

## **XanthosHealth, Inc Financial Conflict of Interest (FCOI) Policy**

**Effective Date:** 08/15/2024

### **1. Purpose**

This policy is established to ensure that XanthosHealth, Inc. (XanthosHealth) complies with the requirements of Federal regulation [42 CFR Part 50 Subpart F](#), which pertains to the disclosure and management of Financial Conflicts of Interest (FCOI) in research.

The purpose of the FCOI regulation is to establish standards and procedures to be followed by Public Health Service (PHS) (e.g., NIH) funded institutions so that the design, conduct, or reporting of research funded by the PHS/NIH will not be biased by any conflicting financial interest of those “[Investigators](#)” responsible for the research. The regulation applies to the project director or principal investigator and any other person, regardless of title or position, the institution determines is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

### **2. Scope**

This policy applies to all Investigators, defined as any individual responsible for the design, conduct, or reporting of research funded by PHS, including collaborators, contractors, consultants, and sub-awardees, regardless of title or position.

### **3. Definitions**

- **Research Project:** A project being funded by the Public Health Service (PHS) including the National Institutes of Health (NIH) or any other agency or part of the United States government.
- **Investigator:** Any person who is responsible for the design, conduct, or reporting of research funded by PHS or proposed for such funding.
- **PHS Awarding Component:** The organizational unit of the Public Health service (PHS) within Health and Human Services (HHS) which funds the investigator’s research project (for example the National Institutes of Health).
- **Institutional responsibilities:** are the professional activities an investigator performs on behalf of Xanthoshealth (e.g., administration, research, or consulting).
- **Financial Conflict of Interest (FCOI):** A Financial Conflict of Interest exists when the company reasonably determines that a Significant Financial Interest (SFI) could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- **Significant Financial Interest (SFI):** A significant financial interest (SFI) is a financial interest consisting of one or more of the following interests of the Investigator (and those

of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(a) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(b) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests which, when aggregated, exceeds \$5,000.

(d) Investigators also must disclose the occurrence of 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, which, when aggregated, exceeds \$5,000 provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education. The details of this disclosure will include, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this FCOI policy, the Institutional Official (s) (see #4 below) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(e) Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

NOTES:

- (1) The term *significant financial interest* **does not include** the following types of financial interests: salary, royalties, or other remuneration paid by XanthosHealth to the Investigator if the Investigator is currently employed or otherwise appointed by XanthosHealth, including intellectual property rights assigned to XanthosHealth and agreements to share in royalties related to such rights; any ownership interest in XanthosHealth held by the Investigator; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.”
- (2) Financial interests are defined as anything of monetary value, whether or not the value is readily ascertainable. Royalties are potentially subject to disclosure, as are other interests related to intellectual property. Royalties from and agreements to share in royalties related to intellectual property rights paid to an Investigator (or his/her spouse or dependent children) are covered by the regulation and are subject to the \$5,000 threshold. If the royalties paid to the Investigator (or his/her spouse and dependent children) satisfy the definition of “Significant Financial Interest,” then they must be disclosed. However, if the royalties or agreement to share in royalties relate to intellectual property owned by XanthosHealth and are licensed or potentially licensed through XanthosHealth (i.e., they are not personally owned by the Investigator), they are considered remuneration from XanthosHealth and would not be considered a Significant Financial Interest of the Investigator. Royalties received by the Investigator from XanthosHealth would be excluded from the definition of Significant Financial Interest if the Investigator is currently employed or otherwise appointed by XanthosHealth. Unlicensed intellectual property that does not generate income is also excluded from the definition of Significant Financial Interest. Nonetheless, such interests have the potential to become significant and generate income, at which point they would become subject to the regulation.
- (3) An SFI is related to PHS-funded research when XanthosHealth, through its Institutional Official (s) (see #4 below), reasonably determines that the SFI:
- could be affected by the PHS-funded research; or

- is in an entity whose financial interest could be affected by the research.

The Investigator may be involved in making the determination of whether the SFI is related to the PHS-funded research.

- Additional definitions are included in the Regulation and can be found at [42 CFR 50.603](#).

#### **4. Disclosure of SFIs**

- XanthosHealth has designated its Chief Scientific Officer, Dr. Pinar Karaca-Mandic, as the Institutional Official to
  - solicit and review Investigator (including spouse and dependent children) SFI disclosures related to an Investigator's institutional responsibilities for a determination if
    - any SFIs related to the investigator's PHS-funded research
    - an FCOI exists (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research);
  - develop and implement a management plan to manage the FCOI(s).
- The Chief Scientific Officer and the Chief Technology Officer, Dr. David Haynes, may jointly undertake the above responsibilities of an Institutional Official on a case-by-case basis. The Chief Technology Officer will undertake the above responsibilities for SFI disclosures of the Chief Scientific Officer.
- All Investigators must disclose their foreign and domestic Significant Financial Interests (SFIs) (and those of the Investigator's spouse and dependent children) to the Institutional Official annually, and within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
- Disclosure is required at the time of application for PHS funding and within 30 days of the identification of a new FCOI during the course of an ongoing research project.

#### **5. Review and Management of FCOI**

- Upon disclosure of an SFI, the Institutional Official (s) will review the disclosure to determine whether the SFI is related to the PHS-funded research and whether it constitutes an FCOI. The requirement that an Investigator discloses an SFI under the terms of this Policy does not in and of itself imply the existence of an actual FCOI. An FCOI exists when Investigator's SFI:
  - Is related to a research project, that is, the SFI could be affected by the research project or is in an entity whose financial interests could be affected by the research project; and

- When the SFI could directly and significantly (could have a material affect on the research) affect the design, conduct, or reporting of the research project.
- If an FCOI is identified, the Institutional Official (s) will work with the Investigator to develop and implement a management plan to address and manage the conflict. Examples of conditions or restrictions that might be imposed to manage an Investigator's Financial Conflict of Interest include, but are not limited to:
  - Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc;
  - For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
  - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
  - Modification of the research plan;
  - Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
  - Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
  - Severance of relationships that create financial conflicts.
- When an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, the Institutional Official (s) will review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's PHS-funded research; determine whether an FCOI exists; and, if so, 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.
- Whenever it is identified that an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institutional Official (s) during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Institutional Official (s) will review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's PHS-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage the FCOI going forward. The Institutional Official (s) shall also, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.



- The Institutional Official (s) will take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

## **6. Reporting of FCOI**

- XanthosHealth will report identified FCOIs to the PHS Awarding Component including the information required in the regulation at [42 CFR Part 50.605\(b\)\(3\)](#)
  - prior to the expenditure of funds
  - within sixty (60) days of identification for an Investigator who is newly participating in the project
  - within sixty (60) days for new, or newly identified, FCOIs for existing Investigators
  - at least annually (at the same time as when XanthosHealth is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
  - after a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.
    - Based on the results of the retrospective review, if appropriate, XanthosHealth shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, XanthosHealth will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
    - The mitigation report will include the details of the FCOI, including the nature of the conflict, the value of the SFI, and whether a bias is found with the design, conduct or reporting of PHS-funded research. In addition, the mitigation report will include the key elements of the Retrospective review plus the management plan implemented to address the FCOI: what action(s) have been or will be taken to mitigate the effects of the bias (i.e., a description of the impact of the bias on the research project and the XanthosHealth's plan of action or actions taken to eliminate or mitigate the effect of the bias.

## **7. Non-Compliance**

- Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of significant financial interest or failure to comply with a requirement of the management plan, disciplinary proceedings may be taken against the violating individual.



- XanthosHealth will notify PHS promptly if an Investigator (or subrecipient Investigator) fails to comply with the XanthosHealth's FCOI policy or noncompliance with a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research.
- If an FCOI is not identified or managed in a timely manner, XanthosHealth will conduct a retrospective review of the Investigator's activities and the research project to determine whether any PHS-funded research, or portion thereof, conducted during the period of non-compliance was biased in the design, conduct, or reporting of such research. The results of the retrospective review will be reported to the relevant PHS Awarding Component (see #6 above).

## **8. Training**

- All investigators will be informed of XanthosHealth's FCOI policy, their disclosure responsibilities of all foreign and domestic SFI, and the Federal regulation on FCOI.
- In compliance with federal regulations, all XanthosHealth Investigators who are planning to participate in or are participating in a Research Project funded by a PHS Awarding Component are required to review this Company FCOI policy and complete the FCOI Training module:
- FCOI Training and other resources are available through the [NIH FCOI Training website](#).
- All Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter.
- Training is also required immediately when XanthosHealth revises its FCOI policy in a manner that affects the requirements of Investigators, or when an Investigator is new to XanthosHealth, or when XanthosHealth finds that an Investigator is not in compliance with the policy or management plan.

## **9. Record Retention**

- XanthosHealth will maintain records of all disclosures, FCOI reviews, and related actions for at least three years from the date of submission of the final expenditures report to the PHS Awarding Component or, where applicable, from other dates specified in 45 CFR 75.361.

## **10. Enforcement**

- Violations of this policy, including failure to file or knowingly filing incomplete, erroneous, or misleading disclosures, may result in disciplinary action, including termination of employment or other professional penalties.
- XanthosHealth will complete a retrospective review within 120 days of its determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:



- Failure by the Investigator to disclose an SFI that is determined by XanthosHealth to constitute a financial conflict of interest;
- Failure by XanthosHealth to review or manage such a financial conflict of interest;
- Failure by the Investigator to comply with the financial conflict of interest management plan;

The retrospective review will include key elements per [42 CFR 50.605\(a\)\(3\)\(ii\)\(B\)](#) and investigators involved will be required to disclose the FCOI in each public presentation of the results of the research, and request an addendum to previously published presentations.

## **11. Subrecipient Requirements**

- When carrying out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), XanthosHealth will take reasonable steps to ensure that any subrecipient Investigator complies with FCOI subrecipient requirements by:
  - Establishing, via a written agreement, whether the subrecipient will follow the FCOI policy of XanthosHealth or the FCOI policy of the subrecipient. The agreement will include:
    - A certification from the subrecipient that its FCOI policy complies with the the 2011 revised FCOI regulation (42 CFR Part 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of XanthosHealth for disclosing significant financial interests that are directly related to the subrecipient's work for XanthosHealth;
    - Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOI to XanthosHealth. Such time period(s) shall be sufficient to enable XanthosHealth to provide timely FCOI reports, as necessary, to the PHS as required by the 2011 revised FCOI regulation;
    - Alternatively, if the subrecipient's Investigators must comply with the XanthosHealth's the FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to XanthosHealth. Such time period(s) shall be sufficient to enable XanthosHealth to comply timely with its review, management, and reporting obligations under the 2011 revised FCOI regulation.
  - Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.





## 12. Public Accessibility

- This policy, along with FCOI disclosures related to PHS-funded research, will be made publicly accessible in accordance with PHS requirements.
- XanthosHealth will make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation [42 CFR 50.605\(a\)\(5\)\(i\)-\(iv\)](#)), by written response to any requestor within five business days of a request prior to the expenditure of funds. The response will include minimum elements as provided in the regulation, will provide updated information as of the date of the request, and will remain available for three (3) years from the date the information was most recently updated.

## 13. Contact Information

- For any questions or further information regarding this policy, please contact the XanthosHealth Institutional Official, Dr. Pinar Karaca Mandic at [pkmandic@xanthoshealth.com](mailto:pkmandic@xanthoshealth.com).

## USEFUL FCOI AND NIH RESOURCES

- **FCOI Regulation 42 CFR Part 50 Subpart F:** <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>
- **FCOI Webpage:** <https://grants.nih.gov/grants/policy/coi/index.htm>
- **FCOI Policy Development Checklist:** <https://grants.nih.gov/grants/policy/coi/FCOI-Policy-Development-Checklist.pdf>
- **FCOI Training Webpage:** <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>
- **2021 FCOI video presentation on the FCOI Regulatory Requirements** (see “[FCOI Presentation](#)”) – “Financial Conflict of Interest – What You Need to Know” located at <https://www.youtube.com/watch?v=D292YZ6BX24>.
- **FCOI FAQ:** <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=alphaHeader3875>
- **Instructions for submitting an FCOI Policy into eRA Commons IPF Module** (10/1/2020) – (PDF) – This document provides the instructions for submitting the institution’s FCOI policy in the eRA Commons IPF Module per NIH Guide Notice [NOT-OD-21-002](#) “Required Submission of Financial Conflict of Interest Policy into the eRA Commons Institution Profile (IPF) Module” dated 9/30/2020.
- **NIH Guide Notices Related to FCOI:**
  - **NIH Notice dated 9/16/2022 related to FCOI Guide:** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-210.html>
- **To stay informed about NIH grants administration matters, subscribe to the:**
  - **NIH Guide to Grants and Contracts:** <https://grants.nih.gov/funding/index.htm>
  - **NIH Extramural Nexus:** <https://nexus.od.nih.gov/all/>

## **Financial Conflict of Interest Disclosure**

This form is to be completed by each XanthosHealth employee who has been identified as someone who is or plans to be an Investigator for a PHS-funded Research Project.

This form must be completed by all Investigators on each research project, even if the Investigator has no relevant Significant Financial Interests (to confirm the lack of such an interest).

A new or updated version of this form must be completed for each Research Project:

- Before applying for and prior to expenditure of any PHS-funded Research Project,
- By January 31st of each year, during the period of the funding award, and
- Within 30 days of discovering or acquiring a new SFI, including due to marriage, purchase, gift, inheritance or otherwise.

The form must be completed with information relating to Investigator (and the Investigator's spouse, registered domestic partner or dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities.

Once completed, the form should be submitted to XanthosHealth's Institutional Official.

### **Investigator and Research Project Identification**

This submittal is a  New Disclosure  Updated Disclosure

**Employee/Researcher Name:** \_\_\_\_\_

**Position:** \_\_\_\_\_

**Email:** \_\_\_\_\_

**Phone Number:** \_\_\_\_\_

**Date:** \_\_\_\_\_

### **Section 1: Disclosure of Financial Interest**

#### **1. Entity Involved:**

- Name of Entity: \_\_\_\_\_
- Type of Entity:  Public  Private  Nonprofit  Other (specify): \_\_\_\_\_
- Nature of Business: \_\_\_\_\_

#### **2. Nature of Financial Interest:**

- Equity Interest (e.g., stocks, options)
  - Type: \_\_\_\_\_
  - Approximate Value: \_\_\_\_\_
- Compensation (e.g., salary, consulting fees, honoraria)
  - Type: \_\_\_\_\_
  - Amount Received: \_\_\_\_\_
  - Date Received: \_\_\_\_\_



- Intellectual Property Rights (e.g., patents, royalties)
  - Description: \_\_\_\_\_
  - Income Received: \_\_\_\_\_
- Other Financial Interest (please describe): \_\_\_\_\_

**3. Duration of Financial Interest:**

- Start Date: \_\_\_\_\_
- End Date (if applicable): \_\_\_\_\_
- Ongoing:  Yes  No

**Section 2: Potential Conflict of Interest**

**4. Does this financial interest relate to your professional responsibilities (e.g., research, teaching, clinical practice)?**

- Yes
  - If yes, please describe how: \_\_\_\_\_
- No

**5. Could this financial interest affect your objectivity in carrying out your professional duties?**

- Yes
  - If yes, please describe potential impact: \_\_\_\_\_
- No

**Section 3: Mitigation Measures**

**6. Proposed or Implemented Mitigation Strategies (check all that apply):**

- Recusal from decision-making processes involving the entity
- Disclosure to colleagues and collaborators
- Divestiture of financial interest
- Oversight by an independent committee
- Adjustment of research or work assignments
- Other (please describe): \_\_\_\_\_

**Section 4: Certification and Signature**

I certify that the information provided in this disclosure is accurate and complete to the best of my knowledge. I agree to abide by the organization’s policies and procedures regarding conflicts of interest and to take any necessary steps to manage or eliminate potential conflicts.

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_





**Supervisor/Chief Scientific Officer Review:**

- Reviewed by: \_\_\_\_\_
- Date: \_\_\_\_\_
- Comments/Recommendations: \_\_\_\_\_

**Action Required:**

- No action required
- Further action required (please specify): \_\_\_\_\_

**Final Approval:**

- Approved
- Not Approved
- Signature: \_\_\_\_\_
- Date: \_\_\_\_\_