Financial Conflict of Interest (FCOI) Policy

1. BACKGROUND

5M Biomed, LLC (5M Biomed) strives in innovative research and development (R&D) to provide solutions and products for healthcare problems and challenges. External or public funding and sponsorship can be involved and used in supporting R&D activities at 5M Biomed. Therefore, the policy should be set in place to ensure proper management of Financial Conflict of Interest (FCOI) and compliance of federal laws and regulations governing FCOI for the sponsored R&D activities. 5M Biomed is committed to comply with the regulations implemented by the Public Health Services (PHS) (Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought) to maintain public trust in the integrity of the related R&D activities. All individuals who participate in the design, conduct, or reporting of research funded by the PHS agencies are required to complete training on managing financial conflicts and disclose personal financial interests that could become an actual conflict of interest or the appearance of a conflict.

2. PURPOSE

The policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the grants or cooperative agreements from PHS agencies will be free from bias resulting from FCOI of the investigators conducting the PHS-funded studies.

3. APPLICABILITY

All 5M Biomed employees who are working on projects sponsored by any agencies of PHS, including National Institutes of Health (**NIH**), Center for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), or National Science Foundation (**NSF**) **must** disclose Significant Financial Interests that are related to the Investigator's institutional or organizational responsibilities. This policy describes certain legal framework to identify, evaluate and correct or remove real, apparent and potential conflicts of interest.

If a project is involved with Subrecipients, 5M Biomed shall have a written agreement that ensure a Subrecipient will follow the FCOI policy of 5M Biomed and FCOI Regulations of PHS (Title 42

Code of Federal Regulations (CFR), Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*) ("FCOI Regulations") in addition to the FCOI policy of the Subrecipient. 5M Biomed shall obtain a certification from a subawardee that its FCOI policy complies with FCOI Regulations of PHS.

4. DEFINITIONS

4.1. **Significant Financial Interests (SFI)**

4.1.1. 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:

4.1.1.1. With regard to any publicly traded entity, a SFI 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;

4.1.1.2. With regard to any non-publicly traded entity, a SFI 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

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

4.1.1.4. 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 details of this disclosure will include, at a minimum the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The PD/PI 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.

4.1.1.5. The term SFI does not include the following types of financial interests:

4.1.1.5.1. 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;

4.1.1.5.2. Any ownership interest in the Institution held by the Investigator, including stock or stock options, if the Institution is a commercial or for-profit organization;

4.1.1.5.3. 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;

4.1.1.5.4. 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

4.1.1.5.5. 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.

4.2. **Disclosure of SFI** means an Investigator disclosing information about a SFI to 5M Biomed.

4.3. **Financial Conflict of Interest (FCOI)** means a SFI that could directly and significantly affect the design, conduct, or reporting of externally or federally funded research.

4.4. **FCOI Report** means a report of a FCOI to an Awarding Component.

4.5. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.

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

4.7. **Independent Review Committee (IRC)** means a committee which may be appointed by the Research Integrity Officer (RIO) to review Investigator's SFI related to PHS funded research, and to serve as regulatory body who determines whether any of the SFI constitutes a financial conflict of interest. At the RIO's discretion, this review may be conducted by the RIO or the IRC.

4.8. **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.

4.9. **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.

4.10. **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.

4.11. **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.

4.12. **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.

4.13. **PHS** stands for 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).

4.14. **PHS Awarding Component** means the organizational unit of the PHS that funds the research that is subject to 42 C.F.R. Part 50, Subpart F.

4.15. **Public Health Service Act (PHS Act)** means the statute codified at 42 U.S.C. 201 et seq.

4.16. **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). 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.

4.17. **Research Integrity Officer (RIO)** means the primary designated institutional official responsible for implementing this Policy. This will be the COO; and CEO or President.

4.18. **Senior/key personnel** means the PD/PI and any other person identified as senior/key personnel by 5M Biomed in the grant application, progress report, or any other report submitted to the PHS Awarding Component by 5M Biomed.

4.19. **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 42 C.F.R. Part 50, Subpart F, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

4.20. **Subrecipient** means an individual or entity receiving federal funds that have come from or through 5M Biomed to conduct a substantive portion of the PHS-funded research and is accountable to 5M Biomed for programmatic outcomes and compliance matters.

5. RESPONSIBILITIES OF INSITUTION REGARDING INVESTIGATOR FCOI

5.1. 5M Biomed shall maintain an up-to-date, written, enforced policy on FCOI that complies with 42 C.F.R. Part 50, Subpart F, and make such policy available to any requestor within five business days of a request.

5.2. 5M Biomed shall inform each Investigator of its policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of SFI, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

5.2.1. Revision of FCOI policies or procedures in any manner that affects the requirements of Investigators;

5.2.2. An Investigator is new to 5M Biomed; or

5.2.3. An Investigator is not in compliance with 5M Biomed’s FCOI policy or management plan.

5.3. 5M Biomed will take reasonable steps to ensure that any Subrecipients (i.e., subcontractors or consortium members) performing work under a PHS-funded research project comply with the PHS FCOI regulations by:

5.3.1. Incorporating as part of a written agreement with the Subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the Subrecipient will apply to the Subrecipient's Investigators.

5.3.1.1. If the Subrecipient's Investigators must comply with the Subrecipient's FCOI policy, the Subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the Subrecipient cannot provide such certification, the agreement shall state that Subrecipient Investigators are subject to the FCOI policy of 5M Biomed for disclosing SFI that are directly related to the Subrecipient's work for 5M Biomed;

5.3.1.2. Additionally, if the Subrecipient's Investigators must comply with the Subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the Subrecipient to report all identified FCOI to 5M Biomed. Such time period(s) shall be sufficient to allow 5M Biomed to provide timely FCOI reports, as necessary, to the PHS Awarding Component as required by this subpart;

5.3.1.3. Alternatively, if the Subrecipient's Investigators must comply with 5M Biomed's FCOI policy, the agreement referenced above shall specify time period(s) for the Subrecipient to submit all Investigator disclosures of SFI to 5M Biomed. Such time period(s) shall be sufficient to enable 5M Biomed to comply timely with its review, management, and reporting obligations under this subpart.

5.3.2. Providing FCOI reports to the PHS Awarding Component regarding all FCOI of all Subrecipient Investigators consistent with this subpart, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

6. DISCLOUSE, REVIEW, AND MONITORING OF FCOI

6.1. 5M Biomed shall designate the Quality Assurance (QA) as the organizational/institutional official to solicit and review disclosures of SFI from each Investigator who is planning to participate in, or is participating in, sponsored research.

6.2. Each Investigator who is planning to participate in the PHS-funded research is required to:

6.2.1. Disclose to the designated official SFI (and those of the Investigator's spouse and dependent children) related to their responsibilities at the institution no later than the time of application for PHS-funded research.

6.2.2. Submit an updated disclosure of SFI at least annually, in accordance with the specific time period prescribed by 5M Biomed, during the period of the award. Such disclosure shall include any information that was not disclosed initially to 5M Biomed, or in a subsequent disclosure of SFI (e.g., any FCOI identified on a PHS-funded project that was transferred

from another Institution) and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

6.2.3. Submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

6.3. If QA receives a disclosure of a potential SFI, QA shall present that to the PI and/or the CEO for review. The PI or the CEO is responsible for determining when an actual or potential FCOI exists in a given situation — that is, when a SFI could directly and significantly affect the design, conduct, or reporting of PHS-funded research — and for taking action as necessary to manage such FCOI, including development and implementation of a management plan.

6.4. If it is found that a SFI could directly and significantly affect the design, conduct, or reporting of the federally-funded research, the PI or the CEO will take actions as necessary to manage FCOI, including any financial conflicts of a Subrecipient Investigator. Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to §50.605(a).

7. MANAGEMENT AND REPORTING FCOI

7.1. Prior to the expenditure of any funds under a PHS-funded research project, the PI shall:

7.1.1. Review all Investigator disclosures of SFI;

7.1.2. Determine whether any SFI relate to PHS-funded research;

7.1.3. Determine whether a FCOI exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI.

7.2. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

7.2.1. Public disclosure of the FCOI (e.g., when presenting or publishing the research);

7.2.2. For research projects involving human subject research, disclosure of FCOI directly to participants;

7.2.3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;

7.2.4. Modification of the research plan;

7.2.5. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;

7.2.6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

7.2.7. Severance of relationships that create financial conflicts.

7.3. For any SFI that 5M Biomed identifies as conflicting subsequent to 5M Biomed's 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), 5M Biomed shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI report regarding the FCOI and ensure that 5M Biomed has implemented a management plan in accordance with 42 C.F.R. Part 50, Subpart F. Pursuant to §50.605(a)(3)(ii), where such FCOI report involves a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by 5M Biomed (e.g., was not timely reviewed or reported by a Subrecipient), 5M Biomed shall also complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. If bias is found, 5M Biomed shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

7.4. FCOI report shall 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 the management plan established by 5M Biomed. Elements of the FCOI report shall include, but are not necessarily limited to, the following:

7.4.1. Project number;

7.4.2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;

7.4.3. Name of the Investigator with FCOI;

7.4.4. Nature of the financial interest (e.g., equity, consulting fee, honorarium, travel reimbursement);

7.4.5. 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;

7.4.6. A description of how the financial interest relates to the PHS-funded research and the basis for 5M Biomed's determination that the financial interest conflicts with such research; and

7.4.6.1. A description of the key elements of 5M Biomed's management plan, including:

7.4.6.2. Role and principal duties of the conflicted Investigator in the research project;

7.4.6.3. Conditions of the management plan;

7.4.6.4. How the management plan is designed to safeguard objectivity in the research project;

7.4.6.5. Confirmation of the Investigator's agreement to the management plan;

7.4.6.6. How the management plan will be monitored to ensure Investigator compliance; and

7.4.6.7. Other information as needed.

7.5. For any FCOI previously reported by 5M Biomed with regard to an ongoing PHS-funded research project, 5M Biomed shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. 5M Biomed shall 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.

8. RECORD MAINTENANCE

Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of an FCOI) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS Awarding Component or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

9. ENFORCEMENT MECHANISMS, REMEDIES, AND NONCOMPLIANCE

9.1. Noncompliance and Remedies

9.1.1. Whenever 5M Biomed identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a Subrecipient), the designated official(s) shall, within sixty days: review the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so, 5M Biomed shall:

9.1.1.1. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward;

9.1.1.2. Complete, within 120 days of the Institution's determination of noncompliance, 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.

9.1.2. The review shall be documented consistent with the FCOI Regulations [§60.605(a)(3)(ii)(B)]. If bias is found during the course of the review, the Signing Official will promptly notify the PHS Awarding Component (which may take its own action and/or require further action by 5M Biomed and/or the Investigator, as it deems appropriate) and submit a mitigation report consistent with the FCOI Regulations [§60.605(a)(3)(iii)]. If appropriate, the Signing Official will update the previously submitted FCOI report. In any event, the Signing Official shall submit FCOI reports annually thereafter.

9.1.3. For clinical research projects supported by the PHS, if the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment was designed, conducted, or reported by an investigator with an FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the Investigator shall disclose the FCOI in each public presentation of the results of the research (such as articles, manuscripts and oral presentations) and 5M Biomed shall request an addendum to previously published presentations.

9.2. All researchers to whom this FCOI Policy applies are expected to fully and promptly comply with it. For employees of 5M Biomed, sanctions may include suspension or dismissal, denial of eligibility to engage in the research at issue or other appropriate penalties. Such sanctions may require giving notice of relevant information to funding agencies, professional bodies or journals, or the public. The Signing Official will determine what sanctions, if any, are to be applied. The Signing Official may impose sanctions for noncompliance, which may include, but is not limited to, the following:

9.2.1. Failure to make timely, full or accurate disclosures;

9.2.2. Failure to provide information requested;

9.2.3. Failure to update a disclosure form as necessary; or

9.2.4. Failure to comply with a management plan.

10. RETROSPECTIVE REVIEW

10.1. Whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by 5M Biomed to constitute a financial conflict of interest; failure by 5M Biomed to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, 5M Biomed shall, within 120 days of the

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.

10.2. 5M Biomed shall document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigator with the FCOI; (5) Name of the entity with which the Investigator has a FCOI; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review. (iii) Based on the results of the retrospective review, if appropriate, 5M Biomed shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the Institution is required to 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 5M Biomed's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, 5M Biomed will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the FCOI, 5M Biomed may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of 5M Biomed's retrospective review.

11. PUBLIC ACCESSIBILITY

5M Biomed shall maintain an up-to-date, written, enforced policy on FCOI that complies with this subpart, and make such policy available via a publicly accessible website. If 5M Biomed does not have any current presence on a publicly accessible website (and only in those cases), 5M Biomed shall make its written policy available to any requestor within five business days of a request. If, however, 5M Biomed acquires a presence on a publicly accessible website during the time of the PHS award, 5M Biomed shall post the information on that website within 30 calendar days. Such information shall consist of that required to be provided under the FCOI Regulations [§50.605(a)(5)(ii), (iii)], shall be updated at least annually and within 60 days of the receipt or identification of information concerning an additional SFI, and shall remain available for three years from the date the information was most recently updated.

12. SUBRECIPENT

12.1. If 5M Biomed carries out the PHS-funded research through a Subrecipient (e.g., subcontractors or consortium members), 5M Biomed will take the following steps to ensure that any Subrecipient Investigator complies with this subpart by incorporating as part of a written agreement with the Subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the Subrecipient will apply to the Subrecipient's Investigators.

12.2. If the Subrecipient's Investigators must comply with the Subrecipient's FCOI policy, the Subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the Subrecipient cannot provide such certification, the agreement shall state that Subrecipient Investigators are subject to the FCOI policy of 5M Biomed for disclosing SFI that are directly related to the Subrecipient's work for 5M Biomed;

12.3. If the Subrecipient's Investigators must comply with the Subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the Subrecipient to report all identified financial conflicts of interest to 5M Biomed. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS Awarding Component as required by this subpart;

12.4. If the Subrecipient's Investigators must comply with the FCOI policy of the awardee Institution, the agreement referenced above shall specify time period(s) for the Subrecipient to submit all Investigator disclosures of SFI to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

13. REPORTING

The designated institutional official will send initial, annual, and revised FCOI reports, including all reporting elements required by the regulation, to the PHS Awarding Component, for the Institution and its Subrecipients, if applicable, as required by the regulation: 1) prior to the expenditure of funds, 2) within 60 days of identification for an Investigator who is newly participating in the project, 3) within 60 days for new, or newly identified, FCOIs for existing Investigators, 4) at least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project, 5) following a retrospective review to update a previously submitted report, if appropriate. The designated institutional official will notify PHS Awarding Component promptly if bias is found with the design, conduct or reporting of PHS-funded research and to include the requirement to submit a Mitigation Report in accordance with and including all reporting elements as required by the regulation 42 CFR 50.605(a)(3)(iii). The designated institutional official will notify PHS Awarding Component promptly if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management

plan appears to have biased the design, conduct, or reporting of the PHS-funded research. 5M Biomed will notify PHS Awarding Component promptly and take corrective action for noncompliance with the policy or the management plan.

All FCOI reports will be reported to the PHS Awarding Component through electronic Research Administration (eRA) commons FCOI module and will contain the following:

1) Project number;

2) PD/PI or Contact PD/PI if a multiple PD/PI model is used;

3) Name of the Investigator with the FCOI;

4) Name of the entity with which the Investigator has an FCOI;

5) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

6) 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;

7) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research;

8) A description of the key elements of the management plan established by 5M Biomed including the following:

(A) Roles 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.

New FCOI Report (Initial submission Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how SFI relates to research, Key Elements of Management Plan.

Annual FCOI Report addresses the status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable. Annual report due at the same time as

when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension.

Revised FCOI Report. If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to the originally submitted FCOI report. Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.

Mitigation Report. Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion. When bias is found as a result of a retrospective review.