

UNIVERSITY OF ALABAMA AT BIRMINGHAM

CONFLICT OF INTEREST REVIEW BOARD (“CIRB”)

The following is an explanation of the Conflict of Interest Management Plan (a “Management Plan”) issued by the CIRB. This is NOT the Plan; the Plan is in table format and consists of information relating to your financial interests and research projects.

1. UAB CIRB HAS ISSUED A MANAGEMENT PLAN THAT RELATES TO YOU AND YOUR RESEARCH PROJECTS.

You have been notified that you have a CIRB Management Plan because the CIRB has determined that one or more of your disclosed financial interest(s) relating to your institutional responsibilities at UAB is/are a financial conflict of interest (a “FCOI”) which relates to one or more of your sponsored research projects that UAB is required to manage in accordance with the UAB Enterprise Conflict of Interest and Conflict of Commitment Policy (refer to [Part D. Research](#)). This UAB policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research performed at UAB is free from bias which may be influenced by your FCOI.

Your Management Plan is effective three (3) business days after being issued by the CIRB Office and will remain in effect until it is withdrawn by the CIRB Office. The CIRB will review your Management Plan (i) periodically, (ii) as you disclose new financial interests to UAB and (iii) when you become involved as a responsible person in a project that is processed by the Office of Sponsored Programs (“OSP”) or is reviewed by the Institutional Review Board (“IRB”). The CIRB will amend your Management Plan, as appropriate, and you will be notified by the CIRB when this occurs.

You can review your Management Plan at any time by accessing your case (record) in the External Interests module of the Integrated Research Administration Portal (IRAP). Information and instructions for using IRAP are available at <http://www.uab.edu/era/Pages/Home.aspx>. For questions about your Management Plan, CIRB rules or UAB’s Policy, please contact the CIRB Office (205-975-9697).

2. YOUR RESPONSIBILITIES.

You should review your Management Plan immediately upon receiving notification from the CIRB Office that a Management Plan has been issued or amended. If you find any inaccuracies in your Management Plan, contact the CIRB Office. You should also periodically review your Management Plan to familiarize yourself with its management requirements and to ensure that the information is accurate and up to date. You may also notify the CIRB once a research project has ended so that the CIRB can amend the Management Plan.

You are required to comply with all of the Management Plan elements issued for each research project that was identified as having a FCOI. A guide to the management plan elements is provided below (see pages 3-5). You must maintain sufficient documentation necessary to demonstrate your compliance with each element of your Management Plan with respect to each research project that was identified as having a FCOI. Different elements may apply to different affected research projects. The CIRB will conduct periodic reviews to ensure your compliance with your Management Plan. Non-compliance will be referred to the CIRB and will be addressed in accordance with the policies and procedures of the CIRB and UAB. Remedial actions may include filing reports with applicable funding agencies and may result in disciplinary action being taken. In addition to any CIRB requirements listed in your Management Plan, you are responsible for complying with all requirements of your school or the Provost regarding disclosure and approval of external activities and any requirements of the IRB for disclosure in consent forms.

In accordance with the UAB Enterprise Conflict of Interest and Conflict of Commitment Policy and federal regulations, you are required to disclose to UAB any financial interest relating to your institutional responsibilities received or acquired by you, your spouse or your dependents. This disclosure is required within thirty (30) days of receipt or acquisition of the financial interest. In addition, UAB Policy requires you to obtain permission before you engage in external activities. With respect to both requirements, use the *Request for External Activity or Disclosure of Potential Conflict of Interest* Form.

3. APPEALS.

If you disagree with the applicability of any management elements contained in your Management Plan, you should appeal to the CIRB for a review of its decision. The decision of the CIRB shall be final.

GUIDE TO THE MANAGEMENT REQUIREMENTS IN THE PLAN

Your Management Plan shows your financial interests that meet the threshold for monitoring (top ordinate of the table), and all research projects with which you are associated as a key/responsible person. With respect to each project, your Management Plan shows financial interests the CIRB has determined are FCOI's which require management. Each management element applicable to a specific research project is represented by an assigned letter. A short explanation of each management element is found on the bottom of your Management Plan itself and in more detail below.

A. TRANSPARENCY IN RESEARCH.

This element in a Management Plan ensures that the existence and nature of your FCOI is disclosed to all personnel and participants involved in the research and to the research community and the general public.

UAB's Responsibilities.

Disclosure of Your FCOI's to Others Involved with Your Projects. All financial interests disclosed to UAB will be published by UAB on its public website. The website is available at www.uab.edu/cirb. UAB employees, trainees and sub-awardees will be informed that this information regarding financial conflicts is available on UAB's website. However, you are encouraged to remind UAB employees, graduate students, postdoctoral fellows, clinical resident fellows and collaborators (co-investigators, other researchers and individuals responsible for quality assurance, data management or data analysis) working with you on any affected projects to review the information on the UAB website as it relates to your FCOI's.

Your Responsibilities.

You must comply with IRB disclosure requirements to disclose the existence and nature of your FCOIs to all human subjects participating in your conflicted research projects.

Publications and Presentations. You must disclose the existence and nature of your FCOIs in all publications and presentations which refer to or include data arising from research projects listed on your Management Plan. This includes the following:

- all presentations to UAB, including the UAB Reporter;
- all external media outlets, print, broadcast media such as radio, television, internet or other electronic or online outlets;
- all speaking engagements; and
- all informal or formal written formats, including books and journals.

This disclosure requirement applies to any reference you make to a research project, even if the research project is no longer being managed under your Management Plan at the time of the publication or presentation. In relation to journal and book publications, you must disclose the information to the publisher or editor who will determine if a disclosure should appear in print, in conformance with their publication policies. You should retain copies of your correspondence with the publisher/editor in which you disclosed your FCOI and any correspondence evidencing the publisher's/editor's decision not to publish. These records should be retained by you for at least three (3) years.

B. PREVENTING UNDUE INFLUENCE ON TRAINEES AND EMPLOYEES.

This element in a Management Plan ensures that the careers and training provided to graduate students, postdoctoral fellows, clinical residency fellows and employees are not negatively impacted by the existence of your FCOIs.

UAB's Responsibilities.

Graduate Students, Postdoctoral Fellows and Clinical Residency Fellows. UAB will provide information to UAB graduate students, postdoctoral fellows and clinical residency fellows regarding their rights to withdraw from participation in any research project in which a UAB employee has a FCOI. In addition, information will also be provided to the above individuals regarding their rights to contact certain UAB employees on a confidential basis if they have concerns participating in a research project in connection with which a FCOI has been identified.

Employees. Based on the nature of your FCOI, the CIRB may request your Department Chair, the Dean of your School, the Provost or the President (as applicable) to appoint a UAB employee to act as an independent counselor to review the job performance evaluations and advancement recommendations of personnel you supervise who are also involved in the research project.

C. MAY NOT SERVE AS PRINCIPAL INVESTIGATOR.

This element in a Management Plan is used in circumstances to maintain the integrity of the research project and reduce the potential for results to be biased and to eliminate the opportunity for the improper exercise of undue influence in research projects arising from the existence of your FCOIs. This element is used primarily in research projects involving the use of human subjects. This element may also apply in other circumstances as deemed appropriate by the CIRB.

D. MAY NOT ENROLL OR CONSENT STUDY SUBJECTS OR PROVIDE PROTOCOL-RELATED CLINICAL CARE.

This element in a Management Plan is used to maintain the integrity of the research project and reduce the potential for the results to be biased and to eliminate the opportunity for the improper exercise of undue influence. This element is only used in research projects involving human subjects. You are prohibited from enrolling or consenting study subjects (including undertaking the assessment of inclusion and exclusion criteria for study eligibility) or providing protocol-related clinical care. You may, however, refer patients who may wish to participate in the study to approved clinical co-investigators for evaluation.

E. MAY NOT PARTICIPATE IN DATA MANAGEMENT OR DATA ANALYSIS.

This element in a Management Plan is used to maintain the integrity of the research project and reduce the potential for the results to be biased. This element is used primarily in research projects involving the use of human subjects. This element may also apply in other circumstances as deemed appropriate by the CIRB. You must have an independent data management and/or analysis plan.

F. REQUIREMENT FOR DATA SAFETY MONITORING PLAN.

This element in a Management Plan is used to maintain the integrity of the research project and reduce the potential for the results to be biased and for ensuring patient safety. This element is only used in research projects involving human subjects. You are required to implement a Data Safety Monitoring Plan to provide for the oversight of data acquisition, review and reporting by an individual or individuals who are not involved in the research project; this is designed to ensure the safety of the human subjects participating in the research project. The Data Safety Monitoring Plan must be submitted to the IRB for approval within 30 days of the issuance of a Management Plan.

G. REQUIREMENTS DUE TO INSTITUTIONAL CONFLICT OF INTEREST – TRANSPARENCY IN RESEARCH.

This element in a Management Plan is used when the University has a potential financial interest in the successful outcome of a research project: for example when UAB is asked to participate in or run a research project at UAB using intellectual property that was created by one or more UAB employees and which has been licensed to a company. This element is used to maintain the integrity of the research project and reduce the potential for results to be biased and to eliminate the opportunity for the improper exercise of undue influence. This element will encompass one or more of the other elements described in this document.

H. OTHER ELEMENTS AS MAY BE DETERMINED BY THE CIRB.

The CIRB may require other restrictions that it deems appropriate.