

IBI NIH Financial Conflict of Interest (FCOI) Policy

Indoor Biotechnologies, Inc. (dba InBio)

700 Harris Street

Charlottesville, VA 22903, USA

Original policy from 2012, updated in August 2020.

Indoor Biotechnologies, Inc.

Policy on Financial Conflict of Interest and Conflict of Commitment

Date: August 21, 2012

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Status: Final

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Oversight Executive:

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Applies to:

Scientists responsible for research at Indoor Biotechnologies, Inc., and sub-contract collaborators for research associated with federal state grants for which the Indoor Biotechnologies is the grantee.

Definitions

Conflict of Commitment (COC). A conflict arising when time expended on Outside Activities such as consulting or entrepreneurial activities interferes with an Employee's ability to meet his or her Company Responsibilities.

Conflict of Interest (COI). A situation occurring when the professional, commercial, or Financial Interests or activities of an Employee outside Indoor Biotechnologies have the potential to or actually influence his or her professional obligations to Indoor Biotechnologies, Inc.

Dependent. Any person, whether or not related by blood or marriage who receives more than one-half of his or her financial support from another individual.

Employee. For annual disclosure, this includes scientists/PI employed by Indoor Biotechnologies involved in research or research proposals funded by federal agencies. The Financial Interest of the individual Employee includes his or her Immediate Family.

Financial Interest. Anything of monetary value including: ownership of stocks, bonds, stock options, partnership or other equity interests, patent rights or royalty payments, consulting fees, speaking fees, salary, loans, gifts, lectureship fees, compensation for serving on boards of directors, scientific and other advisory boards, or other remuneration. Financial

Interests do not include stock owned through mutual funds.

Immediate Family. One's spouse, dependent children, and any other person residing in the same household as the Employee who is a Dependent of that Employee or of whom the Employee is a Dependent.

Company. The private for-profit company Indoor Biotechnologies, Inc.

Company Responsibilities. An Investigator's professional responsibilities on behalf of the Company, which may include activities such as research, consulting, teaching, institutional committee memberships, and service on committees.

Outside Activities. These include self-employment, participation in business partnerships, and employment or consulting arrangements with entities other than Indoor Biotechnologies that relate to an Employee's Company Responsibilities, whether compensated or not.

Research. A systematic investigation designed to develop knowledge encompassing basic and applied research

Trainee. Students or visiting scholars receiving short-term training at the Company.

Reason for this policy

Indoor Biotechnologies encourages its Employees to develop creative ways to perform their tasks, especially when involving research and development of new products. It is of utmost importance that these efforts be conducted with the greatest integrity, avoid the appearance of bias, use the Company's resources appropriately, and maintain public trust.

Occasionally, the interests or commitments of Employees may have the potential to conflict with those of the Company. This policy is designed to educate Employees on actual and apparent Conflicts of Interest and Conflicts of Commitment, to foster a culture of disclosing external financial interests and activities, and to create appropriate administrative procedures for the management of such conflicts.

It is essential that potential Conflicts of Interest be avoided or managed appropriately. Constructive engagements with other corporate or academic sponsors can be beneficial to scientific advancement. There are federal policies that address potential Conflicts of Interest and/or Commitment. This document is intended to identify such policies and to define the process for disclosing and adjudicating potential conflicts.

Policy Statement

Indoor Biotechnologies Employees shall not conduct Outside Activities that interfere with their Company Responsibilities.

Except as approved by the Company, remuneration for the conduct of Employee's responsibilities shall only be received through Indoor Biotechnologies.

Employees shall not conduct Company business, training, or research under circumstances in which a reasonable person would infer that the integrity of their performance of these activities was compromised by the expectation of external personal advantage.

Company resources such as facilities, equipment, computer networks, and personnel shall not be used by Employees for the financial benefit of external entities, unless authorized by the Company (except for incidental use of internet and phone systems).

All Employees shall disclose financial and commitment relationships with organizations outside of Indoor Biotechnologies that relate to their Company Responsibilities, as described herein.

Procedures

Training

Financial Conflict-Of-Interest (FCOI) training is required. Each Investigator must complete training (website link: <http://grants.nih.gov/grants/policy/foi/tutorial2011/foi.htm>) prior to engaging in research related to any NIH-funded grant and at least every four years.

What Financial Interests should be disclosed to the Company

Employees shall disclose the following Financial Interests in organizations outside of the Company that relate to their Company Responsibilities:

- any reimbursed or sponsored travel related to Company Responsibilities during the previous year;
- \$5,000 or more in total remuneration plus equity interest (i.e. stock ownership) in a publicly traded entity;
- \$5,000 or more in remuneration from a non-publicly traded entity during the previous year; and
- Significant equity interest in a non-publicly traded entity.

Disclosure must be made annually and within 30 days of establishment of new Financial Interests that occur between annual declarations.

What Financial Interests should not be disclosed to the Company

Indoor Biotechnologies Employees are not required to disclose:

- reimbursed or sponsored travel paid by a federal, state, or local government, or an institution of higher education/academic medical center/academic research institute, or from *bona fide* professional medical or other business associations;
- income from agreements to which the Company is a party;
- income from financial instruments that are not controlled by the Employee (e.g., mutual funds).

How Financial Interests must be disclosed to the Company

The individual Employee shall disclose his or her Financial Interests as described below:

- *Disclosure to the Company.* Employees are required to disclose annually Financial Interests that relate to their Company Responsibilities using the form provided (IBI SFI_Report_[year]) New Financial Interests must be disclosed within 30 days. New Employees must disclose their Financial Interests within 30 days of their initial appointment. Whenever an application for federal or state research funding is submitted, the principal investigator must certify on the Proposal Approval Form that he or she and all project Investigators, including subcontractors, have disclosed their Financial Interests.
- *Disclosure to the Institutional Review Board.* Principal investigators engaging in human subjects research at the Company are required to ensure disclosure of the Financial Interests of all study personnel to the Institutional Review Board, when proposing a new protocol or when a new Financial Interest arises during the course of an IRB-approved study that might be perceived to influence the outcome of that study. These reports are required in addition to the annual disclosures described above.

Reporting to NIH

The COI regulation does not apply to Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Programs Phase I applications/awards.

The Company provides FCOI reports to NIH through the eRA Commons FCOI Module:

- Prior to the expenditure of funds
- During the period of award
 - Within 60 days of identifying a new FCOI.
- Annually
 - Report on the status of FCOI and any changes in management plan.
 - Due at same time as when grantee submits annual progress report, including multi-year progress report, or at time of extension.

Review of the Institution Financial Disclosures

Review of conflicts of commitment. The President of the Company, Dr. Martin D. Chapman will review the financial disclosures of employees for potential Conflict of Commitment. The Company Chief Financial Officer (CFO) will review the disclosures of the Company's President. If the review suggests that a Conflict of Commitment exists, the reviewer shall discuss the conflict with the employee and take steps to assure management of the conflict. If the reviewer is unable to resolve the conflict, he or she shall consult with the President's designee. The President will make a final determination on the disposition of all conflicts of commitment.

Management of Conflicts of Interest.

Management plans include:

- requirement to disclose the Financial Interest in publications and public presentations;
- requirement that project personnel be notified of the nature of the Financial Interest.

Confidentiality of Financial Disclosures

Financial Conflicts of Interest associated with federal funded research projects will be posted on the Company web site or be made available by the Company in response to any request for that information. The confidentiality of other information contained within these financial disclosures shall be secured. The website will be updated annually and whenever any new FCOIs occur.

Retention of Financial Disclosures and Documentation on Conflicts of Interest and Commitment

- Documentation of COIs shall be retained for three years after filing of the final financial report for that competitive award period.
- Documentation for COI/COC reviews that result in a management plan (non-Public Health Service) shall be retained for three years after completion of the activity requiring management.
- Documentation for COI/COC reviews that do not result in further management shall be retained for three years after the final decision by the President of the Company.

Retrospective Review

Whenever an FCOI is not identified or managed in a timely manner, the company shall complete a retrospective review of the Investigator's activities and the project to determine bias in the research, notify NIH and submit a Mitigation Report.

Penalties for non-compliance with this policy

The President may apply sanctions in the following situations:

- Non-compliance by an Employee with his/her responsibilities under this policy.
- Failure of an Employee to adhere to a decision by President concerning a Conflict of Interest or Conflict of Commitment.
- Inappropriate release of confidential information on financial disclosures by individuals with administrative responsibility under this policy.

Policy History

Created: August 21, 2012

Approved: August 21, 2012



Dr. Martin D. Chapman
President & CEO

Updated August 2020

Indoor Biotechnologies' Annual Disclosure of Significant Financial Interest

Year: xxxx

NIH regulation requires investigators to disclose to their institutions all of their significant financial interests (SFI)* related to their institutional responsibilities. Investigator is the person who is responsible for the design, conduct or reporting of research funded by the Public Health Service, regardless of title or position. Financial interest means anything of monetary value, whether or not the value is readily ascertainable. The SFI threshold to disclose is \$5,000.

Exclusions: Note that SFI excludes salary, royalties, or other remuneration** paid by the institution to the investigator if the investigator is currently employed or otherwise appointed by the institution.

Disclosure:

In the past 12 months did you, or a member of your household or immediate family, have any Significant Financial Interest (SFI) to declare related to your institutional responsibilities?

Answer Yes/No:

If yes, please mention the SFI to declare and the amount (\$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000):

Name:

Job title:

Date:

*Notice that SFI is different from FCOI. *Financial conflict of interest* (FCOI) means a significant financial interest that **could** directly and significantly affect the design, conduct, or reporting of PHS-funded research. The term “significantly” in this context means that the financial interest would have a material effect on the research, which we believe appropriately fulfills the intent of the regulations, i.e., to **maintain objectivity in PHS funded research**.

NIH intended the term “disclosure” to capture communication from an Investigator to an Institution regarding SFIs, whereas the term “report” captures communication from an Institution to the PHS Awarding Component regarding FCOI.

** Other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, include:

- Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

For more information:

<https://www.policymed.com/2011/08/national-institutes-of-health-final-rule-on-conflict-of-interest-summary.html>