

# **Praevium Research, Inc.**

## **Financial Conflict of Interest Policy**

### **I. Introduction:**

Federal regulations require that Praevium Research, Inc. have a written and publicly accessible financial conflict of interest policy before engaging in or applying for funds for Public Health Service sponsored research. This policy is intended to satisfy this requirement, and to instruct Praevium Research, Inc. employees in applying and complying with Praevium requirements regarding financial conflicts of interest in research. Praevium Research policy is to be in full compliance with Financial Conflict of Interest (FCOI) Regulation 42 CFR Part 50 Subpart F (grants and cooperative agreements) and 45 CFR Part 94 (research contracts). More specifically, this policy is intended to be in full compliance with the 2011 revised FCOI regulations. These regulations promote objectivity in research by establishing standards for institutions and investigators, that provide a reasonable expectation that the design, conduct and reporting of research funded under PHS grants, contracts, or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

Praevium Research requires that individuals disclose any relevant financial interests. While full and accurate disclosure is required, Praevium Research recognizes that the existence of a conflict of interest or appearance of conflict does not necessarily constitute wrongdoing on the part of the investigator. Furthermore, the appearance of conflicts or actual conflicts may be acceptable if appropriately managed and monitored.

To address FCOI, Praevium Research has established a process by which Investigators disclose potential conflicts and are evaluated on a case-by-case basis. This policy describes procedures for disclosure, review, and oversight when necessary.

### **II. Guiding Principles**

1. Praevium Research and its investigators must conduct research with the utmost integrity. Praevium and its researchers have a responsibility to conduct research that is free of bias, free of influence by outside financial interests, and free of the appearance of non-objectivity or outside financial influence. Failure to do so may jeopardize future and current funding. It may also damage the reputation of Praevium Research, its employees, and its collaborators.
2. Investigators working with and for Praevium have a responsibility to disclose to Praevium Research, Inc. financial interests that conflict with or appear to conflict with their responsibilities at Praevium Research, Inc.
3. Praevium Research has the responsibility to promptly review all disclosures of financial interests and take measures to identify, manage, reduce, or eliminate any FCOI that may exist, to ensure that the design, conduct and reporting of research will remain free from bias resulting from Investigator financial conflicts of interest.

### III. Definitions

**Investigator:** The project director or Principal Investigator and any other person regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding, which may include collaborators or consultants. Graduate students, interns, some consultants, and others whose work is regularly and closely scrutinized by a senior investigator, and who are not ultimately responsible for design, conduct, and reporting of research, may not necessarily be considered investigators in this sense. Praevium Research may, at its discretion and as a matter of due diligence, place the same requirements on these individuals as on investigators.

**Significant Financial Interest (SFI):** A financial interest consisting of one the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities. As pertains to Praevium Research, a SFI exists:

- If the value of any remuneration received from an entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000.
- When the Investigator (or Investigator's spouse or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interests) in an entity.
- When income is received as related to intellectual property rights and interests (e.g. patents, copyrights).
- Note: Investigators must also disclose any reimbursed or sponsored travel.

*Exclusions:*

- Salary or other remuneration paid by Praevium Research to the Investigator if the Investigator is employed or otherwise appointed by Praevium Research.
- Remuneration paid to an Investigator or investigator's family that would not reasonably appear to be related to an investigator's institutional responsibilities.
- Intellectual Property Rights assigned to Praevium Research and agreements to share in royalties related to such rights.
- Any ownership interest in Praevium Research held by the Investigator.
- Mutual funds and retirement accounts, as long as the investigator does not exercise control or management responsibility, or have investment decision-making authority for these entities.
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, local government agency, an institution of higher learning, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher learning.
- Income from service on advisory committees or review panels for a federal, state, local government agency, an institution of higher learning, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher learning.

### IV. Investigator Training Requirements

Every new employee must be provided a copy of this policy and training materials within 7 business days of hire date. The employee must complete training and submit the training certificate to the designated institutional official within 30 days, and prior to engaging in any PHS funded research or submitting proposals for such research. This certificate must be filed in the employee's record until an updated certificate is received. Training must also be completed and a new training certificate must be filed at the following times:

- Institutional FCOI policies change in a manner that affects Investigator requirements.
- An Investigator is new to the institution.
- An institution finds an Investigator to be noncompliant with the institutions FCOI policy or management plan.

FCOI training includes a thorough review of Praevium Research's financial conflict of interest policy on its website, as well as a thorough review of the NIH powerpoint slides "FCOI Webinar for NIH Grantees" made available to all employees upon hiring. Upon completion of training, Investigators must print and sign a Praevium Research completion of training certificate. Training must be renewed at least every 4 years after initial training or more frequently if NIH regulations or Praevium policies change.

## **V. Disclosure, Review, and Monitoring Requirements**

### **Disclosure Form (Annual and Updated)**

1. An annual disclosure form for each federally funded project is required from:
  - Praevium Research employees responsible for the design, conduct, and reporting of PHS funded research.
  - Investigators and other individuals identified on PHS funded grants and responsible for the design, conduct, or reporting of research.
  - Investigators and other individuals identified on IRB applications and responsible for the design, conduct, or reporting of research.
2. Individuals required to provide an annual reporting form must disclose any SFI greater than \$5,000 (for themselves, spouse, or dependent children).
3. Individuals will receive an annual disclosure form by December 1. Completed disclosure forms are due back Dec. 31.
4. Individuals are responsible for maintaining a current accurate disclosure form. If a new relationship or change in a current relationship could be perceived as a FCOI, individuals must update their disclosure form to reflect such conflicts within 30 days.
5. Investigators are required to disclose all SFI/FCOI at time of application for PHS funds (i.e. complete a disclosure form for proposed research).

### **Review**

The Praevium Research, Inc. CEO will appoint a conflict of interest (COI) officer to review disclosure of all SFIs. After disclosure forms are returned to Praevium Research's COI officer, they will be reviewed to determine whether or not an overlap with research and external interests might exist. In more complex cases, the COI may appoint an internal committee or seek outside counsel to determine whether an FCOI exists, or to establish procedures for managing the FCOI. Individuals will be notified if a COI exists such that it could directly and significantly affect the design, conduct, and reporting of PHS funded research. Individuals will then work with the COI officer to mitigate the conflict (by managing, reducing, or eliminating it).

### **Monitoring**

Acceptable strategies for managing, reducing, or eliminating FCOIs include but are not necessarily limited to:

- Withdrawal of an investigator from a grant application or from participation in the conflicting research effort.
- Severance of financial relationships that create the FCOIs.
- Modification of the research plan.

- Appointment of an independent committee to monitor the research and prevent bias.
- Disclosure of FCOI when publishing or presenting research findings: Investigators will disclose relevant financial interests to all journals where this research will be published and in all public presentations of this research. Investigator must also request an addendum to previously published presentations, if an FCOI needs to be disclosed.
- Disclosure of FCOI to potential human subjects: If deemed necessary by the COI officer, any FCOIs will be disclosed to all potential research participants in the consent process.
- Oversight and monitoring of research and decisions by a Praevium Research or non-conflicted member of the research team:

## **VI. Reporting Requirements to NIH**

NIH will be notified within 30 days if bias is found with the design, conduct, or reporting of research and will include a Mitigation Report outlining the management plan. Initial, annual (ongoing), and revised FCOI reports will be submitted to NIH (via eRA Commons):

- Prior to expenditure of funds.
- Within 60 days of identification for an Investigator who is new to the project.
- Within 60 days for new, or newly identified, FCOIs for existing Investigators.
- At least annually (in conjunction with annual progress reports or at the time of an extension).
- Following a retrospective review to update a previously submitted report.

NIH will be notified within 30 days if an Investigator fails to comply with this policy or if the FCOI management plan appears to have biased the design, conduct, or reporting of research.

## **VII. Maintenance of Records**

All FCOI records (training certificates, disclosures, management plans, retrospective reviews) will be held for three years after the final report is submitted to NIH. If any of the situations specified in 45 CFR 74.53(b) or 92.42(b) apply, the timelines specified in these sections will be adhered to.

## **VIII. Enforcement, Non-Compliance, and Disciplinary Action**

Compliance with Praevium Research's FCOI policy for PHS research is a condition of employment with Praevium Research.

Federal regulations require Praevium Research to impose sanctions where appropriate. Failure to disclose SFIs and abide by this policy may be cause for termination of employment, or restriction of future research submissions or participation in certain research efforts. Other disciplinary actions in proportion to the offense may be taken.

If it has been determined that an Employee or the Institution is in noncompliance with this policy (e.g. SFIs not disclosed, reviewed or managed in a timely or appropriate manner), then Praevium Research must complete and document a retrospective review within 120 days. The retrospective review should be conducted by the SFI disclosure review committee as designated by the CEO. The results of the retrospective review shall be documented and attached to the disclosure documents. If bias is found, Praevium Research must immediately notify the NIH by submitting a mitigation report.

Praevium Research must enforce any sanctions or actions required by the Department of Health and Human Services pertaining to a PHS-funded research project involving clinical research. If an FCOI was not reported or managed according to regulations, then Praevium Research must require the Employee or Investigator to disclose the FCOI in each public presentation of the results or research and request an addendum to previously published results or presentations.

## **IX. Sub-recipient Requirements**

Sub-recipients with an FCOI policy that is compliant with current regulations cited in section I above, may comply with their institution's FCOI policy provided they supply Praevium Research with the necessary disclosure information to meet all reporting obligations and deadlines. If the subrecipient's institution does not have a suitable FCOI policy in place, then they shall adhere to the Praevium Research policy described in this document. A written agreement must exist with the sub-recipient certifying its own policy meets regulations, and that it will provide the required information to Praevium Research, or that the sub-recipient will adhere to the Praevium FCOI policy.

## **X. Public Accessibility**

Praevium Research's FCOI policy will be publicly available on its website at [www.praevium.com](http://www.praevium.com).

In the event that FCOIs are identified, information regarding the COI and the Investigator will also be publicly available on [www.praevium.com](http://www.praevium.com). Publicly available information will be:

- Updated annually at a minimum
- Made available within 5 calendar days of a written request.
- Updated within 60 days of newly identified FCOIs.
- Remain available for 3 years from the most recent update.
- Information to be made publicly available is to include, but is not limited to:
  - Investigator's name.
  - Investigator's title and role with respect to the research project.
  - Name of the entity in which the SFI is held.
  - Nature of the SFI.
  - Approximate dollar value of SFI (or a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value.).