



# Financial Conflicts of Interest in Research: Putting the Pieces Together

A training program for investigators on  
University of Alabama at Birmingham  
(UAB) research projects who are not  
UAB employees or students.

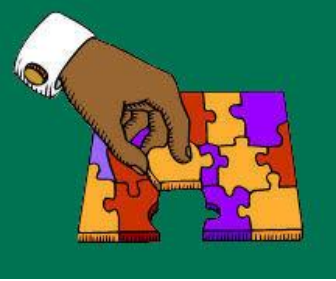


# Who should take this course?

This course is intended for personnel who are not UAB employees or students but who are working on UAB research projects. This includes investigators from organizations outside of UAB , such as consultants, subrecipients, or subgrantees, when required by the terms and conditions of the agreement.

UAB employees (faculty, staff, and students receiving stipends or other payment) involved in research who are required to complete a financial conflict of interest course should take the *Financial Conflict of Interests in Research –CIRB fCOI* course posted in the [Campus Learning System](#).

Contact the Office of the Conflict of Interest Review Board (CIRB) at 975-9691 or [cirb@uab.edu](mailto:cirb@uab.edu) if you have any questions about which course to take.



# Course Topics

- Understanding financial conflicts of interest
- Definition of an Investigator
- Responsibilities of an Investigator
- Definition of a financial interest that must be disclosed
- How to disclose financial interests
- Determining if a financial conflict of interest (FCOI) exists
- Managing an FCOI
- Consequences of noncompliance
- Things to remember

# What is a financial conflict of interest in research?

A financial conflict of interest (FCOI) is a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

UAB, through the Conflict of Interest Review Board (CIRB), must review the significant financial interests disclosed by Investigators working on UAB research projects to determine if a FCOI exists.

# Why is it important to understand FCOIs in research?

## **It is the right thing to do.**

Research conducted without bias and in accordance with the highest scientific and ethical standards preserves the public's trust in the research process and outcomes.



Transparency regarding financial conflicts of interest in research involving human subjects, especially in the informed consent process, serves to protect participants. Objectivity with respect to inclusion and exclusion criteria ensures that participants are enrolled appropriately.

# Why is it important to understand FCOIs in research? (continued)

**It's also required by the federal government and UAB.**

Federal requirements and the UAB policies and procedures that support and accommodate them create important obligations for both UAB and the investigators involved in the research.



# How do I know if I am an “Investigator”?

For any research project, you are an Investigator – regardless of your title, position, or employment status – if you are responsible for the:

- design,
- conduct, or
- reporting of the research.

Investigators also may be referred to as “Key” or “Responsible” personnel.

NOTE: The PI is always an Investigator.

An Investigator is also anyone named on the grant/contract as Key and anyone working on the research project who the PI determines meets the definition.



UAB defines research for purposes of financial conflicts of interest consideration as any externally funded grant/contract application processed by its Office of Sponsored Programs (SOP) and all work involving human subjects, regardless of funding source.

# What does “design, conduct, or reporting” of research mean?



**Design** — The planning of the scientific strategy to test a research proposal.

**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 postdoctoral fellows, graduate students, or other junior researchers.

**Reporting** — The authorship of publications or reports to the sponsor related to the research. This includes anyone who will likely present the data at national/international meetings.

**NOTE:** For studies involving human subjects, **Conduct** also includes anyone who:

- is responsible for explaining to potential participants the study, risk-benefit, and/or alternatives;
- is listed on the 1572 or device agreement; and/or
- must complete a sponsor’s conflict of interest form.



# What do I have to do if I am an Investigator?

You and UAB are required to follow regulations and UAB policy. If you are an Investigator (“Key” or “Responsible”), while you are involved in UAB research activities you are required to:



complete this training course and take a refresher course every four years;

**AND**

disclose all financial interests related to your responsibilities at UAB.

## Newly added Investigator?

Keep in mind that training and disclosure requirements apply immediately if you are added as an Investigator after initiation of the project.

# APPLY YOUR KNOWLEDGE 1

Sally is a project coordinator supporting research work led by a faculty Principal Investigator. In her staff role, she will be:

- Managing tasks and timelines;
- Submitting administrative paperwork;
- Documenting progress; and
- Scheduling meetings.



**Is she or isn't she?**

Is Sally an Investigator for purposes of considering financial conflicts of interest with this project?

# APPLY YOUR KNOWLEDGE 1

**No, she is not.**

Sally is not an Investigator. She is not responsible for the

- design;
- conduct; or
- reporting of research.



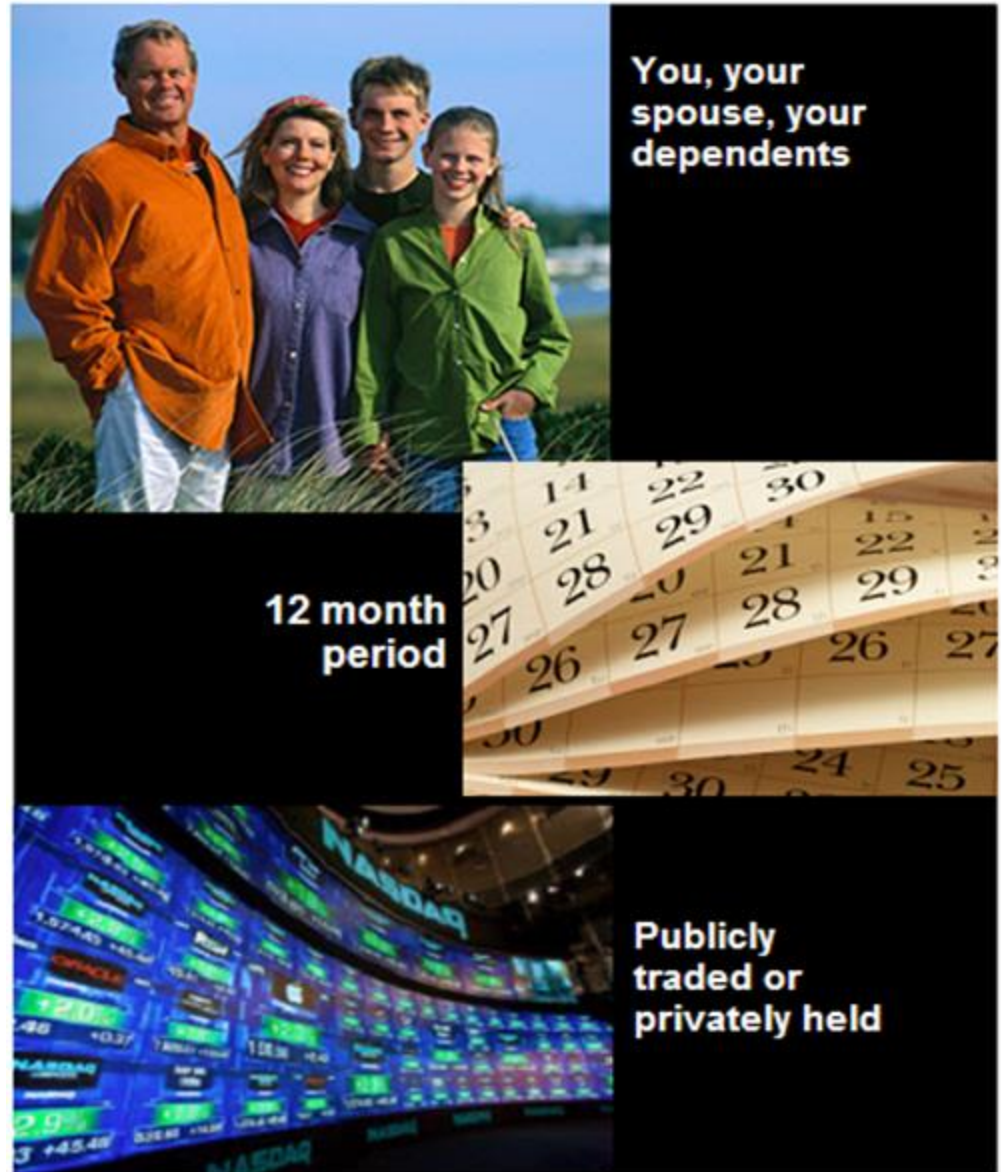
Although she will be fulfilling duties that support the responsibilities of the PI, she has no opportunity to control or influence the research herself.

Sally is not required to complete this training course or disclose her financial interests.

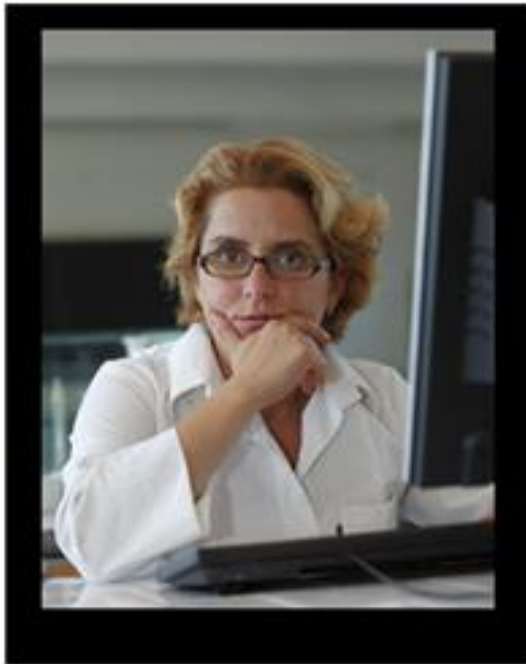
# What financial interests do I need to disclose?

As an Investigator, you must disclose:

- any financial interest related to your responsibilities at UAB that
  - you;
  - your spouse; or
  - your dependents
- received or owned/held in the previous 12 months from
- any entity, whether or not that entity is publicly traded,
- that meets the threshold for disclosure.



# What is a financial interest?



A financial interest is anything of monetary value:

- whether or not the value is readily ascertainable
- related to your UAB research responsibilities
- that is not held in an investment vehicle in which you do not directly control investment decision such as a mutual fund or retirement account.

# What are some examples of financial interests?

- Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
- 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;
- Royalty payments;
- Licensed, optioned, or revenue-generating intellectual property; or
- Sponsored or reimbursed travel.



NOTE: Financial interest does not include your salary from UAB.



# Financial interests DO NOT include:

- travel;
- seminars, lectures or teaching engagements; or
- service on advisory committees or review panels

*IF paid for, sponsored, or reimbursed by*

- a federal, state, or local government agency;
- an US institution of higher education;
- an academic teaching hospital;
- a medical center; or
- a research institute that is affiliated with an institution of higher education.

# What is the threshold for disclosure?

The disclosure threshold is reached when in the 12 months preceding your disclosure:

***for a publicly traded entity***

- the aggregate of any remuneration and any equity (ownership) interest you, your spouse, or your dependents held or received exceeds \$5,000.

***for a privately held entity***

- the aggregate of any remuneration you, your spouse, or your dependents held or received exceeds \$5,000 or
- when you, your spouse, or your dependents held or received any equity (ownership) interest.

***for intellectual property and interests (e.g., patents, copyrights)*** when such are licensed, optioned, or generate income.

***for sponsored or reimbursed travel*** when it is not exempt from disclosure as previously described. Although the value is generally not requested, you must provide a description of the purpose of the trip, identity of the sponsor/organizer, destination, and duration.



# APPLY YOUR KNOWLEDGE 2

Dr. Smith is the PI of a subaward from UAB that involves evaluating the efficacy of a drug produced by XYZ, Inc in the treatment of a common condition in older adults. XYZ Inc is publicly traded.

Does Dr. Smith need to disclose any of the following financial interests that were received or held in the past 12 months?



- His consulting activities for XYZ for \$4500
- His activities on a speaker's bureau for XYZ for which he received \$1000
- His wife's ownership interest in ABCpharma, a privately held company that is developing a drug similar to the XYZ, Inc drug being tested
- His Society for Gerontology board membership for which he received an honorarium of \$6000
- His service as a grant reviewer for NIH
- Royalties (\$100,000) from licensed intellectual property involving a computer program to manage medical records

# APPLY YOUR KNOWLEDGE 2

Dr. Smith should disclose the following financial interests because they 1) are related to the research he is working on for UAB and 2) meet the threshold for disclosure:

- His consulting activities for XYZ for \$4500
- His activities on a speaker's bureau for XYZ for which he received \$1000
- His wife's ownership interest in ABCpharma, a privately held company that is developing a drug similar to the XYZ, Inc drug being tested



*NOTE: The activities (consulting and speaker's bureau) for XYZ Inc, when aggregated for the past 12 months, exceeds \$5,000. As a potential competitor of XYZ Inc the interest in ABCpharma needs to be disclosed. Any ownership in a privately held company reaches the disclosure threshold.*

# APPLY YOUR KNOWLEDGE 2

These financial interests are not related\* to the research for UAB and do not need to be disclosed:

- His board membership with the Society for Gerontology
- His service as a grant reviewer for NIH
- Royalties (\$100,000) from licensed intellectual property involving a computer program to manage medical records



*\* Could the financial interest be affected by the research, or is it in an entity whose financial interest could be affected by the research?*

# When must I disclose my financial interests?

**Prior to serving** as an Investigator on behalf of UAB, you must report whether you have held any financial interests in the previous 12 months related to the UAB research project you will be working on.

In addition, as long as you are an Investigator for UAB, you also must:

- disclose newly discovered or acquired financial interests **within 30 days** and
- update the disclosure **annually**.

How long do I have to disclose that financial interest? How long has it been?!?



# How do I disclose financial interests?



The UAB CIRB Office has developed a form for you to use. This form is provided during agreement negotiations and also is available at [www.uab.edu/cirb](http://www.uab.edu/cirb).

If associated with a subrecipient/subaward agreement, submit the completed form to the UAB Administrative Contact identified on the agreement. The Contact will direct it to the Office of the CIRB. Subsequently or for a disclosure that is not associated with an agreement, submit it to [cirb@uab.edu](mailto:cirb@uab.edu).

# What happens after I submit my disclosure?

The CIRB Office staff will

- enter the information into its electronic record system, and as needed
- assign review of the proposed research and the financial interests to a senior member of the Office staff or one or more members of the CIRB.

The reviewer(s) will

- determine if the financial interest is related to the research and, if so related, whether or not it is a financial conflict of interest, and
- recommend a plan for management if needed.

After the review, the CIRB Office staff will

- record the outcome,
- notify you of the determination,
- provide you with a copy of the management plan if one is necessary, and
- provide reports to the sponsor and others as required.

# How will a FCOI be managed?

Management plans may include one or more of the following elements:

- Ensuring transparency in research through disclosure of the financial interest to all research personnel involved in the study, study participants, and others.
- Preventing undue influence on trainees and employees.
- Restricting the role or responsibilities of the Investigator
  - May not serve as PI
  - May not recruit study subjects or provide protocol-related clinical care
  - May not participate in data management or data analysis
- Requiring an acceptable Data Safety Management Plan or Board for oversight of the data acquisition, analysis, and reporting and subject safety
- Other Elements as determined by the CIRB



NOTE: Management must occur

- for new projects, **prior to the expenditure of funds** and
- for ongoing projects, **within 60 days** of your disclosure to UAB of new or amended financial interests.

# Who can see the information that I disclosed?

Besides the CIRB Office and members, individuals in leadership roles at UAB also have access to your information.

If a FCOI is identified, the CIRB Office will

- make the information publicly available, either on a website or within 5 business days of a written request and
- report the FCOI
  - via eCommons for projects funded by the Public Health Service (PHS) or
  - as required by other sponsors.



NOTE: UAB makes all disclosed financial interests publicly available, whether or not determined to be a FCOI.



# What do I need to remember?

- You – and UAB – are responsible for promoting and maintaining objectivity in research.
- You are responsible for:
  - being familiar with disclosure processes,
  - making sure you have disclosed the required financial information on time, and
  - adhering to the conditions of the management plan if one is required.

## Have questions or need help?

Check the CIRB website ([www.uab.edu/cirb](http://www.uab.edu/cirb)) for more information and FAQs.

Contact the CIRB Office ([cirb@uab.edu](mailto:cirb@uab.edu)).



# You are not finished yet!

To get credit for this course, complete and submit the form certifying that you have reviewed the information presented in this course. Click [here](#) for the form.