



**INTEGRATED LABORATORY SYSTEMS**

**FINANCIAL  
CONFLICT OF INTEREST  
POLICY & DISCLOSURE FORM**

INTEGRATED LABORATORY SYSTEMS  
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# FINANCIAL CONFLICT OF INTEREST POLICY & DISCLOSURE FORM

## Institutional Responsibilities

Integrated Laboratory Systems, Inc. (ILS) is committed to ensuring its staff an open and productive environment in which to conduct research and other business activities. Conflicts of interest, in the most conventional sense, arise because staff members may have the opportunity to influence ILS's business decisions in ways conducive to personal gain and company detriment. Additionally, a staff member's more general commitment to ILS requires that the member perform the duties conventionally associated with the member's position.

It is the policy of Integrated Laboratory Systems, Inc. that:

- The staff has an obligation to avoid unacceptable ethical, legal, financial or other conflicts of interest and to ensure that their activities and interests do not materially conflict with their obligations to ILS or its welfare;
- Any staff member engaging in an outside activity or possessing a personal interest that could lead to a serious conflict of interest must inform ILS of that possibility by consulting with that member's supervisor or designate; and
- Relationships between staff members and outside companies or institutions must not impede or bias the generation and communication of research results at ILS.

This policy is designed to comply with Public Health Service (PHS) regulations (42 CFR Part 50 Subpart F, Financial Conflicts of Interest (FCOI) for Grants/Cooperative Agreements; 45 CFR Part 94, Responsible Prospective Contractors). The goal at ILS is to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or contracts will be free from bias resulting from Investigator Financial Conflicts of Interest (FCOI).

ILS will certify in all PHS research project proposals that ILS (1) has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all PHS research projects; (2) shall promote and enforce Investigator compliance with FCOI requirements, including those pertaining to disclosure of significant financial interest; (3) shall implement FCOI Management Plans; (4) agrees to make information available, promptly upon request, relating to any FCOI; and (5) shall fully comply with the FCOI requirements contained in the referenced regulations in the context of PHS research projects.

All ILS staff members expected to work as Investigators on a PHS research projects must complete and submit the Financial Conflict of Interest Disclosure Form prior to proposal submission. In addition, ILS will obtain assurances (where such assurances are not otherwise included in a Teaming Agreement, a Subcontract, or a Consulting Agreement) from Sub-recipients (if any) that such Sub-recipients: (1) have an FCOI policy that complies with the PHS requirements contained in the referenced regulations and will ensure the disclosure of Sub-recipient Investigator FCOIs to the ILS COI Coordinator, or (2) agree to comply with ILS's FCOI policy and procedure and will ensure the disclosure of Sub-recipient Investigator Significant Financial Interests to the ILS COI Coordinator.

## **Definitions**

- ***Disclosure of significant financial interests*** means an Investigator's disclosure of significant financial interests to an Institution.
- ***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.
- ***FCOI report*** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- ***Financial interest*** means anything of monetary value, whether or not the value is readily ascertainable.
- ***Institution*** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that submits a proposal, or that receives, PHS research funding.
- ***Institutional responsibilities*** means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- ***Investigator*** means 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 PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- ***Manage*** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- ***PHS*** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- ***PHS Awarding Component*** means the organizational unit of the PHS that funds the research that

is subject to this part.

## **FCOI Disclosure Responsibilities**

### **Investigators**

- Must complete FCOI training prior to engaging in a PHS research project and thereafter, every four years.
- Must complete and submit to the COI Coordinator a Financial Conflict of Interest Disclosure Form prior to working on PHS-funded projects.
- Must update the Financial Conflict of Interest Disclosure Form annually or within 30 days of a change in financial status (acquisition of new financial interest), whichever occurs first.

### **COI Coordinator**

- Must review all Financial Conflict of Interest Disclosure Forms from PHS-funded investigators at ILS.
- Must determine whether an ILS investigator working on a PHS-funded research project has an FCOI.
- Must provide required information concerning FCOIs to the project Contract Officer and the Contract Officer's Technical Representative, and must update such information at least annually and within 60 days of changes to Financial Conflict of Interest Disclosure Form, whichever occurs first.
- Must prepare the Financial Conflict of Interest Disclosure Form for reported FCOIs such that it can be made publicly available.
- Must maintain for three years records of all Financial Conflict of Interest Disclosure Forms and FCOI Management Plans.
- Maintains ILS's FCOI Policy on the ILS external website.

### **President & CEO**

- Ensures compliance with FCOI policy.
- In cases where the COI Coordinator determines that a potential FCOI exists, develops and coordinates implementation of FCOI Management Plan in consultation with the COI Coordinator. The FCOI Management Plan must be completed in advance of ILS expending PHS funds – and a summary of the management plan must be included in the FCOI Report.
- Coordinates the submission of annual reports related to the FCOI Management Plans through the COI Coordinator.

When a conflict of interest determination is required by this policy, the employee should contact the COI Coordinator for guidance. Employees are required to cooperate fully in the review process by providing all necessary information. Requests for a conflict of interest determination will be reviewed

on a case-by-case basis through the established conflict of interest review process. The employee should submit a Financial Conflict of Interest Disclosure form in a sealed envelope to the COI Coordinator.

Once a written determination has been made, it continues in effect until it is reversed, modified, or withdrawn. When changed circumstances or new developments occur, the employee is responsible for informing the COI Coordinator. Upon review, the previous decision may be reversed, modified, or withdrawn. Records of conflict of interest reviews will be retained by the COI Coordinator and a copy will be provided to the employee. An employee may appeal a conflict of interest review determination.

### **Enforcement and Sanctions**

Employees who violate company standards of conduct including the Financial Conflict of Interest Policy will be subject to disciplinary action. Such action may include suspension or termination of employment or reimbursement to ILS for financial losses suffered. Violations may also result in civil or criminal penalties.

### **Financial Conflict of Interest Disclosure Form Guidelines**

The requested financial disclosure attempts to balance ILS's needs for information with the individual's reasonable expectation of privacy in his or her personal affairs. There are materiality guidelines to assist staff members with disclosures (see below). Should you need further guidance in preparing your form, please contact the COI Coordinator.

***Significant Financial Interest (SFI)*** is defined by regulation as:

- (1) A financial interest consisting of one or more of 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:
  - a. With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock options, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  - b. With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or

dependent children) hold any equity interest (e.g., stock, stock options, or other ownership interest); or

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

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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. The Investigator's disclosure will include the identity of the sponsor/organizer, the destination, and the duration. The ILS COI Coordinator can request additional information from the Investigator in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term SFI does not include the following types of financial interests:

- a. Salary, royalties, or other remuneration paid by the Institution (i.e., Investigator's employer) to the Investigator if the Investigator is currently employed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- b. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- c. 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;
- d. 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;
- e. 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.

**Financial Conflict of Interest Disclosure Form**

**Assets and Sources of Earned Income:** Identify for you, your spouse and dependent children (PART I) assets with a fair market value of \$5,000 at the time of disclosure; and (PART II) sources of earned income which generated over \$5000 in income during the previous 12 months. *Only include items which reasonably appear to be related to your Institutional Responsibilities.*

**PART I: ASSETS**

Assets include stocks, bonds, tax shelters, pensions, annuities, real estate, commodity futures, trades and business and partnership interests.

<input type="checkbox"/> I do not have any assets requiring disclosure to the ILS COI Coordinator <input type="checkbox"/> I hereby disclose the following assets:				
Name of Asset(s)	Asset belongs to (Employee, Spouse, Dependent Child, or combination)	(X) if no longer held:	Asset Type: (pension, stock, dividends, interest, real estate, capital gains):	Provide the Approximate Dollar Value

**PART II: SOURCES OF EARNED INCOME AND TRAVEL**

Sources of Earned Income include; salaries received from other than your current employer, fees, honoraria and travel.

<input type="checkbox"/> I do not have any Sources of Earned Income requiring disclosure to the ILS COI Coordinator <input type="checkbox"/> I hereby disclose the following Earned Income Sources:			
Name of Earned Income Source(s)	Income Recipient: (Employee, Spouse, Dependent Child, or combination)	Income Type: (salary, consulting fees, honoraria, etc.):	Provide the Approximate Dollar Value
For travel disclosures, please include the following detail: purpose, identity of the sponsor, destination and duration			
Purpose	Sponsor	Destination	Duration

**I hereby acknowledge that I have read and understand the financial conflict of interest policy and that the aforementioned facts and situations may indicate a potential for conflict of interest with regard to my position at INTEGRATED LABORATORY SYSTEMS, INC. If none, this is indicated in the spaces provided.**

\_\_\_\_\_

Date

\_\_\_\_\_

Signature

Printed Name: \_\_\_\_\_

**Review by ILS COI Coordinator**

I have reviewed this disclosure form and believe that:

- No potential for conflict of interest exists.
- Potential for conflict exists, and steps have been taken to resolve the potential conflict, *as outlined in the attached letter.*
- A potential conflict of interest exists which requires the President's attention and may require the approval of the President of ILS.

\_\_\_\_\_

Date

\_\_\_\_\_

Signature