***TITLE:* Conflict of Interest Disclosure**

***SOP #***FM XX.XX

***Author(s):***

 ***Developed by Date***

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***Approval:***

 ***Approved by Date***

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***Annual review of current version Review date Comment***

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2. Anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance.
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**I. SCOPE/PURPOSE** The scope of this SOP is to address Conflict of Interest disclosure as part of UAB research site management. The purpose of this SOP is to provide information to UAB research sites about Conflict of Interest disclosure and to provide guidance to facilitate compliance with UAB Conflict of Interest Review Board policies. This SOP will describe the process and its implementation.

**II. ALLOWABLE EXCEPTIONS**

This SOP will be adhered unless exceptions are required. Exceptions will be noted in a formal note to file (see relevant SOP).

**III. RELEVANT REGULATIONS/GCPS**

Hyperlinks to related conflict of interest regulations may be found at the following UAB Conflict of Interest Review Board (CIRB) web site location:

<http://www.uab.edu/research/adminstration/offices/CIRB/Pages/FederalRegulations.aspx>.

Examples of related regulations found at the CIRB website include:

* Public Health Service, FCOI Final Rule (2011) and FAQs
* National Science Foundation, Investigator Financial Disclosure Policy
* Food and Drug Administration, Financial Disclosure by Clinical Investigators (Federal Register, December 31, 1998, Volume 63, Number 251, pages 72171-72181) and Forms.

**IV. DEFINITIONS/ACRONYMS**

CIRB Conflict of Interest Review Board

COI Conflict of Interest

fCOI Financial Conflict of Interest

OSP Office of Sponsored Programs

OCIRB Office of the CIRB

RPL Responsible Personnel List

SOP Standard Operating Procedure

TKC The Kirklin Clinic of UAB Hospital

**V. RESPONSIBLE PERSONNEL**

The principal investigator/program director and all personnel responsible for the design, conduct, or reporting of research are required to disclose certain information related to financial interests and relationships.

Design is defined as the planning of the scientific strategy to test a research proposal.

Conduct is defined as 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 postdoctoral fellows and graduate students who have significant supervisory roles for junior researcher or technicians who are part of the study. For studies involving human subjects, this includes anyone who is responsible for explaining the study, risk-benefit, and/or alternatives to potential participants, is listed on the 1572 or device agreement, and/or must complete a sponsor’s conflict of interest form. This may include, but not be limited to, principal investigators, co-investigators, sub-investigators, study coordinators, data managers, unit managers, finance staff, pharmacy staff, and others as applicable.

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

For the purpose of reporting financial conflicts of interest, research includes any grant/contract application processed by the UAB Office of Sponsored Programs (OSP) and all work involving human subjects regardless of funding source.

The Office of the CIRB (OCIRB) will conduct a review of conflict of interest disclosures reported by those personnel listed on the Responsible Personnel List (RPL) by the investigator.

**VI. DETAILS**

The UAB CIRB develops ongoing procedures for identifying, reviewing and managing conflicts of interest (COI) as they relate to sponsored research. CIRB contact information as well as related information may be accessed at the CIRB website located at

<http://www.uab.edu/research/administration/offices/CIRB/Pages/default.aspx> .

Conflict of Interest (COI) disclosure at UAB encompasses the following:

1. Training

Federal regulation and the UAB Enterprise Conflict of Interest and Conflict of Commitment Policy require completion of training on conflicts of interest by all responsible individuals

1. Prior to engaging in research, and
2. Prior to charging effort to a federally-sponsored program.
3. Training includes an initial session with additional training every four (4) years thereafter.
4. Required training at UAB is available through the UAB Faculty & Staff Learning Center and is entitled “Financial Conflict of Interests in Research”. Records of completion of the above training will be maintained and monitored within the UAB Faculty & Staff Learning Center.
5. Supplemental training or presentations regarding financial disclosure requirements are available by contacting the CIRB Office.
6. Information is provided to obtain training to view an individual’s disclosed financial interests in the UAB Integrated Research Administration Portal (IRAP) at the CIRB website link noted above.
7. The CIRB website also provides information related to financial conflict of interest training and certification for non-UAB personnel.
8. Information about the active (funded) research projects in which a specific person is responsible **and** holds a significant financial interest determined by the institution to be both related to the research and a financial conflict of interest, may be accessed from the CIRB website noted above.
9. Disclosure Processes
	1. External Activities

Investigators (includes all faculty and staff over grade 20) are required to submit requests to their departments and schools prior to engaging in an activity that draws upon their knowledge, skills, or abilities used to fulfill their institutional responsibilities for an entity outside the UAB Enterprise. Examples of these activities include:

* 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.

If approved by the department and school, for those individuals involved in UAB research, pertinent information about the activity will be communicated to the CIRB for inclusion in the individual's financial interests profile in IRAP. As such, there is no need to separately report approved external activities to the OCIRB or to include the same information in a Disclosure of Financial Interests.

Guidance on the external activity approval process may be found at:

<http://www.uab.edu/research/administration/offices/CIRB/HowTo/Pages/HowToDiscloseActivities.aspx>

* 1. Financial Interests

Investigators must submit a disclosure of financial interests other than those included on an external activity request. The CIRB uses this information to maintain Investigators' financial interests profiles in IRAP.

New Investigators - Investigators that are new to UAB or new to their role in research must complete a Disclosure of Financial Interest prior to undertaking any research, even if there are no financial interests to report.

If no interests are disclosed, no further information is necessary unless something changes. If something does change, Investigators have 30 days to disclose the new financial interest.

If interests are disclosed at the time of the initial disclosure, Investigators must submit another Disclosure of Financial Interests within 30 days of acquiring a new interest or experiencing a change in an interest previously disclosed, or annually to re-certify that the disclosed interests are still current.

Current Investigators - All current UAB Investigators participating in ongoing research should have already submitted an initial financial interest disclosure. All current UAB Investigators must submit a Disclosure of Financial Interest within 30 days of acquiring a new interest or experiencing a change in an interest previously disclosed, or annually to re-certify that the disclosed interests are still current.

Guidance on submitting Disclosure of Financial Interests may be found at:

<http://www.uab.edu/research/administration/offices/CIRB/HowTo/Pages/HowToDiscloseFinancialInterests.aspx>

Investigators must submit a Notice of Professional Public Service Activity if they acquire more than $5,000 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;
* 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.

Guidance on submitting Notice of Professional Public Service Activity may be found at:

<http://www.uab.edu/research/administration/offices/CIRB/HowTo/Pages/NoticeofProfessionalPublicServiceActivity-.aspx>

* 1. Subrecipient Disclosure

UAB is responsible for ensuring that all key or responsible people listed on grants/contracts have complied with the federal regulations regarding financial conflict of interests. If a subrecipient agency is unable to certify that they are complaint with the federal conflict of interest regulations, UAB is then responsible for determining if there are any conflicts of interest and maintaining the training documents for the key or responsible people on that particular subrecipient's project.

Additional guidance may be found at:

<http://www.uab.edu/research/administration/offices/CIRB/HowTo/Pages/HowSubrecipientsDisclose.aspx>

**VII. QA**

 To facilitate the conflict of interest disclosure process and minimize its impact on the research activation process, staff may be identified within a research unit who will coordinate reminders to file disclosures with the appropriate unit personnel.(appendix A)

**VIII. APPENDICES / RESOURCES**

Appendix A – Conflict of Interest Checklist

**IX. RELATED SOPS**

NA

**APPENDIX A**

**CIRB REVIEW CHECKLIST**

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| --- | --- | --- |
| **Date Reminded** | **Personnel Listed on RPL** | **Comments** |
|  | Name *[Principal Investigator]* | Already in Current Disclosure Y NWill require New Disclosure Y N |
|  | Name *[Sub-Investigator A]* | Already in Current Disclosure Y NWill require New Disclosure Y N |
|  | Name *[Sub-Investigator B]* | Already in Current Disclosure Y NWill require New Disclosure Y N |
|  | Name *[Sub-Investigator C]* | Already in Current Disclosure Y NWill require New Disclosure Y N |
|  | Name *[Pharmacist A]* | Already in Current Disclosure Y NWill require New Disclosure Y N |
|  | Name *[Coordinator A]* | Already in Current Disclosure Y NWill require New Disclosure Y N |
|  | Name *[Coordinator B]* | Already in Current Disclosure Y NWill require New Disclosure Y N |
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