

KLEIN BUENDEL, INC.

Financial Conflict of Interest Policy

SUMMARY

Klein Buendel, Inc. (KB) is dedicated to maintaining public trust in the integrity of our research-related activities. The U.S. Department of Health and Human Services (HHS) has issued a final rule in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). This policy addresses the crucially important responsibilities of the Klein Buendel, Inc. (KB) in both safeguarding research objectivity and complying with the requirements of all applicable state and federal regulations.

DEFINITIONS

Disclosure: an Investigator's provision of information about their significant financial interest/s to KB.

Equity Interest: any interest in the profits of or stock of a commercial or non-profit enterprise, a stock option or any other ownership interest in a commercial or non-profit enterprise.

Financial Conflict of Interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the federally funded research.

Institution: any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is the direct and primary recipient of NIH grant funds or that submits an application/proposal for a research grant/contract whether in response to a solicitation from NIH or otherwise, and is accountable to NIH for the performance of the research grant/contract, the appropriate expenditure of grant/contract funds by all parties, and all other obligations of the grantee/awardee, such as compliance with the terms and conditions of NIH grant/contract awards, including FCOI.

Institutional Official: one or more persons designated by KB as having responsibilities and authority under this policy. For the purposes of this policy, this is the FCOI Committee.

Institutional responsibilities: All work performed at or on behalf of KB, including but not limited to: Research conducted at, on behalf of, or through KB.

Investigator: any person, regardless of title or position, who is responsible for the design, conduct or reporting of the results of a Sponsored Research project. In this context, the term "Investigator" includes the Investigator's spouse or domestic partner and dependent children.

Management Plan: a written plan to address a financial conflict of interest to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

Reimbursed Travel: travel that exceeds \$5,000, is related to the Investigator's institutional responsibilities, and is reimbursed to the Investigator. Travel that is reimbursed by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education does not need to be disclosed.

Senior/Key Personnel: any person identified as such, including the PI, in the grant application, award, or contract or in any progress report or any other report pertaining to the research project submitted to the PHS.

Significant Financial Interest (SFI): a financial interest that reasonably appears to be related to an Investigator's Institutional Responsibilities and meets one or more of the following criteria, after accounting for any specified exclusions:

	CRITERIA	EXCLUSIONS
1.	<p>Reimbursed Travel or Sponsored Travel Disclosure will include the following information:</p> <ul style="list-style-type: none"> • Purpose of the trip • Identity of the sponsor/organizer • Destination • Duration (start and end dates) 	<p>Travel that is reimbursed by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education does not need to be disclosed.</p> <p>For example, travel which relates institutional responsibilities paid for by NIH is excluded. However, travel related to institutional responsibilities paid for by a pharmaceutical company or a professional association is not excluded.</p>
2.	<p>Compensation totaling more than \$5,000 received in the preceding 12-month period (e.g. salary, consulting fees, honoraria or other payments)</p> <p>SFI = (\$ in past 12 months) > 5K</p>	<p>Salary, royalties, or other remuneration paid by KB to the Investigator if the Investigator is currently employed or otherwise appointed by KB;</p> <p>Income from seminars, lectures, or other teaching engagements, or from service on advisory panels or review panels from a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.</p>
3.	<p>Any equity in a non-publicly traded entity as of the date of disclosure</p> <p>SFI = Equity at disclosure</p>	<p>Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g. mutual funds, retirement accounts)</p>
4.	<p>Equity in a publicly traded entity valued in excess of \$5,000</p> <p>SFI = Equity at disclosure > 5K</p>	<p>Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g. mutual funds, retirement accounts)</p>
5.	<p>Equity in a publicly traded entity and compensation received from the same entity in the preceding 12 months equals a combined total value exceeding \$5,000</p> <p>SFI = (\$ in past 12 months + Equity at time of disclosure) > 5K</p>	<p>Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g. mutual funds, retirement accounts);</p> <p>Income from seminars, lectures, or other teaching engagements, or from service on advisory panels or review panels from a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is</p>

		affiliated with an Institution of higher education.
6.	Intellectual property rights and income received from such rights	Intellectual property rights from which an Investigator has not received income; Intellectual property assigned to the research institute; Royalty payments paid by the research institute to the Investigator; Agreements entered into by the research institute which, either via the institute's policy or specific provisions of the agreement, provides for the investigator to share in royalties.

Sponsored Travel: travel expenses that exceed \$5,000 and are paid directly by an Entity on behalf of an Investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available. This does not include travel expenses paid directly by research study budget (also known as an activity).

Subrecipient: an entity that provides services under contract issued by, and for the direct benefit or use of, KB in a research project. In this policy referred to as subrecipient.

Travel Expenses: expenses incurred for the purpose of engaging in travel activity, including but not limited to, costs for transportation, parking, food, drink, lodging and related amenities.

POLICY

- A. No research activities occurring at, on behalf of, or through KB shall be adversely affected by the financial interests of persons involved in those activities. Any investigator possessing a significant financial interest related to their Institutional Responsibilities must disclose the interest to the FCOI Committee at least annually and/or prior to participating in a research. The FCOI Committee is responsible for reviewing disclosures and instituting an adequate plan for the elimination, reduction or management of any identified financial conflicts of interest. The ultimate goal of this policy is to protect the integrity and credibility of activities related to research and to maintain public trust and confidence in KB and its employees.
- B. All research undertaken at KB shall be conducted in compliance with PHS regulations on *Responsibility of Applicants for Promoting Objectivity in Research* for which PHS Funding is Sought (42 CFR Part 50, Subpart F August 25, 2011).
- C. Persons failing to comply with this policy shall be subject to sanctions as provided herein.
- D. Investigator Responsibilities - All Investigators are required to:
 - 1. Disclose significant financial interests
 - a. Annually to the FCOI Committee;
 - b. Within 30 days of discovering or acquiring a new significant financial interest.
In the case of Sponsored or Reimbursed Travel, the disclosure must be made within 30 days of the trip end;
 - c. As part of the new-hires process after joining KB; and/or
 - d. Upon direction from the FCOI Committee.
 - 2. Ensure their SFI disclosure is current prior to the submission of a proposal/application.
 - 3. Comply with any Management Plan established by FCOI Committee.

4. Complete FCOI training:
 - a. At least every four years;
 - b. As part of the on new-hires process after joining KB;
 - c. As mandated by the FCOI Committee, upon determination of non-compliance with this policy or an existing Management Plan; and/or
 - d. As otherwise dictated by KB.
- E. Principal Investigator Responsibilities - in addition to the responsibilities outlined for all Investigators above, Principal Investigators are required to:
 1. Ensure all Investigators involved in a research project, including newly hired Investigators, have submitted required SFI disclosures prior to their participation in the project;
 2. Ensure all Investigators involved in a research project promptly disclose any new or updated SFIs (see section D.1. above);
 3. Ensure all Investigators involved in a research project have completed the FCOI training required under this policy; and
 4. Indicate, upon submission of a proposal/application, if they or any project Investigators have SFI that may be related to the proposed project.
- F. Review of Disclosures
 1. The FCOI Committee shall review all Investigator SFI disclosures and determine whether SFI disclosures are related to a specific research project.
 2. Depending on the nature of the disclosed SFI, the FCOI Committee may implement additional interim measures regarding the Investigator's participation in the research project between the date of disclosure and the completion of the SFI review.
 3. Reviews generally will not be conducted until after a research proposal has been funded.
- G. Management of FCOI
 1. If the FCOI Committee determines that a SFI Disclosure constitutes an FCOI relating to a research project, it shall develop and implement a Management Plan specifying actions that have been or will be taken that in the reasonable judgement of the FCOI Committee will reduce or manage such FCOI.
 2. No Investigator having an FCOI may participate in the related research project without prior written approval from the FCOI Committee. A completed or updated Management Plan will generally serve as such written approval.
 3. In developing a Management Plan, the FCOI Committee may conduct factual inquiries and consult with and receive recommendations from such persons or committees as the FCOI Committee deems necessary and appropriate.
 4. The actions detailed above (sections F and G) will be completed prior to the expenditure of any research project funds, or within 60 days of a disclosure of a SFI during the course of a research project by an existing Investigator or an Investigator new to the project.
 5. Whenever a Management Plan is implemented, the FCOI Committee shall take such actions as it deems reasonable to audit and/or monitor compliance with the Management Plan until the completion of the research project or until the Management Plan is no longer required.
- H. Management of Other Interests
 1. When a disclosed SFI is determined not to constitute an FCOI, KB may nonetheless determine that some type of management or oversight of the interest is appropriate before certain research activities may proceed. KB may develop additional procedures or guidance regarding these types of interests and any associated limitations or requirements.
- I. FCOI Reporting to PHS Awarding Components for PHS-Funded Research
 1. The FCOI Committee will submit FCOI reports to a PHS Awarding Component:
 - a. Prior to expenditure of any funds under a PHS-Funded Research project, if an FCOI has not been eliminated;

- b. Within 60 days of identifying an FCOI during an ongoing research project; and
 - c. Annually for any FCOI previously reported in regard to an ongoing PHS- Funded Research project. The report shall specify the status of the FCOI (if the FCOI is still being managed or explain why it no longer exists) and if appropriate, any changes to the Management Plan. The report shall be submitted annually for the duration of the research project.
 - 2. Any FCOI report submitted to a PHS Awarding Component shall include the minimum elements as required by 42 CFR Part 50 Subpart F and contain sufficient information to understand the nature and extent of the financial conflict and assess the appropriateness of the Management Plan.
- J. PHS-Funded Research through Subrecipients
- 1. If the PHS-Funded Research or portions of it is carried out through a subrecipient, KB will take reasonable steps to ensure that any subrecipient Investigator complies with 42 CFR Part 50 by incorporating the following as part of the written agreement with the subrecipient:
 - a. terms that establish whether this policy or the subrecipient’s FCOI policy will apply to the subrecipient Investigators; and
 - b. time period(s) for the subrecipient to report all identified FCOI or for submission of all subrecipient Investigator SFI disclosures to Seattle Children’s Research Institute.
- K. Publicly Accessible Information
- 1. This policy shall be available via KB’s publicly accessible web site.
 - 2. For PHS-Funded Research, the FCOI Committee shall make information concerning significant financial interests that meet the criteria below available to the public, upon written request for such information:
 - a. SFI was disclosed and is still held by Senior/Key Personnel (as defined in this policy);
 - b. The FCOI Committee determined the SFI is related to a PHS-Funded Research project; and
 - c. The FCOI Committee determined the SFI constitutes a FCOI.
 - 3. The above information made available shall consist of the minimum elements as required by 42 CFR Part 50 Subpart F, and shall be provided by written response to the requestor.
 - 4. The above information shall remain available for public request for at least three years from the date that the information was most recently updated.
- L. Retrospective Review of PHS-Funded Research
- 1. Whenever the FCOI Committee identifies a SFI that was not disclosed in a timely manner or was not previously reviewed by the FCOI Committee during an ongoing PHS-Funded Research project, the FCOI Committee shall within 60 days:
 - a. Review the SFI;
 - b. Determine whether it is related to a PHS-Funded Research project;
 - c. Determine whether a FCOI exists;
 - d. If the FCOI Committee determines a FCOI exists, the FCOI Committee shall implement (at least on an interim basis) a Management Plan that specifies the actions that have been taken and will be taken to manage such FCOI.
 - 2. Whenever a FCOI related to a PHS-Funded Research project is not identified or managed in a timely manner due to noncompliance by KB or an Investigator, including if an Investigator fails to comply with a Management Plan, the FCOI Committee shall:
 - a. Notify the President of KB and the Board of Directors of KB (see section M of this policy).
 - b. Within 120 days of non-compliance identification, complete and document a retrospective review of the Investigator’s activities and the research project. Documentation of the review will include all elements as specified by 42 CFR Part 50 Subpart F.
 - c. Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report and specify the actions that will be taken to manage the FCOI moving forward.

- d. If bias is found, notify the PHS Awarding Component promptly and develop and submit a mitigation report. The mitigation report shall consist of the minimum elements as required by 42 CFR Part 50 Subpart F.
- e. Submit FCOI reports to the PHS Awarding Component annually thereafter for the duration of the research project.

M. Sanctions and Remedies for Violation of Policy

1. If the FCOI Committee determines an Investigator has violated this policy, including failure to submit required disclosures or failure to comply with the requirements of a management plan, the FCOI Committee shall report the violation to the President of KB and the Board of Directors. The President and Board shall take reasonable steps to respond appropriately to violations, including, but not limited to:
 - a. Suspending research activity expenditures;
 - b. Administratively suspending any research study related to the FCOI; and/or
 - c. Instituting disciplinary measures up to and including suspension or termination.
2. In the case in which it is determined that a PHS-Funded Research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported, the research institute shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and shall request an addendum to previously published presentations.

N. Record Keeping

1. The FCOI Committee shall maintain records relating to:
 - a. all Investigator disclosures of financial interests;
 - b. the FCOI Committee's review and response to such disclosures; and/or
 - c. actions taken under this policy or retrospective reviews.
2. For PHS-Funded Research, these records shall be maintained for at least three years from the date the final expenditures report is submitted to the PHS Awarding Component or as required by 45 CFR 74.53(b) and 92.42(b).

Please contact the Compliance Manager if any of the following situation arises:

1. You are incorporating or organizing a new company within the sphere of KB's research and mission;
2. You are looking into selling a research-related product or service before the study or its data collection are completed
3. You are invited to serve on a board or advisory committee of a for-profit company within the sphere of KB's research and mission; and/or
4. You are participating in consulting (or service of any kind or amount) for a company that may be in conflict with our health promotion/disease prevention mission (e.g., tobacco, fast food, indoor tanning).

KB expects advanced knowledge of a scientist applying for a grant or other research funds from a for-profit company.