

Praxis, Inc.
Financial Conflict of Interest (FCOI) Policy

Introduction

This policy pertains to the main requirements of and the responsibilities for compliance with the 2011 revised Federal regulations on Financial Conflict of Interest (FCOI) for grants or cooperative agreements)42 CFR Part 50 Subpart F, Promoting Objectivity in Research).

The purpose of the FCOI regulation is to ensure objectivity in research through standards that guide the design, conduct, and reporting of research that is funded by the National Institutes of Health (NIH).The regulation also seeks to ensure that research will be free from investigator bias or conflicts of interest.

These regulations do not cover Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase 1 applications/award, but do apply to Phase II applications/awards.

Key Definitions

Institution refers to any domestic or foreign, public or private, entity or organization that applies for or received NIH research funding. In this policy, the Institution refers to Praxis, Inc.

Investigator is defined as the Project Director, Principal Investigator, or any other individual who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for funding. This may include collaborators and consultants who are working on Praxis, Inc. projects.

Institutional responsibilities refers to an Investigator's responsibilities on behalf of the Institution that includes (but is not limited to) activities such as: research, research consultation, teaching, professional practice, and service on panels such as IRBs or Data and Safety Monitoring Boards.

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

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

Significant Financial Interest (SFI) is defined as:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or dependent children) that reasonably appears to be related to the Investigator's responsibilities with the Institution:

a. Publicly traded entities: An SFI exists if the Investigator receives funds that exceed a total \$5,000 in the 12 months preceding the disclosure or as of the date of disclosure. This may include salary, payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), as well as equity interest in stock, stock options, or other ownership interests.

b. Non-publicly traded entities: An SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure exceeds a total of \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);

c. Intellectual property rights and interests (e.g., patents, copyrights): An SFI exists upon receipt of income related to such rights and interests.

d. Sponsored Travel: Investigators must disclose reimbursed or sponsored travel related to their responsibilities with the Institution. Disclosure is not required for travel that is reimbursed or sponsored by a federal, state, or local government agency, or an Institution of higher education (i.e., an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education). The Investigator must disclose the purpose of the trip, the sponsor/organizer, the destination, and the duration of travel. Praxis' institutional official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI.

e. An SFI does not include the following types of financial interests:

- Salary
- Royalties
- Other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights and agreements to share in royalties, ownership interest in a company held by the Investigator
- Income from investments, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, medical center, or research institute that is affiliated with an Institution of higher education.

Policy

Investigators:

(1) All Investigators associated with Praxis, Inc. are responsible for:

- complying with the FCOI policies and procedures
- completing yearly training on FCOI
- disclosing the required information whether they are planning to participate in or are participating in NIH-funded research.

(2) Investigators must complete FCOI training on a yearly basis and provide evidence of the completed training to Praxis, Inc. An online training module can be accessed at the NIH website, and a certificate of completion is available, which can be furnished to Praxis, Inc. as evidence of compliance with the training requirement. The online training module can be accessed here:

https://grants.nih.gov/grants/policy/coi/fcoi_web-based_tutorial.pdf

(3) On at least an annual basis, Investigators are required to disclose to the designated official at Praxis, Inc. of any SFIs that they have, which also include those of the Investigators' spouses and dependent children. The SFI must reasonably appear to be related to the Investigator's responsibilities with Praxis, Inc. The SFIs must be disclosed no later than at the time of application for NIH-funded research and/or within 30 days if a new SFI is discovered or acquired (which can occur through purchase, marriage, and/ or inheritance).

Praxis, Inc.:

Praxis, Inc. is responsible for maintaining an up-to-date, written, and enforced FCOI policy that complies with the regulation and is publicly available. Additional responsibilities include, but are not limited to:

- Soliciting and reviewing Investigators' SFI disclosures
- Verifying that Investigators have completed the FCOI training on an annual basis
- Determining whether an SFI is related to the NIH-funded research and, if found to be related, whether it constitutes an FCOI

- Developing and implementing plans to manage FCOIs for all applicable Investigators
- Submitting an initial and annual FCOI report to NIH
- Completing retrospective reviews if non-compliance with the FCOI policy has been discovered and updating any previously submitted FCOI reports if applicable. If bias is found in the course of a retrospective review, Praxis will submit a mitigation report to the NIH.
- Praxis, Inc. will make information about any FCOIs that have been identified available within 5 business days of a written request.
- Praxis, Inc. will maintain records related to all disclosures made by Investigators for at least three years.
- Praxis, Inc. will employ appropriate enforcement and sanction procedures to ensure that all Investigators covered by this policy are in compliance.

Financial Conflict of Interest (FCOI) Disclosure Form

Individuals completing this form are expected to have read and understood the Praxis, Inc. Financial Conflict of Interest Policy (FCOI) and to have completed FCOI training on a yearly basis. Please contact Praxis, Inc. if you have any questions or need additional clarification about the policy.

1. Do you, your spouse, or dependent children have a significant financial interest (SFI) (as defined on the Praxis, Inc. FCOI Policy) that would reasonably appear to affect your research at Praxis, Inc.?

- Yes
 No

If Yes, please describe the nature and extent of the SFI:

2. Do you, your spouse, or dependent children have a significant financial interest (SFI) in any business or legal entity whose financial interests would reasonably appear to affect your research at Praxis, Inc.?

- Yes
 No

If Yes, please describe the nature and extent of the SFI:

(3) Were you reimbursed or sponsored for travel related to your responsibilities with Praxis, Inc.? (Note that this does not include travel that is reimbursed or sponsored by a federal, state, or local government agency, or an institution of higher education, i.e., an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education).

- Yes
 No

If Yes, please describe the purpose and duration of the travel and the entity that reimbursed or sponsored you:

I hereby certify that:

- I have read Praxis, Inc.'s policy on Financial Conflict of Interest on federal grants and contracts.
- I have made all required financial disclosures.

Investigator's Printed Name

Investigator's Signature

Date