Purpose: The goal of this Policy is to assure the objectivity in Public Health Service (PHS) funded research by establishing standards to ensure that the design, conduct and reporting of such research will not be biased and/or influenced by financial conflicts of interest of an Investigator. This Policy implements federal disclosure requirements pertaining to objectivity in research promulgated by the U.S. Public Health Service (PHS) in 42 CFR Part 50 and 45 CFR Part 94.

This Policy is intended to supplement, but not replace, the AMITA Health Corporate Responsibility and conflict of interest policies and procedures referenced below.

Scope: This Policy applies to all personnel who conduct Research, or assist in the performance of such Research activities, where that Research is performed at or under the auspices of any AMITA Health facility or subsidiary organization.

This Policy applies only to Research projects for which the facility submits a proposal to, or receives research funding from, directly or indirectly, the Public Health Service (PHS). This Policy sets forth requirements that each Investigator who is planning to participate in, or is participating in, such Research, must follow; however, this Policy does not apply to SBIR (Small Business Innovation Research) Program Phase I applications.

Definitions:

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research.

Reviewing Official: an official designated by AMITA to solicit and review completed Disclosure Forms from each Investigator, and to determine whether any reported Significant Financial Interest is a Financial Conflict of Interest.

Institutional Responsibilities: an Investigator's professional responsibilities on behalf of AMITA, including activities such as research, teaching, clinical or other professional practice, Facility committee memberships, and service on panels such as the Institutional Review Board (IRB).

Investigator: For the purposes of this policy, an Investigator is any individual responsible for the design, conduct, or reporting of Research funded by the PHS. This includes the Principal Investigator, Co-Investigators, and any other individual, regardless of title or position, who is responsible for the design, conduct, or reporting of this Research.

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Significant Financial Interest (SFI): For the purposes of this Policy, a Significant Financial Interest is either of the following:

- Any interest 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, including, but not limited to, one or more of the following:
  - With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  - With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
  - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
  - 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 the Investigator's 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 term Significant Financial Interest does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by AMITA to the Investigator if the Investigator is currently employed or otherwise appointed by AMITA, including intellectual property rights assigned to AMITA and agreements to share in royalties related to such rights;
- 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, an Institution of higher education as defined at 20 U.S.C.;
- 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.

PHS Awarding Component: The organizational unit of the Public Health Service (PHS) that funds the Research. This includes, but is not limited to, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ).

POLICY
This Policy establishes a process of disclosure and independent review when an Investigator has Significant Financial Interest(s). When AMITA determines that such an interest might reasonably appear to affect the
Research directly and significantly, AMITA will take steps to manage or to eliminate the conflict.

Investigator Responsibilities

• Training

Prior to engaging in PHS-funded Research, each Investigator must complete the AMITA designated training program with regard to the PHS COI regulations. This training will include information regarding this Policy, the Investigator’s responsibilities regarding disclosure of Significant Financial Interests, and the Federal Financial Conflict of Interest (fCOI) regulations. Training must be repeated at least every four (4) years thereafter, and within thirty (30) days of when any of the following occurs:

• When this Policy, the Disclosure Form, or AMITA procedures related to this Policy are revised in any manner that affects the Investigator’s responsibilities thereto;
• An Investigator is newly hired, is appointed by, or receives approval of medical staff privileges from, AMITA; or,
• An Investigator is found to not be in compliance with this Policy or a management plan.

• Disclosure

When an Investigator has a Significant Financial Interest, as defined above, a written Significant Financial Interest Disclosure Form (and Appendix A; Attachments A & B) detailing that interest is required to be submitted to AMITA’s designated Reviewing Official. This Disclosure Form must be filed no later than at the time of application for PHS funded Research. The lead principal investigator on a proposed application for PHS funding is responsible for ensuring submission of a Disclosure Form for all participating Investigators.

Each investigator must update his or her SFI disclosures by completing a new Disclosure Form. Throughout the period of the award, this update must occur at least annually, as well as within thirty (30) days of a new SFI being discovered or acquired. One annual disclosure will be sufficient to cover all on-going PHS-funded Research.

The Investigator must cooperate with all requests from the applicable PHS Awarding Component and/or AMITA for additional information as needed. All such internal disclosures will be treated as confidential personal information.

Facility Responsibilities

Review of Disclosures and Management of fCOI

Initial review and management:

Prior to AMITA’s expenditure of any funds under a PHS-funded Research project, the Reviewing Official will review all Investigators’ Disclosure Forms; determine whether any Significant Financial Interests relate to PHS-funded Research; determine whether a fCOI exists; and, if so, develop and implement a management plan that specifies the actions that have been, and will be, taken to manage such fCOI.

Review and management in the course of a PHS-funded Research project:

Whenever, in the course of an ongoing PHS-funded Research project, an Investigator who is new to participating in the Research project discloses a Significant Financial Interest; an existing Investigator discloses a new Significant Financial Interest; or AMITA identifies a Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by AMITA during an ongoing PHS funded Research project, the Reviewing Official will, within sixty (60) days: review the disclosure of the Significant Financial Interest; determine whether it is related to PHS-funded Research; determine
whether a financial COI exists; and, if so, implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such fCOI. Depending on the nature of the Significant Financial Interest, AMITA may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded Research project between the date of disclosure and the completion of AMITA's review.

**Examples of conditions or restrictions that may be imposed to manage an fCOI include, but are not limited to:**

- Public disclosure of the fCOI;
- For Research projects involving human subjects, disclosure of the fCOI 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 fCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
- Reduction or elimination of the financial interest; or
- Severance of relationships that create financial conflicts.

**Requirements for retrospective review:**

In addition to the above requirements, whenever an fCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest that is determined by AMITA to constitute an fCOI; failure by AMITA to review or manage such an fCOI; or failure by the Investigator to comply with an fCOI management plan, AMITA will, within 120 days of AMITA's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research. AMITA is required to document the retrospective review, including all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the fCOI;
- Name of the entity with which the Investigator has an fCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, AMITA will update the previously submitted fCOI report, specifying the actions that will be taken to manage the fCOI going forward. If bias is found, the facility will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the Research project and the facility's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the Research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the Research project is salvageable). Thereafter, the facility will submit fCOI reports annually. Depending on the nature of the fCOI, AMITA may determine that additional interim measures are necessary with regard to the
Investigator's participation in the PHS-funded Research project between the date that the fCOI or the Investigator's noncompliance is determined and the completion of AMITA's retrospective review.

Monitoring:
Whenever AMITA implements a management plan, AMITA will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS funded Research project.

Reporting of Financial Conflicts of Interest

Initial fCOI Report:
Prior to AMITA's expenditure of any funds under a PHS-funded Research project, the facility will provide to the PHS Awarding Component an fCOI report regarding any Investigator's Significant Financial interest found by AMITA to be an fCOI and ensure that AMITA has implemented a management plan in accordance with this Policy. In cases in which AMITA identifies an fCOI and eliminates it prior to the expenditure of PHS-awarded funds, AMITA does not need to submit an fCOI report to the PHS Awarding Component.

Subsequent fCOI Reports:
For any Significant Financial Interest that AMITA identifies as conflicting after AMITA's initial fCOI report during an ongoing PHS-funded Research project, AMITA will provide to the PHS Awarding Component, within sixty (60) days, an fCOI report regarding the fCOI and ensure that AMITA has implemented a management plan in accordance with this Policy and, if required, a retrospective review and a mitigation report according to this Policy.

Contents of an fCOI report:
Any fCOI report required under this Policy will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of AMITA's management plan. Elements of the fCOI report will include, but are not necessarily limited to the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the fCOI;
- Name of the entity with which the Investigator has an fCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000–$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the PHS-funded Research and the basis for the facility's determination that the financial interest conflicts with such Research; and
- A description of the key elements of the facility's management plan, including:
  - Role and principal duties of the conflicted Investigator in the Research project;
  - Conditions of the management plan;
  - How the management plan is designed to safeguard objectivity in the Research project;
  - Confirmation of the Investigator's agreement to the management plan;
  - How the management plan will be monitored to ensure Investigator compliance; and
  - Other information as needed.

Annual fCOI Report:
For any fCOI previously reported by AMITA with regard to an ongoing PHS-funded Research project, AMITA
will provide to the PHS Awarding Component an annual fCOI report that addresses the status of the fCOI and any changes to the management plan for the duration of the PHS-funded Research project. The annual fCOI report will specify whether the fCOI is still being managed or explain why the fCOI no longer exists. AMITA will provide annual fCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

**Enforcement**

Failure to comply with this Policy, including failure to file a complete or timely Disclosure Form or update or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy, including a management plan, will be grounds for discipline up to and including termination of employment, appointment, and/or medical staff privileges.

In addition, if the failure of an Investigator to comply with this Policy or an fCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded Research, AMITA is required to promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to AMITA for further action, which may include directions to AMITA on how to maintain appropriate objectivity in the PHS-funded Research project. In addition, federal regulations may require reports to the federal sponsor of any information which may show a violation of AMITA policy. Sponsors may impose special award conditions or may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of Significant Financial Interests related to federally sponsored projects.

**Records**

Records regarding Disclosure Forms, the Reviewing Official's determinations, and AMITA's actions regarding management of an fCOI will be retained by AMITA for three years beyond the date of the final expenditure report submitted to PHS under an award.

**Public Accessibility**

In compliance with Federal regulations, this Policy will be made publicly accessible through the AMITA Health Web site. Information (including, at least, the minimum elements as provided in the regulation) regarding fCOIs identified under this Policy held by senior/key personnel (as defined by regulation), will be made provided to a requestor within five (5) calendar days of a written request.

**REFERENCES:** Federal Regulations at 42 CFR Part 50 and 45 CFR Part 94

AMITA Health Policy: Corporate Responsibility and Conflicts of Interest

AMITA Health Policy: Outside Business Activities

AMITA Health Procedure: Conflicts of Interest

AMITA Health Policy: Code of Conduct

AMITA Health Policy: Conflict of Interest

**Significant Financial Interest Disclosure Form (Appendix A)**

**Significant Financial Interest Form - Additional**
## Approval Signatures

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<tr>
<th>Step Description</th>
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<th>Date</th>
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<td>CR Compliance Committee</td>
<td>ROBERT BURGESS: VP COMPLIANCE &amp; IA</td>
<td>7/21/2017</td>
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<td>John Guidotti: Regional Corporate Responsibility Officer – South</td>
<td>1/19/2017</td>
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<td>ROBERT BURGESS: VP COMPLIANCE &amp; IA</td>
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<td>Elizabeth Contant: Regional Corporate Responsibility/Privacy Officer</td>
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<td>PAIGE ENGLISH: ASSOCIATE VP CORP RESP</td>
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