

<b>Sanford Health Policy ENTERPRISE Compliance:</b>	<b>Conflict of Interests - Research, Individual</b>
<b>DATE REVIEWED/REVISED:</b> 04-2019	<b>APPROVED BY:</b> VICE PRESIDENT, CHIEF COMPLIANCE OFFICER
	<b>FORMULATED BY:</b> Executive Director, Compliance

### **Purpose**

To assure professional and commercial integrity in all research matters, Sanford maintains a Research Conflict of Interests (“COI”) Program that identifies and addresses conflicts of interest in research.

### **Policy Statement**

#### Presumption Against Participating in Research When Personal Financial Interests Exist

If a *Covered Individual* has a *Significant Financial Interest* (“SFI”) and that SFI is considered to be a *Conflict of Interest* (“COI”), (or a *Public Health Service* (“PHS”)-Reportable *Financial Conflict of Interest* (“FCOI”), the *Covered Individual* must obtain approval from the Research COI Program to participate in human subjects and/or non-human subjects research.

### **Scope**

*Covered Individual* includes:

- any individual employed by Sanford Research; or
- any individual meeting the definition of an *Investigator*; or
- any individual employed by Sanford or any official, employee, consultant, agent, student, trainee, or administrator who is planning or actively involved in any *Research* activities involving Sanford patients.

### **Policy Procedure**

The Research COI Program must approve an *Investigator’s* participation or continued participation in the research when either a *COI* or a *PHS*-Reportable *FCOI* exists.

If it is determined a *COI* exists, for human or non-human subjects *Research*, approval to begin or continue research may be granted only if the Research COI Program determines that a *Management Plan*, (or a *PHS*-Reportable *Management Plan*), will, to the extent possible, ensure that the design, conduct or reporting of the research will be free from bias that may result from the *COI* (or *PHS*-Reportable *FCOI*). The approved *Management Plan* or a *PHS*-Reportable *Management Plan* is subject to modification by the Institutional Review Board (“IRB”) or Institutional Animal Care and Use Committee (“IACUC”), as applicable. The Research COI Program will monitor compliance with such *Management Plans* or *PHS*-Reportable *Management Plans*.

## Determination of a *COI*

A *COI* exists when:

- the *Investigator* has a *SFI* in the commercial sponsor of the research or any other *Financially Interested Company* (this includes the manufacturer of products under investigation or in use in the study); or
- the *Investigator* has a *SFI* that could affect or be affected by the *Research*.

A *SFI* from a [\*Financially Interested Company\*](#) is one or more of the following:

- For a publicly traded entity, a *SFI* exists if the aggregate 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 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, payments not described in the research contract); *Equity Interest* includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measure of fair market value; or
- For a non-publicly traded entity, a *SFI* exists if the aggregate value of any *Remuneration* received from the entity in the twelve months preceding the disclosure exceeds \$5,000, **or** any *Equity Interest* in the non-publicly traded entity “e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- *Covered Individuals* must also disclose the occurrence of any *Reimbursed or Sponsored Travel*, when aggregated with any other *Remuneration* from an outside entity, that when aggregated, exceeds \$5,000.

The term *SFI* does not include the following types of *Financial Interests*:

- any ownership or *Equity Interest* in a Sanford subsidiary held by the *Covered Individual*, if the Sanford subsidiary is a commercial or for-profit organization; or
- 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; or
- 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; 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 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.

### **Non-*PHS* Reportable *FCOI* Interests**

A *PHS*-Reportable *FCOI* exists if the Research COI Program finds that the *COI* could directly and significantly affect the design, conduct, or reporting of the research that is funded by *PHS* in any amount. Note that while the following situations could create a *COI*, they do not create a *PHS*-Reportable *FCOI*:

- Royalties to be paid by Sanford to the *Investigator* if the *Investigator* is employed by Sanford.
- An *Investigator* has an ownership, investment, or other pecuniary interest in Sanford Health or any of its subsidiaries.

### **Compelling Circumstances**

In addition to the approval and management requirements above, the Research COI Program must find *Compelling Circumstances* to justify the *Investigator*'s participation in the research when the *COI* or *PHS*-Reportable *FCOI* exist. *Compelling Circumstances* are those facts that convince the Research COI Program that the *Investigator* may participate in the research despite the *COI* or *PHS*-Reportable *FCOI*.

### **Disclosure to Sanford**

*Investigators* participating in *Research* must submit disclosures of all *Financial Interests* in non-Sanford entities annually, prior to application for funding from *PHS* agencies, and within 30 days of a material change in their *Financial Interests*. The initial disclosure must occur prior to participating in research. The Research COI Program will review all disclosures and determine whether any of the *Financial Interests* that are *SFIs* constitute a *COI* or a *PHS*-Reportable *FCOI*. This *Disclosure* is in addition to any disclosure requirements of the IACUC, IRB or other Sanford policies.

### **Protection from Discovery**

The Research COI Committee, in administering its responsibilities as described in this policy and its appendices, is a peer review committee entitled to protections from discovery in legal proceedings afforded by applicable state law. A Summary Report is prepared for public disclosure and is not intended to be protected from discovery.

### **Coordination with IRB, IACUC and Commercialization Office**

Neither the IRB nor the IACUC may approve *Participation in Research* that has been disapproved by the Research COI Program. Neither the IRB nor the IACUC may approve monitoring procedures or other conditions that are less protective than those imposed by the Research COI Program. No authorization granted by the Research COI Program may supersede the authority of either the IRB or IACUC. The IRB or IACUC may impose more stringent restrictions upon *Research* than those imposed by the Research COI Program. The IRB or IACUC may disapprove *Research* despite a determination by the Research COI Program that *Compelling Circumstances* exist.

The IRB, IACUC and/or Commercialization shall notify the Research COI Program whenever a *Covered Individual* known to have a *SFI* proposes to conduct *SFI*-related *Research* or commercialization of intellectual property without attesting that the interest has been reviewed under this policy.

### **Failure to Comply**

Failure to comply with the provisions of this Policy may result in loss of research privileges or disciplinary action up to and including termination from employment in accordance with applicable Sanford policies and procedures. Failure to comply with this Policy includes but is not limited to failing to file a *Disclosure* form, knowingly filing an incomplete, erroneous, or misleading *Disclosure* form, and/or non-compliance with prescribed monitoring procedures or *Management Plan*.

### **Retrospective Review and Mitigation Reports**

Whenever the Research COI Program becomes aware of a *PHS-Reportable FCOI* that was not timely disclosed or was not timely identified while *Research* was ongoing, the *Investigator* would be allowed to participate in the research only pursuant to a *PHS-Reportable Management Plan*. In the case of such noncompliance involving *PHS-funded Research*, the Research COI Program will have a *PHS-Reportable Management Plan* in place within 60 days of the disclosure of the *SFI*.

In addition, within 120 days of the finding of such noncompliance, or a finding of noncompliance with a *PHS-Reportable Management Plan*, the Research COI Program will complete and document 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. If bias is found, the Research COI Program will provide the required notification and mitigation report to the *PHS Awarding Component*.

In the cases of such noncompliance involving non- *PHS-funded Research*, the parameters of the retrospective reviews will be determined on a case-by-case basis at the discretion of the Research COI Program.

### **Public Accessibility**

This policy shall be provided to the public via Sanford's public web site, and any future revisions will be posted on the website within 30 days of approval. For *PHS-funded Research*, the Research COI Program will make available via a written response within five business days of the receipt of a request for information concerning any *PHS-Reportable FCOI* with respect to *Senior/Key Personnel* identified by the *Institution*. Written requests must specifically name the individual for which the information is requested.

## **Disclosures to the Scientific Community**

Compensation of any amount from a research sponsor or other *Financially Interested Company* (any entity with financial interests that would reasonably appear to affect or be affected by the conduct or outcome of the research) as well as the existence of a *Conflict of Interest* or PHS-Reportable *Financial Conflict of Interest* in research, must be disclosed as follows and as applicable:

- in or with a manuscript submitted for publication;
- in any substantive public presentation of the research results;
- in or with any medical or public presentation that references products of the sponsor or other *Financially Interested Company* used in the research;
- to research funders or sponsors;
- to the government as required by law; and
- to the principal investigator, co-investigators, collaborators, and other research personnel working on the research project.

For human subjects *Research*, disclosures are also required:

- in IRB-approved consent forms, as required by the IRB, with an explanation that additional information would be provided to the research subjects upon request;
- to the sponsor of multi-center trials; and
- to the IRBs of the other participating institutions.

## **Training**

Pursuant to Federal conflict of interest regulations, the Research COI Program will provide *COI* training to *Investigators* on PHS-funded *Research* projects. *Investigators* on PHS-funded *Research* projects will undergo training prior to engaging in *Research* and at least every four years thereafter, and immediately (at the next available training session) whenever: there is a change to Sanford policy; the *Investigator* is new to Sanford; or the *Investigator* is found to be not in compliance with Sanford policy, *Management Plan* or PHS-Reportable *Management Plan*. *COI* training will be provided to other *Investigators* as deemed appropriate by the Research COI Program.

## **Donating to Charities Part or All of Honoraria or Consulting Compensation, Royalties and Other Revenues from Commercialization Received from Non-Sanford Entities**

The potential of a *SFI* to create either a *COI* or PHS-Reportable *FCOI*, is not eliminated by donating honoraria or consulting compensation or royalties and other revenues from commercialization received from non-Sanford entities to a charity designated by the individual with the *SFI*.