

## Policy on Financial Conflicts of Interest in Research

As an entity engaged in research, Planned Parenthood Federation of America (“PPFA”) has an obligation to assure that its scientific and clinical research is conducted pursuant to the highest standards of ethical conduct and free from any improper external bias. At the same time, PPFA encourages scientific collaboration with industry and supports collaborative research geared towards developing new and improved diagnostic and therapeutic products. PPFA economic relationships with industry have the potential to directly and significantly affect the approval, design, conduct, monitoring or reporting of a research study. Situations can occur in which an independent observer might reasonably conclude that the potential for individual or institutional profit could influence the outcome of a research study. Therefore, to safeguard the integrity of both PPFA and its investigators, we have adopted a rigorous conflicts policy predicated on full disclosure and appropriate management. The Policy sets out the requirements for disclosing potential conflicts of interest in research and specifies the procedures for reviewing such disclosures and determining what corrective measures, if any, should be instituted. Furthermore, the policy subjects clinical trials that evaluate the safety and efficacy of a drug, medical device or treatment, and research on technology in which the Investigator/Covered Person and/or PPFA has an ongoing financial interest, to the most rigorous review and stringent conditions.

This Policy is based on the standards set forth in the federal regulations governing research funded by the National Institutes of Health (NIH), Public Health Service (PHS) or the National Science Foundation (NSF) (*42 CFR Part 50 Subpart F*).

### A. Definitions

1. **Disclosure:** Reporting by Covered Persons of compensation or other financial relationships with companies having a financial interest in the investigators' research or its results.
2. **Covered Persons:**
  - a. **Investigators:** includes the principal investigator, co-investigator and any other person who is responsible for the design, conduct or reporting of research. This term further includes investigators who are sub-recipients of a federal grant or who work at an institution that is a sub-recipient of a federal grant. The responsibility for ensuring that disclosure forms are submitted for the entire research team lies with the Principal Investigator.
  - b. **Principal Investigator's and Team Members' Related Parties:** includes spouse/ domestic partner and dependent children.

3. **Institutional Officials:** All senior management including President/CEO, Vice Presidents, Members of the Board of Directors, and other employees as identified by PPFA Board of Directors. These individuals shall submit an annual disclosure form to the FCOIRC (as defined below) specifying all remuneration from and/or equity in entities that sponsor research and shall provide updates as appropriate and otherwise specified herein.
4. **Financially Interested Company:** Financially Interested Company means an entity whose financial interests would reasonably appear to be affected by the conduct or outcome of the research. This term also includes not-for-profit organizations and foundations.
5. **Equity Interest:** Equity interest includes stocks, stock options, convertible notes, and other ownership interests (e.g., non-publicly traded company).
6. **Intellectual Property:** Intellectual Property includes patent applications; pending, issued, or licensed patents; copyrights; or royalties from such rights.
7. **Financial Interest:** Anything of monetary value from a Financially Interested Company, including but not limited to: director's fees; consulting fees; honoraria; equity interest; and intellectual property. This also includes other payments or "in kind" compensation from a Financially Interested Company or those from a third party if the original source is a Financially Interested Company), for any services not directly related to the reasonable costs of conducting the research.

Financial interest does not include salaries from PPFA, salary support from grants, or reasonable business meals and travel provided in the regular course of business, nor does it include 401K/403B retirement funds or shares held in mutual funds not controlled by you.

8. **Significant Financial Interest:**
  - a. Amounts for covered persons that in aggregate:
    - Exceed \$5,000 during the twelve months preceding submission of the research disclosure statement; or
    - Are anticipated to exceed \$5,000, during the twelve months following submission of the research disclosure statement
  - b. Equity interest of any kind and in any amount, including options or entitlement to the same, in a non-publicly traded Financially Interested Company.
  - c. Aggregated equity interest of any kind, including options or entitlement to the same, in a publicly traded, Financially Interested Company that exceeds \$5,000 in value.
  - d. License fees, royalty income or the right to receive such payments pursuant to a license, option or other entitlement to a patent, pending patent or copyright that is directly related to the proposed research or services.

9. **Financial Conflict of Interest in Research Committee ("FCOIRC"):** Committee which determines whether a financial conflict of interest exists in a research project and helps to manage such conflict. The committee consists of three volunteers from PPFA, one each from the Finance, Legal and Research Departments.
10. **Management Plan:** Actions or conditions intended to manage, reduce, or eliminate a conflict of interest. Management plans must be approved by the FCOIRC.

## B. Who Must Disclose

All Covered Persons as defined above in Sections A (2) (a, b) must disclose to PPFA their Financial Interests. Principal Investigators and PPFA senior management personnel who are aware of relevant Financial Interests of other family members should report such interest but are not expected to inquire into the detailed personal matters of others.

As noted in the definition section, "Investigators" include investigators performing programmatic activity pursuant to a sub-award agreement. If the grant involves sub awards, then the sub-recipient affiliate must complete an PPFA sub-award agreement that includes a discrete COI section directing the sub-recipient to certify that the affiliate has a conflict of interest policy consistent with the federal requirements in *42 CFR Part 50 Subpart F*. The affiliate must further identify each investigator with a conflict of interest and report to the FCOIRC how the conflict of interest has been managed, reduced, or eliminated. Finally, the sub-recipient must provide PPFA with any relevant management plans on an annual basis. PPFA will make the requisite notifications to the NIH of the sub-recipient investigator(s)' conflict of interest. If the sub-recipient does not have a compliant Conflict of Interest policy then the investigators must comply with the PPFA policy, complete the necessary disclosure questionnaire and comply with the FCOIRC's management plan for any identified conflict.

This obligation applies to all sub-recipients, sub-grantees, contractors or collaborators carrying out a component of PPFA's programmatic activity. It does not apply to vendors or consultants providing routine goods or services, such as data processing, routine analytical or testing services.

## C. What Must Be Disclosed

All Financial Interests must be disclosed by each Covered Person.

All PPFA senior management personnel must disclose all Financial Interests or other relationships with any Financially Interested Company in their annual disclosure form and provide updates as appropriate.

#### **D. When Disclosure Must Be Made**

Disclosure must be made at the time of submission of a research application and within thirty (30) days of discovering or acquiring a Significant Financial Interest. Annual disclosure updates will be required for all Covered Persons for the duration of the research and up to one year after the study is closed. Annual disclosures will be required for all senior management personnel.

#### **E. Disclosure Procedure: Certification of Compliance**

##### **1. When Submitting a Research Application:**

As part of the research application that is submitted to the Grants and Contracts Office, Covered Persons must complete the confidential disclosure forms provided by PPFA. Investigators conducting human subjects' research and disclosing a Significant Financial Interest must submit convincing reasons detailing why the research should be performed by that Investigator at PPFA.

In submitting the research application, Covered Person(s), including the Chairpersons, will be certifying that: they have read and understood this Policy; they have made all the required disclosures; and they will comply with any conditions imposed by PPFA to manage, reduce or eliminate actual or potential financial conflicts of interest. For NIH funded grants, the official signing the grant application for PPFA will be certifying to the governmental agency that: a written and enforced conflicts of interest policy is in place; to the best of his/her knowledge, all required disclosures have been made; and that any actual or potential conflicts will be adequately managed, reduced or eliminated before expenditure of funds from the grant begins.

##### **2. During the Period of the Research:**

If a change in Financial Interests occurs as a result of acquiring a new Financial Interest or an increase in the value of a previously disclosed Financial Interest, the disclosure statement must be updated promptly. New investigators who join the research during the grant-funding period must disclose their Financial Interests in accordance with this Policy before they begin such work. In addition, updates must be filed annually with the non-competitive renewal of the grant. For NIH-funded grants, the existence of any new financial conflict of interest not covered in the original report to the funding agency must be reported by PPFA to the funding agency and assurances given that it has been resolved or will be resolved within sixty days of its identification.

#### **F. Institutional Financial Interests Data**

1. The FCOIRC shall maintain a database of the following:

- a. All technology licensing activities involving PPFA or any of its faculty members;
  - b. Disclosure forms of Institutional Officials and Covered Persons for outside activities and research;
  - c. Donations through PPFA Development Office greater than \$100,000 from Financially Interested entities;
  - d. Departmental donations/grants exceeding \$5,000 from a Financially Interested entity as provided by the Department Chairperson and/or Administrator.
2. Individual investigators will be provided with information to determine if a potential Institutional conflict exists.

#### **G. Review Procedure; Management of Conflicts**

The FCOIRC will review all disclosure statements indicating Significant Financial Interests, and will retain discretion to review disclosures below this threshold. In its review, the Committee will consider the foreseeable material effect of the Financial Interest on the research. If a protocol presents both an institutional conflict and an individual one, the Committee shall review the proposal first, and will make a determination as to whether the institutional conflict can be appropriately managed and the research can proceed at PPFA. The Committee shall review the individual conflict only after resolution of the Institutional conflict. The FCOIRC review and management procedures detailed in this Section shall apply to all investigator Significant Financial Interest disclosures, including for investigators who are new to participating in a research project, for an existing investigator who discloses a new Significant Financial Interest, or for Significant Financial Interests which were not disclosed timely by an investigator or not previously reviewed by PPFA.

1. **For Research Involving Human Subjects:** In the event that the Committee determines that a Covered Person, including all members of the research team and their related parties, or the Institution holds a Significant Financial interest, the Committee will presume that there is a conflict of interest and will evaluate convincing reasons for whether and how the research could be conducted at PPFA. This presumption will apply to all research involving human subjects, regardless of whether the research is funded by a public agency, a non-profit entity, a commercial sponsor or a private source, and wherever the research is carried out. This presumption will not apply, however, to phase II or phase III multi-center trials, where there is an independent data monitoring organization and PPFA is not the coordinating site.

The FCOIRC will develop a written management plan to manage, reduce or eliminate the conflict. The Committee must be provided with compelling information indicating that the financial conflict will not taint the research and may consider the following factors in making their determination:

- a. the nature of the research and the extent to which the research could be performed at other centers;
- b. the degree of risk to the human subjects involved that is inherent in the research protocol;
- c. the extent to which the investigator and/or the institution is uniquely qualified to perform the study;
- d. the magnitude and type of the financial interest and the degree to which it is related to the research;
- e. the extent to which the financial interest could be directly and substantially affected by the research such as increasing financial gains for the investigator and/or institution.
- f. the extent to which the financial interest can be minimized by effective oversight and management

#### **H. Possible Management Plans to Neutralize Conflicts**

When a Financial Interest is directly related to the research and may be substantially affected by it, e.g., an equity interest in a start-up company that manufactures the investigational product, the risk is great and the bar must be high. Yet, carrying out the research at PPFA when the covered person has Significant Financial Interests may be justified in some circumstances, for example, when the individual holding such interests is uniquely qualified by virtue of expertise and experience and the research could not otherwise be conducted as safely or effectively without that individual.

If the Committee determines that the conflict can be neutralized by an appropriate and enforceable management plan, the Committee will allow the research to proceed at PPFA, subject to the implementation of the proposed management plan for the conflict.

These management plans may include, but are not limited to the following:

1. Disclosure - Disclosure is required in every case regardless of the magnitude of the interest, including: (i) public disclosure of the financial interests of the investigator and of PPFA, if applicable, in all relevant publications, presentations (whether or not academic presentations), including presentations at the level of the covered party's primary department or higher, and (ii) disclosure to the appropriate co-investigators, members of the laboratory or research group, and students or trainees, and (iii) disclosure on human subject consent forms;

2. Restriction on Equity - (i) placement of stock in escrow until a trigger date specified by the Committee, or (ii) requirement that options, warrants, and similar instruments not be exercised without the prior permission of the Committee;
3. Limiting the Role of the Investigator with a Financial Interest - requiring that the role of the individual with the financial interest be limited in some way, e.g., the investigator may not be allowed to (i) serve as principal investigator, (ii) analyze data, (iii) determine whether potential subjects are eligible for enrollment, (iv) solicit consent, or (v) determine whether an adverse event report is required;
4. Oversight - appointment of a disinterested individual or group to monitor the research activity. An oversight committee might be charged, at a minimum, with reviewing abstracts and manuscripts before they are submitted for publication to ensure that the research is conducted and reported according to scientific and ethical standards and that conflict of interest management measures are observed. In other cases, an oversight committee might meet quarterly and review protocols, subject accrual, complications, and other issues as appropriate;
5. Divestiture - allow research to go forward contingent upon the sale or disposal of specified financial interests by a date certain to eliminate or reduce the financial conflict of interest;
6. Severance of relationships that pose actual or potential conflicts - for example, relinquishing a seat on a board of directors or terminating a consulting arrangement with an outside entity in order to reduce or eliminate the financial or fiduciary conflict of interest.

The management plan developed by the FCOIRC will be provided to the Principal Investigator, Conflicted Investigator(s), and/or the IRB. All final decisions require the majority of the total number of the committee membership. Only the members of the Committee shall vote on the application for reconsideration, and the Committee's decision shall be binding.

For human subject, the IRB may either accept the decisions of the FCOIRC or adopt more stringent requirements. The final decision of these respective Committees will be communicated to the Principal Investigator, Conflicted Investigator(s) and the FCOIRC.

No research application will be considered complete until approval/clearance has been given by the FCOIRC and the IRB, as applicable.

#### I. **Reporting to NIH by PPFA**

**For NIH grants, PPFA** must report to NIH the existence of a conflicting interest and certify that it has been managed, reduced or eliminated satisfactorily:

- a. before any expenditure of funds may begin;
- b. within 60 days of identification for an investigator who is newly participating in the project;
- c. within 60 days for a new, or newly indentified, financial conflict of interests for existing investigators;
- d. at least annually (at the same time when PPFA is required to submit an annual progress report, multi-year progress report, if applicable, or at the time of extension) to provide the status of the financial conflict of interest and any changes to the management plan, if applicable, until the completion of the project; or
- e. following the retrospective review to update a previously submitted report, if appropriate.

NIH shall be notified by PPFA promptly if bias is found with the design, conduct or reporting of NIH-funded research and PPFA will include a mitigation report in accordance with *42 CFR Part 50 Subpart F*. Such report shall include all reporting requirements required there under. NIH shall also be notified promptly if an investigator fails to comply with PPFA's financial conflicts of interest policy or a financial conflicts of interest management plan appears to have biased the design, conduct, or reporting of the NIH-funded research. PPFA shall take corrective action for PPFA financial conflicts of interest policy or the management plan.

#### **J. Records**

Records of all disclosures and actions taken will be kept by the FCOIRC for a minimum of three years from the date of submission of the final expenditure report or, where applicable, from other dates specified in *45 CFR 74.53(b)* for different situations.

#### **K. Administration and Enforcement**

The FCOIRC will be responsible for the administration and enforcement of this Policy, and will designate an Institutional Financial Conflict of Interest in Research officer who will receive and review all disclosures with the Financial Conflict of Interest in Research Committee under this Policy. All Covered Persons must comply fully with this Policy and all applicable regulations. Disciplinary action may be taken by the Chief Human Resources Officer in accordance with the procedures on disciplinary actions set forth in the PPFA employee manual. In the case of research funded by the PHS, if the failure of a Covered Person to comply with this Financial Conflict of Interest Policy has biased the approval, design, and conduct or reporting of the PHS-funded research, the Chief Human Resources Officer must promptly notify the Public Health Service Awarding Component of the corrective action taken or to be taken. The PHS may take further action or may refer the matter to the Chief Human Resources Officer with directions for further action. For research funded by the NSF, any unresolved Financial Conflicts of Interest must be reported to NSF by the Chief Human Resources Officer. Any questions concerning the application or interpretation of this Policy should be directed to the Chair of the FCOIRC. PPFA shall



complete and document retrospective reviews within 120 days of PPFA's determination of noncompliance for Significant Financial Interests not disclosed timely or previously reviewed or whenever a financial conflict of interest is not identified or managed in a timely manner and to document the reviews consistent with the regulation. In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research which has a purpose to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by as required under 42 CFR Part 50 Subpart F, PPFA will require the investigator involved with the research to disclose the financial conflict of interest in each public presentation of the results of the research and request an addendum to previously published publications about such research.

#### **L. Applicability; Coordination with Other Policies**

This Policy is not intended to supersede or replace any other regulations or policies of PPFA

#### **M. Training**

Mandatory training on PPFA Conflict of Interest Policies must be completed by:

- Members of the Conflict of Interest Committee
- All personnel involved in the design, conduct or reporting of the research
- All staff involved in the grant submission process
- All Institutional Officials as defined herein

Mandatory refreshers must be completed every 24 months by persons defined in L above.

#### **N. Public Accessibility**

This policy will be made publicly available on the PPFA website.

The FCOIRC will make information about identified Financial Conflicts of Interest held by Covered Persons publically accessible prior to the expenditure of funds. The information will:

- Include necessary information about the financial conflict of interest(s) as provided in 42 CFR Part 50 Subpart F;
- Be posted on a public website or made available within 5 calendar days of a written request;
- Updated annually;
- Be updated within 60 days of a newly identified financial conflict of interest; and
- Remain available for three years from the date the information was most recently updated.