

	<b>POLICY &amp; PROCEDURE</b>	
	<b>TITLE:</b> Conflicts of Interest in Research	<b>NUMBER:</b> HS001
	<b>ISSUE DATE:</b> June 1999, revised October 2018	<b>EFFECTIVE DATE:</b> 10/03/2018
	<b>DEVELOPED / REVISED BY:</b> Lynn Shaffer, PhD and Lisa Cline, CCRC, Revised by Adam McClintock, MBA	
	<b>REVIEWED BY:</b> Office of Human Subjects Protection OhioHealth Office of General Counsel OhioHealth Ethics & Compliance	<b>DATE REVIEWED:</b> 10/03/2018 10/03/2018 09/25/2018
<b>APPROVED BY:</b> System VP, Academic Affairs and Chief Academic Officer		

**SCOPE:**

This policy is in effect for OhioHealth.

This policy applies to investigators participating in research and/or clinical investigations at OhioHealth (whether or not employed by OhioHealth) and includes any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research performed under the auspices of OhioHealth.

**STATEMENT OF PURPOSE:**

To assure professional and commercial integrity in all matters, OhioHealth maintains a program that identifies and addresses conflicts of interest in research. This policy presents procedures regarding financial Conflicts of Interest in relation to research studies sponsored, funded, or otherwise supported by external entities and conducted at OhioHealth. OhioHealth has adopted and implemented this policy to demonstrate its commitment to compliance with all federal laws and regulations applicable to research.

**DEFINITIONS:**

1. **Conducting Research** means, with respect to a research protocol, designing research, directing research or serving as the principal investigator, enrolling research subjects (including obtaining subjects' informed consent) or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication.
2. **Conflict of Interest (COI)** exists when:
  - The investigator has a Significant Financial Interest (SFI) in the external entity sponsoring, funding, or otherwise supporting the research or any other financially interested company associated with the research. (This includes the 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 Public Health Service (PHS) reportable financial COI exists if it is determined that the COI could directly and/or significantly affect the design, conduct or reporting of the research.

3. **Covered Individual** includes any OhioHealth investigator(s) participating in research and/or clinical investigations at OhioHealth (whether or not employed by OhioHealth) and includes any other person,

regardless of title or position, who is responsible for the design, conduct, or reporting of research performed under the auspices of OhioHealth.

4. **Grant** in the context of this policy will broadly cover all external support mechanisms including grants, cooperative agreements and contracts.
5. **Institution** refers to the OhioHealth Corporation and any affiliated or subsidiary institutions.
6. **Investigator** means the Principal Investigator (PI) and any other person who is responsible for the design, conduct, or reporting of research sponsored, funded, or otherwise supported by external entities and conducted research at OhioHealth.

The term will also include any individual(s) working on the study that may reasonably appear to have the potential, as determined by the PI, to directly and/or significantly have an impact on the design, conduct, or reporting of the research.

7. **Significant Financial Interest** in a non-OhioHealth entity is one or more of the following financial interests of an investigator (or immediate family member or entity controlled by any of them):
  - Honoraria or consulting compensation exceeding \$5,000 in the previous 12 months, from a single non-OhioHealth entity, including speaking, advising, other fees for services, paid authorship and other remuneration – whether cash or non-cash,
  - Equity, including stock, stock options, or other ownership interests of any amount,
  - Royalty payments or the written contractual right to future royalties or other income related to intellectual property rights and interests, including licensing and option assignment fees,
  - Payments not described in the research contract,
  - Fiduciary service, such as an appointment as an officer, chief medical officer, director, trustee, partner, or governing board member, whether compensated or not.

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, however, that this disclosure requirement does not apply to travel that is reimbursed or 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.

The term “Significant Financial Interest” **does not include** the following types of financial interests:

- 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,
- 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
- 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;
- 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
- 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.

**FINANCIAL INTEREST DISCLOSURE:**

For each research protocol for which a governmental agency or private external entity is sponsoring, supplying funds, or otherwise supporting the study, the covered individuals who will be involved with the research will have the following responsibilities:

1. For each proposed study that receives external support, the covered individual must submit an OhioHealth Research Institute (OHRI) Financial Interest Disclosure & Management Form (see Attachment I). The covered individual must certify either that the covered individual and his/her immediate family members do not have an SFI with respect to the research, or disclosing fully any SFI that does exist.
2. Disclosure forms shall be submitted to the Office of Human Subjects Protections (OHSP) in conjunction with a submission for IRB review.
3. All disclosures must be updated whenever new SFI are acquired, as well as annually for externally supported studies.

It is the covered individual's responsibility and duty to assure that updated disclosures are on file on an on-going basis.

4. To the extent permitted by law, disclosure forms will be held confidential.

It is ultimately the responsibility of the PI to solicit and present the appropriate disclosure forms of individuals listed on their grant or research protocol in a timely fashion and in no event later than concurrent with the submission of a protocol to OHSP for administrative review. Failure to comply with this disclosure requirement will result in administrative approval for protocol submission being withheld. No protocol may be submitted to the IRB of record for the study, or industry contracts executed, without the appropriate administrative approval by OHSP.

**DISCLOSURE REVIEW:**

The OHSP at OhioHealth shall review all OHRI Financial Interest Disclosure & Management Forms. If a financial interest is disclosed that does not meet the definition of an SFI, as defined above, the investigators will be advised to include the generic consent disclosure language (see Attachment 2) in all applicable study consent forms. If an SFI, as defined above, is disclosed, the following actions will be taken:

1. OHSP will advise the investigator(s) to include specific consent disclosure language (see Attachment 2) in all applicable study consent forms.
2. The COI management plan identified in the OHRI Financial Interest Disclosure & Management Form, along with any relevant materials (i.e., research protocol, consent forms, etc.) will be forwarded for review by the Office of Research Compliance (ORC) and the Office of General Counsel (OGC).
3. ORC will review and provide a recommendation on the adequacy of the management plan to OGC, which will make a final determination about the COI and any conditions or restrictions to be imposed.

4. Upon approval from OGC and issuance of study administrative approval by OHSP, the study may be submitted to the IRB of record for review and approval.

#### **MANAGEMENT OF CONFLICTING INTERESTS:**

When an SFI is identified, the Director of Research Business Services (or a designee) will ensure that the conflict is reported to the appropriate governmental agency or sponsor, along with the assurance that the conflict has been managed, reduced or eliminated, in accordance with federal regulations and policies. Examples of conditions or restrictions that might be incorporated into a COI management plan include, but are not limited to:

1. Public disclosure of the SFI.
2. Disclosure of the SFI in any publications, oral presentation, or other dissemination of the results of the research.
3. Disclosure of the SFI to the research subjects in the consent document.
4. Monitoring of research (and/or fiscal considerations) by independent reviewers.
5. Modification of the research plan.
6. Disqualification from participation in all or a portion of the research study (for example, the covered individual with the SFI may be precluded from enrolling and/or obtaining informed consent from study subjects for the research study, or may be precluded from interpreting the results of the research).
7. Divestiture of the SFI.
8. Severance of the relationships that create actual or potential conflicts.

#### **RECORD RETENTION:**

All Financial Interest Disclosure forms will be maintained in the pending protocol file until such time as a decision regarding external sponsorship, funding, or other support is made. If a study is externally sponsored, funded, or otherwise supported, the Financial Interest Disclosure forms, together with all applicable documentation and COI management plan(s) approved by ORC and OGC, will become part of the official file maintained by OHSP and will be subject to the standard sponsor record retention requirements. Absent more stringent sponsor record retention requirement, the records will be maintained for a period of not less than three (3) years following the submission of a final Financial Status Report.

#### **REFERENCES:**

- 42 FR 50, Subpart F
- 45 CFR 94

#### **ATTACHMENTS:**

Attachment 1: OHRI Financial Interest Disclosure & Management Form

Attachment 2: Consent Disclosure Language

**RESCISSION(S):** None

## ATTACHMENT 1: OHRI Financial Interest Disclosure & Management Form

Covered Individual: Click or tap here to enter text.

Grantor: Click or tap here to enter text.

*Financial Interest Disclosure:*

- No Significant Financial Interest related to this protocol (complete Section I only)
- Significant Financial Interest as described below ( complete Sections I & II)

*Covered Individual's Affiliation:*

- Principal Investigator
- Sub-Investigator
- Other Research Staff: Click or tap here to enter text.
- Immediate Family Member of PI or study staff (spouse or dependent children)
- Institutional Conflict of Interest

**Section I: Financial Interest Disclosure**

*Nature of Financial Interest:*

- Equity: *Publicly traded*  
Number of Shares, etc.: Click or tap here to enter text.
- Equity: *Not publicly traded:*  
Number of Shares Held: Click or tap here to enter text.  
Approximate Total Number Issued: Click or tap here to enter text.
- Consulting Fees during last 365 days
- Speaking Fees during last 365 days
- Gifts during last 365 days
- Corporate Officer or Board of Directors
- Other Employment Relationship
- Trademarks
- Copyrights
- Licensing Agreements
- Royalty Payments
- Patent Holdings
- Other (please describe): Click or tap here to enter text.

*Approximate Dollar Value:*

- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.
- \$Click or tap here to enter text.

Signature:	Date:
------------	-------

*By signing above, you certify that the above information is complete and accurate, and you agree to promptly update the above information in accordance with OhioHealth policy if any relevant changes occur to your above answers during the research or within one year after its completion.*

## Section II: Conflict of Interest Management Plan

<input type="checkbox"/> <b><i>Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research)</i></b>
<input type="checkbox"/> <b><i>Disclosure of financial conflicts of interest directly to study participants (i.e., via the consent form)</i></b> Provide Consent Disclosure Statement: Click or tap here to enter text.
<input type="checkbox"/> <b><i>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</i></b> Describe: Click or tap here to enter text.
<input type="checkbox"/> <b><i>Modification of the research plan</i></b> Describe: Click or tap here to enter text.
<input type="checkbox"/> <b><i>Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research</i></b> Describe Action Plan: Click or tap here to enter text.
<input type="checkbox"/> <b><i>Reduction or elimination of the financial interest (e.g., sale of an equity interest)</i></b> Describe: Click or tap here to enter text.
<input type="checkbox"/> <b><i>Severance of relationships that create financial conflict</i></b> Describe: Click or tap here to enter text.
<input type="checkbox"/> <b><i>Other action(s) to mitigate the potential financial conflict</i></b> Describe: Click or tap here to enter text.

## ATTACHMENT 2: Consent Disclosure Language

### **Generic Disclosure**

The Principal Covered Individual of this medical research study might benefit financially from this study. The Institutional Review Board has reviewed the possibility of financial benefit. They believe that the possible financial benefit to the Principal Covered Individual is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

### **Specific Disclosure**

The Principal Covered Individual of this medical research study might benefit financially from this study. Specifically, *[insert appropriate description from below]*.

The Institutional Review Board and a committee at OhioHealth have reviewed the possibility of financial benefit. They believe that the possible financial benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

### ***Descriptions***

The relevant description below should be inserted into the above disclosure as indicated, except for the description of unrestricted finder's fees, which should be used instead of the “specific disclosure” language given above.

### ***Salary Support***

The study sponsor is paying some or all of the salary for the doctors and staff who are working on this research study.

### ***Money Received Outside of the Study***

This research study is supported by money from the sponsor. In addition, the Principal Covered Individual receives extra money from the sponsor for work that is not a part of this study. These activities may include consulting, advisory boards, giving speeches, or writing reports.

### ***Per Capita Payments***

The sponsor pays the OhioHealth for study supplies, staff salaries, and for each person who agrees to participate in the study. This amount of money is just enough to cover the cost of running the study.

### ***Researcher Holds a Patent***

The Principal Covered Individual owns [or has applied for] a patent on the new [test, drug, treatment, device] being studied. Research studies like the one you are thinking about joining are done to determine whether the new [test, drug, treatment, device] is safe and effective. If research shows the new [test, drug, treatment, device] is safe and effective, the Principal Covered Individual would receive a part of the profits from any sales of this [test, drug, treatment, device].

### ***OhioHealth Holds a Patent***

Research studies like the one you are thinking about joining are done to determine whether the new [test, drug, treatment, device] is safe and effective. OhioHealth Corporation owns [or has applied for] a patent on the new [test, drug, treatment, device] being studied. If research shows the new [test, drug, treatment, device] is safe and effective, OhioHealth Corporation would receive a part of the profits from any sales of this [test, drug, treatment, device].

*Researcher Owns Equity*

This research study is designed to test a product made by the sponsor. The Principal Covered Individual has an investment in the sponsor, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that the Principal Covered Individual running this study could gain or lose money depending on the results of this study.

*OhioHealth Owns Equity*

This research study is designed to test a product made by the sponsor. OhioHealth Corporation has an investment in the sponsor, such as stock. The financial value of this investment might be affected by the results of this study. This means that OhioHealth Corporation could gain or lose money depending on the results of this study.