



# CHAMPAIGN IMAGING

## **Champaign Imaging LLC** **Financial Conflict of Interest Policy**

Financial conflicts of interest are those in which a financial interest has the potential to influence the impartial business judgment of an employee. Given Champaign Imaging LLC's (C-Imaging) reliance on governmental funding, the company has established this policy to ensure that employees understand potential sources of conflict and their consequences.

### **I. POLICY**

Champaign Imaging strives to create a climate that promotes objectivity in research by establishing standards such that the design, conduct and reporting of Public Health Service (PHS, which includes NIH and NIMH)-funded research is free from bias resulting from financial conflict of interest (FCOI).

This policy is applicable to each employee who is planning to or is participating in research activity that is either partially or wholly supported by PHS funds.

Each such employee must:

1. **disclose** his or her significant financial interests (SFI) in non-C-Imaging's entities that would appear to be related to the employee's professional responsibilities on behalf of C-Imaging;
2. **comply** with a FCOI management plan, if a FCOI is identified;
3. **undergo** FCOI training, at least once every year; and
4. **sign** this document, indicating having read and understood the policy.

Disclosure of SFI is essential for C-Imaging to determine if a FCOI exists, and in cases of FCOI determine how it will be managed and reported in full compliance with government regulation. ***Non-disclosure of SFI or non-compliance with FCOI management plan may subject the employee to employment discipline including, without limitation, suspension or termination of employment.***

## II DEFINITIONS

A. *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.

B. Significant Financial Interest (SFI) exists if the value of remuneration received by the employee, employee's spouse or dependent children that reasonably appear to be related to the employee's C-Imaging responsibilities exceeds \$5000;

1. Including:

- Salary or other payments for services (e.g., consulting fees or honoraria); received in the twelve months preceding disclosure;
- Equity interests (e.g., stocks, stock options or other ownership interests). Equity interest in a non-publicly traded entity, no matter the amount, constitutes an SFI; and
- Income from intellectual property rights owned by the employee.

2. Excluding:

- Salary, royalties, stock options or other remuneration from C-Imaging;
- Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, derived from excluded sources<sup>D</sup>;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the employee does not directly control the investment decisions; and,
- Unlicensed intellectual property owned by the employee that does not generate income. Note that Intellectual property owned by C-Imaging is excluded.

3. SFI disclosure also includes travel that is externally funded, reimbursed, or sponsored that appears to be related to employee's C-Imaging responsibilities, but is not funded by C-Imaging. Such travel must be disclosed, no matter the amount, except when the expenses are covered by any of the excluded sources<sup>D</sup>.

Note that the threshold of \$5000 is applied to the aggregation of 1a and 1b, or to 1c.

C. *Employee's professional responsibilities on behalf of C-Imaging* means conducting research, submitting patent applications and publications, technical committee membership, and teaching as adjunct faculty at an institute of higher education.

D. *An excluded source means* a source of remuneration that is excluded from disclosure. With reference to the SFI (2b and 3), excluded sources are federal, state, or local government agencies, institution of higher education, academic teaching hospital, a medical center, or research institutes that are affiliated with an institution of higher education.

## III PROCEDURE

Employees who are planning to or participating in research activity that is either partially or wholly supported by PHS funds must disclose their SFI in a timely fashion to the C-Imaging

Management Team (C-Imaging MT). The C-Imaging MT will determine whether the SFI constitutes an FCOI, based on guidance set by the C-Imaging MT, this policy, and [42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought"](#) (FCOI Regulation), as implemented in the 2011 [Final Rule](#) for grants and cooperative agreements.

Consistent with the attached Protocol for Handling Financial Conflict of Interest, if the SFI is determined to be an FCOI, the C-Imaging MT will take actions to discuss and approve the implementation of an FCOI management plan consistent with government regulation and, furthermore, to promptly notify the PHS funding component (e.g., NIH) via a FCOI report.

As a part of the FCOI management plan, the C-Imaging MT will determine one or more actions depending upon the situation, including requiring certain disclosure in public presentations, employee role reassignment, reduction or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that create financial conflicts. Employees with an identified FCOI must comply with the FCOI management plan.

## **IV RELATED POLICIES AND PROCEDURES**

### **Protocol for Handling Financial Conflict of Interest**

This protocol and the policy and procedure titled Financial Conflict of Interest in PHS-Funded Projects constitute the C-Imaging FCOI policy. Capital terms in this protocol shall have the same meaning as set forth in the policy. This protocol outlines the procedure that will be followed as per regulation (Title 42 CFR 50.601-50.607).

This document specifies the FCOI protocol for PHS-funded research, that is, the step-by-step implementation of the C-Imaging FCOI policy.

### **1. Who is required to disclose financial interests**

Employees planning to or participating in research activity that is either partially or wholly supported by PHS funds are required to disclose financial interests ("PHS-funded Investigators").

### **2. SFI disclosure**

PHS-funded Investigators are required to disclose SFIs to either a member of the C-Imaging MT as follows:

- 1) Employees planning to participate in PHS-funded research are required to disclose all SFI's prior to submission of an application for PHS-funded research.
- 2) Once the research project has been funded all PHS-funded investigators shall submit SFI Disclosures within thirty (30) days of acquiring any new or increased SFI. When a new investigator joins an ongoing PHS-funded project, the investigator shall submit SFI disclosures within thirty (30) days of joining the project.
- 3) All PHS-funded investigators shall submit an updated SFI disclosure annually.
- 4) SFI disclosures (except travel) must include the following information:
  - a. Identity of the sponsor/organizer; and
  - b. Nature of SFI (e.g., salary, license income, stock).
- 5) Externally funded travel also constitutes SFI, and therefore the disclosure requirements in 2 (i)-(iii) apply. That is, PHS-funded investigators shall submit SFI Disclosures for externally funded travel: prior to submission of an application for PHS-funded research;

and for PHS-funded projects within thirty (30) days of externally funded travel and in an annual update. The following travel related information must be disclosed:

- a. Purpose,
- b. Identity of the sponsor/organizer,
- c. Destination, and,
- d. Duration.

### **3. Review of disclosures**

All SFI disclosures, including those submitted by a new investigator who joins an ongoing PHS-funded project, will be reviewed by the C-Imaging MT. The review will determine whether an SFI is related to the PHS-funded research and therefore an FCOI. The C-Imaging MT may involve the relevant investigator in the review and request additional information from the investigator.

When an SFI that was not disclosed by a PHS-funded Investigator in a timely manner is identified, C-Imaging MT will determine if FCOI exists, develop and implement a management plan within sixty (60) days after the identification of the SFI. In addition, a designated FCOI official from the C-Imaging MT will conduct a retrospective review of SFIs for the PHS-funded investigator within one hundred twenty (120) days and document it.

### **4. Management of FCOI**

For each disclosure that leads to determination of FCOI, the C-Imaging MT will discuss and approve the implementation of a management plan, developed by the C-Imaging MT. PHS-funded Investigators with an identified FCOI must comply with the management plan. The management plan will include the following elements at a minimum:

- 1) The role and principal duties of the conflicted PHS-funded investigator in the research project;
- 2) Conditions of the management plan (see examples below);
- 3) How the management plan is designed to safeguard objectivity in the research project;
- 4) Confirmation of the PHS-funded investigator's agreement to the management plan; and
- 5) How the management plan will be monitored to ensure PHS-funded investigator compliance.

Examples of conditions or restrictions that might be imposed to manage a PHS-funded Investigator's FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s));
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;

- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

## **5. Reporting FCOI to PHS Awarding Component (e.g. the NIH)**

Based on the FCOI management plan, the C-Imaging MT will submit an initial FCOI report to the PHS-funding component, for example NIH. The report will be submitted, for example using eRA Commons for NIH, and consist of all elements required by the regulation.

The FCOI report will be submitted prior to the expenditure of funds under the Notice of Award. FCOIs identified during the period of award will be submitted to NIH within sixty (60) days of identification, including for new investigators joining an ongoing PHS-funded project.

Annual FCOI reports (or revised reports as a result of retrospective reviews) will also be submitted and will include the status of financial conflict, i.e., whether the financial conflict is still being managed or explains why the financial conflict no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

## **6. Training for FCOI**

PHS-funded Investigators must undergo training with respect to this Policy and PHS FCOI rules and regulations, as follows:

- 1) When a new employee joins C-Imaging;
- 2) Prior to participating in PHS-funded research, and at least once every year;
- 3) When the C-Imaging FCOI policy changes in a manner that affects PHS-funded investigator disclosure or compliance requirements; and,
- 4) If C-Imaging MT determines that a PHS-funded investigator is not compliant with the FCOI Policy or an FCOI Management Plan.

As stated above, trainings must be signed as having been read and understood for the C-Imaging files. NIH web-based training (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) will be used. Employees must save and print the FCOI Certificate as proof of completion.

## **7. Sanctions for violation of policy**

Disclosure of SFI is essential for C-Imaging to implement its FCOI policy. If a PHS-funded Investigator fails to comply with this policy (with regard for instance to the SFI disclosure requirement or implementation of an FCOI management plan), and appears to have biased the PHS-funded research, the C-Imaging MT will implement a mitigation plan and require that the Investigator disclose the FCOI in each public presentation of the results of the research, and to remedy previously published presentations with an FCOI disclosure addendum. In addition, the employee may be subject to employment discipline including, without limitation, suspension or termination of employment.

In any case, the PHS-funding agency will be promptly notified.

## **8. Retention of records**

Records of financial disclosures and any resulting action will be maintained for three (3) years from the date of submission of the final expenditures report.

## **9. Subrecipient compliance**

When working with a subrecipient, a written agreement will be put in place to clarify: (a) which organization's (prime awardee or subrecipient) FCOI policy will be followed, and, (b) in either case, clarify the timeline for disclosure and reporting. Note that the prime awardee is responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest.

## **10. Public Accessibility**

As required by PHS regulation, the C-Imaging FCOI policy is being made accessible on C-Imaging web site.

If a PHS-funded investigator holds financial interests that are determined to be FCOI, as required by PHS regulation, these will also be posted on the web site, as follows:

- 1) Include the minimum elements required by the regulation;
- 2) Update within sixty (60) days of a newly identified FCOI;
- 3) Update annually; and
- 4) Remain available for three (3) years.

## **V ADMINISTRATION**

The designated C-Imaging MT is responsible for administration of this policy.

For the purposes of illustration, the following figure is used

### Financial Conflict of Interest (FCOI) illustration

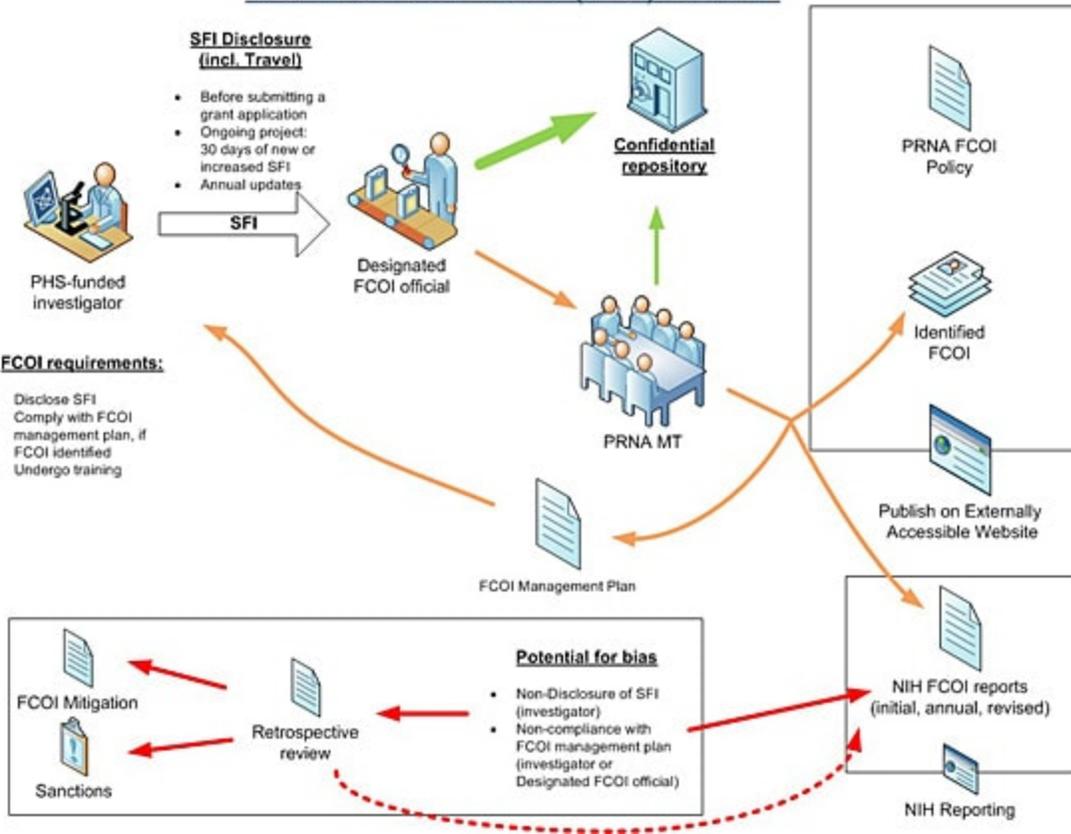


Figure 1: An illustration of Financial Conflict of Interest Policy at C-Imaging.