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1.0 PURPOSE

To set forth the requirements and responsibilities associated with identifying and managing actual or potential Financial Conflicts of Interest 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").

2.0 SCOPE

This Policy applies to all directors, officers, and employees, consultants, agents, contractors, vendors, service providers, subgrantees and collaborators who are participating directly or indirectly on behalf of Emergent in PHS-Funded Research (collectively, "Emergent Personnel").

3.0 POLICY STATEMENT

Emergent shall make reasonable efforts to verify and warrant that the design, conduct and reporting of its PHS-Funded is protected from bias resulting from Financial Conflicts of Interest (FCOI).

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


All Emergent Personnel are required to (i) familiarize themselves with this Policy and the FCOI Regulations and (ii) not participate in any PHS-Funded Research if any of their Financial Interests could interfere with their objectivity, and potentially introduce bias in the design, conduct or reporting of such Research activity.

Should Emergent identify a potential or actual FCOI, immediate actions shall be taken by the FCOI Working Group to manage, reduce or eliminate any such conflict, or where impossible to do so, sever such relationship prior to spending any funds for any related PHS-Funded Research.

3.1 Transparency

In the spirit of transparency, and consistent with FCOI Regulations, this Policy shall be made available on Emergent's publically accessible website ("Website"). Should a Significant Financial Interest (SFI) that is an FCOI involving Key or Senior Personnel be identified, Emergent shall post the following information on its Website prior to spending any further funds for related PHS-Funded Research:

- 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: \$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

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reference to public prices or other reasonable measures of fair market value.

Additionally, Emergent will provide a written response to any requestor for such information within five (5) business days of receipt of the request.

Emergent will update FCOI information on its Website at least annually or within sixty (60) days of any of the following: a) receipt of information concerning any FCOI that was not previously disclosed, or b) disclosure of any PHS-Funded Research program FCOI involving Key or Senior Personnel.


4.0 RESPONSIBILITIES

4.1 Grants and Contracts


- 4.1.1 Identify all agreements that are related to PHS-Funded Research.
- 4.1.2 Review list of Investigators at least annually with Legal Affairs.
- 4.1.3 Assist Legal Affairs with overseeing and managing the identification of Emergent Personnel who are employees and subject to this Policy.
- 4.1.4 Oversee and manage the identification of Subrecipients subject to this Policy; audit this list at least annually.
- 4.1.5 Manage the distribution and collection of Subrecipient Financial Interest disclosures required under this Policy and the FCOI Regulations.
- 4.1.6 Maintain a list of cost centers for PHS-Funded Research Grants and Contracts.
- 4.1.7 Prepare and submit a report to the FCOI Working Group within ten (10) days of a determination of non-compliance for an SFI not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner.
- 4.1.8 Review this Policy and its procedure(s) with Legal Affairs at least biennially and address any identified deficiencies in a timely manner.
- 4.1.9 When managing other persons that perform services on behalf of Emergent, periodically review the SharePoint site to ensure that Emergent Personnel have completed and executed Financial Interest Disclosure Forms and completed required training prior to participating in any Research.

4.2 Legal Affairs

- 4.2.1 Assist Grants and Contracts with the identification of agreements that are related to PHS-Funded Research.
- 4.2.2 Assist Grants and Contracts with overseeing and managing the identification of Emergent Personnel who are employees and subject to this Policy.
- 4.2.3 Review Investigator and Subrecipient Financial Interest disclosures required under this Policy and the FCOI Regulations.
- 4.2.4 Track any modifications to the FCOI Regulations and communicate same to Compliance and Grants and Contracts.
- 4.2.5 Determine the composition of the FCOI Working Group.

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- 4.2.6 Review this Policy and its related procedure(s) with Grants and Contracts at least biennially and address any identified deficiencies in a timely manner.
- 4.3 Human Resources
 - 4.3.1 Generate and send weekly new hire employee list to Grants and Contracts.
- 4.4 Compliance
 - 4.4.1 Manage the distribution and collection of Investigator Financial Interest disclosures to those employees who are identified by Grants and Contracts and Legal Affairs as described above.
 - 4.4.2 Manage the distribution and completion of training to those employees identified by Grants and Contracts and Legal Affairs teams as described above.
 - 4.4.3 Retain completed Financial Interest Disclosure Forms and any training completion certificates pursuant to Emergent's document retention policy and relevant laws and regulations.
 - 4.4.4 Work with Grants and Contracts to identify and communicate with Emergent Personnel who have not satisfied their disclosure and/or training requirements under this Policy and the FCOI Regulations.
 - 4.4.5 Notify Legal Affairs of any disclosed Financial Interest.
 - 4.4.6 Regularly, and at least annually, review and update the Emergent SharePoint site with relevant forms and any training completion certifications.
 - 4.4.7 Provide guidance where this Policy or its related procedure(s) parameters are not clear.
 - 4.4.8 Oversee implementation of operational changes necessary to comply with FCOI Regulations, including revisions to any related procedures, as warranted.
 - 4.4.9 Oversee auditing and monitoring activities related to employee adherence to this Policy and any related procedures.
- 4.5 Finance
 - 4.5.1 On at least an annual basis, provide Grants and Contracts with a list of cost centers associated with any PHS-Funded Research.
- 4.6 FCOI Working Group
 - 4.6.1 Review Financial Interest disclosures.
 - 4.6.2 If necessary, develop a Management Plan to manage or eliminate a Significant Financial Interest.
 - 4.6.3 Communicate any Management Plan to the Investigator or Subrecipient verbally or in writing, as deemed appropriate.
 - 4.6.4 Within one hundred and twenty (120) days of a determination of non-compliance, conduct and document a retrospective review of such non-compliance.
- 4.7 Directors, Officers and Employees


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- 4.7.1 Comply with this Policy, related procedure(s) and all applicable laws, rules and regulations, as well as other Emergent policies and procedures that relate to interactions covered by this Policy.
- 4.7.2 Require that all external Emergent Personnel (e.g. contractors, consultants and agents) comply with this Policy, related procedure(s) and all applicable laws, rules and regulations, as well as other Emergent policies and procedures that relate to interactions covered by this Policy.
- 4.7.3 Seek guidance from the Senior Vice President, Chief Ethics and Compliance Officer in situations where policy or procedure parameters are not clear.
- 4.8 Individuals acting on Emergent’s behalf other than Employees, including Subrecipients.
 - 4.8.1 Know, understand and comply with this Policy, related procedure(s) and all applicable laws, rules and regulations, as well as other Emergent policies and procedures that relate to interactions covered by this Policy.

5.0 DEFINITIONS AND ABBREVIATIONS


The following definitions may be used in this Policy as well as its related procedure(s):

- 5.1 Designated Official (DO): The FCOI Working Group will serve as Emergent’s DO and shall be a cross-functional team comprised of individuals deemed appropriate by Legal Affairs. The FCOI Working Group is responsible for: a) reviewing Financial Interest disclosures; and b), if necessary, developing a plan (“Management Plan”) to manage or mitigate any identified actual or potential Significant Financial Interest, as defined herein.
- 5.2 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.
- 5.3 Financial Interest (FI): Any interest of economic value in or relationship with an entity, including, but not limited to, ownership of stocks, bonds, stock options, partnership or other equity interests, rights to patent or royalty payments, receipt of consulting fees, speaking fees, salary, loans, gifts, lectureship fees, compensation for serving on boards of directors, scientific and other advisory boards, reimbursed or sponsored travel expenses related to Investigator's Institutional Responsibilities, or other remuneration.
- 5.4 FCOI Working Group: See the definition for Designated Official.
- 5.5 Financial Conflict of Interest (FCOI): Any situation in which a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of Research, or the objectivity with which Emergent Personnel discharge their responsibilities.
- 5.6 Key or Senior Personnel: The Project Director, Principal Investigator, Co-Principal Investigator, and any other persons identified as key or senior personnel in Emergent’s grant or contract application or proposal, progress report, or other report submitted to the PHS-funding agency.
- 5.7 Management Plan: A written plan that describes the actions taken by Emergent for the management, reduction or elimination of a Conflict of Interest relating to PHS-Funded Research. The objective of the plan shall be to verify and confirm,

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to the extent possible, that the design, conduct and reporting of Research by Emergent Personnel will be objective and free of bias.

- 5.8 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.
- 5.9 Institutional 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.
- 5.10 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.
- 5.11 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.
- 5.12 PHS Awarding Component: means the organizational unit of the PHS that funds the Research that is subject to the FCOI Regulations.
- 5.13 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) and Small Business Technology Transfer Research (STTR) Phase I Programs.
- 5.14 Significant Financial Interest (SFI): means a Financial Interest consisting of one or more of the following interests of the Investigator (and those of its Immediate Family and Dependents) that reasonably appears to be related to Investigator's Institutional Responsibilities:
- Remuneration received from a publicly traded entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure that, when aggregated, exceeds \$5,000. For the 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 a fair market value;
 - Remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure that, when aggregated, exceeds \$5,000 or any equity interest in such entity;
 - Intellectual property rights and interests (e.g., patents, copyrights, trademarks) upon receipt of income related to such rights and interests (including but not limited to royalties and/or licensing revenues) that exceeds \$5,000 in the previous twelve months;
 - Non-Emergent reimbursed or sponsored travel expenses for the Investigator and/or their Immediate Family and Dependents that, when aggregated, has a value of greater than \$5,000 per year.

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Sponsored travel means travel that is paid for on behalf of an Investigator and not reimbursed to the Investigator directly; and/or

- Non-Emergent reimbursed or sponsored travel expenses that are reimbursed or sponsored by the following do not need to be disclosed as an SFI: a) federal, state or local governmental agencies in the United States; b) a U.S. academic institution as defined in 20 U.S.C. 100(a); c) a U.S. academic teaching hospital; d) a U.S. medical center; or d) a research institute that is affiliated with a U.S. academic institution as defined in 20 U.S.C. 100 (a).

A SFI does not include any of the following:

- Salary or other remuneration from Emergent;
- Any ownership interests in Emergent, such as mutual funds and retirement accounts, as long as Investigator does not directly control the investment decisions made in such 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; and
- Reimbursed or sponsored travel expenses 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.

5.15 **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.

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6.0 REFERENCES AND RELATED DOCUMENTS

6.1 External References

- 6.1.1 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
- 6.1.2 Title 45 CFR Part 94, Responsible Prospective Contractors for Research contracts
- 6.1.3 NIH Frequently Asked Questions on 42 CFR Part 50 (http://grants.nih.gov/grants/policy/coi/coi_faqs.htm)
- 6.1.4 NIH Office of Extramural Research FCOI on line tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>