

# Automated Imaging Diagnostics (AID) Policy on Research Conflicts of Interest

## 1. Policy Statement.

This policy and related guidelines set forth the process to identify and manage conflicts of interest related to research. The Chief Scientific Officer at AID will serve as the institutional official responsible for this policy and the oversight, review and management of conflicts in research.

## 2. Applicability.

This policy applies to AID employees when they are Investigators, regardless of title or appointment type. Additionally, AID investigators shall comply with all applicable statutory and regulatory requirements published by federal agency sponsors regarding Financial Conflict of Interest (FCOI) related activities sponsored by those agencies. As detailed in Section 4(c) below, under specific circumstances, this Policy may be applicable to Subrecipient Investigators.

## 3. Definitions.

*Conflict of Interest:* Occurs when an employees' financial, professional, commercial or personal interests or activities affects, or appears to affect, their professional judgment or obligations to AID.

*Entity:* Any business, company, or other organization, whether public or private, including without limitation any partnership, corporation, limited liability corporation, unincorporated association, or other institution or organization, whether for-profit or not-for-profit.

*Financial Conflict of Interest (FCOI):* A Financial Conflict of Interest exists when the AID determines that an Investigator's Significant Financial Interest is related to research and could directly and significantly affect the design, conduct or reporting of the research or present the appearance thereof.

*Immediate Family Member:* Includes an Investigator's spouse, domestic partner, and dependent children.

*Institutional Responsibilities:* Include professional activities that relate to an Investigator's responsibilities on behalf of AID, such as research, product and business development, marketing, sales, professional practice, and administrative activities and responsibilities for AID.

*Interventional Human Subjects Research:* Research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome.

*Investigator:* Includes the principal investigator and anyone proposing to be or who is responsible for the design, conduct, or reporting of research, regardless of title or position.

*FCOI Management Plan:* Documented strategies designed to mitigate the potential for an Investigator's Significant Financial Interests to impact or bias research objectivity and/or the safety or welfare of human research participants.

*PHS Investigator:* An Investigator who is participating or planning to participate in research funded by Public Health Service (PHS) or any other agency or sponsor that has adopted the PHS Objectivity in Research Rule.

*Related Research:* A Significant Financial Interest is related to the research in question if the Significant Financial Interest: (1) Could be affected by the research; or (2) Is in an entity whose financial interests could be affected by the research.

*Research Conflict of Interest (RCOI) Administrator:* The designated institutional official responsible for implementing this policy, reviewing Significant Financial Interests and managing FCOI. The RCOI Administrator may appoint a designee to assist with the implementation of this policy and any related procedures.

*Significant Financial Interest (SFI):* A Significant Financial Interest includes a financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator’s Immediate Family Members) related to their Institutional Responsibilities, when combined for the 12 months preceding the disclosure date, from a single Entity:

| Nature of SFI  | Disclosure Threshold |
|--|----------------------|
| Remuneration, compensation, and/or other payments for services (e.g. consulting, speaking) when combined with any equity interest in a publicly traded entity. | Exceeds \$5,000      |
| Remuneration, compensation, and/or other payments for services (e.g., consulting, speaking) from a non-publicly traded entity                                  | Exceeds \$5,000      |
| Equity interests in a non-publicly traded company (e.g. start-up company). Equity includes stock, stock options, or other ownership interest.                  | \$0 / Any Value      |
| Intellectual property rights and interests   | Exceeds \$5,000      |
| Sponsored or reimbursed travel*  | Exceeds \$5,000      |

*Exclusions to SFI:* The disclosure related to travel excludes reimbursed travel related to Federal, State, or Local Government related travel. The exclusion also includes a United States academic institution, medical center, teaching hospital, and research institute within the United States. In addition, the term SFI does not include the following financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including 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 located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

#### 4. Policy.

**a. General Principles.** The general principles set forth below apply to the disclosure and review of financial interests as it applies to research.

i. **Federal Research Disclosure and FCOI Policies.** The AID shall comply with the statutory and regulatory requirements published by federal agency sponsors regarding FCOI related to activities sponsored by those agencies.

ii. Disclosure Requirement. When required by certain sponsors, Investigators must disclose any SFI that reasonably appear to be related to the Investigator's Institutional Responsibilities at the time of proposal submission. At award, all Investigators must disclose any SFI or, when applicable, verify their previously disclosed SFI and throughout an award, Investigators must disclose a new SFI within 30 days of discovery or acquisition of the SFI and at least annually.

iii. Research Conflict of Interest Review Committee: The Chief Scientific Officer, at their sole discretion, may elect to appoint a committee to assist with, or perform, the Review (outlined in section 4(b) below).

**b. AID Review.**

i. Review. The RCOI Administrator, or designee, will conduct reviews to assess whether each Investigator's disclosed SFI involves Related Research, and if so, whether or not the SFI could directly and significantly affect the design, conduct, or reporting of research, thus presenting an FCOI, or an appearance thereof. FCOI determinations take into account:

1. The nature and extent of an Investigator's role on a project;
2. The nature and extent of an Investigator's Significant Financial Interest(s), and;
3. The nature of the research activity under review.

ii. Timing of Reviews. Reviews and determinations must occur prior to expenditure of funds for new awards and within 60 days of newly-disclosed Significant Financial Interests. Reviews and determinations must occur prior to the addition of new Investigators to awards during the life of an award. Additionally, whenever AID identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution, the SFI will be reviewed as outlined below.

iii. Relatedness Review. The RCOI Administrator may make determinations, on a project-by-project basis and upon review of an Investigator's SFI, that there is not Related Research. The RCOI Administrator may refer reviews to an appropriate subject matter expert or the COI committee for further evaluation and disposition. If the RCOI Administrator determines there is Related Research, the RCOI Administrator will initiate an FCOI Review.

iv. FCOI Review. The determination of whether or not a Significant Financial Interest represents a Financial Conflict of Interest will be made by the RCOI Administrator, with the input of the COI Committee when needed. If a SFI is determined to be an FCOI, the RCOI Administrator will proceed to manage the conflict, as outlined in section v., below.

v. Management. If an FCOI is determined to exist, the RCOI Administrator, or designee, in conjunction with the appropriate college official, will develop an FCOI Management Plan to manage, reduce, or eliminate the FCOI.

1. Management Plans. Depending on the nature of the FCOI and nature of the research activity, FCOI Management Plan controls may include:

- a. Disclosure of the Financial Conflict of Interest (to study teams, collaborators, the Institutional Review Board, human research participants, and in presentations and publications);
- b. Reduced role in the research, and/or independent review of research data and results;
- c. Additional conflict of interest management strategies, as appropriate,
- d. In extreme cases, prohibition from participating in research or divestment of financial interests may be required.

2. Agreement to the Management Plan. Investigators must agree to FCOI Management Plans in order to engage in research for which FCOI determinations are made.

vi. Reporting. Pursuant to sponsor requirements, the RCOI Administrator or designee will provide to the sponsor initial and ongoing reports describing an FCOI and related management.

1. For PHS-funded research, FCOI reports must be submitted to the PHS awarding component prior to the expenditure of funds for new projects, within 60 days of newly determined FCOI (whether the result of a new Investigator, newly disclosed Significant Financial Interest (SFI), or identification of an SFI that was not disclosed timely or an SFI that was not previously reviewed), and on an annual basis during the life of the project.

2. In addition, PHS requires AID to make available to the public, upon request, specific information regarding FCOI relative to senior/key personnel and PHS-funded research. AID is required to provide specific information relative to such public requests within five business days of the request.

vii. Human Subjects Research. In general, there is a rebuttable presumption that Investigators with Financial Conflicts of Interest will not participate in Interventional Human Subject Research unless there are compelling circumstances.

1. Compelling Circumstances. The RCOI Administrator may consider compelling circumstances when making a determination about a conflicted Investigator's permitted involvement in Interventional Human Subject Research. The RCOI Administrator will make the final determination as to whether compelling circumstances exist. The following factors will be considered when determining whether compelling circumstances exist:

- a. the nature of the research;
- b. the magnitude of the SFI and the degree to which it is related to the research;
- c. the extent to which the SFI could be directly and substantially affected by the research;
- d. the degree of risk to the human subjects involved that is inherent in the research protocol;
- e. the extent to which the conflicted Investigator is uniquely qualified to perform a research study with important public benefit; and
- f. the extent to which the FCOI is amenable to effective oversight and management.

2. Notification and Review. The SFI Committee will be notified of FCOI determinations, and conflict of interest management strategies implemented, relative to research involving human research participants. It is in the purview of the SFI Committee to review the conflict of interest management strategies associated with IRB protocols and determine whether the conflict of interest management is sufficient with respect to the rights and welfare of human research participants or requires additional mitigation.

viii. FCOI Management Review. The conditions of, and compliance with, Investigator FCOI Management Plans are reviewed on at least an annual basis by the RCOI Administrator or designee. On an ad hoc basis, the RCOI Administrator or designee will also conduct independent monitoring and verification to ensure that the conditions of conflict of interest management plans are being met.

**c. Subrecipients.** AID must apply relevant originating sponsor conflict of interest requirements to Subrecipients. Therefore, if required by the originating sponsor, AID must identify whether or not a Subrecipient has a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements. If a Subrecipient does not have a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements, in order to proceed with the AID collaboration, the Subrecipient must agree to abide by this Policy relative to the Subrecipient Investigators and the specific Subrecipient research activity for the duration of that activity. The subward must incorporate terms that establish whether the conflict of interest policy of AID or that of the Subrecipient will apply to Subrecipient Investigators, and obligations of the Subrecipient relative to conflict of interest in either case.

**d. Training.** Investigators may be required to complete research conflict of interest training at the sole discretion of the Institutional Official. AID may also require training if there is a substantive change to this policy or in specific instances of noncompliance.

i. For PHS Investigators, AID will require the completion of training before engaging in PHS funded research, at least every four years thereafter, and immediately when:

1. AID revises its financial conflict of interest policies or procedures in any manner that affects the requirements of PHS Investigators.
2. A PHS Investigator is new to AID; or

3. AID finds that a PHS Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

**e. Record Retention.** AID will securely maintain all review files and associated reports and management plans for three (3) years after any applicable research project's final financial report is submitted to the sponsor, or until three years after the final action has been taken on any audit, litigation, or claim.

**5. Review and Adjudication a.** Up to ten (10) days after an FCOI Management Plan is finalized and provided to an Investigator, an Investigator may submit to the RCOI Administrator a written request to modify the approved management controls. The RCOI Administrator will escalate the request to the Chief Scientific Officer or designee for review and determination of whether the requested modifications will be implemented.

## **6. Policy Violations**

**a. Examples of Non-Compliance:** The following are examples of noncompliance with this Policy:

i. Failure to submit a timely disclosure (e.g. more than 30 days after discovery or acquisition of a new Significant Financial Interest);

ii. Submission of an incomplete, erroneous or misleading initial, updated or annual disclosure;

iii. Failure to disclose information as required by this Policy;

iv. Failure to comply with prescribed management plans; or

v. Other instances as determined by the RCOI Administrator.

**b. Non-Compliance.** Any instances of Investigator noncompliance may require that the Investigator repeat AID's research conflict of interest training module. Additional disciplinary action for noncompliance with this Policy will be decided in accordance with applicable AID disciplinary policies, regulations and procedures.

**c. Non-Compliance Involving PHS-funded Research.** Whenever a FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, or failure of an Investigator to comply with the conditions of a FCOI Management Plan, AID must conduct a retrospective review of the Investigator's research activities on the project to determine if there is bias in the design, conduct, or reporting of the research resulting from the FCOI.

i. Retrospective Review. The retrospective review must be completed within 120 days of the determination of noncompliance. The retrospective review will be documented by the RCOI Administrator or designee. If bias is found in the course of the retrospective review, AID must promptly notify PHS and submit a mitigation report that addresses the impact of the bias on the research and the AID's plan of action to eliminate or mitigate the effect of the bias.

ii. PHS-funded Clinical Research. In instances of non-compliance in PHS Clinical Research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Investigator is thereafter required to disclose the FCOI in each public presentation of the results of the relevant research and also request an addendum to previously published presentations of the relevant research.

**7. Questions.** Any questions related to this policy should be directed to AID Chief Scientific Officer.