

# **ACOUSTIC MEDSYSTEMS, INC. – COMPANY POLICY**

## Financial Conflict of Interest Policy

<b>Responsible Officers:</b>	Chief Executive Officer; VP - Research
<b>Responsible Office:</b>	GCA – Grants and Contracts Administration
<b>Issuance Date:</b>	8/24/2012
<b>Effective Date:</b>	6/6/2016
<b>Scope:</b>	This policy for disclosure and management of conflicts of interest applies to all grants and cooperative agreements (other than Phase I SBIR and STTR applications) with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are submitted to PHS (NIH, CDC, FDA, etc.) and other non-federal sponsors that adopt the PHS policy for research

## **I. POLICY SUMMARY**

### **PURPOSE, SCOPE AND APPLICATION**

The federal Department of Health and Human Services (HHS) has determined, pursuant to 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, as revised on August 25, 2011, that effective no later than August 24, 2012, Public Health Service (PHS)-sponsored Investigators shall be subject to specific requirements regarding the disclosure and management of conflicts of interest with regard to research in order to provide a reasonable expectation that PHS-sponsored research will be conducted free of bias resulting from Investigator financial conflicts of interest.

These regulations require Acoustic MedSystems (AMS) to maintain a written policy on conflict of interest disclosure as a condition for receiving PHS awards. Therefore, the Company is obligated to establish this policy consistent with these regulations to require disclosure, and identification and management of financial conflicts of interest for all Investigators supported by PHS (NIH, CDC, FDA, etc.) research awards and other non-federal sponsors that adopt the PHS policy, (for example, American Heart Association and the American Cancer Society).

This policy applies to all grants and cooperative agreements with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are for research. These federal requirements are applicable to all proposals for extramural awards submitted to PHS.

Consistent with PHS regulations, this policy will be made available via a publicly-accessible website. All AMS Investigators (that is, individuals who, regardless of position or title, are responsible for the design, conduct or reporting of PHS supported research, and Investigators seeking PHS research support) shall be informed where this policy and relevant reporting requirements may be accessed via the web.

## **II. DEFINITIONS**

### **Designated Official(s)**

An official or officials designated by the Chief Executive Officer, or designee, to solicit and review Investigators' completed Disclosure of Financial Interest forms and who may determine whether the Investigator has a Financial Conflict of Interest.

### **Financial Conflict of Interest**

A Significant Financial Interest that is related to the PHS-funded research activity in which the Investigator is engaged and that could directly and significantly affect the design, conduct and/or reporting of PHS-funded research activity.

### **Independent Substantive Review Committee (ISRC)**

A Committee which may be appointed (in lieu of or in addition to a designated individual) by the CEO to review Investigators' significant financial interests related to PHS funded research, and to serve as the Designated Official(s) who determines whether any of the significant financial interests constitutes a financial conflict of interest. This review may be conducted by either an individual designated as a Designated Official or the ISRC.

### **Institutional Responsibilities**

Teaching/education, research, product development, outreach, and public service on behalf of the AMS which are in the course and scope of the Investigator's AMS employment.

### **Investigator**

Any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the PHS-sponsored project. This includes the Principal Investigator, Co-Investigators, Collaborators, Consultants, and any other individual who has responsibility for designing, conducting, or reporting of research funded by PHS or proposed for such funding.

### **Principal Investigator**

An Investigator, (normally senior professional personnel), who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.

### **Key Personnel**

A PHS research Project Director, Principal Investigator and any other personnel considered essential to work performance and identified as Key Personnel in the proposal, grant, or contract.

### **Research**

As used in this Policy, any activity for which research funding is available from a PHS-awarding agency, including but not limited to research grants, cooperative agreements, career development awards, center grants, individual fellowship awards, infrastructure awards, Institutional training grants, program projects or research resources awards, conference grants, and Phase II Small Business Innovative Research (SBIR) and Phase II Small Business Technology Transfer Research (STTR) awards. Excluded from this Policy, consistent with the underlying federal regulations, are Phase I Small Business Innovative Research (SBIR) and Phase I Small Business Technology Transfer Research (STTR) awards.

### **Significant Financial Interest (SFI)**

Consistent with federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator or the Investigator's spouse or registered domestic partner<sup>1</sup> and dependent children for

the following categories, except in the case of travel:

Financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's family members) that reasonably appears to be related to the investigator's institutional responsibilities:

A. With regard to any publicly-traded entity, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in Paragraph 5, below) 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. Included are salary (other than salary described in Paragraph 5, below), consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value.

Any equity interest in a non-publicly traded entity other than AMS or any financial remuneration received from the entity in the twelve (12) months preceding the disclosure that, when aggregated, exceeds \$10,000;

B. With regard to any non-publicly-traded entity, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in Paragraph 5, below) 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, registered domestic partner, or dependent children) holds any equity interest.

An equity interest in a publicly traded Company that is 5% or greater or any financial remuneration received from the entity in the twelve (12) months preceding the disclosure that, when aggregated, exceeds \$10,000; and

C. Intellectual property rights and interests, upon receipt of income, exceeding \$5,000 during the twelve months preceding disclosure from such rights and interests. However, Significant Financial Interests do not include royalties received from AMS.

D. In the case of travel, sponsored travel or reimbursements made to or on behalf of, the Investigator, regardless of amount, by a for-profit or non-profit entity related to the Investigator's Institutional Responsibilities. However, Significant Financial Interests do not include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.

The term "Significant Financial Interest" does not include the following types of financial interests:

- Salary, bonus, royalties, or other payments made by AMS to an AMS Investigator who is currently employed or otherwise appointed by the Company;
- income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government, agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.
- Income from investment vehicles, such as mutual funds and retirement funds, in which the Investigator does not directly control investment decisions.

The above terms do not include the following types of 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. The term also does not apply to diversified mutual funds in which the shareholder has no control over the equities held by the fund.

The terms also do not include income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, an accredited U.S. college or university, a U.S.

academic health center, or a U.S. research institution that is formally affiliated with a U.S. college or university.

The terms do not include income from serving on advisory committees or review panels for a federal, state or local government agency, an accredited U.S. college or university, a U.S. academic health center, or a U.S. research institution that is formally affiliated with a U.S. college or university.

### **Sponsor or financially interested Company**

A commercial entity, or in certain cases, a not-for-profit entity that is sponsoring research to commercialize a product, whose financial interests would reasonably appear to be affected by the conduct or outcome of the research, including commercial companies that directly sponsor research, companies that hold patent rights for discoveries, drugs, or devices being studied in research protocols, or companies that provide financial or “in-kind” support for research projects. A financially interested company may also include a company that competes with the sponsor of the research or the manufacturer of the investigational product, if the researcher knows that the financial interests of such a company would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a sponsor or financially interested company such as a contract research organization.

## **III. LEGAL OBLIGATIONS**

Investigators should be aware that financial interests in companies or external entities may result in personal or institutional obligations under federal and state laws, formal contractual requirements of commercial research sponsors, as well as with conflict of interest requirements of accreditation entities. The Company is also required to comply with federal conflict of interest regulations, including maintaining a written and enforced financial conflict of interest policy, managing, reducing or eliminating identified conflicts, and reporting identified conflicts to federal agencies within prescribed timeframes.

When the institution carries out federally-funded research through a subrecipient (e.g., subcontractors, subawardee, or consortium members), the institution must also meet applicable agency requirements to ensure that subrecipient investigators also comply with the federal conflict of interest regulations.

The Office of Grants and Contracts Administration will be responsible for complying with sponsor and regulatory agency reporting requirements, as well as the maintenance of conflict of interest records, pursuant to applicable federal and state requirements and Company record retention policies.

### **A. Public Health Service (PHS)/National Science Foundation (NSF)**

Individuals who receive research funding from either the Public Health Service (PHS) (including the National Institutes of Health) or National Science Foundation (NSF) must comply with agency regulations, which ensure that personal financial interests do not affect the design, conduct, or reporting of federally-funded research. The PHS regulations on “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (42 C.F.R. Part 50, Subpart F) and “Responsible Prospective Contractors” (45 C.F.R. Part 94) can be found at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>. The NSF conflict of interest policy can be found in Chapter V, Grantee Standards, Section 510, Conflict of Interest Policies, in the NSF Grant Policy Manual at [http://www.nsf.gov/pubs/manuals/gpm05\\_131/gpm5.jsp#510](http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510).

## **B. Food and Drug Administration (FDA)**

The FDA requires applicants, under its regulations at 21 CFR Part 54, to submit to FDA a list of clinical investigators who conduct covered clinical studies and to certify the absence of and/or disclose the existence of certain financial arrangements. The FDA's most recent guidance is available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM256525.pdf> (May 2011).

In cases where an individual investigator holds an Investigational New Drug application (IND) for a study drug, or an Investigational Device Exemption (IDE) for an experimental study device, the investigator him/herself may be required to personally comply with the above FDA conflict of interest reporting requirements and should consult the FDA or AMS Grants and Contracts Administration concerning applicable rules and regulations.

The Office of Grants and Contracts Administration, will be responsible for complying with sponsor and regulatory agency reporting requirements, as well as the maintenance of conflict of interest records, pursuant to applicable federal and state requirements and AMS record retention policies.

## **C. Securities and Exchange Commission (SEC)**

The SEC enforces regulations concerning equity ownership, including insider trading, which may affect investigators who hold equity in research sponsors. For additional information, investigators should seek advice from their personal legal counsel. It is the obligation of the financially interested individual to ensure that s/he complies with applicable SEC regulations.

## **D. Other sponsors**

Outside sponsors may also have specific requirements regarding investigators who have personal interests with the sponsor. For more information, contact AMS Grants and Contracts Administration.

## **E. Accreditation entities**

Outside academic accreditation entities and programs, such as the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), require that the institution's human research protection program specifically include policies and procedures to identify and manage potential personal financial conflicts of interest, as well as potential institutional conflicts of interest, to ensure that all human research participants are respected and are protected from unnecessary harm. For more information on these AAHRPP requirements, contact AMS Grants and Contracts Administration.

## **IV. POLICY TEXT**

### **A. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS**

Investigators seeking PHS research funding or receiving PHS research support are required to disclose Significant Financial Interests related to their Institutional Responsibilities. These Investigators shall submit a disclosure of Significant Financial Interests in accordance with implementation procedures.

The requirement that an Investigator disclose a Significant Financial Interest under the terms of this Policy does not in and of itself imply the existence of an actual or potential financial conflict of interest. The existence of a financial conflict of interest, based upon the relationship of the Investigators' Significant Financial Interests to the Investigators' Institutional Responsibilities, is determined by a Designated Official(s) or an Independent Substantive Review Committee (ISRC) with input from the Investigator. If a financial conflict of interest is identified, the Designated Official(s) or the ISRC shall recommend additional steps to manage or eliminate the conflict, to the CEO or designee who is authorized to act on that recommendation.

Investigators as defined by this policy, shall disclose to their campus all Significant Financial Interests related to their Institutional Responsibilities, no later than at the time of application for PHS funding.

This initial disclosure responsibility is separate from and in addition to an Investigator's ongoing duty throughout the period of a PHS research award to disclose to the designated official his or her Significant Financial Interests, and those of his or her spouse or registered domestic partner, and dependent children) related to the Investigator's Institutional Responsibilities:

- Within 30 days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest (with the exception of travel disclosures, noted below); and
- At least annually throughout the period of the award.

Before joining an ongoing PHS-funded research project new Investigators must submit a disclosure of Significant Financial Interests to the AMS Grants and Contracts Administration.

Under the terms of this Policy, Principal Investigators must identify all Investigators on the award who (that is, all individuals who will have responsibility for designing, conducting, or reporting the research to be funded by PHS) are required to disclose Significant Financial Interests.

Sponsored or reimbursed travel may be disclosed:

a) Prospectively listing all anticipated travel (including information about the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration of the trip, as well as any other information that may be required by the campus) for the 12 month period following the filing of the Investigator's annual disclosure form; and/or

b) Within 30 days of the occurrence of travel that either was not listed on the prospective annual travel report pursuant to paragraph a) or that significantly varied in the threshold reporting details from what was listed in the prospective report.

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from the Company are expected to comply with the policies and procedures for disclosure and review of a

Significant Financial Interests at the institution at which they are employed or, if their institution does not have a conflict of interest policy that complies with the DHHS regulations, they must comply with the AMS policies and procedures for disclosure and review of a Significant Financial Interests related to PHS sponsored awards. Subawards issued by AMS will ask the subrecipient institution to certify that its policy is in compliance with DHHS conflict of interest regulations, and unless the subrecipient does not have a DHHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a Financial Conflict of Interest is identified, for sending AMS notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.

Collaborators who share responsibility for the design, conduct, and reporting of research results and who will participate in research under an independent consulting agreement issued by the Company should be identified as Investigators by the Principal Investigator and should complete the Company disclosure forms. If, upon review, the Company determines that these financial interests could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, consultants will be expected to adhere to the plans put in place to eliminate, reduce or manage the identified conflicts of interest.

The vice president for research or CEO will be responsible for administering the Financial Conflict of Interest Policy. The vice president for research or CEO may designate the research grants administrator to perform his/her responsibilities under the policy.

The Designated Official will appoint a conflict of interest administrator in consultation with the CEO. The conflict of interest administrator will provide professional staff support for implementation of the policy. With the approval of the CEO, and in consultation with the Conflicts of Interest Policy Advisory Committee (COIAC), the conflict of interest administrator will design procedures for the reporting of potential conflicts of interest. The administrator will also assist investigator and other Company employees in identifying, managing or eliminating conflicts of interest and will periodically inform employees about the policy and other issues relating to conflicts of interest.

The AMS general counsel will designate a conflict of interest legal advisor who will assist the vice president for research, the COIAC, and the conflict of interest administrator with respect to the requirements of state and federal law. Counsel represents the Company and not the individual. Joint representation can be provided where warranted if there is no conflict of interest or the conflict is waived in writing by both parties after full disclosure. Further, investigators have the right to have their own (private) attorney.

The Designated Official will be responsible for providing reports to outside funding agencies as may be required by federal regulations or the terms of sponsored research agreements.

## **B. REVIEW OF DISCLOSURES; MANAGEMENT PLAN**

With each PHS proposal, progress report, incremental funding or extension, Investigators' Significant Financial Interests disclosures will be reviewed by the Designated Official(s) to determine whether there are any Significant Financial Interests that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged. Investigators shall have an opportunity to indicate whether or not they believe the Significant Financial Interest(s) they reported are related to their PHS-funded research activities.

In the event that the Designated Official(s) conclude that an Investigator's Significant Financial Interest reasonably appears to directly and significantly affect the design, conduct or reporting of the

PHS-funded research; or is in an entity whose financial interest could be affected by the research, the Disclosure and appropriate documentation shall be forwarded to the Designated Official for consideration. When it is determined that there is a financial conflict of interest, the ISRC shall make a final recommendation to the CEO about whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest before the support can be accepted.

The management plan is to be implemented prior to the Company's expenditure of PHS funds awarded for the research project, and shall specify the actions that are required to manage the Financial Conflict of Interest, and shall include:

- The role and principal duties of the conflicted Investigator;
- Conditions of the management plan;
- How the plan will safeguard objectivity in the research activity;
- Confirmation of the investigator's agreement to the plan; and
- How the plan will be monitored.

The same review process takes place when an Investigator reports a new Significant Financial Interest.

### **C. REPORTING TO PHS**

Prior to the Company's expenditure of any funds provided under a PHS award, the Company must provide to the PHS funding agency an initial report regarding Investigator Financial Conflict of Interest if such Financial Conflict of Interest exists. If Financial Conflicts of Interest are eliminated before research funds are expended, the Company is not required to submit a report to the PHS funding agency.

During the period of the award, the Company shall, within 60 days of receipt of disclosure of a new or newly-discovered Significant Financial Interest, review the disclosure, determine whether it is related to PHS-funded research, determine whether it constitutes a Financial Conflict of Interest, and if so, implement a management plan and report the Financial Conflict of Interest to the PHS funding agency.

For any Financial Conflict of Interest that the Company reports to a PHS awarding agency, the Company shall provide to the PHS awarding agency an annual Financial Conflict of Interest report that addresses the status of the conflict and any changes to the management plan, for the duration of the project. The annual report shall specify whether the financial conflict is still being managed or explain why it no longer exists. The Company must provide annual reports to the PHS awarding agency for the duration of the project period ((including extensions with or without funds).

Within 60 days of determining that a Financial Conflict of Interest exists for a new Investigator who joins an ongoing PHS-funded research activity, the Company must implement a management plan and submit a report to the PHS funding agency.

In any case in which the Department of Health and Human Services (DHHS) determines that a PHS-sponsored project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by the Company as required by this policy and Federal regulation, the Company shall require the Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.



## **D. MONITORING**

The management plan put in place shall specify the way in which the Investigator's compliance with the management will be monitored on an ongoing basis until completion of the PHS-funded research project.

## **E. RETROSPECTIVE REVIEWS AND MITIGATION REPORTS**

When during the course on ongoing PHS-funded research project, the Company identifies a Significant Financial Interest that was not disclosed in a timely manner by an Investigator or which was not previously reviewed, the Designated Official will, within 60 days, review the Significant Financial Interest to determine whether it is related to PHS-funded research activity, determine whether a Financial Conflict of Interest exists, and if so, implement a management plan on at least on an interim basis.

In addition, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an SFI that was later determined to be a Financial Conflict of Interest, or the Company did not review or manage the Financial Conflict of Interest, or the Investigator failed to comply with a previously implemented management plan, the Company must within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research. The purpose of this retrospective review is to determine if the ongoing PHS-funded research was biased in its design, conduct or reporting. The Company will document the retrospective review; such documentation will include the project number; project title; name of Investigator with the Financial Conflict of Interest; name of the entity with which the Investigator has a Financial Conflict of Interest; the reasons for the retrospective review; detailed methodology used for the retrospective review; findings; and conclusions.

- Based on the results of the retrospective review, if appropriate, the previously submitted Financial Conflict of Interest report should be updated to specify the actions that the Company will take to manage the identified Financial Conflict of Interest going forward.

If bias was found during the retrospective review, the Company will promptly notify the PHS funding agency and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the Company's plans to eliminate or mitigate the effect of the bias.

## **F. RECORD RETENTION**

Records of financial disclosures and the Company's review of, or response to such disclosures, whether or not a disclosure resulted in the Company's determination of a Financial Conflict of Interest, and all actions under this policy or retrospective review shall be maintained for at least 3 years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report. for the subject award or as otherwise required under 45 CFR 74.53(b) and 92.42(b)(pertaining to pending litigation and audits, or where real property and equipment purchased under the award are retained beyond 3 years, when records are transferred to or maintained by the HHS awarding agency, or indirect cost proposals and cost allocation plans. Records relating to unfunded awards need not be retained.

## **G. TRAINING**

Each Investigator, including collaborators, consultants or subcontractors, must complete NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded project and at least every 4 years thereafter, while receiving PHS research funding, and at other times as may be required by the Company in accordance with DHHS regulations. For PHS-funded Investigators who are new or who are joining an ongoing PHS Research Activity, AMS will establish a reasonable, expeditious timeframe when Investigators must complete training.

The federal financial conflict of interest regulations also require that the institution provide formal conflict of interest training to investigators. The COIAC shall recommend a formal training process, which will reasonably comply with the applicable federal regulations. Supervisory officials will be responsible for ensuring investigators complete the required formal conflict of interest training before engaging in research related to any PHS-funded grant and at least every four (4) years and immediately when any of the following circumstances apply:

- The Company substantially revises its financial conflict of interest policy in a manner that affects the requirements of investigators;
- An investigator is new to the Company; or
- The Company finds an investigator that is not in compliance with the Company's financial conflict of interest policy or management plan.

## **H. PUBLIC ACCESS TO INFORMATION**

The Designated Official at Company shall identify one e-mail address and one office address as the recipient addresses for public requests for information under the PHS regulations and this policy, and shall take action necessary to provide reasonable notice of those addresses to the public, including prominently posting this information on the campus web site.

The Company must respond within 5 business days to any request for information about Significant Financial Interests held by Key Personnel when the Company has determined that the disclosed Significant Financial Interests are related to the PHS-funded research, and constitute Financial Conflicts of Interest. The 5-day response time shall be measured from the date that the request for information is received at the company-designated address until the date a response is sent to the requestor.

Disclosure forms, Disclosure Update forms, and Management Plans including determinations of Financial Conflicts of Interest under this policy are public records open to public inspection, under federal and state law.

## **I. SANCTIONS**

Failure of an individual to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed award monitoring bodies, will be grounds for discipline pursuant to the Company Policy on Investigator Conduct and the Administration of Discipline and/or other applicable employee disciplinary policies. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and Company policy.

## V. COMPLIANCE / RESPONSIBILITIES

<b>Function</b>	<b>Responsibilities</b>
Investigators, as defined by this policy	<ul style="list-style-type: none"> <li>▪ Must disclose all Significant Financial Interests (SFIs) related to the Investigator's Institutional Responsibilities, no later than at the time of application for PHS funding.</li> <li>▪ Throughout the period of the PHS research award, must disclose their SFIs, and those of their spouse or registered domestic partner and dependent children:               <ul style="list-style-type: none"> <li>▫ Within 30 days of discovering or acquiring any new SFI; and</li> <li>▫ At least annually throughout the period of the award.</li> </ul> </li> <li>▪ Before joining an ongoing PHS-funded research project new Investigators must submit a disclosure of Significant Financial Interests.</li> <li>▪ Principal Investigators must fully identify all Investigators on the award who are required to disclose SFIs under the terms of this Policy.</li> <li>▪ Investigators must complete NIH-compliant training about the Company's PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded project and at least every 4 years thereafter, while receiving PHS research funding and at other times as may be required by the Company under this Policy.</li> <li>▪ In cases where the Company has identified a financial conflict of interest held by the Investigator and has implemented a management plan to eliminate, reduce or manage the conflict, must adhere to the terms of the management plan.</li> <li>▪ Where DHHS determines that a PHS-sponsored project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by the Company as required by this policy and federal regulation, the Company shall require the Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.</li> </ul>
<b>Function</b>	<b>Responsibilities</b>
Non-Company collaborators, consultants or subcontractors who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from the Company	<ul style="list-style-type: none"> <li>▪ Must comply with the policies and procedures for disclosure and review of SFIs at the institution at which they are employed, or, if their institution does not have a conflict of interest policy that is compliant with the DHHS regulations, they must comply with this policy and procedures for disclosure and review of SFIs related to PHS-sponsored awards.</li> <li>▪ Must comply with all requirements of their institution's (or this) policy that pertain to Investigators, including completing NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded contract and at least every 4 years thereafter, while receiving PHS research funding</li> </ul>
Institutions that receive subawards issued by the Company for PHS-funded research	<p>In cases where the agreement between the Company and the subrecipient specifies that the subrecipient's conflict of interest policy shall apply:</p> <ul style="list-style-type: none"> <li>▫ Must certify that the subrecipient's conflict of interest policy complies with the requirements of the DHHS regulations</li> </ul>

	<ul style="list-style-type: none"> <li>▫ Must review financial disclosures made by Investigators at the subrecipient institution and, if any Financial Conflicts of Interest are identified, send the Company notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.</li> </ul> <p>In cases where the agreement between the Company and the subrecipient specifies that the Company's conflict of interest policy shall apply, subrecipient must submit to the Company, within the time period specified in its subrecipient agreement with the Company, all disclosures by subrecipient Investigators of Significant Financial Interests, for the Company's review.</p>
Designated Official	<ul style="list-style-type: none"> <li>▪ Must solicit and review Investigators' SFI disclosures for each PHS proposal, progress report, incremental funding or extension, to determine whether there are any SFIs that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged.</li> <li>▪ If an SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded research activity, the Campus Designated Official shall forward the disclosure and appropriate documentation to the Company or Laboratory ISRC for consideration.</li> <li>▪ Upon the ISRC's determination of a Financial Conflict of Interest (see below), must develop a Management Plan specifying actions required to manage the Financial Conflict of Interest, how the plan will safeguard objectivity in the research activity, confirms the investigator's agreement to the plan, and specifies the way in which the Investigator's compliance with the management plan shall be monitored.</li> <li>▪ Must respond within 5 business days to any request for information submitted in accordance with this policy about SFIs held by Key Personnel when the Company has determined that the disclosed SFIs are related to the PHS-funded research, and constitute Financial Conflicts of Interest.</li> <li>▪ Prior to the Company's expenditure of any funds provided under a PHS award (and within 60 days of any subsequently identified financial conflict of interest), must provide to the PHS funding agency an initial report regarding Investigator Financial Conflict of Interest (including financial conflicts of interest of subrecipient investigators in cases where the agreement with the subrecipient institution specifies that they will follow the Company financial conflict of interest policy).</li> <li>▪ During the period of the award shall, within 60 days of receipt of disclosure new or newly-discovered SFI, must review the disclosure, determine whether it constitutes a Financial Conflict of Interest, and if so, report the Financial Conflict of Interest to the PHS-funding agency. If a Financial Conflict of Interest ceases to exist during the course of the award, updated information about the status of that Financial Conflict of Interest should be reported to the PHS funding agency.</li> <li>▪ Must provide an annual Financial Conflict of Interest report to the PHS awarding agency addressing the status of the conflict and any changes to the management plan, for the duration of the project period (including extensions with or without funds).</li> </ul>

	<ul style="list-style-type: none"> <li>▪ Must submit a report to the PHS-funding agency within 60 days of determining that a Financial Conflict of Interest exists for new Investigator who joins an ongoing PHS-funded research activity.</li> <li>▪ If AMS is a subrecipient of a PHS award from another institution, must report to that institution any FCOIs that AMS identifies for AMS investigators.</li> </ul>
Independent Substantive Review Committee (ISRC)	<ul style="list-style-type: none"> <li>▪ Must determine whether, based on documentation from designated Official, there is a financial conflict of interest, and makes a final recommendation to the CEO (or designee) about whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest.</li> </ul>
Contracts & Grants office	<ul style="list-style-type: none"> <li>▪ If the PHS award is to be conducted thru a subaward, must incorporate as part of a written agreement with subrecipients terms that establish whether the AMS PHS COI policy or the policy of the subrecipient (which must be compliant with DHHS regulations) will apply to the subrecipient's investigators.</li> </ul>
CEO (or designee)	<ul style="list-style-type: none"> <li>▪ Must determine, based on final recommendation of the ISRC, the conditions or restrictions that should be placed on the project to eliminate or manage the Financial Conflict of Interest.</li> </ul>

## VI. PROCEDURES

Acoustic MedSystems shall develop procedures to implement this policy.

## VII. RELATED INFORMATION

For the Company Conflict of Interest Policy Related to (non-PHS) NSF-Sponsored Research, please see: Section III.A of this Company Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects.

For the Company Policy Related to Disclosure of Financial Conflicts of Interest in Private Sponsors of Research please see: Section III.D of this Policy.

For the Company Policy on Conflict of Commitment and Outside Activities of employees, please refer to the Company Policy Manual.

## VIII. FREQUENTLY ASKED QUESTIONS

NIH website: [Frequently Asked Questions - Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought \(42 CFR Part 50 Subpart F\)](#) applicable to grants and cooperative agreements (2011 Revised Regulations)

## IX. REVISION HISTORY

As of August 24, 2012, this is a new policy that applies to PHS-funded research.

On June 6, 2016 revisions were made to incorporate the table of functions and responsible officials and their respective responsibilities, and to revise formatting to be consistent through the policy document.