

Financial Conflict of Interest Policy-020

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1. INTRODUCTION

This policy is intended to be consistent with federal and state laws and regulations. Where there is a discrepancy, the applicable federal or state law or regulation will take precedence.

This policy applies to Invicro whereas the company is an Institution having responsibilities under 42 CFR 50, Subpart F. "Company" is defined as Invicro, LLC and all of its Affiliates throughout this policy. Affiliates are defined, for current purposes, as all entities in which Invicro, LLC owns or controls 50% or more of the stock.

The scope of this policy specifically applies to staff who meet the definition of Investigator under 42 CFR 50, Subpart F. The Code of Conduct, however, contains general guidelines consistent with those set forth by this policy which are applicable to all staff.

2. BACKGROUND

Invicro is committed to ensuring that staff and others with designated research related responsibilities at the company are provided an open and productive environment in which to conduct research. Conflict of interest, which arises when a secondary objective could affect the performance of a person's primary mission, is a normal part of human existence. The potential for financial gain is one of many potential incentives that can lead to bias in a subjective activity. While Invicro encourages interaction with outside institutions and persons, the company also defines clear boundaries within which to operate to ensure that company research and participant care are performed in a manner that maintains the utmost in integrity and objectivity.

3. TRAINING REQUIREMENTS

Invicro personnel working on PHS-funded projects who meet the classification of Investigator and personnel providing oversight to PHS-funded projects, as determined by the FCOI Committee.

4. DEFINITIONS

Financial Interest: Anything of monetary value or potential monetary value that reasonably appears to be related to the individual's duties and responsibilities, including, but not limited to:

- Payment for service (e.g., a consulting fee, reimbursed travel, lecture payment, or honorarium), except as otherwise excluded by this policy
- A gift (e.g., money, hospitality, or a physical item);
- An equity interest (e.g., stock, stock option, security, or other ownership interest);
- An intellectual property right (e.g., a patent, copyright, or royalty from such right); and

- Other interests as determined by the company. For example, a financial interest may only have potential to be of value, like an option in a non-publicly traded company. Because this potential value may be an economic incentive, a situation like this is considered a financial interest.

The term does not include:

- Ownership of a share in a mutual fund;
- Salary or other remuneration from Invicro,, or an accredited institution of higher education;

and

- Salary or other remuneration from the U.S. Department of Veterans Affairs or another federal, state, or local government entity.

Financial Conflict of Interest ("FCOI"): A financial interest that could directly and significantly affect the design, conduct or reporting of PHS funded research.

A significant FCOI can exist in a variety of situations, including the following example: FCOI is present in a situation in which a primary interest or responsibility is affected, perhaps unduly, by a secondary interest or responsibility. This means that a subjective component of a primary interest (e.g. research) is affected, or potentially affected, by a financial secondary interest, either ongoing (e.g. consulting) or where there is the potential for increased valuation (of stock or an option). FCOI is present when the outcome of the research could affect future income or the value of an asset (including an option for equity).

Institution: Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Investigator: Any person who is independently responsible for making decisions regarding PHS funded research. This would include both the Principal Investigator on a research study, and anyone else, regardless of title, who is responsible for the design, conduct, or reporting (i.e. key personnel) of research funded by the PHS. For any one individual, the policy includes a financial interest of any immediate family member (spouse or spousal equivalent, and dependent children) as if any financial interest of that family member were one of the individual. Investigators include both those currently working on PHS projects, and those who may in the future become associated with PHS projects.

PHS: Public Health Service of the U.S. Department of Health and Human Services, including the National Institutes of Health (NIH).

5. POLICY AND PROCESS

Statement of Policy

It is the policy of Invicro that an Investigator is obligated to appropriately disclose any financial interest to Invicro the company, and if after review it is determined necessary by the FCOI committee, the company is obligated to ensure the establishment of a management plan which has been developed, approved and implemented by the company, with commitment of compliance by the Investigator and all other involved parties per the company's procedures.

Identification of Potential Financial Conflicts of Interest

An Investigator will be required to report to the company her/his direct or indirect financial interests in any entity involved in the development, assessment or marketing of pharmaceutical products on an annual basis and at the time of a reportable change. The company reserves the right to request additional information, as deemed necessary.

Establishment of Financial Conflict of Interest Committee

A financial conflict of interest committee will be appointed by the Officers of the company and the committee will report to them.

Procedures for Evaluation of Potential Financial Conflicts of Interest

The FCOI committee will determine who is classified as an Investigator. Training on this policy and the annual disclosure requirements will be held annually. Disclosure statements will be required of all Investigators of the company annually (prospective, for the upcoming year) and when an Investigator identifies a new financial interest during the year. The committee will review all disclosure statements and determine if a significant FCOI exists. If the committee determines that a significant FCOI exists, the committee will develop a management plan for the FCOI, meet with the Investigator to review the plan and obtain the Investigator's acceptance of the plan. Annually, the FCOI committee will present the status of disclosures and management plans to the company Officers. The FCOI committee will also be responsible for all required reporting of significant FCOI to NIH as required by the regulation.

Management of Financial Conflicts of Interest

The FCOI committee will oversee the implementation of the management plan, which may include the elimination of the financial conflict of interest, approval of a management plan, or adoption of an alternative course of action.

6. REFERENCES

42 CFR 50, Subpart F

7. DOCUMENT HISTORY

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