



Policy APO-01-01			
FINANCIAL CONFLICT OF INTEREST			
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I PURPOSE

One of Imaging Biometrics' (IB) core competencies is the translation of research lab algorithms and processes to commercial products. As such, there is an ongoing need for IB to participate closely in the research process, including the application for and receipt of grant funding. Implicit in the funding process is the need for integrity in research efforts. However, IB recognizes the potential for a conflict of interest where research efforts and financial interests intersect.

This policy supports Public Health Service (PHS) Regulations 42 CFR Part 50 Subpart F, Promoting Objectivity in Research and 45 CFR Part 94, Responsible Prospective Contractors (the Regs). This policy and these Regulations promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting research funded under PHS grants or cooperative agreements or PHS contracts will be biased by any conflicting financial interest of a Covered Person.

II APPLICATION AND RESPONSIBILITY

This policy applies to those employees, contractors, and other individuals who meet the definition of Covered Person. It is the responsibility of the COO, as defined by QF-56-02-1, to implement and execute this policy. If the COO meets the definition of Covered Person in certain circumstances, the President shall be responsible for the implementation and execution of this policy as it relates to the COO.

IB has adopted this policy because IB meets the definition of Institution provided in 42 CFR 50 F (section 50.603), and is thus subject to the requirements detailed in sections 50.604 through 50.606.

IB intends this policy to fully meet the requirements of the regulations at 42 CFR 50 F, but, to provide maximum flexibility in its research environment, does not intend this policy to be any more restrictive or stringent than the regulations. Even if a policy element can be interpreted to be more stringent than the regulation, an interpretation consistent with the less-stringent regulatory requirement shall apply instead.

III DEFINITIONS

The definitions listed here apply specifically to this policy, and to no other, unless the other policy explicitly references these definitions.

If a definition here conflicts with the definition of the same term in 50.603, the regulatory definition shall apply. Terms not defined here shall be interpreted using the definitions in 50.603.

Covered Person – any employee of or consultant to IB who is responsible for the design, conduct, or reporting of research sponsored by any U.S. Department of Health and Human Services (DHHS) PHS agency including the National Institutes of Health (NIH). Covered Persons include but are not limited to Principal Investigators, Co-Investigators and other Key Personnel as identified by IB in the grant application and others who influence or are responsible for the design, conduct, or reporting of PHS funded research as determined by IB (e.g. other employees, collaborators, or consultants).

Covered Person's Professional Responsibilities – activities performed on behalf of IB. These responsibilities may include but are not limited to activities such as research,

research consultation, and software design, development, and testing.

Financial Conflict of Interest (FCOI) – a Covered Person’s Significant Financial Interest that has been determined by the IB Institutional Official (IO) is related to PHS research funding and could directly and significantly affect the design, conduct, or reporting of those research outcomes and/or results.

Institution – any domestic or foreign, public or private, entity, or organization (other than a federal agency) that is applying for, or that receives, PHS research funding.

Institutional Official (IO) – IB designates the COO as the Institutional Official responsible for the implementation and administration of this Policy. In those situations where the COO is considered a Covered Person, the President will act as the IO. The IO may delegate the day to day performance of these functions to other IB personnel. The IO is responsible for soliciting and reviewing disclosures from each Covered Person.

Significant Financial Interest (SFI) –

- 1) A financial interest consisting of one or more of the following interests of the Covered Person (and those of the Covered Person’s spouse and dependent children) that reasonably appears to be related to a Covered Person’s Professional Responsibilities at IB:
 - a) Publicly-Traded Entity – an SFI exists if the aggregated amount of remuneration received in the 12 months preceding the disclosure or the value of any equity interest as of the date of disclosure exceeds \$5,000.
 - b) Non-Publicly Traded Entity – an SFI exists if the aggregated amount of remuneration received in the 12 months preceding the disclosure exceeds \$5,000, or if any amount of equity interest is held as of the date of disclosure.
 - c) Intellectual Property Rights and Interests– an SFI exists upon receipt of any income related to such rights and interests from the entity.
- 2) Reimbursed or Sponsored Travel paid on behalf of the Covered Person where the travel is related to his or her Professional Responsibilities must be disclosed. This disclosure does not apply to travel that is reimbursed or sponsored by:
 - a) a federal, state or local government agency;
 - b) an institution of higher education (as defined at 20 USC 1001(a)); or
 - c) an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

The following types of interests are not considered Significant Financial Interests:

- (1) Salary or other compensation paid by IB to the Covered Person.
- (2) Equity interest in IB held by the Covered Person.
- (3) Income or equity in investment vehicles such as mutual funds and retirement accounts as long as the Covered Person does not directly control the investment decisions made in these vehicles.
- (4) Income from seminars, lectures, or teaching engagements sponsored by, or service on advisory or review panels for, a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a

research institute that is affiliated with an institution of higher education.

A financial interest reasonably appears to be related to a Covered Person's Professional Responsibilities if it is an interest in an organization, entity or person that develops, markets, or sells products or services related to the research work being performed at IB.

IV PROCEDURE

1 IB Requirements

1) Policy Maintenance

- a) IB shall review this policy at least once every calendar year.
- b) This policy shall be posted on the IB web site.

2) Policy Communication

- a) IB shall inform each Covered Person of this policy, his or her responsibilities regarding disclosure and the regulations at 42 CFR 50 F.
- b) IB shall require each Covered Person to complete training on the items noted above:
 - i) prior to engaging in research related to a PHS-funded grant;
 - ii) at least every four years; and
 - iii) immediately, when:
 - (1) changes in this policy affect the requirements of Covered Persons;
 - (2) a Covered Person is new to IB; or
 - (3) IB finds a Covered Person is not in compliance with this policy or an applicable management plan.

3) Sub-recipient (SR) Compliance: This section applies if IB carries out PHS-funded research with the assistance of a sub-recipient. If so, IB will take reasonable steps to ensure any sub-recipient Covered Persons complies with the Regs by:

- a) Ensuring the agreement between IB and the SR incorporates terms establishing whether the FCOI policy of IB or the SR applies. The agreement will contain language addressing:
 - i) If the SR policy applies, the SR shall certify that its policy complies with the Regs, and the time period for the SR to report all FCOIs to IB will be specified. The time period will be sufficient to allow IB to provide timely reports to the PHS as required.
 - ii) If the SR cannot provide compliance certification, the SR Covered Persons shall be subject to the IB FCOI policy.
 - iii) If the IB policy applies, the agreement will specify the time period for the SR to report all SR Covered Person SFI disclosures to IB. The time period will be sufficient to enable IB to comply timely with the review, management, and reporting obligations under the Regs.

- b) Providing SR FCOI reports to the PHS awarding component prior to the expenditure of funds and within 60 days of any subsequently-identified FCOI.
- 4) FCOI Management: If the IO determines an FCOI exists, the IO will develop and implement a plan to manage the FCOI. If necessary, the IO will also perform a retrospective review and create a mitigation report. [50.605(a)] See the IB FCOI Management and Reporting procedure, APR-01-01, for more details.
- 5) FCOI Reporting: The IO will provide periodic reports to the PHS as required. [50.605(b)] See the IB FCOI Management and Reporting procedure, APR-01-01, for more details.
- 6) Records Management: The IO will maintain the following IB FCOI-related records for a period of 3 years following the date the final expenditures report is submitted to the PHS:
 - a) Covered Person disclosures of financial interests;
 - b) IB review of the Covered Person disclosures;
 - c) IB response to the Covered Person, if any;
 - d) All actions taken under this policy, including those performed under the guidance of the IB FCOI Management and Reporting procedure, APR-01-01.
- 7) Policy Enforcement: The IO, in conjunction with IB senior management, is authorized and charged with the responsibility to enforce this policy. The IO and management may choose any appropriate enforcement mechanism(s) to ensure Covered Person compliance. These potential mechanisms should be reasonable, but, if the situation warrants, may include termination of, and reimbursement of funding proceeds by, the Covered Person.
- 8) Application Certification: In each application for PHS funding, the IB applicant shall certify that IB:
 - a) Has an up-to-date, written, and enforced process to identify and manage FCOIs;
 - b) Shall promote and enforce Covered Person compliance with this policy, including disclosure requirements;
 - c) Shall manage FCOIs and provide periodic FCOI reports to the PHS awarding component as required by the Regs
 - d) Will make available to the HHS promptly upon request, information related to:
 - i) Covered Person disclosures;
 - ii) IB's review of the Covered Person disclosures;
 - iii) IB's response to the Covered Person disclosures; and
 - iv) Based on the disclosures, whether or not an FCOI was deemed to exist.
 - e) Shall fully comply with the Regs.

2 Covered Person Requirements

- 1) Disclosure
 - a) Each Covered Person must disclose any SFIs to the IO by the time of application for

PHS funding.

- b) Each Covered Person participating in PHS-funded research must submit an updated disclosure by June 30 of every year, during the time the funding is being received.
 - c) Each disclosure must include updated information for any previously-disclosed SFI as well as information on any SFI that was not previously disclosed.
 - d) Each Covered Person must submit an updated disclosure within 30 days of discovering or acquiring a new SFI.
- 2) Compliance
- a) If an FCOI is determined to exist, the Covered Person must comply with the Management Plan implemented by the IB IO.

3 FCOI Determination Guidelines

- 1) The IO is responsible for making the FCOI determination, but must involve the Covered Person in this process to ensure the factual basis for the determination is accurate.
- 2) For an FCOI to exist, first the Covered Person must have an SFI. See the definition of SFI above.
- 3) SFI to PHS-funded research relationship: If a covered person has an SFI, the next step is to determine if the SFI is related to the PHS-funded research. The IO should consider the following questions in making this determination. If either condition is true, an SFI-to-Research relationship exists.
 - a) Can the SFI be affected by the PHS-funded research? Examples of possible effects include:
 - i) Bonus payment for specific research outcomes
 - ii) Equity change based on research outcomes
 - b) Is the SFI in an entity whose financial interest can be affected by the research? Examples of possible entity financial interest effects include:
 - i) FDA approval or denial of an entity-produced drug being tested
 - ii) The research to be funded assesses the entity's product performance
- 4) FCOI: Finally, an FCOI is deemed to exist if the SFI could directly and significantly affect the design, conduct, or reporting of the related PHS-funded research. The ultimate question of direct and significant effects is based on the judgment of the IO.

V ASSOCIATED DOCUMENTS

- PHS Regulation 42 CFR Part 50 Subpart F – Promoting Objectivity in Research: <http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/pdf/CFR-2011-title42-vol1-part50-subpartF.pdf>
- PHS Regulation 45 CFR Part 94 – Responsible Prospective Contractors: <http://www.ecfr.gov/cgi-bin/text-idx?SID=15777174aca027ddeadfddb938f4ef8&node=45:1.0.1.1.51&rgn=div5>
- NIH FCOI FAQ: <http://grants.nih.gov/grants/policy/coi/>

VI ASSOCIATED RECORDS

- **Related Financial Interest Disclosure:** Includes entity name, entity type, interest type, interest value (by range).

VI REVISION HISTORY

Revision	Author	Changes	Reason for Changes	Release Date
A	Timothy Dondlinger		Original document	6/10/2014
B	Timothy Dondlinger, Michael Schmainda	Added examples of SFI to PHS-Funded research relationships; removed "other Institution" from SFI exclusion definitions	Improve guidance to IO; correct SFI exclusion definition	2/9/2016