**POLICY**

It is the policy of the Upstate Carolina NCORP (UC-NCORP) to adhere to the NIH Policy Guidance on Financial Conflict of Interest.

**DEFINITIONS**

A financial conflict of interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

**GUIDELINES**

*4.1.10 Financial Conflict of Interest*

*NIH requires recipients and investigators (except Phase I SBIR/STTR applicants and recipients) to com-ply with the requirements of 42 CFR 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought.” A Final Rule amending the 1995 PHS regulation (and the companion regulation at 45 CFR 94, “Responsible Prospective Contractors,” imposing similar requirements for research contracts) was published on August 25, 2011 in the Federal Register (*[*http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf*](http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf)*).*

*The requirements under the 2011 revised regulation promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator, defined as the PD/PI and any other person, regardless of title or position, who 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. These requirements do not apply to Federal employees or Federal agencies. Federal agencies have their own set of rules governing financial conflicts of interest for employees. When submitting a grant application, the signature of the AOR certifies the applicant Institution’s compliance with the requirements of 42 CFR 50, Subpart F, including that:*

1. *There is in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which NIH funding is sought or received;*
2. *The Institution shall promote and enforce Investigator compliance with the regulation’s requirements including those pertaining to disclosure of Significant Financial Interests;*
3. *The Institution shall identify and manage FCOIs and provide initial and ongoing FCOI reports to the NIH consistent with this subpart;*
4. *When requested, the Institution will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution’s review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution’s determination of an FCOI;*
5. *The Institution shall fully comply with the requirements of the regulation.*

*When the Institution determines that an FCOI exists (see #3 above), the Institution must report to the NIH awarding IC through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module. The initial FCOI report will include the following information:*

* *Grant number and PD/PI or Contact PD/PI if the grant is awarded under the multiple PI model;*
* *Name of Investigator (if different from the PD/PI) with the FCOI;*
* *Name of the entity with which the Investigator has an FCOI;*
* *Nature of the FCOI (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel);*
* *Value of the financial interest $0-4,999; $5,000-9,999; $10,000-19,999; amounts between $20,000-100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000 or a statement that a value cannot be readily determined;*
* *A description how the financial interest relates to the NIH-funded research and the basis for the Institution’s determination that the financial interest conflicts with such research; and*
* *Key elements of the Institution’s management plan, including: 1.*
1. *Role and principal duties of the conflicted Investigator in the research project;*
2. *Conditions of the management plan;*
3. *How the management plan is designed to safeguard objectivity in the research project;*
4. *Confirmation of the Investigator’s agreement to the management plan;*
5. *How the management plan will be monitored to ensure Investigator compliance; and*
6. *Other information as needed.*

*The annual FCOI report must be submitted to the NIH through the eRA Commons FCOI Module each year within a competitive segment or until the Institution reports that the FCOI no longer exists. The annual FCOI report will include the following information:*

* *Status of the FCOI*
* *Changes to the management plan, if applicable*

*The Institution will incorporate, as part of a written agreement with a subrecipient, terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must report identified Financial Conflicts of Interest to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the NIH to meet its reporting obligations. (See Consortium Agreements, 15.2.1 Written Agreement.)*

*The Institution will make certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the regulation.*

*Each Institution shall maintain and up-to-date, written, enforced policy on financial conflicts of interest that complies with the regulation, and make the policy available via a publicly accessible Web site.*

*The Institution will require each Investigator (including subrecipient Investigators, if applicable) to complete training prior to engaging in NIH-supported research and at least every four years, and immediately under the designated circumstances:*

* *Institutional FCOI policies change in a manner that affects Investigator requirements*
* *An Investigator is new to an Institution*
* *An Institution finds an Investigator noncompliant with the Institution’s FCOI policy or management plan.*

*As described in the regulation, examples of how FCOIs might be addressed include but are not limited to, the following:*

*Public disclosure of FCOI (e.g., when presenting or publishing the research);*

* *Disclosure of FCOI directly to human subjects research participants;*
* *Monitoring of research by independent reviewer(s);*
* *Modification of the research plan;*
* *Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research*
* *Reduction or elimination of Significant Financial Interests (e.g., sale of an equity interest)*
* *Severance of relationships that create financial conflicts.*

*The information above is only a sample of the regulatory requirements found in 42 CFR 50, Subpart F. Applicants and recipients must review the regulation in its entirety to ensure compliance with all of the requirements. Resources applicable to FCOI, including Frequently Asked Questions, etc. can be found on OER's Conflict of Interest Web site at* [*http://grants.nih.gov/grants/policy/coi/index.htm*](http://grants.nih.gov/grants/policy/coi/index.htm)*.*

*4.1.30 Standards of Conduct*

*The recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the IC CGMO if the infraction is related to an NIH award*

**REFERENCES:**

**ASSOCIATED FORMS:**

NA

**COMMITTEE APPROVAL:**

Policy and Procedure Committee