Instructions: Please carefully read each regulation, policy, and procedure. You will then be asked to initial on this form that you have read, understood, and will comply with both federal regulations and University of Alabama policies and procedures regarding Investigator’s responsibilities for disclosing significant financial interests. Please contact the Office for Research Compliance via phone (205-348-8461) or email (rscompliance@fa.ua.edu) should you have any questions regarding the below regulations and/or policies.

THE UNIVERSITY OF ALABAMA POLICY ON CONFLICT OF INTEREST/FINANCIAL DISCLOSURE IN RESEARCH AND OTHER SPONSORED PROGRAMS
Available at http://osp.ua.edu/site/RC_CoI.html

I have read the UA Policy on Conflict of Interest and I understand that I am responsible for complying with the policies set forth by The University of Alabama.

initials

THE UNIVERSITY OF ALABAMA FINANCIAL CONFLICT OF INTEREST TRAINING PRESENTATION
Available at http://osp.ua.edu/site/RC_CoI.html

I have reviewed the UA FCOI Training Presentation and I understand that I am responsible for complying with the information outlined in the training.

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INVESTIGATOR’S RESPONSIBILITIES

Who must complete the Investigator Statement of Financial Interest Form?

At a minimum, the term Investigator includes the following:

- Project Directors, Principal Investigators, and/or members of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report;

- Individuals identified by the Principal Investigator or Project Director who are responsible for and have substantial independent decision-making in respect to the design, conduct, or reporting of the research, such as Collaborators or Consultants named on the grant; and

- The Investigator must report Significant Financial Interests for himself/herself, as well as for his/her spouse and dependent children that are related to the Investigator’s institutional responsibilities.

What Must Be Reported?

The following financial interests in entities related to an Investigator’s teaching, research, administrative, or clinical duties at UA must be reported:

- $5,000 or more including salary, consulting fees, honoraria, and/or gifts received within the past 12 months (excluding salary, grant support, and other payments for services received from The University of Alabama);

- Equity or ownership interest (including stock options) worth $5,000 or more as determined by reference to the entity’s publicly listed price (excluding mutual funds);
• Any equity or ownership interest in an entity if the entity's value cannot be determined by reference to publicly listed prices (e.g., privately held companies, such as start-up companies);

• A position as director, officer, partner, trustee, employee, or any other position of management;

• Receipt of patent/copyright licensing fees or royalties from an entity or for a technology related to an Investigator’s teaching, research, administrative, or clinical duties at UA;

• Any compensation whose value could be affected by the outcome of the research; or

• HHS Investigators must disclose sponsored travel.

When Should This Be Reported?

The University of Alabama will not submit a proposal and an award cannot be issued to UA unless and until UA has on file all Investigators’ Financial Interests on the Statement of Financial Interest Form associated with a proposal.

• Each Investigator must report any Significant Financial Interest prior to submitting a formal proposal to any proposed sponsor of the research; or

• Report any Significant Financial Interest prior to conducting the research, if the research is internally funded.

• Investigators are required to update their reports in real time to reflect changes in or additions of Significant Financial Interests Requiring Disclosure. In cases where Investigators are not aware of the existence of a Significant Financial Interest at the time of a proposal, or if the Significant Financial Interest develops after submission of a proposal, then Investigators shall report the interest to the Office for Research Compliance within 30 days of learning of the interest. This can be done by amending the Investigator Statement of Financial Interest Form.

• Each year of a grant or contract, an Investigator must update his/her Investigator Statement of Financial Interest Form. The form must be updated at the time of the annual progress report, twelve (12) months after the notice of award or the initiation of research, whichever date is earliest.

Consequences of Non-Compliance

• Failure to make the necessary disclosure or follow an agreed upon management plan is a violation of University policy.

• The Vice President for Research shall review and take appropriate action as he/she deems appropriate in the circumstance.

• Sanctions for non-compliance may include reprimands or other appropriate measures, up to and including termination.

A. Required HHS procedures for failure to comply with policy or management plan:

In addition to the above review and sanctions, UA and HHS Investigators are subject to the following procedures when Financial Conflict of Interest (FCOI) is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest that is determined by UA to constitute a Financial Conflict of Interest, failure by the UA 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.

1) UA must implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such Financial Conflict of Interest going forward.

2) Within 120 days of UA’s determination of non-compliance, UA must complete a retrospective review of the Investigator’s activities and the HHS-funded research project to determine whether any HHS-funded research, or
portion thereof, conducted during the time of the non-compliance, was biased in the design, conduct, or reporting of such research.

3) UA must document the retrospective review and include a detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed).

4) Based on the results of the retrospective review, if appropriate, UA shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

If bias is found during the retrospective review, UA is required to notify the HHS awarding component promptly and submit a mitigation report to the HHS awarding component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and UA’s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., 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, UA will submit to the HHS awarding component FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the Financial Conflict of Interest, UA may determine that additional interim measures are necessary with regard to the Investigator’s participation in the HHS funded research project between the date that the Financial Conflict of interest or the Investigator’s non-compliance is determined and the completion of UA’s retrospective review.

I have reviewed the Investigator’s Responsibilities and I understand that I am responsible for complying with the policies and procedures set forth by The University of Alabama.

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By submitting this form, I certify that:

• I have read the policies and procedures outlined by The University of Alabama.
• I agree to comply with the policies and procedures outlined by The University of Alabama.
• I am the person named above submitting this report.

Signature: _______________________________ Date: ______________

Investigator