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**CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT POLICY
FOR RESEARCH FUNDED BY THE UNITED STATES PUBLIC HEALTH SERVICE**

Effective on August 24, 2012

Section 1. Scope

This policy applies to all **employees of SOUTHERN RESEARCH INSTITUTE (hereinafter referred to as “Southern Research”)** who propose to perform or engage in performance under any **United States Public Health Service funding instrument**. Certain **employees** and other individuals who engage in **research** on behalf of Southern Research, identified by this policy as **designated individuals**, have additional requirements for **disclosing financial interests**.

Section 2. Background

Southern Research is committed to conducting its activities in ways that promote and maintain public trust. Southern Research encourages professional interactions, activities, and development that enhance an **employee's** value to Southern Research; that enhance Southern Research's presence in the local, national, or international communities; and that provide public service. Nonetheless, in the complex operating environment of a nonprofit research entity, these opportunities may also present potential for, or appearance of, conflicting loyalties and responsibilities. The purpose of this policy is to implement the goals of the Southern Research *Code of Business Conduct and Ethics* and to provide guidelines to protect Southern Research, its **employees**, and the public.

Southern Research has entered into an agreement with its affiliate, The University of Alabama at Birmingham (hereinafter “UAB”), under which the UAB Conflict of Interest Review Board (hereinafter “CIRB”) will work with Southern Research to ensure compliance with federal regulations related to financial conflict of interest.. The CIRB will review the financial disclosures made by Southern Research employees to identify potential or actual conflict of interests and take such actions as agreed to in the contract between Southern Research and the CIRB. The CIRB will also review pertinent sections of grant applications and contract proposals prior to submission to PHS funding agencies.

Section 3. General Principles

The Southern Research Code of Business Conduct and Ethics requires **employees** to be aware of the potential for **conflicts of interest** and **conflicts of commitment** and to exercise initiative to identify, review, and manage those conflicts appropriately. All **employees** are expected to comply with this policy, as well as any other applicable policies or procedures adopted by Southern Research.

Section 4. Definitions

The following defined terms are used for purposes of administering this policy but may be defined differently elsewhere in other Southern Research policies and materials.

Conflict of interest - a circumstance in which an individual's financial, professional, or personal interests affect, or have the appearance of affecting, judgment in exercising a duty or responsibility owed to Southern Research. **Financial conflict of interest related to the design, conduct, or reporting of research** is defined separately below.

Conflict of commitment - a circumstance in which an employee's engagement in external or internal activities compromises the ability to carry out his/her primary obligations and commitments to Southern Research. Because conflicts **of commitment** generally arise from allocation of time, the primary commitment of **employees'** time should be toward their **institutional responsibilities**, as defined below.

Designated individual - any individual, regardless of position, title, or employment, who is:

- **responsible for the design, conduct, or reporting of research** (also defined here as an **investigator**); and/or
- otherwise designated as such by Southern Research based upon the individual's role or responsibility.

Dependent - any individual, regardless of his or her legal residence or domicile, who receives 50% or more of his or her support from a **designated individual** or his/her spouse or who resided with the **designated individual** or his/her spouse for more than 180 days during a calendar year.

Employee - an individual who receives a W-2 from Southern Research as a regular or temporary full-time employee, regular or temporary part-time employee. (For purposes of this policy, individuals receiving a W-2 as a student assistant, federal work study, or graduate assistant are not included as **employees**, although they may be considered **designated individuals** if they are deemed **responsible for the design, conduct, or reporting of research.**)

Entity- a company, association, organization, institution, or any other type of entity with a separate legal identity, including a for-profit, not-for-profit, or an organization of higher education. For purposes of reporting **financial interests** under this policy, it also includes an individual.

External activities - activities that draw upon the knowledge, skill, or abilities an **employee** uses to fulfill his or her **institutional responsibilities** at Southern Research and that are performed for an **entity**

outside Southern Research, whether or not for compensation. Examples of external **activities** include, but are not limited to, the following:

- external employment, including moonlighting and/or *locum tenens* activities;
- consulting;
- lecturing, presenting, or speaking;
- establishing and/or supporting a start-up company;
- serving as an expert witness;
- participating in a board of directors; or
- participating in a scientific advisory board.

Financial conflict of interest - a reasonable determination made by the UAB CIRB and/or Conflict of Interest Office that an investigator's significant financial interest is related to and could significantly and directly affect the design, conduct, or reporting of research.

Financial interests - anything of monetary value accepted or owned by an **individual**, his/her spouse, or his/her **dependents**, not held in an investment vehicle such as a mutual fund or retirement account in which the owner does not directly control investment decisions, whether or not the value is readily ascertainable. Examples of **financial interests** include, but are not limited to:

- remuneration for participation in **external activities** (e.g., salary, consulting and other fees, gifts, honoraria, etc.);
- acquisition or ownership of stock, shares, or other types of equity interests;
- options to acquire stock, shares, or other types of equity interests;
- income arising from stock, shares and other types of equity interests;
- income from royalties;
- licensed, optioned, or revenue-bearing intellectual property;
- acquisition of a license of Southern Research or other intellectual property; or
- sponsored or reimbursed travel.

Institutional responsibilities - all activities, duties, and responsibilities performed by an employee in the course of his/her employment or other relationship with Southern Research, including but not limited to **research**, research consultation, administration, contracting or procurement responsibilities, or **professional public service activities**.

Internal activities - activities that draw upon the knowledge, skill, or abilities an **employee** uses to fulfill his or her **institutional responsibilities** at Southern Research.

Investigator/Responsible personnel - any individual, regardless of title, position, or employment, who is **responsible for the design, conduct, or reporting of** proposed or active **research**. An **investigator** is also a **designated individual**.

Professional Public Service Activities - activities listed below that are performed outside Southern Research and are considered part of an **employee's institutional responsibilities**, whether or not separately compensated:

- seminars, lectures, service on advisory committees or boards of directors, or review panels for US federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical centers or research institutes;
- professional studies, services, participation on boards of directors, or participation in manuscript review, grant/contract review, or academic program review for nonprofit/philanthropic entities, professional societies, or professional associations, that are not affiliates of or affiliated with industry or other for-profit entities;
- seminars, presentations, performances, or board service for civic groups; and
- participation on boards of directors.

Research - any activity for which funding is sought and/or received through a grant or cooperative agreement such as a research grant, career development award, center grant, individual fellowship award, contract, infrastructure award (construction, renovation, equipment, etc.) institutional training grant, program project, or research resources award.

Responsible for the design, conduct, or reporting of research - a **designated individual** who is responsible for controlling the **design, conduct, or reporting of research** (also defined here as an **investigator**):

Design - the development of the strategy and means to test a research question or hypothesis.

Conduct - the supervision or management of a study's execution. This is typically done by the principal investigator (PI) and co-investigators, but also may be performed by other project personnel, such as research scientists, postdoctoral fellows, graduate students, or other junior researchers.

Reporting - the authorship of publications or reports that describe the results of the study. Such reports may be to the sponsor of the **research** or to academic or scientific meetings.

Significant financial interest (SFI) - a **financial interest** of an **investigator**, his/her spouse, or his/her **dependents** that reasonably appears to be related to the **investigator's institutional responsibilities**.

- With regard to any publicly-traded entity, a **significant financial interest** exists if the value of the **financial interest** received from the **entity** in the current or prior calendar year, when aggregated, exceeds \$5,000.
- With regard to any non-publicly traded **entity**, a **significant financial interest** exists if:
 - the value of any remuneration received from the **entity** in the current or prior calendar year, when aggregated, exceeds \$5,000; or
 - when the **investigator** (or the **investigator's** spouse or **dependents**) holds equity interest (e.g., stock, stock option, or other ownership interest).
- With regard to intellectual property rights and interests (e.g., patents, copyrights), a **significant financial interest** exists for any intellectual property licensed, optioned, or that has generated income/revenue.
- **Significant financial interest** does NOT include remuneration for **professional public service activities**, textbook royalties, peer reviewed journal editorship activities for publishing companies, or other related items as determined by the CIRB in accordance with federal regulations.

Section 5. Policy Statement

All Southern Research employees subject to this agreement are required to:

- abide by all requirements outlined in this policy;
- use Southern Research resources, including confidential or privileged information, only for Southern Research purposes or as allowed by applicable law and policy;
- seek approval prior to engaging in **external or internal activities** in accordance with this policy;
- notify unit leadership of any **financial interests** that relate to their **institutional responsibilities** in accordance with this policy; and
- adhere to any **conflict of interest or conflict of commitment** management or monitoring plan prescribed by their leadership.

All designated individuals are required to:

- abide by the requirements above; and
- complete formal processes for disclosure of **financial interests** related to their **institutional responsibilities**, as described *Section 5. Policy Statement C Disclosure of Financial Interest* below.

All Vice Presidents, Directors, Managers and other employees responsible for approving requests submitted by those they supervise are required to:

- administer this policy;
- ensure adequate controls are in place to review and approve **external and internal activity** requests submitted by **employees** in their units;
- determine whether requested **external activities** are more properly conducted as official Southern Research activities;
- ensure proper accounting of **employees'** time away for purposes of **external or internal activities**;
- ensure written financial arrangements are in place for payment of the portions of **employees'** salaries attributable to appointments/assignments/work projects performed for other organizations;
- adopt specific procedures or more restrictive standards, if desired for their units.

A. Use of Southern Research Information and Resources

Employees, by accepting employment at Southern Research, make a commitment to Southern Research that includes the appropriate and responsible use of Southern Research information and resources, including facilities, personnel, equipment, patents, copyrights, technology, logos, and work product, as well as Southern Research 's more intangible reputation and prestige. **Employees** must ensure that their use of Southern Research information and resources, their **external and internal activities**, and their **financial interests** do not interfere with, or appear to interfere with, their **institutional responsibilities** (i.e., their primary obligations to Southern Research).

Employees are prohibited from engaging in activities from which they, their families, or their businesses will gain financially or personally because of the **employee's** position at Southern Research or because of the use of Southern Research resources or information. It is the responsibility of the involved **employee** to inform his or her immediate supervisor of any potential or actual use of Southern Research resources or information in the **employee's external activities or financial interests**. If, through the course of the appropriate review, it is determined that such use exceeds thresholds allowed by law and policy, the **employee** will be required to contract with Southern Research or otherwise reimburse Southern Research for the fair market value of the use of the resource or information.

B. External and Internal Activities

External and internal activities are encouraged. However, any perceived, potential, or actual **conflicts of interest or conflicts of commitment** caused by such activities must be administered in accordance with this policy.

Southern Research must ensure that participation in **external and internal activities**:

- does not interfere with the performance of other **institutional responsibilities** as an **employee**;
- is compatible with the interests of Southern Research as a nonprofit institution; and
- does not violate law and policy related to use of Southern Research resources or facilities.

Approval of External and Internal Activities

All **employees** must request and receive pre-approval of **external and internal activities**. The decision whether to approve an **external or internal activity** resides with divisional leadership.

Examples

1. Professional Public Service Activities

The following **external activities** are considered **professional public service activities** but may have to be reported or approved in accordance with Southern Research policies, whether or not compensated. **Investigators** have special disclosure requirements as outlined in Section D.

- seminars, lectures, service on advisory committees or boards of directors, or review panels for US federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical centers or research institutes;
- professional studies, services, participation on boards of directors, or participation in manuscript review, grant/contract review, or academic program review for nonprofit/philanthropic entities, professional societies, or professional associations, that are not affiliates of or affiliated with industry or other for profit entities;
- seminars, presentations, performances, or board service for civic groups; and
- participation on boards of directors with Southern Research affiliated entities.

2. Secondary Appointments/Assignments/Work Projects

A secondary (or otherwise additional) appointment or assignment or other work project with another organization, in which an **employee's** time or effort is shared or which is part of an **employee's** job expectations is not considered an **internal activity**. In these instances, the organization receiving the services must make appropriate financial arrangements for payment and/or distribution of the portion of the **employee's** salary attributable to that appointment, assignment, or other work project.

Considerations

Employees are responsible for ensuring that their **external activities**, and any contracts they sign with external **entities** for their **external activities**, are conducted in accordance with Southern Research policies related to disclosure of discoveries and inventions, patents, and use of computer software. It is

the responsibility of division leadership to exercise judicious oversight and control of **external activities** so that no Southern Research functions or policies are compromised.

Leave for External and Internal Activities

Employees must properly account for time spent on **external and internal activities**. Time away is allowed at the discretion of a staff member's supervisor. Standards for applying leave time, as well as maximum time allowed, for **external and internal activities** must be managed in accordance with applicable human resource policies.

Conflicts of Commitment

All **employees** are expected to devote their primary professional loyalty, time, and energy to their position at Southern Research. Accordingly, **external and internal activities** must not require such extensive absence as to cause the **employee** to neglect **research** or business obligations or become regularly unavailable to colleagues. **External and internal activities** should not create a **conflict of commitment** with the **employee's institutional responsibilities**. It is possible to have a **conflict of commitment** even with an uncompensated activity.

C. Disclosure of Financial Interests

Employees must fulfill their **institutional responsibilities** based on sound professional judgment unimpaired by their personal **financial interests** or relationships. When participating in or influencing an official Southern Research decision (e.g., purchase of equipment, Southern Research contract for service with an external **entity**, approval or administrative control of **research**, etc.), **employees** are required to notify their supervisor of any **financial interests** or personal relationships the **employees**, their spouse, or their **dependents** have that may or may be perceived to influence that decision. Such notification of financial interests should take place prior to any official action, but no forms, other than those described elsewhere in this policy, are required for submission. Based on their notification, appropriate action may be taken to manage the actual, potential, or perceived **conflict of interest** between the **employees' institutional responsibilities** in this regard and their personal **financial interests**, ranging up to recusal from the decision.

In addition to any required approvals related to **external and internal activities**, **designated individuals** are required to submit formal disclosures of **financial interests to the CIRB**. Individuals **responsible for the design conduct, or reporting of research**, also known as **investigators**, must submit the appropriate **UAB Electronic Form**, which will be processed through the CIRB as described below in *Section 5. Policy Statement D. Research*.

D. Research

Southern Research is committed to promoting objectivity in **research**. The aim of this policy is to provide an expectation that the **design, conduct, and reporting of research** will be free from bias resulting from **financial interests** held by **investigators**. All **investigators** are expected to comply with any applicable laws, regulations, and Southern Research policies pertaining to financial **conflicts of interest**. This

includes but is not limited to the timely disclosure of **financial interests**, completing requisite training, and, as applicable, compliance with the CIRB rules and management plans.

For all projects seeking or receiving extramural funding from any department of the United States Public Health Service (including any grant/contract application or proposal processed by Southern Research, participating Southern Research **Investigators** are expected to comply with Southern Research Policy, CIRB rules, and the NIH rule "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors" (**42 CFR Part 50 and 45 CFR part 94**). Each **investigator** is required to disclose to the CIRB all **financial interests** related to his/her **institutional responsibilities** that are owned or held by him/her, his/her spouse, or his/her **dependents** prior to the application or proposal for research and within 30 days of discovering or acquiring new **financial interests**. **Investigators must** update any such disclosed financial interests not less than annually while involved in **research**.

Investigators' disclosures must include any **financial interest** exceeding \$5,000 acquired from any one entity in the previous 12 months for their participation in the following **professional public service activities**:

- professional studies, services, participation on boards of directors, or participation in manuscript review, grant/contract review, or academic program review for nonprofit/philanthropic entities, professional societies, or professional associations, that are not affiliates of or affiliated with. industry or other for profit entities; and
- seminars, presentations, performances, or board service for civic groups.

The CIRB considers **Investigators'** approved **external activities** to be a disclosure of **financial interest** when the amount of remuneration from any activity or multiple activities for any one **entity** in the current and prior calendar year reaches the **significant financial interest** thresholds defined in Section 4.

The CIRB is responsible for identifying and reviewing **significant financial interests** for the current and past calendar year to determine if any such interests are financial **conflicts of interest** related to **research**. The CIRB must manage and Southern Research must report to the Public Health Service awarding agency as required any identified **financial conflict of interest**. Management of an identified financial conflict of interest requires development and implementation of a management plan, which may include but is not limited to reducing or eliminating the conflict of interest. The CIRB must also conduct non-compliance reviews and institute corrective actions as indicated. The CIRB must review significant financial interests related to the research of external consultants, subgrantees, and subcontractors that do not have policies meeting **NIH regulations**.

Section 6. Disciplinary Action

Violations of this policy are grounds for disciplinary action up to, and including, discharge.

Section 7. Implementation

The Ethics Officer, Chief Financial Officer and Chief Executive Officer of Southern Research are responsible for overall implementation of this policy. The Vice Presidents of the divisions where any PHS work is proposed or performed are responsible for the development and enforcement of procedures to implement the portions of this policy related to **research**.
