

KLEIN BUENDEL, INC.

Financial Conflict of Interest Policy

I. Introduction and Purpose

This “Financial Conflict of Interest Policy” (hereinafter referred to as the “FCOI policy”) was crafted in response to federal regulations that require all Investigators to disclose any potential financial conflict of interest (FCOI) to Klein Buendel, Inc. (KB) prior to undertaking federally funded research. This policy is applicable to all federally funded sponsored project activity at KB, including federal flow-through projects.

This policy is designed to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by federal grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. It applies to all Investigators involved in federally funded research.

In response to the new regulations, KB has formed a FCOI Committee, which is responsible for determining whether a Significant Financial Interest (SFI; see definition below) relates to NIH-funded research and if it is a FCOI. If the FCOI Committee determines that a Significant Financial Interest is a FCOI, it will be reported to NIH via the eRA Commons.

The responsibilities of KB’s FCOI Committee include the following:

- Maintain an up-to-date, written, enforced policy that complies with the FCOI regulation;
- Make the policy publicly accessible;
- Maintain records of all Investigator disclosures of financial interests;
- Maintain records of the FCOI Committee’s review of and response to such disclosures (whether or not a disclosure resulted in the FCOI Committee’s determination of a FCOI);
- Promote and enforce Investigator compliance with the regulation pertaining to disclosure of SFIs;
- Develop management plans that specify the actions that have been and shall be taken to manage FCOIs; and
- Submit initial and ongoing FCOI reports to NIH.

This policy does not apply to Phase I Small Business Innovative Research or Small Business Technology Transfer applications.

II. Definitions

The following definitions apply to this policy unless a specific federal policy uses a different definition, in which case that agency's definition will apply.

Disclosure of significant financial interests: means an Investigator's disclosure of significant financial interests (SFI) to KB.

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

Financial interest: means anything of monetary value, whether or not the value is readily ascertainable.

Institution: means 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.

Investigator: means the principal Investigator (PI), co-Investigator (Co-I), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of federally funded research, which may include collaborators, consultants, research assistants, project coordinators and key personnel. In this context, the term "Investigator" includes the Investigator's spouse or domestic partner and dependent children.

Sponsored Travel: means travel that exceeds \$5,000, is related to the Investigator's institutional responsibilities, is paid on behalf of the Investigator and is not reimbursed to the Investigator. The exact monetary value may not be readily available.

Reimbursed Travel: means 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.

Research: encompasses any basic and applied research, be it bench work, creative activity (e.g., a published article, book, or book chapter), or product development (e.g., website, clinical trials, diagnostic test, or drug). As used in this policy, the term includes any such activity for which research funding is available from a federal agency through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, training grant, program project, or research resources award.

Senior/key personnel: means the PI and any other person identified as senior/key personnel by KB in the grant application, progress report, or any other report submitted on the research to the federal funding agency by KB under the scope of this policy.

Significant financial interest (SFI): refers to anything of monetary value, including a salary, consulting fee, honorarium or other payment for service; equity interests, including stocks, stock options or other ownership interests; and intellectual property rights, including patent rights owned by the Investigator or on which a clinical Investigator is a named inventor (whether licensed or not), copyrights and royalties. Significant Financial Interests include reimbursed or sponsored travel that is in excess of \$5,000, equity interests in excess of \$5,000 in a publicly or non-publicly traded entity and all other financial interests having a value in excess of \$5,000. Financial interests of a lesser amount do not require handling under this FCOI Policy.

- A. A significant financial interest exists if the following situations apply to the Investigator and/or the Investigator's spouse or domestic partner and/or dependent children, involving companies that reasonably appear to be related to the proposed research:

- i. If income in excess of \$5,000 (in the aggregate) is received from a publically traded company during the 12 months preceding the disclosure. Examples of income include salary, consulting fees, honoraria, paid authorship, stock, stock options, or other ownership interests (based on public prices or other reasonable measures of fair market value).
 - ii. If income in excess of \$5,000 (in the aggregate) is received from a non-publically traded company during the 12 months preceding the disclosure, or when any equity interest is held (e.g., stocks, stock options, or other ownership interests).
 - iii. If income in excess of \$5,000 is received from intellectual property rights and interests (e.g., patents and/or copyrights).

- B. A significant financial interest exists for travel that is related to the Investigator's Institutional responsibilities and paid for *on behalf of the Investigator* and not reimbursed to the Investigator (so that the exact monetary value may not be readily available). A significant financial interest does not exist for travel that is reimbursed by a federal, state, or local government agency. Travel in excess of \$5,000 and paid for by any entity other than a federal, state or local government, an Institution of higher education, an academic teaching hospital, a medical center or a research institute associated with an Institution of higher education must be disclosed. This disclosure will include, at a minimum, the purpose of the trip, identity of the sponsor/organizer, destination, and duration. In accordance with KB's FCOI policy, KB's Director of Finance and Research Administration will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the federally funded research.

- C. Significant financial interest does not include the following types of financial interests:
 - i. Salary, royalties, or other remuneration paid by the Institution (KB) to the Investigator if the Investigator is currently employed or otherwise appointed by Institution;
 - ii. Intellectual property rights assigned to KB and agreements to share in royalties related to such rights;
 - iii. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
 - iv. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - v. 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.

III. Training

Training will be provided for all Investigators prior to engaging in federally funded research. The training course used by KB is the NIH Financial Conflict of Interest web-based tutorial. [The NIH tutorial](#) is designed to provide education training on what constitutes FCOI.

As of August 24, 2012, all Investigators are expected to complete required training by the issue date of the Notice of Award issued subsequent to the Institution's implementation date. Training must be repeated at least every four years, and immediately when KB revises its FCOI policies or procedures in

any manner that affects the requirements of Investigators; an Investigator is new to KB; or an Investigator is found to be in non-compliance with KB's FCOI policy or management plan.

IV. Disclosure Requirements

Upon completion of Financial Conflict of Interest training, all affected researchers will be required to complete Financial Interest Disclosure forms.

At the time of submission of a grant to a federal agency, participating Investigators are required to complete and submit a project-specific FCOI form, which will be reviewed by KB's Compliance Coordinator (and if a SFI is noted, it will be reviewed by KB's FCOI Committee). In addition, all Investigators must submit a project-specific FCOI form annually during the period of the award (at the time of submission of Progress Reports) to include any information that was not disclosed previously, and to include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest). Any newly discovered or acquired SFI (e.g., through purchase, marriage, or inheritance) must be disclosed to KB within 30 days.

V. Subcontracts

If the federally funded research involves a subrecipient (e.g., subcontractors or consortium members), KB (as the awardee Institution) will take reasonable steps to ensure that any subrecipient Investigator complies with the federal policies by implementing the following procedures:

- A. KB will establish, in writing with the subrecipient, whether the FCOI policy of KB or that of the subrecipient will apply to the subrecipient's Investigators.
 - i. If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify that its policy is in compliance with federal policies. In the absence of this certification, the Subaward Agreement will state that subrecipient Investigators are subject to KB's FCOI policy for disclosing significant financial interests that are directly related to the subrecipient's work for KB.
 - ii. Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the written agreement will specify a deadline for the subrecipient to report all identified financial conflicts of interest to KB so that KB can submit timely FCOI reports, as necessary, to the relevant federal agency.
 - iii. Alternatively, if the subrecipient's Investigators must comply with KB's FCOI policy, the written agreement will specify a deadline for the subrecipient to submit all Investigator disclosures of significant financial interests to KB so that KB can submit timely FCOI reports, as necessary, to the relevant federal agency.
- B. KB will provide FCOI reports to the relevant federal agency regarding financial conflicts of interest of subrecipient Investigators consistent with this policy, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

VI. Review of FCOI and Management of Conflicts

An Investigator's significant financial interest is related to federally funded research if KB's FCOI Committee reasonably determines that the significant financial interest: a) could affect the research, or b) is in an entity whose financial interest could be affected by the research. A FCOI exists if KB's FCOI Committee reasonably determines that the significant financial interest could directly and significantly

affect the design, conduct, or reporting of the federally funded research.

At the time of submission of a grant or a Progress Report to a federal agency, all participating Investigators are required to complete and submit a project-specific FCOI form. If the FCOI form indicates a significant financial interest, it will be reviewed by KB's FCOI Committee.

Financial conflicts of interest will be addressed by one of the following approaches:

- A. KB's FCOI Committee will work with the Investigator to develop a management plan that will eliminate the FCOI. The plan will be approved by KB's Director of Finance and Research Administration.
- B. If it is not possible to eliminate the FCOI, a plan to reduce or manage the conflict must be developed by the Investigator in consultation with KB's FCOI Committee. The plan will be approved by KB's Director of Finance and Research Administration. All FCOI must be resolved and management plans approved before the research project can begin.

If a disclosure of a new conflict arises or the discovery of an undisclosed conflict is uncovered, KB's FCOI Committee will review and make recommendations within 60 days of the new conflict disclosure or unreported disclosure discovery.

KB's FCOI Committee will review all of the submitted material and either accept or suggest modifications to further eliminate the conflict. This could involve, at either the committee's request or at the Investigator's request, a meeting with the committee. External expert opinions may also be sought by KB's FCOI committee. Investigators may appeal any final decision in writing within 14 days. Examples of approaches that could be used to manage a FCOI include, but are not limited to the following:

- Public disclosure of FCOI (e.g., when presenting or publishing research findings);
- For research projects involving human subjects, disclosure of FCOI directly to participants;
- Appointment of an independent monitor 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;
- Change in personnel or personnel responsibilities, or disqualification 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.
- When a management plan is implemented, KB's FCOI Committee will monitor Investigator compliance with the management plan on an ongoing basis until completion of the affected federally funded research project.

When KB's FCOI Committee finds that an Investigator has a FCOI, it will be reported to NIH via the eRA Commons. KB is not required to submit a copy of the actual management plan, as any information submitted will be publicly accessible. KB will submit an overview of the management plan.

If KB discovers a SFI that was not disclosed by an Investigator or was not previously reviewed by KB's FCOI Committee, KB's FCOI Committee shall, within 60 days, review the disclosure of SFI, determine whether it is related to NIH-funded research, determine whether a FCOI exists and if necessary, implement a management plan.

In addition, KB's FCOI Committee shall, within 120 days* of the determination of noncompliance, complete a retrospective review of the Investigator's activities and of the NIH-funded research project to determine whether any NIH-funded research conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting. KB is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- A. Grant or Contract number;
- B. Grant or Contract title;
- C. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- D. Name of the Investigator with the FCOI;
- E. Name of the entity with which the Investigator has a FCOI;
- F. Reason(s) for the retrospective review;
- G. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- H. Findings of the review; and
- I. Conclusions of the review.

* The retrospective review may still be in process when the report is due (120 days). In this case, the report will be as up-to-date as possible, with the expectation that the report will be revised when the retrospective review is complete.

VII. Reporting to NIH

KB must certify in each application for funding to which this policy applies, that KB has a written and enforced administrative process to identify and manage financial conflicts of interests and that KB will ensure compliance with all such related federal policies regarding FCOI.

In cases in which KB identifies a FCOI and eliminates it prior to the expenditure of NIH-awarded funds, it is not required to be reported to NIH. KB will submit an Initial FCOI Report prior to the expenditure of funds.

If an Investigator is a new participant on the project, and a FCOI is identified, KB must report the FCOI to the NIH within 60 days. For any new or newly identified FCOI (after KB's initial FCOI report), KB has 60 days to report the FCOI to the NIH.

For any FCOI previously reported (with regard to an ongoing NIH-funded project), KB shall provide NIH with an Annual FCOI Report. The Annual FCOI Report shall specify whether the financial conflict of interest is still being managed or explain why the FCOI no longer exists. KB shall provide Annual FCOI Reports to the NIH for the duration of the project period (including extensions with or without funds). Annual FCOI Reports are due at the same time Progress Reports are due (or when an extension goes into effect).

If an Investigator fails to comply with KB's FCOI Policy or if a FCOI Management Plan appears to have biased the design, conduct, or reporting of the NIH-funded research, KB must report to the NIH and take corrective action.

If bias is found with the design, conduct, or reporting of NIH-funded research, KB must perform a retrospective review of the research project and provide a Mitigation Report to NIH. KB shall update the

previously submitted FCOI Report, specifying the actions that will be taken to manage the FCOI going forward. 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 the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

All FCOI reports to the NIH will include:

- A. Grant or Contract number;
- B. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- C. Name of the Investigator with the FCOI;
- D. Name of the entity with which the Investigator has a FCOI;
- E. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement,
- F. honorarium);
- G. Value of the financial interest (dollar ranges are permissible: \$0 - \$4,999; \$5,000 - \$9,999; \$10,000 - \$19,999; amounts between \$20,000 - \$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- H. A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- I. A description of the key elements of the Institution's management plan, including:
 - i. Role and principal duties of the conflicted Investigator in the research project;
 - ii. Conditions of the management plan;
 - iii. Explanation of how the management plan is designed to safeguard objectivity in the research project;
 - iv. Confirmation of the Investigator's agreement to the management plan;
 - v. Description of how the management plan will be monitored to ensure Investigator compliance; and
 - vi. Other information as needed.

KB is required to maintain records relating to all Investigator disclosures of financial interests and KB's review of and response to such disclosures (whether or not a disclosure resulted in KB's determination of a FCOI) and all actions under KB's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the federal agency, or as required by the specific agency.

VIII. Public Accessibility to FCOI Information

Prior to KB's expenditure of any funds under a federally funded research project, KB shall ensure public accessibility (via its website) of information concerning any significant financial interest disclosed to KB that meets the following three criteria:

- A. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by federal policies;
- B. KB determines that the significant financial interest is related to the federally funded research; and
- C. KB determines that the significant financial interest is a FCOI.

The information that KB must make available via its website will include the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in

which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (or a statement that the interest is one whose value cannot be readily determined by normal assessments of fair market value). This posted information must be updated at least annually and will remain accessible for at least three years from the date that the information was most recently updated.

The FCOI section on the KB website shall be updated at least annually. In addition, KB shall update the website within 60 days of the receipt or identification of information concerning any additional SFIs of the senior/key personnel for NIH-funded research project (if it was not previously disclosed), or upon the disclosure of a SFI of senior/key personnel; or upon the disclosure of a SFI of senior/key personnel new to NIH-funded research, if the Institution determines that the SFI is related to NIH-funded research and is a FCOI. The website shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new FCOI.

IX. Enforcement

Investigators will not be able to receive funds without first submitting FCOI reporting documents and approval of a management plan. Noncompliance must also be reported to the appropriate federal funding agency. Certain agencies (e.g., NIH grants for clinical research) require public disclosure of FCOI on all public presentations and publications (including addendums for previously published items) for any funded research that did not comply with federal disclosure regulations.

Failure of Investigators to comply with this policy, including restrictions put in place by the management plans, will be grounds for discipline and sanctions.

For further information, see:

http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

The full text of the regulation titled, "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors," which was published in the Federal Register (Vol. 76, No. 165, August 25, 2011), is available via a link from the NIH Conflict of Interest homepage (<http://grants.nih.gov/grants/policy/coi/index.htm>).