

## **Klein Buendel, Inc. (KB)**

### **Financial Conflict of Interest (FCOI) Policy — NIH / Public Health Service (PHS)**

#### **SUMMARY**

Klein Buendel, Inc. (KB) is committed to maintaining public trust in the integrity and objectivity of its research activities. The U.S. Department of Health and Human Services (HHS) has issued regulations governing the responsibility of applicants for promoting objectivity in research for which Public Health Service (PHS) funding is sought and the responsibilities of prospective contractors. This policy implements the requirements of 42 CFR Part 50, Subpart F and 45 CFR Part 94.

This policy applies solely to PHS-funded research, including research funded by the National Institutes of Health (NIH), and establishes procedures for identifying, reviewing, managing, and reporting Financial Conflicts of Interest (FCOIs).

#### **DEFINITIONS**

**Disclosure:** An Investigator's provision of information about significant financial interests to KB.

**Equity Interest:** Any interest in the profits of, stock of, stock option in, or 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 PHS-funded research.

**Institution:** Klein Buendel, Inc., as the entity applying for or receiving PHS funding and accountable for compliance with applicable federal regulations.

**Institutional Official:** One or more persons designated by KB to oversee compliance with this policy.

**Institutional Responsibilities:** All professional activities performed at or on behalf of KB, including research, consulting, teaching, and administrative duties.

**Investigator:** Any person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research. Disclosure obligations include the financial interests of the Investigator's spouse or domestic partner and dependent children.

**Management Plan:** A written plan specifying actions that have been or will be taken to manage, reduce, or eliminate a financial conflict of interest.

**Senior/Key Personnel:** Individuals identified as such by NIH in grant applications, awards, progress reports, or other official submissions.

#### **SIGNIFICANT FINANCIAL INTEREST (SFI)**

A Significant Financial Interest (SFI) is a financial interest that reasonably appears to be related to an Investigator's Institutional Responsibilities and meets one or more of the criteria below, after accounting for applicable exclusions.

## 1. Travel

All reimbursed or sponsored travel related to an Investigator's Institutional Responsibilities must be disclosed, regardless of dollar amount. Disclosures must include:

- Purpose of the trip
- Identity of the sponsor or organizer
- Destination - Duration (start and end dates)

Excluded travel: Travel reimbursed or sponsored by a federal, state, or local government agency; an Institution of higher education; an academic teaching hospital; a medical center; or a research institute affiliated with an Institution of higher education.

## 2. Compensation

Compensation totaling more than \$5,000 received from a single entity in the preceding 12 months, including salary, consulting fees, honoraria, or other payments.

Exclusions:

- Salary, royalties, or other remuneration paid by KB
- Income from seminars, lectures, teaching engagements, or service on advisory or review panels sponsored by excluded entities

## 3. Equity Interests in Non-Publicly Traded Entities

Any equity interest held in a non-publicly traded entity at the time of disclosure.

Exclusions:

- Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g., mutual funds, retirement accounts).

## 4. Equity Interests in Publicly Traded Entities

Equity interests in a publicly traded entity valued in excess of \$5,000 at the time of disclosure.

## 5. Combined Equity and Compensation

Equity interests in a publicly traded entity and compensation received from that entity in the preceding 12 months that, when combined, exceed \$5,000.

## 6. Intellectual Property

Intellectual property rights and income received from such rights.

Exclusions:

- Intellectual property from which no income has been received
- Intellectual property assigned to KB
- Royalty payments paid by KB to the Investigator
- Agreements that provide the Investigator a right to share in royalties through KB

## **POLICY STATEMENT**

- A. Research conducted at, on behalf of, or through KB shall not be adversely affected by the financial interests of Investigators.
- B. All PHS-funded research shall be conducted in compliance with 42 CFR Part 50, Subpart F and 45 CFR Part 94.
- C. Failure to comply with this policy may result in sanctions.

### **INVESTIGATOR RESPONSIBILITIES**

Investigators are required to:

1. Disclose all SFIs:
  - At least annually;
  - Within 30 days of discovering or acquiring a new SFI;
  - Prior to engaging in PHS-funded research;
  - As part of the new-hire process; and
  - Upon request of the FCOI Committee.

Investigators must certify that each disclosure is complete and accurate to the best of their knowledge.

2. Complete FCOI training:
  - Prior to engaging in PHS-funded research;
  - At least every four years;
  - Immediately upon policy revision; and
  - Upon determination of noncompliance.
3. Comply with any Management Plan issued under this policy.

### **REVIEW AND MANAGEMENT OF FCOIs**

The FCOI Committee shall:

- Review all disclosed SFIs;
- Determine whether an SFI is related to PHS-funded research (the SFI will be affected by the research or influence the design, conduct, or reporting of research);
- Determine whether an FCOI exists; and
- Develop and implement a Management Plan when required.

All identified FCOIs will be reviewed and managed prior to the expenditure of PHS research funds, or within 60 days of identification during an ongoing project.

The FCOI Committee will monitor Investigator compliance with Management Plans for the duration of the research.

### **RETROSPECTIVE REVIEW & MITIGATION**

If an FCOI is discovered after funds are expended or if an Investigator fails to disclose in a timely manner, a retrospective review will occur within 120 days of discovery. If bias is identified, a mitigation report will be submitted to NIH.

### **REPORTING TO PHS AWARDING COMPONENTS**

KB will submit FCOI reports to the appropriate PHS Awarding Component:

- Prior to the expenditure of any funds if an FCOI has not been eliminated;
- Within 60 days of identifying an FCOI during an ongoing project; and
- Annually for previously reported FCOIs for the duration of the project.

All reports will include the elements required by 42 CFR Part 50, Subpart F.

### **SUBRECIPIENTS**

For PHS-funded research involving subrecipients, KB will:

- Require subrecipients to comply with this policy or certify compliance with their own PHS-compliant FCOI policy; and
- Establish reporting timelines in written agreements sufficient for KB to meet its PHS reporting obligations.

### **PUBLIC ACCESSIBILITY**

Information concerning identified FCOIs held by Senior/Key Personnel will be:

- Posted on a publicly accessible website, or
- Provided in writing within five (5) business days of a request.

Public disclosures include:

- Investigator name
- Role in the research
- Nature of the SFI
- Approximate value range
- Whether the interest is still held

Such information will remain available for at least three years from the date it was most recently updated.

### **SANCTIONS AND REMEDIES**

Violations of this policy or failure to comply with a Management Plan may result in corrective actions, including suspension of research activities, disciplinary action, or termination of employment.

### **RECORD RETENTION**

Records relating to Investigator disclosures, FCOI reviews, management plans, mitigation reports and related actions will be retained for at least three years from the date the final expenditures

report is submitted to the PHS Awarding Component, or longer if required by applicable regulations.

**EFFECTIVE DATE**

This NIH/PHS Financial Conflict of Interest Policy is effective upon approval by KB leadership and applies to all ongoing and new PHS-funded research.