

Corporate Policy : Financial Conflict of Interest - Federally Funded Research

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Purpose & Scope

The **purpose** of this Policy is to:

- Define the requirements and responsibilities associated with identifying and managing actual or perceived Financial Conflicts of Interest (FCOI) that could impact the integrity of Public Health Service (PHS)-Funded Research conducted by Emergent BioSolutions Inc. or any of its wholly owned subsidiaries (collectively, “Emergent”).
- Provide a reasonable expectation that the design, conduct, reporting data and information under US Government funded programs and research are protected from bias resulting from FCOI.

This Policy’s **scope**:

- Applies to all Emergent employees regardless of title or position, consultants, agents, contractors, vendors, service providers, subgrantees and collaborators (collectively, “Investigators”) who are participating directly or indirectly in Emergent PHS-Funded Research, excluding Phase I Small Business Innovation Research (SBIR).

OUR COMMITMENT

This policy is based on the following commitments:



We follow all applicable laws and recognize industry codes of practice.



We all own Compliance.



We interact responsibly with all stakeholders.

Following these commitments helps you live our value:
Lead with Integrity.

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Policy Guiding Principles

Emergent participates in Health and Human Services (HHS) Government Funded Grants, Contracts and Cooperative Agreements. To protect the Government's interest and avoid bias in research findings or program results, employees defined as "Investigators" must disclose any Significant Financial Interests (SFIs) to prevent individual financial gain.

Therefore, Emergent is responsible for the training, review, compliance and reporting of FCOIs of Investigators. If Emergent identifies an actual or perceived FCOI, prompt actions are taken to manage, reduce or eliminate any such conflict. Where impossible to do so, Emergent will sever such relationship prior to spending any funds for any related PHS-Funded Research.

PRINCIPLE 1: We train our Investigators prior to engaging in any PHS-Funded Research projects.

All Investigators must complete the FCOI Training Curriculum which includes a:

- Read and attest of the FCOI Federally Funded Research Policy (POL005200)
- Review of the NIH Office of Extramural Research FCOI Training
- Annual Disclosure of SFI's

FCOI Training Curriculum must be completed at least every four (4) years, and immediately when any of the following circumstances apply:

- Emergent revises its FCOI policy or procedure in any manner that affects the requirements of Investigators.
- An Investigator is new to Emergent; or
- Emergent finds that an Investigator is not in compliance with our FCOI policy or a management plan that was put in place because of an identified FCOI.

PRINCIPLE 2: We disclose all domestic and foreign Significant Financial Interests.

Investigators must disclose all their domestic and foreign SFIs (and those of their spouse and dependent children) related to the Investigator's Emergent professional responsibilities that are received from and/or held in an entity outside Emergent, such as:

- research
- research consultation
- teaching
- professional practice

- Institutional Review Boards

Disclosures must be made:

- No later than at the time of application or date of submission of the Emergent's proposal for PHS funded research;
- And at least annually during the period of the award;
- And within 30 days of discovering or acquiring a new SFI.

Disclosable interests include, but are not limited to:

- Compensation that could be affected by study outcome(s);
- Proprietary interests involving investigational product in privately held company(-ies) sponsoring research such as trademarks, patents, licenses, or copyrights;
- Any equity interest exceeding \$50,000 in publicly traded company involved with the clinical study; and
- Significant payments in excess of \$25,000 exclusive of study-related payments.

PRINCIPLE 3: We conduct a thorough review of Financial Disclosure Forms.

Emergent's Designated Official:

- Reviews all SFI disclosures;
- Determines if any SFIs related to PHS- funded research exist;
- Determines if any FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of the NIH- funded research); and
- Develops, implements, and monitors management plans, as needed to manage FCOIs for both Emergent and Subrecipient Investigators until completion of the project.

PRINCIPLE 4: We hold our Subrecipient partners to the same FCOI Requirements.

We establish, via a written agreement-

- That the subrecipient has an FCOI Policy in place. If not, they are required to follow Emergent's FCOI Policy
- If the Subrecipient is following Emergent's FCOI policy, the Subrecipient permits Emergent to solicit and review the Subrecipient disclosures resulting in the identification, management and reporting of identified FCOIs to the NIH.

- If the subrecipient organization is following their own FCOI Policy, a written certification is obtained that the Policy complies with FCOI Federal Regulation 42 CFR 50 Subpart F.
- The requirement for the subrecipient to report identified FCOIs for its Investigators to Emergent within 60 days to allow Emergent to report the identified FCOI to the NIH as required by the regulation

PRINCIPLE 5: We check for research bias after non-compliance and implement disciplinary measures as necessary.

After non-compliance is identified, we:

- Conduct a retrospective review within 120 days of Emergent's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner
- Document findings consistent with the regulatory requirements.

In any case in which the Department to 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 Emergent as required by the regulation, Emergent requires the Investigator(s) (or Subrecipient Investigator(s)) involved to:

- Disclose the FCOI in each public presentation of the results of the research, and
- Request an addendum to the previously published presentation.

Investigators who are directors, officers or employees and fail to comply with FCOI Regulations and the requirements of this Policy are subject to sanctions, up to and including termination of employment.

Investigators who are consultants, agents, contractors, vendors, service providers, subgrantees or collaborators and fail to comply with FCOI Regulations and the requirements of this Policy are subject to sanctions, up to and including termination of their contractual relationship with Emergent.

PRINCIPLE 6: We are transparent and compliant with FCOI Regulations.

Employee Transparency

Lead with Integrity is one of our Core Values at Emergent. As an Emergent employee, directly or indirectly supporting an Emergent PHS-Funded Research project (Investigator), disclosing any newly acquired or discovered SFIs related to a project must be reported within 30 days to your manager, Government Contracts Manager or to the Financial Conflicts of Interest Mailbox (fcoi@ebsi.com)

Corporate Transparency

We approach corporate transparency in two ways:

1. Emergent posts this policy on our publicly accessible website
2. We submit, disclosures annually to the National Institutes of Health (NIH) or within 60 days of a Significant Financial Interests (SFI) disclosure. In the event of a SFI involving Key or Senior Personnel, and prior to spending any additional funds for related PHS-Funded Research, the following information is made available on our website and submitted to NIH.
 - Individual's name;
 - Individual's title and role with respect to the Research;
 - Name of the entity in which the SFI is held;
 - Nature of the SFI; and
 - Approximate dollar value of the SFI (dollar ranges are permissible. For example: \$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.

The publicly posted information remains available for three (3) years from the date the information was most recently updated. Additionally, we provide a written response to any request for such information within five (5) business days of receipt of the request.

In addition to publicly posting an FCOI, we provide initial, annual and revised FCOI reports to the NIH for Emergent and our Subrecipients based on the following requirements:

- Prior to the expenditure of funds;
- Within 60 days of identification for an Investigator **who is newly participating** in the project; or new, or newly identified, FCOIs **for existing Investigators**;
- At least annually (at the same time Emergent is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and
- Following a retrospective review to update a previously submitted report, if applicable.

We promptly notify NIH with all the reporting elements required by the regulation:

- If bias is found with the design, conduct or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report;

- If an Investigator or Subrecipient fails to comply with the Emergent's (or the Subrecipient's) FCOI policy or a FCOI Management plan appears to have biased the design, conduct or reporting of the NIH- funded research;
- If non-compliance with the Emergent's (or Subrecipient's) FCOI Policy or resulting Management Plan and take corrective action.

We are responsible for reporting to the applicable PHS funding agency all SFIs in accordance with federal requirements. We promptly notify the applicable PHS funding agency in accordance with federal regulations if bias is found with the design, conduct or reporting of any Research. This report addresses the impact of the bias of the Research and the actions we took, or will take, to eliminate or mitigate the bias.

- Records of and related to SFI disclosures are retained by Emergent for no less than three (3) years after final expenditure report is submitted to the PHS funding agency or from other dates specified in the Code of Federal Regulations 45 CFR 75.361, where applicable.

Definitions

FCOI Regulations: All applicable federal and state laws pertaining to financial conflicts of interest, including but not limited to Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for grants and cooperative agreements and Title 45 CFR Part 94 for Research contracts.

Financial Interest (FI): means anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI): Any situation in which a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of NIH-funded Research, or the objectivity with which Emergent Personnel discharge their responsibilities.

Management Plan: A written plan that describes the actions taken by Emergent for the management, reduction or elimination of a FCOI relating to PHS-Funded Research. The objective of the plan shall be to verify and confirm, to the extent possible, that the design, conduct and reporting of Research by Emergent Personnel will be objective and free of bias.

Immediate Family and Dependents: A (i) spouse, (ii) child, or (iii) any other person residing in the same household as the Investigator who is a dependent of the Investigator or of whom the Investigator is dependent.

Emergent Responsibilities: means an Investigator's professional responsibilities on behalf of Emergent, including, but not limited to, activities such as research, research consultation, teaching, professional practice, committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.

Investigator: means any person, regardless of title or position, who is responsible for or has the ability to make independent decisions regarding the design, conduct or reporting of Research under PHS-Funded contracts, grants or cooperative agreements, including Investigators working for Subrecipients.

Public Health Service (PHS): means the operating division of the U.S. Department of Health and Human Services, which includes, without limitation, the National Institutes of Health and the Centers for Disease Control.

PHS Awarding Component: means the organizational unit of the PHS that funds the Research that is subject to the FCOI Regulations.

Research: means any systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development that may or may not be published. This term includes any such activity for which research funding is available from a PHS Awarding Component through a contract, grant, or cooperative agreement, excluding Small Business Innovation Research (SBIR).

Significant Financial Interest (SFI):

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 Emergent 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 Emergent 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 Emergent 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 PHS and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this part, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Subrecipient: means an individual or entity receiving federal funds flowed down from or through Emergent to conduct a substantive portion of the PHS- Funded Research.

References and Supporting Documents

External References

- [Title 42 Code of Federal Regulations \(CFR\) Part 50 Subpart F Promoting Objectivity in Research](#)
- [Title 45 CFR Part 94, Responsible Prospective Contractors](#)
- [Title 45 CFR Part 75 Subpart D, Retention Requirements for Records](#)
- [HHS 76 FR 53283 Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors](#)

- [NIH Office of Extramural Research FCOI online tutorial](#)

Related Documents

- [POL040177: Code of Conduct and Business Ethics Policy](#)
- [SOP043100: Financial Disclosure Related to Clinical Study Conduct](#)