



POLICY TITLE
Research Financial Conflict of Interest (FCOI) Policy

POLICY NUMBER
11-004

Responsible Unit: <i>Office of Research, Strategic Initiatives & Economic Development</i>	Effective Date: <i>06/30/2021</i>
Responsible Official: <i>Vice Chancellor for Research, Strategic Initiatives & Economic Development</i>	Last Reviewed Date:
Policy Classification: <i>Research Expenditures & Sponsored Funds Administration</i>	Origination Date: <i>04/26/2021</i>

I. POLICY STATEMENT AND RATIONALE

The purpose of the Research Financial Conflict of Interest Policy is to demonstrate that Southern University and A&M College (SU) promotes objectivity in all externally funded research by establishing guidelines to recognize and address any potential, actual, and apparent **financial conflicts of interest (FCOI)** and authorizes the Southern University Research Council (SURC) to implement this policy and review any infractions, whether directly or through the creation of an appropriate SURC subcommittee. If an employee of Southern University and A&M College (SU) has an outside economic interest that can/may affect the conduct of their SU institutional duties, a **financial conflict of interest** exists that may threaten the objectivity and integrity of research. Consideration must be given to determine if and when these outside economic interests may bias, or have the appearance of biasing the design, conduct, or reporting of externally funded research. The objectivity of researchers is essential in scientific research for the maintenance of the public trust, and the health and safety of those relying on the integrity of research results.

II. POLICY SCOPE AND AUDIENCE

This policy governs the disclosure of individual's *significant financial interests* and the management and reporting of an individual's *financial conflict of interest* in research performed at SU and implements the federal regulations promulgated by the Public Health Service (PHS) of the US Department of Health and Human Services (DHHS), as well as those adopted by the National Science Foundation (NSF) [42 CFR Part 50; 45 CFR Part 94; NSF 20-1: National Science Foundation Proposal and Awards Policies and Procedures Guide].

This policy applies to all individuals engaged in externally funded/sponsored research who, regardless of title or position, are responsible for the design, conduct, or reporting of the funded research, including but not limited to principal investigators, co-investigator/co-principal investigators, project directors, and/or senior research personnel.

- **Principal Investigator (PI)** – the individual (project leader) designated by the proposer (institution), and approved by the external funding agency, who will be responsible for the scientific or technical direction and outcomes of the project.
- **Co-Investigator (Co-I/Co-PI)** – the individual(s) jointly responsible for scientific or technical activity and submission of the requisite project reports and designated as such by the proposer (institution) and approved by the external funding agency.
- **Project Director (PD)** – the individual designated by the proposer (institution) and approved by the external funding agency, who will be responsible for the fiscal management of the project’s activities. *Note: In some instances (depending upon the funding agency, the terms Principal Investigator and Project Director are interchangeable as is the case with the National Institutes of Health (NIH). Project leads are termed PDs).*
- **Senior Research Personnel (SRP)** – an individual other than the PI, Co-I/Co-PI, and PD considered by the performing institution to be a member of its faculty (or equivalent) or who holds an appointment as a faculty member at another institution, who will participate in the project activity.

Individuals and offices responsible for affecting this policy include:

- **Office of Sponsored Programs (OSP)** – reviews all faculty submitted declaration of financial conflict of interest to determine if there may be conflict. Any notification of faculty impropriety or financial conflict of interest from the funding agency or the SUS must also be reviewed. Approves project submission/activity and forwards the endorsed activity to the COI Committee for review and then to the VC for ORSI-ED for final approval (prior to funding by agency and/or after notification of FCOI).
- **Southern University Research Council (SURC)** – reviews all declarations of financial conflict of interest forms prior to the VC’s signature and advises the Authorized Institutional Official for all sponsored program activity and on any FCOI matters.
- **Vice Chancellor for ORSI-ED** – is the Authorized Institutional Official for research and sponsored projects and reviews all approved declarations of FCOI and provides final approval to only those requests that 1) meet the guidelines of the funding agency and/or 2) have exceptional circumstances and potential benefits that are compelling and well-justified.
- **Chancellor of SU (Baton Rouge Campus Only)** - has final authority over all declarations of FCOIs and can override a decision made by any supervisor in the initiate’s (PI, Co-I/Co-PI, PD, SRP) chain of command to deny said declaration.

III. POLICY COMPLIANCE

Compliance with this policy ensures that the faculty and staff adhere to the general federal regulations and cost accounting practices as stipulated in the Office of Management and Budget Cost Principles for Educational Institutions OMB Circular A-21 (**2 CFR Part 220**) as well as agency stipulated regulations (**42 CFR Part 50; 45 CFR Part 94; NSF 20-1: National Science Foundation Proposal and Awards Policies and Procedures Guide**).

IV. POLICY DEFINITIONS

- **Southern University Research Council (SURC)** - the Institution's council and/or subcommittee or individual that advises the Institutional Official on Financial Conflict of Interest matters. Its membership includes thirteen representatives placed as follows:
 - one dean appointee from each college;
 - one representative from the Faculty Senate;
 - the dean of the Graduate School (or appointee);
 - one representative each from OSP, OSPA, the library, and the Center for International Studies; and
 - the IRB Chair.
- **Entity** - any domestic or foreign, public or private, organization (excluding a federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.
- **Family** - any member of the Investigator's immediate family, specifically, any dependent children and spouse.
- **Financial Conflict of Interest** - a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of externally funded research.
- **Authorized Institutional Official** - the individual within the Institution who is responsible for the solicitation and review of disclosures of significant financial interests related to research and sponsored programs including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this Policy, the Authorized Institutional Official is designated as the Vice Chancellor for Research, Strategic Initiatives & Economic Development (VC ORSI-ED) or their designee.
- **Investigator** - the project director, principal Investigator, co-investigator, and any other individual, regardless of title or position, who is responsible for the design, conduct, or reporting of externally funded research, or proposals for such funding.
- **Investigator's Institutional Responsibilities** - the Investigator's responsibilities associated with their Institutional appointment or position, such as research, research consultation, teaching, clinical activities, administration, internal professional

committee service such as a committee membership in Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), and external professional committee service.

- **Significant Financial Interest**

1) a financial interest of the Investigator and their Family that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- A. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds **\$5,000**;
- B. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds **\$5,000**;
- C. if with a non-publicly traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or
- D. is income related to intellectual property rights and interests not reimbursed through the Institution.

2) also includes any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator 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 U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

3) does **NOT** include:

- A. salary, royalties, or other remuneration from the Institution;
- B. income from the authorship of academic or scholarly works;
- C. income from seminars, lectures, teaching engagements, advisory committees or review panels sponsored by or from U.S. federal, state, or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- D. equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

- **Research** - a systematic investigation, study, or experiment designed to contribute to generalizable knowledge. The term encompasses basic and applied research, product development, and educational activities.

V. **POLICY IMPLEMENTATION PROCEDURES**

A. When to Disclose a Financial Conflict of Interest

1. Time of Application

Prior to submitting an application for proposal, investigators must have submitted a Financial Conflict of Interest Declaration. Investigators shall further certify that the proposed project conforms to this policy. Investigators must also sign an acknowledgement of their obligation for annual and ad hoc disclosure at this time. All forms are attached hereto.

2. Annual Disclosure

Investigators with active external funding shall submit an updated Significant Financial Interests Disclosure Report on an annual basis.

3. Ad Hoc Disclosure

Within **30 days** of acquiring or discovering a new Significant Financial Interest, the investigator shall submit an updated Significant Financial Interests Disclosure.

4. Additional Sponsor Requirements

For all externally funded sponsored projects, disclosure shall be in accordance with sponsor requirements if they are more restrictive than this policy.

B. Review, Determination and Management of Financial Conflict of Interest

1. Review and Determination

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Authorized Institutional Official for a determination of whether it constitutes a Financial Conflict of Interest. The Authorized Institutional Official may refer any disclosure of significant financial interest to the SURC for review, consultation, and guidance in specific or complex cases, or the application of the policy to a particular situation. Examples of SURC referrals would be any conflict reported to the OSP by a colleague or funding agency, any unclear but disclosed significant financial interest related to an intended project, department, college, or principal investigator.

A Financial Conflict of Interest will exist when the Authorized Institutional Official determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of externally funded research.

2. Management

If the Authorized Institutional Official determines that there is a Financial Conflict of Interest, they must require and approve a written management plan before any related research goes forward or any funds can be expended. The affected Investigator or the SURC Committee, as appropriate, is responsible for developing and submitting a proposed management plan for approval by the Institutional Official.

A management plan may impose any condition and prescribe any action necessary to manage a Financial Conflict of Interest, including an action reducing or eliminating the Financial Conflict of Interest, *to ensure that the design, conduct, reporting of, and any product resulting from the research is free from bias or the appearance of bias*. Examples of conditions or actions that may be prescribed include, but are in no way limited to:

- a) public disclosure of the conflict of interest in presentations and publications;
- b) for human subjects' research, direct disclosure of the conflict of interest to research participants;
- c) appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;
- d) modification of the research plan;
- e) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) divestiture or reduction of the newly proposed financial interest; or
- g) severance of relationships that create an actual or potential Financial Conflict of Interest.

The management plan must be in the form of a written agreement and must provide that the Investigator acknowledges receipt of the approved plan and understands the requirements of this Policy and the required actions and other terms of the plan.

3. Reporting

Should any Financial Conflict of Interests or non-compliance require reporting to funding agencies which require such disclosure and reporting, the Office of Sponsored Programs (OSP), in consultation with the Authorized Institutional Official or the SURC Committee, will report as required by the funding agency.

- a) The SU Authorized Institutional Official to submit an FCOI report within **sixty (60) days** after the determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing

Investigator who discloses a new Significant Financial Interest to the OSP during the period of award.

- b) Whenever an Investigator does not disclose timely a previously existing Significant Financial Interest or the OSP fails to review a previously existing Significant Financial Interest during an ongoing externally funded project, SU's Authorized Institutional Official shall, within **sixty (60) days**: review the Significant Financial Interest; determine whether it is related to the externally funded research; determine whether a Financial Conflict of Interest exists. If so, the OSP must implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such Financial Conflict of Interest going forward and submit an FCOI report to the funding agency.

In addition to the FCOI report, the OSP must, within **120 days** of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's research activities and the externally funded research project to determine whether any externally funded research, or portion thereof, conducted during the period of the noncompliance, was biased in the design, conduct or reporting of such research.

4. Non-Compliance

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Authorized Institutional Official may suspend all relevant externally funded activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Authorized Institutional Official is implemented.

The Authorized Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Authorized Institutional Official, will be described in a written explanation of the decision to the Investigator or the SURC, as applicable, and will notify the individual of the right to appeal to the SURC regarding the decision.

b) Retrospective Review

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
- Failure by the Institution to review or manage such a Financial Conflict of Interest; or

- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

the OSP shall, within **120 days** of determination of noncompliance, complete a “retrospective review” of the Investigator’s activities and the externally funded research project to determine whether any externally funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

The OSP shall document the retrospective review which must include at least the following:

- If bias is found, *the OSP must notify the funding agency promptly and submit a mitigation report.* If the FCOI was previously reported to the funding agency, the mitigation report is submitted as a “Revised FCOI Report.”
- The mitigation report must include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the OSP’s plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the OSP will submit FCOI reports annually as prescribed by the regulation.
- If no bias is found, no action need be taken.

5. Training Required in Conflicts of Interest

Each Investigator must complete training with the OSP and will be provided with an electronic certificate of completion of training on this Policy prior to engaging in research as required by the funding agency. For projects funded by the PHS, specialized training through its institutions is required and must be renewed at least every four years thereafter. Investigators will be required to pay this cost upfront and, if allowable, can be reimbursed through the agency’s funding apparatus. Investigators must also complete training within a reasonable period as determined by the Authorized Institutional Official or prior to the submission of an Annual or Ad Hoc disclosure in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, when an investigator is new to the institution, or if it is determined that the Investigator has not complied with this Policy or with a management plan related to their activities. The Office of Sponsored Programs (OSP), in consultation with the Authorized Institutional Official, is responsible for ensuring that each Investigator, as defined herein, completes training as required under this Policy.

6. Record Retention

The Authorized Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of **three years** from the date the final expenditure report is submitted to the funding agency, the date of final resolution of any investigation, audit, or similar action involving the records, or as specifically required by the funding agency, whichever is later.

7. Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available when required by law, mandated by funding agency, or determined to carry out the purpose and administration of this policy. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

8. Public Accessibility

a) Public Accessibility Required by PHS

Institution shall make this Policy available via a publicly accessible website. Institution will respond to any requestor of public records in accordance with **LSA R.S. 44:1**, et seq., other federal and state laws, and its internal policies within **ten (10) business days** (excluding holidays and other official university breaks) of the official receipt of request concerning any Significant Financial Interests held by Investigators. Information on how to make a request can be found at the following link: <https://www.sus.edu/page/how-to-request-a-public-record-from-the-southern-university-system>. Considerations regarding requests will include the following criteria:

- i. The Significant Financial Interest was disclosed and is still held by the Investigator;
- ii. A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- iii. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.
- iv. The information to be made publicly available shall be consistent with the requirements of the PHS policy.
- v. If the Institution uses a publicly accessible Web site for making the information publicly accessible, the information shall be updated at least annually. In addition, the Institution shall update the Web site within **sixty (60) days** of the Institution's receipt or identification of information concerning any additional Significant Financial Interests of the senior/key personnel for the

externally funded research project that was not previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel; or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the NIH-funded research, if the Institution determines that the Significant Financial Interest is related to the NIH-funded research and is a Financial Conflict of Interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within **60 days** of the Institution's identification of a new Financial Conflict of Interest. If the Institution responds to written requests, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within **60 days** of the Institution's identification of a new Financial Conflict of Interest, which should be requested subsequently by the requestor.

b) Public Accessibility Required by Other Agencies

Should any other funding agency require public accessibility of Financial Conflict of Interests, the Institution shall provide such public access as required.

9. Subrecipients

If externally funded research involves a subrecipient, the Institution will take reasonable steps to ensure that any subrecipient investigator complies with the funding agency's Financial Conflict of Interest policy by:

- a) Establishing in writing with the subrecipient whether this Policy or the subrecipient's Financial Conflict Interest policy will apply to the subrecipient's Investigators.
- b) Requiring Financial Conflict of Interest reports regarding all identified Financial Conflict of Interests of all subrecipient Investigators be provided to Institution for reporting to funding agency as applicable.

10. Retrospective Review

- a) Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:
 - Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
 - Failure by the Institution to review or manage such a Financial Conflict of Interest; or

- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

the Institution shall, within **120 days** of the Institution’s determination of noncompliance, complete a “retrospective review” of the Investigator’s activities and the externally funded research project to determine whether any externally funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

b) The Institution shall document the retrospective review which must include at least the following:

- If bias is found, the Institution must notify the funding agency promptly and submit a mitigation report. If the FCOI was previously reported to the funding agency, the mitigation report is submitted as a “Revised FCOI Report.”
- The mitigation report must include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution’s plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation.
- If no bias is found, no action need be taken.

VI. POLICY RELATED INFORMATION

2 CFR Part 220 of the OMB Circular A-21 establishes principles for determining costs applicable to grants, contracts, and other agreements with educational institutions (<https://www.govinfo.gov/content/pkg/CFR-2012-title2-vol1/pdf/CFR-2012-title2-vol1-part220.pdf>).

The 2 CFR Part 220 is the basis for the fiscal management for all SU sponsored grants activity.

The following documents provided background information and guidance for the SU Research Financial Conflict of Interest Policy:

Public Health Service (PHS) of the US Department of Health and Human Services (HHS), (42 CFR Part 50; 45 CFR Part 94)

<https://www.govinfo.gov/content/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

National Science Foundation Proposal and Awards Policy and Procedures Guide.

https://www.nsf.gov/pubs/policydocs/pappg20_1/nsf20_1.pdf

Federal Demonstration Partnership (FDP) Model Financial Conflict of Interest Policy
http://thefdp.org/default/assets/File/Documents/fdp_model_coi_policy.docx

Southern University may utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at <http://grants.nih.gov/grants/policy/coi/> to satisfy some of the training requirements as required by this policy and that of NIH and other funding agencies.

VII. POLICY HISTORY AND REVIEW CYCLE

This is a new policy and is subject to the Board approved five-year review cycle at the latest.

Internally, the policy shall be revisited every two years by staff in the ORSI and Office of Sponsored Programs in consultation with the Southern University Research Council (SURC) and will include representation from the following offices:

- a. Academic Affairs or any Dean/Center Director;
- b. Budget Office;
- c. SPADCO, hereby charged with providing to the SURC all amendments/revisions to the 2 CFR Part 220 and other applicable federal and state regulations;
- d. Faculty Researchers;
- e. Faculty Senate;
- f. Office of Research, Strategic Initiatives and Economic Development, hereby charged with providing the SURC with trends and policies at other institutions; and
- g. Human Resources (HR), hereby charged with providing to the SURC all applicable state laws and regulations, particularly as they pertain to the Louisiana Code of Government Ethics and Classified Employees;

VIII. POLICY URL

Effective upon Board approval and final signature, this Research Financial Conflict of Interest Policy, the Financial Conflict of Interest Declaration form, and the Financial Conflict of Interest Significant Financial Interests Disclosure and Reporting form will be retroactive to April 1, 2021 and maintained in the ORSI-ED office as well as posted on www.subr.edu/ORSI and www.sus.edu

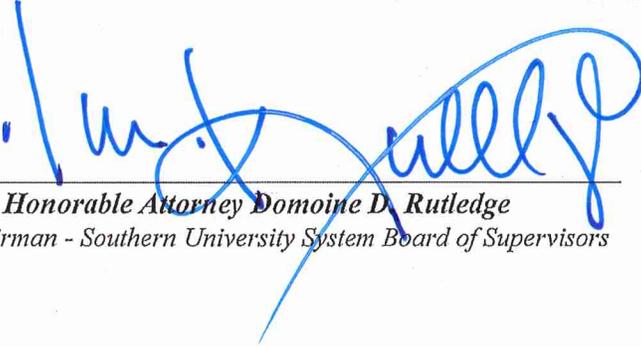
IX. POLICY APPROVAL

This section identifies the appropriate approval official(s).



Ray L. Belton, Ph.D.
President-Chancellor, Southern University and A&M College System

Effective Date of Policy



The Honorable Attorney Domoine D. Rutledge
Chairman - Southern University System Board of Supervisors

Effective Date of Policy