OhioHealth	POLICY & PROCEDURE
TITLE: Conflict of Interest for an Individual Involved in Research	**NUMBER:** OH.POL.A-430.003
ISSUE DATE: 6/18/2021	**EFFECTIVE DATE:** 1/31/2022
DEVELOPED BY: OhioHealth Research Institute (OHRI)	
REVIEWED BY: Ethics and Compliance Senior Leadership Committee OhioHealth System Policy & Procedure Management Committee OhioHealth Office of the General Counsel	**DATE REVIEWED:** 4/21/2021 May 2021 12/20/2021
APPROVED BY: Quality, Safety & Service Council	

SCOPE:
This policy is in effect for all OhioHealth business units.

STATEMENT OF PURPOSE:
The purpose of this policy is to set forth the requirements for disclosure of potential or actual conflicts of interest (COI) in Human Subjects Research and the process of managing or eliminating such conflicts. This policy is to provide those individuals involved in research (including: OhioHealth associates, Independent Physicians, or Other Individuals) with guidance regarding COI in Research conducted at OhioHealth facilities.

OhioHealth recognizes the importance in outside activities that advance and communicate knowledge through interaction with government, industry, the community and the public. The financial interest in a company or other organization of an Investigator (or that of his or her Family), may produce a real or perceived financial conflict of interest if the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of research. OhioHealth is deeply committed to protecting the safety and welfare of subjects involved in research, maintaining scientific integrity in all research activities, safeguarding the reputation and integrity of the institution, and supporting the development of useful knowledge.

DEFINITIONS:
- **Associate:** For the purposes of this policy only, (i) any individual employed by OhioHealth or any of its affiliates, including full-time, part-time, and contingent employees; (ii) any physician independently contracted to provide services, or (iii) any independent contractor who serves on an evaluation or selection committee which may make a decision resulting in a contractual relationship between OhioHealth and a third party.
- **Conducting Research:** With respect to a research protocol, designing research, directing research or serving as the Principal Investigator, enrolling research subjects (including obtaining a subject's informed consent) or making decisions related to an individual's eligibility to participate in research, analyzing or reporting research data, or submitting research manuscripts for publication.
- **Conflict of Interest (COI)** exists when:
  - The Investigator has a Significant Financial Interest (SFI) (see Section II.A below) in the external entity sponsoring, funding, or otherwise supporting the research or any other financially interested company associated with the research. (This includes manufacturer of products under investigation or in use in the study); or
  - The Investigator has an SFI that could be affected by the research.

  A PHS reportable financial COI exists if it is determined that the financial COI could directly and/or significantly affect the design, conduct, or reporting of the research.
- **Covered Individual:** Any OhioHealth Investigator (whether or not employed by OhioHealth) and Key Personnel.
- **Disclosure:** The process of reporting relationships or interest in outside organizations.

- **Externally Supported:** Research funded by a public or private entity separate from OhioHealth through a gift, grant, award, contract, cooperative agreement or similar arrangement.
- **Family:** Spouse or dependent children.
- **Independent Physician or Other Individual:** Not employed or does not have an employment contract with OhioHealth where Research is within the scope of their employment.
- **Institutional Review Board (IRB):** An Institutional Review Board is a committee established in accordance with the regulations described in 21 CFR 56 and 45 CFR 46, whose purpose is to review and to have authority to approve, require modifications in, or disapprove proposed research involving human subjects.
- **Investigator:** The Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research at OhioHealth, and may include, for example, collaborators or consultants.
- **Institution:** Refers to the OhioHealth Corporation and any affiliated or subsidiary institutions.
- **Management Plan (MP):** A plan developed to manage, reduce, or eliminate an identified financial Conflict of Interest. The plan is developed based on the outcome of the conflicts of interest disclosure review process (see Sections II and III below).
- **OhioHealth Facilities:** Facilities that are wholly owned or operated by OhioHealth.
- **Research Conflict of Interest Committee (RCOIC):** Committee responsible for reviewing individually and institutionally disclosed research financial interests, making determinations about whether those outside financial interests constitute conflicts of interest and making recommendations about how those conflicts of interest can be eliminated, reduced, or managed.

POLICY:

I. Individuals responsible for the design, conduct, or reporting of research conducted at OhioHealth Facilities or on behalf of OhioHealth must disclose financial or other interests, which may be, or appear to be, a conflict of interest.

II. It is the policy of OhioHealth that Covered Individuals disclose certain financial interests when conducting research.
   A. Disclosure enables OhioHealth to determine if a financial interest creates a conflict of interest or the appearance of a conflict of interest.
   B. The existence of a conflict of interest, or the appearance of one, does not imply wrongdoing on anyone's part and does not necessarily mean that a Covered Individual may not retain his or her financial interest and undertake the affected research.
   C. Some conflicts must be eliminated, but often OhioHealth can work with the Covered Individual to manage a conflict, or in the appearance of a conflict, so that the research can continue in a way that minimizes the possibility of bias in the research to preserve the objectivity of the research.
   D. Proper management of a conflict depends on full and prompt disclosure.

PROCEDURE:

I. DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST:
   A. For each proposed study that receives external support, the Covered Individual must have completed financial interest disclosure process.
      1. The Covered Individual must certify either that the Covered Individual and/or Family do not have a financial interest with respect to the research or disclose any financial interest that may exist and agree to a plan for reducing or eliminating the potential conflict.

B. PHS regulations require each Covered Individual involved in PHS (including National Institutes of Health) funded research to submit a conflict-of-interest disclosure to the Institution upon initial submission and at least annually.
    1. If a current conflict of interest disclosure is not on file, one must be submitted:
        a. At the time of the grant application submission,
        b. When an individual is assigned to a project, or
        c. Within 30 days of developing a new relationship or obtaining a new interest.
C. Subrecipients as defined in 42 CFR 50.604 (b)(3)(c) who participate in PHS-funded research shall agree in writing to either:
    1. Comply with the applicable requirements of this policy; or
    2. Certify that the subrecipient has a conflict-of-interest policy that complies with 42 CFR 50.604(b)(3)(c) and timely report any related conflicts of interest to OhioHealth.
D. In the event a COI arises during the conduct of the research, a new relationship is developed, or a new interest is obtained, the Covered Individual must update the financial interest disclosure within 30 days of identifying a potential financial conflict of interest.

II. CONFLICT OF INTEREST DISCLOSURE REVIEW PROCESS – REVIEW PROCESS FOR ALL RESEARCH:

A. Individual(s) designated by the Research Conflict of Interest Committee (RCOIC) will be responsible for the review of all conflict-of-interest disclosures for Covered Individuals.
B. Questions regarding a conflict-of-interest disclosure will be directed to the disclosing Covered Individual unless otherwise initiated or directed by the disclosing Covered Individual.
C. The RCOIC designated reviewer(s) will determine whether a disclosure: 1) is related to any current or proposed research, and 2) represents a Significant Financial Interest in a non-OhioHealth entity, as defined by PHS, based on one or more of the following financial interests of a Covered Individual and/or Family:
    1. Any equity interest, including stock, stock options, or other ownership interests of any amount, which directly affects, or could reasonably appear to affect, the research being reviewed, funded or proposed for funding.
        a. This includes investments in a study sponsor or its parent company (if a publicly or non-publicly traded company is involved).
    2. Honoraria, salary, or consulting compensation, which in total exceeds $5,000 in the previous 12 months, from a single non-OhioHealth entity, or is expected to in the next year.
        a. This includes any and all types of income including speaking, advising, authorship, other fees for services, honoraria (including from a third party if original source is the study sponsor), gifts or payment for consulting, lecturing, paid authorship, travel, or service on an advisory board.
    3. Financial arrangements where the value of the compensation could be influenced by the outcome of the study. Examples include:
        a. Compensation explicitly for a favorable outcome;
        b. Equity interest in the sponsor;
        c. Royalty payments or the written contractual rights to future royalties or other income related to intellectual property rights and interests, including licensing and option assignment fees;
        d. Any payment in connection to research that is not specified in the Research Agreement between the sponsor and the institution;
        e. A proprietary or financial interest in a test product such as a patent, trademark, copyright or licensing agreement; or

f. Serving as an officer, director, trustee, partner, governing board member, employee or functioning in any other fiduciary role for a sponsor, sponsor parent company or sponsor subsidiary, regardless of whether compensation for the service is provided.

4. Covered Individuals also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the covered individual and not reimbursed to the covered individual so that the exact monetary value may not be readily available) related to their institutional responsibilities, provided that this disclosure requirement does not apply to travel that is reimbursed or sponsored by:
   a. A federal, state or local government agency;
   b. An institution of higher education;
   c. An academic teaching hospital;
   d. A medical center; or
   e. A research institute that is affiliated with an institution of higher education.
5. The term "Significant Financial Interest" does not include the following types of financial interests:
   a. Salary, royalties, or other remuneration paid by the Institution to the Covered Individual if the Covered Individual is currently employed or otherwise appointed by the Institution;
   b. Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the institution held by the Covered Individual;
   c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual does not directly control the investment decisions made in these vehicles;
   d. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
   e. Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

D. If a conflict exists, the RCOIC will determine whether the conflict can be managed to eliminate the introduction of bias to the research and if so, take steps to manage, reduce, or eliminate the conflict.

III. MANAGEMENT PLAN:

A. If it is determined there may be a COI or the appearance of a conflict, the reviewer(s), at the direction of the RCOIC, will prepare a Management Plan (MP) recommendation including the Covered Individual's plan for reducing or eliminating potential conflict.
B. The MP will be designed to address the conflict specific to the individual's role in the study and will reflect the extent of the potential conflict and the level of risk to any human participants.
C. Management Plan requirements may include, but are not limited to:
   1. A disclosure of the income, relationship or interest in the Informed Consent and Authorization document so prospective participants may make an informed decision about participation in the study utilizing OhioHealth Office of the General Counsel approved consent form language;

2. A disclosure of the income, relationship or interest in public releases of information about the study (e.g., advertising, press releases, abstracts, presentations, publications);
3. Limits on the conflicted individual's role in the study (e.g., may not serve as principal investigator, may not be involved in administering informed consent, may not analyze data, etc.);
4. Independent reviewers, either institutional (internal) or external;
5. Placement of his/her investment in escrow for the duration of the study, and for a suitable period after the completion of the research;
6. Divestiture of the financial interest;
7. Severance of the relationship(s) with the sponsor or competitor, which caused the conflict or perceived conflict;
8. Disqualification of the covered individual from conducting the research in part or in its entirety;
9. Oversight by a non-conflicted individual;
10. Modification of the research plan;
11. External monitoring of the study, particularly endpoint assessments or study audits (e.g., patient eligibility, data integrity);
12. Use of an external Data Safety Monitoring Board or similar review committee to perform the normal duties of a data safety monitoring board, but also to consider COI issues. The DSMB should evaluate the design, analytical protocols, primary and secondary endpoint assessments, and provide ongoing evaluation of the study for safety, performance issues and the unbiased reporting of results; or
13. Non-approval of the study at OhioHealth.

D. Process for Management Plans:
   1. The reviewer will prepare the final MP and review with the PI and obtain signatures.
   2. The conflicted individual, the PI (if other than the conflicted individual), the clinical research manager and the Clinical Leader (or next higher non-conflicted individual on the applicable organization chart) must sign the MP document acknowledging the MP and return it to RCOIC.
   3. Upon approval of the fully signed MP, the research may proceed for IRB submission.
   4. The MP will be placed on file.

E. Approval of Research:
   1. For research involving human subjects, the IRB has the final authority in determining if the MP is appropriate for research participant protection, given the interests disclosed and the MP developed to manage those interests.

IV. NOTIFICATION TO PHS:

A. Consistent with the regulations, if it is determined a significant financial conflict of interest exists related to a PHS funded project, the conflict and MP details will be reported to PHS when the MP is instituted and prior to expenditure of any funds, then annually thereafter.
B. If OhioHealth is participating as a sub-contractor, OhioHealth will report the required information to the sub-contractor for subsequent reporting to PHS.
C. OhioHealth will make information regarding COI and how they have been managed, reduced, or eliminated upon request, to Department of Health and Human Services (HHS).
D. In the event the HHS determines that a PHS-funded research project 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 conflicting interest that was not appropriately

disclosed or managed, OhioHealth will require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

V. NON-COMPLIANCE AND CORRECTIVE ACTION:

A. Failure to disclose a financial COI within the specified timeframe or non-compliance with a MP may result in corrective action, as determined by the IRB, RCOIC, OhioHealth Administration and/or regulatory agencies.
    1. Corrective action may include, but is not limited to:
        a. Completion of additional research education;
        b. Restrictions on the use of data derived from the research;
        c. Suspension or termination of the research project;
        d. Withdrawal of funding;
        e. Loss of research privileges at OhioHealth; or
        f. Report of actions to external regulatory agencies.
B. When non-compliance with a COI management plan related to a PHS funded project occurs, a retrospective review will be conducted.
    1. If bias in the research is found, a mitigation report will be filed with PHS within 120 days of discovery and include:
        a. Key elements documented in the retrospective review;
        b. A description of the bias identified in the research; and
        c. The plan of action(s) to eliminate or mitigate the effect of the bias.

VI. MONITORING AND AUDITING:

A. The OhioHealth Research Compliance team, in conjunction with each approval committee, will conduct periodic audits of research records to assure compliance with each MP.
B. Audit results will be provided to study PI and RCOIC.

VII. EDUCATION AND TRAINING:

A. All individuals responsible for the conduct of research must be knowledgeable about this policy and research conflict of interest.
B. Additionally, researchers are required to review this policy as part of the annual research compliance training.
C. Education regarding changes or new procedures will be communicated and incorporated into the annual training module.
    1. Education will be required immediately when:
        a. Financial conflict of interest policies are revised in a manner that changes Covered Individual's requirements;
        b. A Covered Individual is new to the Institution; or
        c. A Covered Individual is non-compliant with financial conflict of interest policies and procedures, including a violation of a MP.
D. Consistent with federal regulations, researchers involved in PHS funded research will be required to complete a training course specific to PHS requirements.
    1. The training must be completed prior to engaging in PHS funded research and at least every four (4) years thereafter.

VIII. RESPONSIBILITIES:

A. This policy applies to all individuals involved in OhioHealth research.

B. Disclosures required by this policy are in addition to, and in coordination with, disclosures required by OhioHealth's Office of General Counsel.
C. All financial disclosures for Covered Individuals will be reviewed by RCOIC or a designee of RCOIC.
    1. The RCOIC works in conjunction with the Corporate Compliance Office and Office of General Counsel.
    2. Conflict of Interest Disclosure information may be shared between the Corporate Compliance Office and Research Institute Administration to assure appropriate review and management of conflicts.

IX. PUBLIC ACCESS TO COI INFORMATION:

A. As required by regulation, this policy will be made available to the public on OhioHealth's website.
B. Additionally, within five (5) days of a request, information on conflicts of interest for individuals involved in PHS funded research will be provided.

X. RECORD RETENTION:

A. All records relating to conflict-of-interest disclosures, review, and management plans will be retained subject to the standard sponsor record retention requirements or for a period of not less than three (3) years past the date of submission of the final expenditures report.

XI. CONFLICT DISCLOSURES OUTSIDE OF RESEARCH:

A. This policy governs conflicts of interest for an Individual involved in Research.
B. All Associates are required to comply with OhioHealth's *Conflict of Interest* policy OH.POL.HR-703.005 regarding conflicts of interest in employment.
    1. For questions regarding disclosure requirements for Associates generally, please refer to OH.POL.HR-703.005 *Conflict of Interest*.

XII. POLICY DISCLOSURE:

A. This policy will be made publicly available on the OhioHealth website.

XIII. CONFIDENTIALITY:

A. The information received to comply with this policy shall be handled confidentially, to the extent possible and/or as described in this policy, unless public disclosure is part of the management plan or such disclosure is required by OhioHealth, federal regulations, or sponsoring agencies.

REFERENCES:

- 42 CFR 50 Subpart F Promoting Objectivity in Research
- 45 CFR 94 Responsible Party Contractors
- 21 CFR part 54 Financial Disclosures by Clinical Investigators
- OhioHealth policies:
    - OH.POL.A-430.001 *Protection of Human Subjects Research*
    - OH.POL.HR-703.005 *Conflict of Interest*

RESCISSION:

HS001 Conflicts of Interest in Research (OHRI-level SOP)