

	<b>POLICY TITLE:</b> Financial Conflict of Interest - Research
<b>MANUAL NAME:</b> Clinical Operations Manual	<b>POLICY NUMBER:</b> <input type="checkbox"/> Addendum to Corporate Policy <input type="checkbox"/> Form Available In I-REPP System
<b>SECTION (as applicable):</b> Clinical Research	<b>POLICY OWNER:</b> Tedd S. Adair, Chief Clinical Officer
<b>ORIGINATION DATE:</b> 06/19/2015	<b>FINAL APPROVAL DATE:</b> June 19, 2015

**POLICY:**

The purpose of this policy is to set forth the principles for identifying the potential for financial conflicts and the procedures for reviewing and addressing those potential conflicts that occur to assure that they do not improperly affect IASIS Healthcare research and other activities. IASIS Healthcare, its employees, and others affiliated with IASIS Healthcare, are committed to conducting themselves and IASIS Healthcare activities in accordance with the highest standards of integrity and ethics and in compliance with applicable state and federal laws related to financial conflict of interest and objectivity in research.

**SCOPE:**

IASIS Healthcare employees, non-employees, medical staff members, non-medical staff members, or other person conducting, participating in, reviewing or approving research in whole or in part at an IASIS Healthcare facility or using IASIS Healthcare non-public information, patients, or resources for purposes of research. This applies to research projects supported wholly or in part by the U.S. Public Health Service, the National Institutes of Health, the National Science Foundation, and other U.S. government agencies.

**DEFINITIONS:**

Associated Entity: "Associated entity" means any trust, organization, or enterprise over which the IASIS Healthcare Researcher, alone or together with a family member, possesses a business or financial interest that would be required to be disclosed under this guideline.

Business: "Business" means that any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, Joint Stock Company, receivership, business or real estate trust, or any other nongovernmental legal entity organized for profit, nonprofit, or charitable purposes.

Business Interest: "Business interest" means holding an executive position or membership on a board regardless of compensation.

Contribution: "Contribution" means a donation of any property, tangible or intangible, to an IASIS Healthcare entity or an IASIS Healthcare Foundation Executive Position: "Executive position" means any position that includes responsibilities for a significant segment of the operation or management of a business.

Financial Interest: "Financial Interest" means anything of value as defined below:

1. An interest in a business consisting of any stock, stock option, or similar ownership interest in such business, but excluding any interest arising solely by reason of investment in such business by a mutual, pension, or other institutional investment fund over which the employee does not exercise control and excluding any direct or indirect ownership of less than five percent in a publicly traded organization; or
2. Receipt of, or the right or expectation to receive, any income from such business in one or more of the following forms: a consulting fee, honoraria, salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing technology or other processes or products, rent, capital gain, or any other form of compensation.

Family: "Family" means the person's spouse or domestic partner, dependent children, parents, siblings, in-laws, grandparents, or step-children.

IASIS Healthcare Researcher: "IASIS Healthcare Researcher" means any IASIS Healthcare employee and any non-employed medical staff member or other person conducting or participating in research in whole or in part at an IASIS Healthcare facility or using IASIS Healthcare non-public information, patients or resources for purposes of research.

Participate: "Participate" means to be a part of the described activity in any capacity including, but not limited to, serving as the principal investigator, co-investigator, research collaborator, or provider of direct services or patient care, or having authority over any of the above. The term does not apply to the study participants, unless they are in a position to influence the study's results or have privileged information as to the outcome.

## **PROCEDURE:**

Individuals and others affiliated with IASIS Healthcare who are responsible for, or in a position to influence, the design, conduct or reporting of research or other scholarly activity must comply with all applicable state and federal laws and regulations, including those related to conflict of interest and objectivity in research and must disclose potential conflicts of interest and otherwise comply with the terms of this guideline.

A conflict of interest occurs when an IASIS Healthcare Researcher compromises professional judgment in carrying out the review and approval of, teaching, research, outreach, or public service activities because of an external relationship that directly or indirectly affects the financial or business interest of the IASIS Healthcare Researcher, an immediate family member, or an associated entity.

IASIS Healthcare assumes that potential for conflicts will occur regularly in the normal conduct of activities. However, it is essential that the potential for conflicts be disclosed and reviewed. After disclosure, IASIS Healthcare can then make an informed judgment about a particular case and require appropriate oversight, limitations, or prohibitions on the activity in accordance with this policy. IASIS Healthcare Researchers may not engage in activities in which an actual conflict of interest occurs.

Requirements, Explanations, and Illustrations:

- A. General: Individuals responsible for, or in a position to influence, or in a position responsible for the approval of, the design, conduct, or reporting of research or other scholarly activity must comply with all applicable state and federal laws and regulations, including those related to conflict of interest and objectivity in research. These laws include, but are not limited to, Federal Public Health Service regulations 42 CFR, part 50, subpart F, and 45 CFR, part 94, and National Science Foundation Grant Guideline Manual 510 as amended by 60 CFR 35820 (1995).
- B. Potential Conflicts of Interest: Potential conflicts of interest arise when an IASIS Healthcare Researcher participates in teaching, research, outreach or public service activities and the IASIS Healthcare Researcher, family members or associated entities have any discloseable financial or business interest in the technology, process, product or other subject matter of the activity or in any business supporting the activity. In general, a potential conflict exists if the IASIS Healthcare Researcher family member or associated entity has a business or financial interest that could be enhanced based on the outcome of the activity. Some activities that raise potential conflicts of interest are ordinarily allowable following disclosure and where necessary, the implementation of oversight or other management procedures, recusing themselves from participation in the discussion and voting of the research project. Other activities and external relationships require case-by-case review and only some of the specific relationships may be approved. Special oversight or management procedures are likely to be required.

Disclosure Requirements:

Researchers: Any time an IASIS Healthcare Researcher plans to initiate an activity that may be classified under Paragraph B above, the IASIS Healthcare Researcher must disclose relevant financial or business interests before commencing the activity.

Relevant financial or business interests that require disclosure by an IASIS Researcher are defined as follows:

1. IASIS Healthcare Researcher, family members, or associated entity have an equity interest in a business that is privately held or an aggregated equity interest in a publically held company representing ownership of 5 percent or more or a value of \$10,000 or more, as determined through reference to public prices or other reasonable measures of fair market value;

2. IASIS Healthcare Researcher, family members, or associated entity are expected to receive an aggregated annual income of all types from a business equal to or exceeding \$10,000 over the next 12 months;
3. IASIS Healthcare Researcher, family members, or associated entity have a commitment for future royalties from a business beyond the next 12 months that is expected to equal or exceed \$10,000 in aggregated annual income;

In addition to the disclosure requirements set forth in this guideline, various government agencies and sponsors may have additional disclosure requirements. All IASIS Healthcare Researchers are required to comply with such additional requirements.

IASIS Healthcare Researchers must disclose relevant financial or business interests to sponsors of research and in reporting by either written or publication; they must disclose to the editor any financial or business interest that may be related to the publication. This provision also applies to release of information to news media.

Disclosure of a relevant financial or business interest must also be made by any IASIS Healthcare Researcher who makes an appearance, either in person, or by way of a written communication, before any public body, commission, group, or individual, to present facts or to give an opinion respecting any issues or matters up for consideration discussion, or action.

When IASIS Healthcare Researchers participate in sponsored research involving sub-grantees, contractors, or collaborators outside of IASIS Healthcare, IASIS Healthcare, to the extent required by the sponsor will take reasonable steps to ensure that investigators working for these outside entities comply with appropriate conflict of interest disclosure and review requirements. These steps may include requiring the investigators to comply with IASIS Healthcare's guideline or obtaining written assurances from the outside entity that it complies with applicable federal regulations or sponsor guidelines on conflict of interest.

#### How Disclosures are Made:

IASIS Healthcare Researchers are required to complete and submit a disclosure form reporting all financial or business interests related to research activities. An IASIS Healthcare Researcher must disclose relevant financial or business interests at the time of application for research support (from internal or external funding sources) or at the time an application is submitted to the I-CARE Research Supervisor, if the proposal falls under the provisions of this guideline.

Approval for the project will not be accessible to the employee until the disclosure of the financial or business interest is reviewed and approval is given, and other appropriate measures have been implemented in accordance with this guideline. The Form attached as Exhibit A should be used and such disclosure should be made to I-CARE Research Supervisor.

Whenever substantial changes occur that the IASIS Healthcare Researcher believes may alter the financial or business interests previously disclosed, an updated form must be submitted within 30 days. The form attached as Exhibit A should be used and all such disclosures shall be made to I-CARE Research Supervisor.

## Procedures for Resolving Conflicts of Interest:

The I-CARE Research Supervisor will forward all disclosed potential conflicts of interest to IASIS Healthcare's Chief Compliance Officer (CCO). The CCO shall either decide:

- That no potential conflict of interest exists;
- That an impermissible conflict of interest exists and the research project cannot go forward; or
- That an impermissible conflict of interest exists but an alternate management plan shall be provided that allows the project to go forward.

IASIS Healthcare's Chief Compliance Officer shall be accountable to the IASIS Healthcare Board of Directors regarding conflicts related to board members and senior IASIS Healthcare management. Special situations may be brought to the IASIS Healthcare Board of Directors.

The Chief Compliance Officer will maintain records of all disclosure statements filed and all actions taken by the institution, for at least three years beyond the termination of the award or until resolution of any action by IASIS Healthcare or governmental agencies involving the records. All records will be maintained in a manner to protect confidentiality but will be accessible to sponsoring agencies as required by federal regulations or sponsor guidelines. In addition, the I-CARE Research Supervisor will maintain records of all disclosures in the I-CARE research office.

Prior to the expenditure of sponsored research funds, IASIS Healthcare to the extent required by the sponsor will notify it of the existence of any potential conflict of interest and provide assurance that the interest has been managed, reduced or eliminated.

## Sanctions:

Breaches of this guideline include, but are not limited to, failure to file, intentionally filing an incomplete, erroneous, or misleading disclosure form or failing to provide additional information as required by the approving authority. A violation of this guideline may be the basis for discipline of an employee or other person acting as an IASIS Healthcare Researcher. If sanctions are necessary, they will be imposed in accordance with other applicable IASIS Healthcare policies and procedures. The potential sanctions may include, but are not limited to the following:

1. letter of admonition;
2. ineligibility of the IASIS Healthcare Researcher to use IASIS Healthcare facilities for research, the imposition of conditions on or supervision of such research, ineligibility for grant applications, or other appropriate sanctions;
3. suspension; or
4. dismissal

If an IASIS Healthcare Researcher who is involved with sponsored research fails to comply with this guideline, then IASIS Healthcare's I-CARE Research Supervisor must promptly inform the Chief Compliance Officer of the violation. To the extent required by the sponsoring agency, the

Chief Compliance Officer will then notify the agency of the violation and any corrective action taken or to be taken.

**FORM REFERENCES:**

See Financial Conflict of Interest – Research Disclosure form.

**REFERENCES:**

Federal Public Health Service regulations 42 CFR, part 50, subpart F, and 45 CFR, part 94, and National Science Foundation Grant Guideline Manual 510 as amended by 60 CFR 35820 (1995).

<b>Review/Revised Date:</b>	<b>Title:</b>	<b>Description of Change or Location of Change in Document:</b>