and submit a mitigation report to the PHS Unit, in accordance with the PHS Regulations. Thereafter, the COI Officer shall submit Financial Conflict of Interest reports annually.
- ii. Depending on the nature of the Financial Conflict of Interest, the COI Officer may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-Funded Research project between the date that the Financial Conflict of Interest or the Investigator's non-compliance is determined and the completion of the retrospective review.

## 9. Monitoring / Reporting to COI Officer

Whenever a Management Plan is implemented, the COI Officer is responsible: (a) to monitor and to take reasonable steps to ensure Investigator compliance with the Management Plan on an ongoing basis until the completion of the PHS-Funded Research project; and (b) to report to the COI Officer any non-compliance with the Management Plan.

## 10. Public Accessibility

- a. Prior to UNOS's expenditure of any funds under a PHS-Funded Research project, UNOS shall ensure public accessibility of information concerning any disclosed Significant Financial Interest that meets the following three criteria: (a) the Significant Financial Interest was disclosed and is still held by Senior/Key Personnel; (b) the COI Officer determines that the Significant Financial

Interest is related to the PHS-Funded Research; and (c) the COI Officer determines that the Significant Financial Interest is a Financial Conflict of Interest.

- b. Such information shall be made accessible via a publicly accessible website or written response to any requestor within five (5) business days of a request. Such information shall include at a minimum the information required by the PHS Regulations. Such information shall be updated at least annually.
- c. In addition, UNOS shall update the website within sixty (60) days of UNOS's receipt or identification of information concerning any additional Significant Financial Interest of the Senior/Key Personnel for the PHS-Funded Research project that was not previously disclosed, or upon the disclosure of a Significant Financial Interest of Senior/Key Personnel new to the PHS-Funded Research project, if the COI Officer determines that the Significant Financial Interest is related to the PHS-Funded Research and is a Financial Conflict of Interest. The website shall 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 sixty (60) days of the COI Officer's identification of a new Financial Conflict of Interest.
- d. Information concerning the Significant Financial Interests of an individual subject to this section shall remain available, for responses to written requests or for posting via UNOS's publicly accessible website, for at least three (3) years from the date that the information was most recently updated.

#### **11. Subrecipient Collaborations (UNOS as Prime Recipient)**

- a. If UNOS carries out PHS-Funded Research through a subrecipient (e.g., subcontractors, or consortium members), UNOS's Sponsored Research Programs Administration shall be responsible to ensure that there is a written agreement with the subrecipient which contains terms that establish whether this Policy or the financial conflicts of interest policy of the subrecipient will apply to the subrecipient's Investigators.
  - i. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement shall require that the subrecipient certify as part of the agreement that its policy complies with this Policy and the PHS Regulations. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to this Policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for UNOS;
  - ii. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to UNOS. Such time period(s) shall be sufficient to enable UNOS to provide timely Financial Conflict of Interest reports, as necessary, to the PHS Unit as required by this Policy and the PHS Regulations;
  - iii. Alternatively, if the subrecipient's Investigators must comply with UNOS's financial conflicts of interest policy, the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to UNOS. Such time period(s) shall be sufficient to enable UNOS to comply timely with its review, management, and reporting obligations under this Policy and the PHS Regulations.
- b. The COI Officer shall be responsible to provide Financial Conflict of Interest reports to the PHS Unit regarding all financial conflicts of interest of all subrecipient Investigators consistent with

this Policy and the PHS Regulations, i.e., prior to the expenditure of funds and within sixty (60) days of any subsequently identified Financial Conflict of Interest.

#### **12. UNOS as a Subrecipient**

- a. If UNOS is a subrecipient of PHS-Funded Research where another entity is the prime recipient, UNOS's COI Officer shall be responsible to ensure that there is a written agreement with the prime recipient which contains terms that establish whether this Policy or the financial conflicts of interest policy of the prime recipient will apply to UNOS's Investigators.
- b. If the agreement specifies that UNOS's Investigators must comply with the prime recipient's financial conflicts of interest policy, then UNOS's Investigators shall so comply with the prime recipient's policy, and this Policy shall not apply.
- c. If the agreement specifies that UNOS's Investigators must comply with this Policy, then UNOS's Investigators shall so comply with this Policy, and this Policy shall apply.

#### **13. Record Retention**

- a. The COI Officer shall retain all records relating to Investigator disclosures of financial interests; the COI Officer's review of and response to such disclosures (whether or not a disclosure resulted in the COI Officer's determination of a Financial Conflict of Interest); and all actions under this Policy or retrospective review, if applicable.
- b. Such records shall be retained for at least three (3) years from the date of submission of final expenditure reports to PHS for each PHS-funded project (or where applicable from other dates specified in the PHS Regulations for different situations).
- c. Such records shall be destroyed within ninety (90) days following the expiration of the three (3) year retention period, unless there is relevant pending or active administrative or legal action.

#### **14. Noncompliance**

- a. It shall be considered a violation of UNOS policy, subject to disciplinary action in accordance with applicable policies, if an Investigator: (a) fails to comply with an established Management Plan; (b) fails to provide timely annual report information or other required information; or (c) fails to comply with any other requirement of this Policy.
- b. If the failure of an Investigator to comply with this Policy or a Management Plan appears (in the reasonable judgment of the COI Officer) to have biased the design, conduct, or reporting of PHS-Funded Research, the COI Officer shall be responsible to promptly notify the PHS Unit of the corrective action taken or to be taken, as required by the PHS Regulations.
- c. In the event that the U.S. Department of Health and Human Services determines that a PHS-Funded Research project involving 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 UNOS in accordance with the PHS Regulations and this Policy, such Investigator shall be required 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.

## Definitions

1. **COI Officer:** UNOS's Conflict of Interest Officer is the UNOS General Counsel.
2. **Financial Conflict Of Interest:** A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-Funded Research.
3. **Institutional Responsibilities:** An Investigator's professional responsibilities on behalf of UNOS which fall within UNOS's mission of research, education, or service, and which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the Institutional Review Board, Institutional Animal Care and Use Committee, or data and safety monitoring board or committee.
4. **Investigator:** This term refers to: (1) The project director or principal investigator of any PHS-Funded Research; and (2) any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-Funded Research, or proposed for such funding, which may include, for example, collaborators or consultants.
5. **Manage:** Taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the Financial Conflict of Interest, to ensure to the extent possible that the design, conduct, and reporting of PHS-Funded Research will be free from bias.
6. **Management Plan:** A plan to Manage a Financial Conflict of Interest.
7. **PHS-Funded Research:** Any Research which is funded by the PHS.
8. **PHS Regulations:** PHS regulations promoting objectivity in research (set forth at 42 CFR §50.601 et seq. and 45 CFR §94.1 et seq.), as they may be amended, supplemented, or replaced from time to time, and any other similar PHS regulations that may be promulgated.
9. **PHS Unit:** The organizational unit of the PHS that funds PHS-Funded Research.
10. **Research:** A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter), and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Unit through a grant, cooperative agreement, or contract, whether authorized under the Public Health Service Act (42 U.S.C. §201 et seq.) or other statutory authority, including without limitation a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
11. **Senior/Key Personnel:** This term includes the project director or principal investigator and any other personnel considered to be essential to work performance in accordance with 48 CFR §352.242–70, and identified as key personnel in the contract proposal and contract.
12. **Significant Financial Interest:**
  - a. One or more of the following financial interests (i.e. anything of monetary value, whether or not the value is readily ascertainable) of an Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:



- i. Remuneration of any value from any entity during the twelve (12) months preceding the disclosure, including without limitation salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
  - ii. Any equity interest in any entity (including any stock, stock option, or other ownership interest);
  - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
  - iv. 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);
- b. The term "Significant Financial Interest" does not include the following:
- i. Salary, royalties, or other remuneration paid by UNOS to the Investigator if the Investigator is currently employed or otherwise appointed by UNOS, including intellectual property rights assigned to UNOS and agreements 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. An asset in a blind trust, but only if (i) the asset is not known to the Investigator (e.g. it was purchased by the trust with proceeds from assets originally placed in the trust), and (ii) the trust is managed by an independent fiduciary;
  - iv. Income from seminars, lectures, or teaching engagements sponsored by: a federal, state, or local government agency; an institution of higher education (as defined at 20 U.S.C. §1001(a)); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education;
  - v. Income from service on advisory committees or review panels of: a federal, state, or local government agency; an institution of higher education (as defined at 20 U.S.C. §1001(a)); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education; or
  - vi. Travel that is reimbursed or 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.

## Scope and Exceptions

1. This Policy applies to any application for or receipt of research funding from the PHS, including without limitation the National Institutes of Health ("NIH"), whether such funding is by means of a grant, cooperative agreement, or contract. However, this Policy shall only apply to PHS-Funded Research with an issue date of the Notice of Award on or after August 24, 2012.
2. This Policy applies to any person (regardless of title or position) who is responsible for the design, conduct, or reporting of PHS-Funded Research (or proposed for such funding), which may include, for example, collaborators or consultants.