Public Health Service (PHS) Requirements for Financial Disclosures and Conflict of Interest Policy

I. Purpose

The following Biomedical Engineering BMES (BMES) policy on financial conflict of interest (FCOI) in U.S. Public Health Service (PHS) funded research situations has been adopted for the purpose of promoting objectivity in grant activity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, subawards and cooperative agreements will be free from bias resulting from any Investigator financial conflicts of interest. This policy applies to BMES and all Investigators (including subrecipient investigators) involved in federally funded grants, subawards or cooperative agreements applied for, or awarded to, BMES. This policy is compliant with current federal FCOI regulations entitled "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (42 CFR Part 50, Subpart F).

II. Applicability

The policy applies to any person that meets the federal definition of an Investigator (see Definitions section below) and requires compliance with the policy and procedures outlined below. An Investigator is defined as the Project Director (PD), Principal Investigator (PI) or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposal for such funding. Investigators also include collaborators and consultants.

Investigators are required to:

1. Disclose any significant financial interests (SFIs) at the time of application for federal PHS funding by completing and signing a disclosure form, and submitting this to the Office of Sponsored Projects;
2. Disclose SFIs using the disclosure form at least on an annual basis during the course of an award;
3. Disclose within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) any new SFI; and
4. Take part in FCOI training at least once every four years.

PHS-Funded Subrecipients:

For PHS-Funded Research that involves a subrecipient (i.e., subcontractor, subgrantee or subawardee) at other Institutions, BMES requires a written agreement from the subrecipient that establishes whether BMES’ policy or the subrecipient’s policy shall
apply to the subrecipient’s Investigators. In all cases, BMES will comply with all provisions of 42 CFR Part 50.604 and must report to the PHS-Funding agency any subrecipient FCOI (as defined below) prior to the execution of the subcontract or within 60 days of identification of a new FCOI that arises during the term of the subcontract.

If the subrecipient’s policy is used, the subrecipient must certify that its FCOI policy is compliant with 42 CFR Part 50, Subpart F and that they will be responsible for ensuring that the subrecipient Institution and its Investigators comply with the federal regulations. Subrecipients must report to BMES, as the awardee Institution, any identified FCOI. The details of the FCOI will be reported to the funding agency as required under applicable regulations or policies.

If BMES’ policy is used, the subrecipient must ensure that its Investigators disclose to BMES all Significant Financial Interests (“SFI”) as defined below) that are directly related to the subrecipient’s work for BMES at the time of submission of the application by BMES or at the time the subrecipient signs an institutional letter of support if during an on-going award grant or contract.

III. Definitions

Disclosure of significant financial interests means an Investigator’s disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator’s professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee
memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests 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:
(i) 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;

(ii) 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); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of 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 their 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 Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does 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, 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, 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; 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.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

IV. Training

Investigators are required to complete FCOI training. The BMES Education Director is responsible for ensuring that each Investigator is informed about this FCOI policy and procedures for disclosure, and ensuring that each Investigator has completed FCOI training prior to engaging in PHS-funded research and at least once every four years. Training will also be required immediately when any of the following occurs:

1. This FCOI Policy, the SFI Disclosure Form, or BMES' procedures are revised in any manner that affects the requirements of Investigators;
2. A PHS-supported Investigator is newly appointed to BMES; or
3. BMES determines that an Investigator is not in compliance with this policy or an FCOI management plan.

"Immediately" means that training will be provided or made available and that Investigators will participate in the training expeditiously after one of the aforementioned qualifying events. The BMES Education Director will be responsible for retaining records of FCOI training.

BMES has chosen to utilize the Financial Conflict of Interest online tutorial developed by the National Institutes of Health for satisfying training requirements. Investigators must provide assurance they have completed the NIH tutorial by sending a copy of the Certificate of Completion to the Education Director at BMES. The NIH tutorial is available at: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html
V. Disclosure Procedures and Responsibilities

The Education Director is responsible for collecting SFI Disclosure Forms prior to proposal submission to external PHS funding agencies. The SFI Disclosure Form conforms to the requirements of PHS FCOI Regulations (42 CFR Part 50.604). The following procedures will be followed:

1. All Investigators involved in the project/proposal are required to complete, sign and submit the SFI Disclosure Form prior to BMES approving and submitting a proposal to a PHS agency or pass-through (prime) entity.

2. The Investigator must list all of their SFIs (and those of the Investigator’s spouse or domestic partner and dependent children) that reasonably appear to be related to the Investigator’s institutional responsibilities in teaching, scholarship or service.

3. The form requires the Investigator to include, at minimum, the name of the entity, the nature of the financial interest (e.g., equity, consulting fee), the monetary value of the financial interest or its approximate value if the interest is one whose value cannot readily be determined. If needed, BMES may request supporting documentation to determine whether an FCOI exists.

4. For SFI disclosures related to sponsored or reimbursed travel, the disclosure must include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the approximate monetary value.

5. The Investigator is required to submit an updated SFI Disclosure Form during the period of the award at least annually, and within 30 days of discovering or acquiring a new SFI. The SFI Disclosure Form notifies the Investigator of this requirement to provide updated disclosures.

**Significant Financial Interest (“SFI”) Is Defined As**

Any financial interests (i.e., anything of monetary value) consisting of one or more of the following interests 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:

1) SFI in Publicly Traded Entities
   - Value of remuneration (e.g., salary, income, consulting fees, honoraria, paid authorship or any other payment) in the 12 months preceding disclosure and the value of any equity interest (e.g., stock, stock option, or other ownership interest) as of the date of the disclosure that, when aggregated, exceeds $5,000.
2) SFI in Non-Publicly Traded Entities
   • Value of remuneration (e.g., salary, income, consulting fees, honoraria, paid
     authorship or any other payment) in the 12 months preceding disclosure
     exceeding $5,000; or
   • Any equity interest in a non-publicly traded entity (e.g., stock, stock option, or
     other ownership interest).

3) Intellectual Property (IP) Right and Interests
   • Intellectual property rights and interests (e.g., patents, copyrights), upon receipt
     of income related to such rights and interests.

4) Reimbursed or Sponsored Travel
   • Travel reimbursed or paid on behalf of the Investigator and not reimbursed to
     the Investigator so that the exact monetary value may not be readily available,
     and related to their Institutional Responsibilities that exceeds $5,000 in value (in
     the last 12 months).

An SFI does not include the following types of financial interests:
   • Salary, royalties, or other remuneration paid by BMES to the Investigator if the
     Investigator is currently employed or otherwise appointed by BMES, including
     intellectual property rights assigned to BMES 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; and
   • Income from service on advisory committees or review panels that are sponsored
     by a federal, state, or local government agency within the United States, a
     United States 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 a United States Institution of higher education.

VI. Review of SFI Disclosures

BMES has designated the Executive Director/CEO as the institutional official who initially
reviews disclosures and determines whether a disclosed SFI is related to the PHS-
funded research, and if so, whether it constitutes an FCOI.

An Investigator’s SFI is related to PHS-funded research when the Institution, through its
designated official, reasonably determines that the SFI: could be affected by the PHS-
funded research; or is in an entity whose financial interest could be affected by the
research. An FCOI exists when the institution reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

BMES may request additional information from the Investigator to determine whether an SFI is related to the PHS-funded research. In making these determinations, BMES may take into account financial interests in a previously disclosed entity related to PHS- or other federally-funded research. The Executive Director/CEO may consult with the Board of Directors or appropriate institutional and agency officials during the review process.

If it is determined that an FCOI exists, the conflict will either be approved with conditions or restrictions in place (subject to a management plan), or prohibited.

**VII. Managing and Monitoring Compliance**

Management plans shall be implemented by an oversight committee comprised of the Executive Director/CEO and BMES Board of Directors. The management plan shall be completed prior to the expenditure of any funds under a PHS grant, cooperative agreement, subaward, or contract. BMES, via the management plan committee, will monitor compliance with management plans on an ongoing basis until the completion of the PHS-funded research project.

For all management plans, examples of conditions or restrictions that may be imposed to manage conflicts of interest include, but are not limited to: (1) public disclosure of SFIs; (2) for research projects involving human subjects, disclosure of FCOIs directly to participants; (3) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI; (4) modification of the research plan; (5) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all, or a portion of the research; (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (6) severance of relationships that create financial conflicts.

When an Investigator who is new to a PHS-funded research project discloses an SFI or an existing Investigator discloses a new SFI, BMES will within 60 days: review the disclosure; assess whether the SFI constitutes an FCOI with PHS-funded research; and if so, implement, at least, on an interim basis, the actions that have been, and will be, taken to manage such FCOI.

**VIII. Reporting Financial Conflicts of Interest**
Prior to the BMES’ expenditure of any funds under a PHS-funded research project, BMES will provide to the PHS Awarding Component (e.g., NIH) an FCOI report regarding any Investigator’s significant financial interest found by BMES to be conflicting and ensure that BMES has implemented a management plan. In cases in which BMES identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, BMES is not required submit an FCOI report to the PHS Awarding Component.

For any significant financial interest that BMES identifies as conflicting subsequent to BMES’ initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), BMES will provide to the PHS Awarding Component, within 60 days, an FCOI report regarding the financial conflict of interest and ensure that BMES has implemented a management plan.

Any FCOI report required by PHS 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 BMES’ 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 financial conflict of interest; name of the entity with which the Investigator has a financial conflict of interest; 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 be readily 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 BMES’ determination that the financial interest conflicts with such research; and a description of the key elements of BMES’ management plan, including:

(a) Role and principal duties of the conflicted Investigator in the research project;
(b) Conditions of the management plan;
(c) How the management plan is designed to safeguard objectivity in the research project;
(d) Confirmation of the Investigator’s agreement to the management plan;
(e) How the management plan will be monitored to ensure Investigator compliance; and

(f) Other information as needed.

For any financial conflict of interest previously reported by BMES, with regard to an ongoing PHS-funded research project, BMES will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. BMES 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.

**IX. Noncompliance Reporting and Mitigation**

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by BMES to constitute a financial conflict of interest; failure by BMES to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, BMES will, within 120 days of BMES' 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.

BMES is required to document the retrospective review; such documentation will include, but not necessarily be limited to, 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 a financial conflict of interest;
- 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, BMES will update any previously submitted FCOI report, as applicable, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, BMES 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 BMES’ 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, BMES will submit FCOI reports annually, as specified elsewhere in 42 CFR Part 50, Subpart F. Depending on the nature of the financial conflict of interest, BMES 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 financial conflict of interest or the Investigator's noncompliance is determined and the completion of BMES' retrospective review.

Whenever BMES implements a management plan pursuant to this policy, BMES will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

**X. Remedies, Enforcement and Sanctions**

If an Investigator fails to comply with this policy or a management plan and the noncompliance appears to have biased the design, conduct or reporting of the PHS-funded research, BMES will promptly notify the agency of the corrective action taken or to be taken. BMES will ensure compliance with the requirements for retrospective review and prepare a mitigation report, as applicable, for submission to the funding agency as required under PHS FCOI regulations. The agency may take its own action as it deems appropriate, which may include suspension of funding, or require BMES to take further action to maintain the objectivity of the research.

All BMES Investigators proposing or conducting PHS-funded research are subject to this policy (except those applying to or funded by the Phase I Small Business Innovative Research or the Small Business Technology Transfer program). Investigators are expected to comply with it fully. Whenever an Investigator has violated this policy, BMES will take appropriate action.

*Note on Clinical Research*
In any case in which the Department of Health and Human Services determines that a PHS-funded research 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 an FCOI that was not managed or reported by BMES as required by the regulation, BMES will require the Investigator involved to: 1) disclose the FCOI in each public presentation of the results of the research, and 2) request an addendum to previously published presentations.

**XI. Records and Public Access**

BMES, via the Education Director, will maintain all SFI Disclosure Forms, training certifications, management plans, reports and all related records of actions taken by BMES with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS as governed by 42 CFR Part 50 Subpart F, and from other dates specified in 45 CFR 75.361, where applicable.

BMES has posted this policy on BMES website in accordance with the PHS regulations. In addition, this policy allows for certain information concerning identified FCOIs held by Investigators to be made available upon request. The information will include the minimum elements as provided in the regulation, be made available within 5 calendar days of a written request, be updated, at least annually, be updated, within 60 days of a newly identified FCOI, and remain available for three years from the date the information was most recently updated.

**For more information, visit:**


Biomedical Engineering Society (BMES)

Financial Conflict of Interest (FCOI) Disclosure Form
PHS and National Institutes of Health (NIH)

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DISCLOSURE FOR PHS/NIH PROPOSALS AND FUNDED PROJECTS

Per federal regulations (2 C.F.R. Part 50 Subpart F), all Investigators applying for and working on PHS/NIH funded research must disclose significant financial interests (SFIs) that are related to the Investigator’s institutional responsibilities. Investigators are all persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for funding by PHS agencies, including collaborators or consultants.

In making this certification, all Investigators must disclose SFIs related to their institutional responsibilities (and those of the Investigator’s spouse, domestic partner and dependent children). SFIs are defined below and all SFIs that meet the listed thresholds listed must be disclosed.

- **SFI In Publicly Traded Entities** – the value of remuneration in the 12 months preceding disclosure and the value of any equity interest as of the date of disclosure that, when aggregated, exceeds $5,000.
- **SFI In Non-Publicly Traded Entities** - the value of remuneration in the 12 months preceding disclosure exceeding $5,000; or any equity interest in a non-publicly traded entity (e.g., stock option, or other ownership interest).
- **Intellectual Property** - (IP) rights and interests, upon receipt of income related to such rights and interests.
- **Reimbursed or Sponsored Travel** - any and all travel paid on behalf of the Investigator and not reimbursed directly to Investigator so that the exact monetary value may not be readily available, and related to their Institutional Responsibilities that exceeds $5,000 in value (in the last 12 months).

An SFI does **not** include:

- Salary, royalties, or other remuneration paid by BMES to the Investigator, if the Investigator is currently employed or otherwise appointed by BMES, including income from IP rights assigned to BMES;
- 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. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; 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.
Biomedical Engineering Society (BMES)
PHS / NIH FCOI CERTIFICATION AND DISCLOSURE FORM

Project Status/Reason for Disclosure (check one):
- [ ] New Submission
- [ ] New/Change of Investigator

Title of Proposal:

CERTIFICATION (Indicate one option and please sign.)
- [ ] 1. I hereby certify that I have read and understand the BMES PHS/NIH FCOI Policy. I certify that to the best of my knowledge neither I, my spouse, partner, nor my dependents hold any SFIs that would reasonably appear to be related to my research, teaching, and service responsibilities to BMES.

- [ ] 2. I hereby certify that I have read and understand the BMES PHS/NIH FCOI Policy. I have the following relationships, affiliations, activities, or interests which constitute SFIs under the BMES PHS/NIH FCOI Policy (complete section 2.a. below).

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Role on project (e.g., PI, Co-PI, Senior/Key Personnel, Consultant, Unpaid Consultant/Collaborator, Other):

2.a. Please describe the SFI below or attach separate document: