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.