

## **IRB Policy on Research Conflict of Interest and Financial Disclosure Policy**

### **Guideline Statement of Purpose**

The purpose of the policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from financial conflicts of interest.

This policy establishes guidelines to assist investigators in managing external professional activities or relationships so as not to interfere with their primary duties to the college nor compromise the educational interests of college students with whom they work.

It is not the intent of this policy to eliminate or prohibit all situations involving potential conflicts of interest. Rather, the policy is intended to enable investigators to recognize situations that may pose a financial conflict of interest, to provide a process for disclosing these situations to the college, and for working with the Southeastern Community College IRB to manage these situations.

The college believes that with clear guidelines and principles, and with appropriate supervision and monitoring, it is possible for interaction between outside entities and the college to take place in a manner that prevents real or perceived bias.

### **Applicability**

This policy applies to all faculty, staff and students at the college.

### **Definitions**

**Investigator** means the project director/principal investigator and any other person regardless of title or position, who, in the course of their association with the college, are or will be responsible for the design, conduct, administration, collaboration, analysis, and/or reporting of research, or proposal for funding, including persons who are subcontractors, collaborators, or consultants.

**Financial Interest** means any financial or other personal involvement of the investigator, his or her spouse, domestic partner, children, parent, or siblings who reside in the same household including, but not limited to:

- income; honoraria or other payment for services;
- reimbursed or sponsored travel for services
- equity such as stock, stock options or other ownership rights, excluding interests of any amount in publicly traded, diversified mutual funds, pension funds, or other institutional investment funds over which the faculty member does not exercise control;
- patents and copyrights;
- contracts, licensing and other agreements;
- royalties (including those royalties distributed by the University);
- employment; and services, relationships or positions, even if uncompensated

**Institutional Responsibilities** means an investigator's professional responsibilities on behalf of the college, including research, consultation, teaching, professional practice, and service.

**Research** means a systematic investigation designed to develop or contribute to generalizable knowledge. It includes basic and applied research. It includes activities sponsored through a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

**Financial Conflict of Interest** means a significant financial interest that could directly and significantly affect the design, conduct or reporting of research. Examples include, but are not limited to, the following:

- a. Investigator (and/or an Investigator's spouse and/or dependent children) entering into a paid consultancy with an outside entity that has an interest in the investigator's college-based research;
- b. Using students or employees of the college to perform services for an outside entity in which an investigator (and/or investigator's spouse and/or dependent children) has an ownership interest or from which he/she receives any remuneration;
- c. Investigator (and/or an investigator's spouse and/or dependent children) receiving royalties or non-royalty payments related to ongoing research;
- d. Investigator (and/or an investigator's spouse and/or dependent children) having an equity interest (e.g., stocks, stock options, warrants) related to ongoing research;
- e. Serving as an officer, director, or in any other fiduciary role for an outside entity that is financially interested in the investigator's college-based research, whether or not remuneration is received for such service.

This policy addresses individual financial conflicts of interest; however, the college may also have conflicts of interest in research whenever the financial interests of the college, or of a college official acting within his or her authority on behalf of the college, might affect—or reasonably appear to affect—college processes for the conduct, review, or oversight of research. If institutional conflicts of interest are identified via the disclosure process described below, they will normally be addressed in a manner that is consistent with this policy.

#### **Investigator Responsibilities**

Investigators are responsible for the following:

- a. Reading and understanding this policy;
- b. Disclosing financial interests to the college by completing appropriate form to accompany submission of the IRB application;
- c. Updating disclosure statements as changes occur, so that the statement on file is current and accurate at all times when an award is pending or in force; and
- d. Complying with any and all provisions and monitoring requirements of plans developed by investigators and college administrators to manage, reduce, or eliminate conflicts of interest.

#### **Disclosure**

Each year an investigator must disclose in writing all financial interests that are relevant to an investigator's institutional research responsibilities or within 30 days after he/she becomes aware of new financial interest or after a financial conflict of interest has been eliminated.

Investigators are required to complete the annual "Research Investigator Financial & Other Personal Interests Disclosure Form" (Appendix I) even if they have no financial interest to report. Disclosure is required at the time a research proposal and protocol is submitted to the college's IRB or an external Institutional Review Board (IRB).

#### **Review**

The IRB Chair conducts an initial review of all IRB applications and accompanying Disclosures. If the existence of financial interest is disclosed, the Chair convenes the IRB for full review. Consideration will be given to the following:

- Impact of the conflict on the integrity of research data;
- Risks to rights and safety of animal and/or human research subjects;
- Risks to the rights of students participating in research; and

- Appearance of conflict of interest.

If a financial conflict of interest is identified, the IRB will determine whether the research can be undertaken with appropriate college management, and the project, with the IRB recommendation, will be referred to the college president or his/her designee to work with the investigator to develop a formal management plan. Compliance with the plan will be monitored by whomever the college president designates.

#### **Record Retention**

The college will maintain records of all financial disclosures and all actions taken by the college with respect to each financial conflict of interest for at least three years after the termination or completion of the award, and in the case of federally funded research, at least three years from the date of submission of the final expenditures report.

#### **Confidentiality**

All information related to the review and management of financial interests is strictly confidential. The information is only made available to the persons within the college charged with the review of an individual case, including the appropriate dean or administrative official.

#### **Enforcement**

Possible violations of this policy will result in termination of IRB approval for the project, and persons involved will be referred to the college president and the director of human relations.

#### **Policy Revisions**

Revision of this policy requires, at minimum, the approval of all current members of the IRB and the director of institutional advancement.

## Appendix I

### RESEARCH INVESTIGATOR FINANCIAL & OTHER PERSONAL INTERESTS DISCLOSURE FORM

#### INSTRUCTIONS AND DEFINITIONS

EACH "investigator," as defined below, on a research project when human subjects are involved must complete his/her section of the Disclosure Form which must then be submitted with the proposal to the SCC IRB. This requirement pertains to both funded and unfunded research.

The term "investigator" means:

- the principal investigator,
- co-principal investigators, co-investigators, and
- any other college personnel who, in the course of their association with the college, are or will be responsible for the design, conduct, administration, collaboration, analysis and/or reporting of either research or training activities funded or proposed for funding by any sponsor, or of unsponsored research or training activities. These persons may include faculty, non-faculty employees, technicians, consultants, graduate and other students.

*(NOTE: If one or more such individuals had not been named at the time of proposal submission, a form or forms must be subsequently completed by the(se) individual(s) and submitted by the principal investigator to the director of*

The term "interest" means any financial or other personal involvement of the investigator, his or her spouse, domestic partner, children, parent, or siblings who reside in the same household including, but not limited to:

- income; honoraria or other payment for services;
- reimbursed or sponsored travel for services
- equity such as stock, stock options or other ownership rights, excluding interests of any amount in publicly traded, diversified mutual funds, pension funds, or other institutional investment funds over which the faculty member does not exercise control;
- patents and copyrights;
- contracts, licensing and other agreements;
- royalties (including those royalties distributed by the University);
- employment; and services, relationships or positions, even if uncompensated.

***If there is a financial or other personal interest requiring disclosure, provide on Part 2 of this form all relevant details about the relationship of the interest to the Investigator's Institutional responsibilities, and sufficient information for the IRB to determine if a conflict of interest exists. Use additional pages if needed. Be as specific as possible.***



**RESEARCH INVESTIGATOR FINANCIAL & OTHER PERSONAL INTERESTS DISCLOSURE FORM - Part 1**

PROJECT TITLE:			
PRINCIPAL INVESTIGATOR:	DEPT:	PHONE:	EMAIL:
FUNDING AGENCY OR SPONSOR:	PROJECT AMOUNT:	START DATE:	
TYPE: <input type="checkbox"/> RESEARCH <input type="checkbox"/> EDUCATION/TRAINING <input type="checkbox"/> SERVICE <input type="checkbox"/> OTHER			

**NOTHING TO DISCLOSE:** CHECK "NO" COLUMN BELOW

**I, and/or my spouse, domestic partner, children, parents, and siblings who reside in the same household do not have any financial or other personal interests (as defined on the next page of this document) to disclose.**

**DISCLOSURE TO BE MADE:** CHECK "YES" COLUMN BELOW and complete Part 2 below.

**I, and/or my spouse, domestic partner, children, parents, and siblings who reside in the same household DO/DOES have financial or other personal interests (as defined on the next page of this document) to disclose.**

*I certify that the information on this form is correct; that I have read and understood the Southeastern Community College Policy on Research Conflict of Interest and Financial Disclosure Policy; that, to the best of my knowledge, all required disclosure of financial and other personal interests have been made herein; that I will complete a Disclosure Form on an annual basis during the duration of the research, or more frequently as new interests are obtained or if my situation with respect to potential conflict of interest otherwise changes since my original disclosure, and submit it to the IRB Chair; that I will comply with any conditions or restrictions imposed by Southeastern Community College to manage, reduce or eliminate conflicts of interest caused by my interests.*

NAME (Print and Sign) (see definition of "investigator" on the reverse side)	NO	YES	DATE
PRINCIPAL INVESTIGATOR: Sign:	<input type="checkbox"/>	<input type="checkbox"/>	
"INVESTIGATOR": Sign:	<input type="checkbox"/>	<input type="checkbox"/>	
"INVESTIGATOR": Sign:	<input type="checkbox"/>	<input type="checkbox"/>	
"INVESTIGATOR": Sign:	<input type="checkbox"/>	<input type="checkbox"/>	
"INVESTIGATOR": Sign:	<input type="checkbox"/>	<input type="checkbox"/>	

USE ADDITIONAL FORM(S) FOR ADDITIONAL INVESTIGATORS.

- This project involves a contract, subcontract or collaboration with an outside institution or group.
- Attached is a written assurance from an appropriate official of this outside entity that individuals from the outside entity who will participate in this project comply with the outside entity's investigator conflict-of-interest policy.
- In the event the outside entity has no investigator conflict-of-interest policy, attached are a written assurance from an appropriate official of this outside entity that individuals from the outside entity who will participate in this project comply with Southeastern Community College's conflict-of-interest and financial disclosure policy, with appropriate forms completed by these individuals.

\_\_\_\_\_  
Signature of IRB Chair

\_\_\_\_\_  
Date



**RESEARCH INVESTIGATOR FINANCIAL & OTHER PERSONAL INTERESTS DISCLOSURE FORM - Part 2**

PROJECT TITLE:			
PRINCIPAL INVESTIGATOR:	DEPT:	PHONE:	EMAIL:
FUNDING AGENCY OR SPONSOR:	PROJECT AMOUNT:	START DATE:	

TYPE:  RESEARCH  EDUCATION/TRAINING  SERVICE  OTHER

NAME OF "INVESTIGATOR" MAKING DISCLOSURE (see definition of "Investigator" on the reverse side):

**DISCLOSURE TO BE MADE:** I and/or my spouse, domestic partner, children, parents, and siblings who reside in the same household **DO/DOES** have financial or other personal interests that are related to the Investigator's Institutional/Professional research responsibilities, as itemized below.

NATURE OF INTEREST	VALUE (\$)
INCOME	Consulting fees
	Honoraria
	Lecture fees from a Speakers' Bureau
	Lecture fees from other than a Speakers' Bureau
	Other payment for employment or services
	Other
TRAVEL	Reimbursed travel
	Sponsored travel
EQUITY	Stock, stock options, warrants (number of shares:      )
	Other ownership rights
INTELLECTUAL PROPERTY	Patents or patent applications
	Copyrights
	Royalties
	Licensing and other agreements
	Contracts
	Other
POSITIONS/ RELATIONSHIPS (COMPENSATIONS)	Corporate officer
	Board of directors or trustees
	Advisory board
	Other

*I certify that the above information is correct; that I have read and understood the Southeastern Community College Policy on Research Conflict of Interest and Financial Disclosure Policy; that, to the best of my knowledge, disclosure of all required financial and other personal interests has been made herein; that I will complete a Disclosure Form on an annual basis during the duration of the research or more frequently as new interests are obtained or if my situation with respect to potential conflict of interest otherwise changes since my original disclosure, and submit it to the IRB Chair; that I will comply with any conditions or restrictions imposed by Southeastern Community College to manage, reduce or eliminate conflicts of interest caused by my interests.*

\_\_\_\_\_  
Signature of Investigator Making Disclosure \_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of IRB Chair \_\_\_\_\_  
Date