

PHS Financial Conflict of Interest (FCOI) Management Plan

Investigator:

Date:

STATUS

Annual FCOI Management Plan

Updated FCOI Management Plan (describe changes/reason for changes below)

The Financial Conflict no longer exists (explain below)

Status Notes:

BACKGROUND

Record information about the Investigator, including your role and principal duties, general area of study, and research focus, as it relates to the FCOI.

Record information about the Company/Entity, with which the SFI exists, including a discussion about the ownership of the company, the location, and the nature of its business.

SIGNIFICANT FINANCIAL INTEREST

Include information about the relevant PHS grant, cooperative agreement or contract research that may be affected in the conduct, design or reporting of such research.

List details of all Significant Financial Interest(s) that you, your spouse, and/or dependent children hold or receive that have a potential, perceived or actual Conflict of Interest that need to be managed. Explain how these interests relate, or appear to relate to your Institutional Responsibilities. Refer to Section C of the PHS Supplemental Disclosure Statement, and KSU Policies & Procedures Manual (4090).

MANAGEMENT PLAN

Address how the SFI will be managed. All cases will be different: see guidelines below for guidance. Contact the University Research Compliance Office with any questions at PHSFCOI@ksu.edu

Examples of conditions or restrictions that might be imposed to manage an Investigator’s Financial Conflict of Interest include, but are not limited to:

- Public disclosure of financial conflicts of interests (FCOI) in publications and oral presentations (i.e. when presenting or publishing the research; to staff members working on the project; to the Institution’s Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc).
- For projects involving human research subjects: disclosure of FCOI directly to participants; informed consent obtained by person(s) other than investigator and supervisees.
- Appointment of an independent monitor or oversight body capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Double blind data analysis.
- Data analysis and interpretation by independent reviewers or review of raw data and manuscript by an external independent reviewer.
- Protection of the academic rights and interests of students/fellows involved in the project.
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts

SAFEGUARDING OBJECTIVITY

Describe specifically how the conditions of the management plan (listed above) will safeguard objectivity in the research project.

MONITORING

Describe how the management plan will be monitored to ensure Investigator compliance.

REVIEW

This PHS Financial Conflict of Interest Management Plan will be reviewed annually, or sooner when circumstances warrant.

FACILITIES USE AGREEMENT

If any K-State laboratories or property will be used by, or on behalf of the Company/Entity, a Facilities Use Agreement must be completed and approved by the Associate VP for Research.

OTHER (attach additional sheets if necessary)

Other documentation that may be included in the PHS FCOI Management Plan (if applicable):

- Intellectual property developed/utilized by the PI that is or may be owned by Company/Entity.
- Documentation of any arrangements with the Company/Entity that restrict publication or presentation of research reports and other scholarship.
- Documentation of an impartial third party to develop and execute purchases from the Company/Entity, if the Investigator intends to purchase items from the Company/Entity. The third party should not be under the Investigator’s supervision or control.
- Identification of other K-State activities and/or sponsored projects that could reasonably be seen as overlapping with activities or projects for which the Company/Entity receives benefit. If overlap is determined to exist, then the management plan should address how the overlap will be managed, such as the Investigator informing the sponsors of overlapping projects.
- Any formal K-State agreement that is related to the Company/Entity.

AGREEMENT

I have read, understand, and will abide by the PHS FCOI management plan guidance and procedures mentioned herein.

Investigator’s Name (print)

Investigator’s Signature

Date

APPROVAL

Immediate Supervisor Printed Name Date

Department/Unit Head Printed Name Date

Dean/Appropriate Vice President Printed Name Date

Provost Printed Name Date