**Compsit3, Inc.**

**Financial Conflict of Interest (FCOI) Policy**

**Adopted on:**

Compsit3, Inc. strives to ensure that all work performed under Government Awards is free of any real or perceived conflicts of interest that could harm patients, and as well meets the highest standard of integrity. In addition, Compsit3 will assure that the reputation of the Company, the governmental agency providing the funding, and/or external partners is maintained. This policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in Governmental Awards. The policy is intended to comply with the requirements of federal regulations, which include, but are not limited to, the conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service (“the PHS FCOI Rules”) as found in 42 CFR Part 50 Part F (titled Promoting Objectivity in Research) and 45 CFR Part 94 (titled Responsible Prospective Contractors) and the Federal Acquisition Regulation FAR 52.203-16 (collectively referred to as the “Financial Conflict of Interest Rules”). These regulations describe the actions an individual and an organization must take in order to promote objectivity in PHS-funded research, and apply within CompSit3 to all funded grants, cooperative agreements, research contracts, and subawards where the originating sponsor is PHS.

**B. Scope**

Any employee or contractor of Compsit3, Inc. who submits a grant or contract proposal or conducts research under a PHS Organization’s funding grants or contracts, must adhere to the applicable requirements of the PHS Organization, including those involving the disclosure and regulation of outside activities and financial interests. These specific FCOI laws and regulations are applicable to all project directors and principal investigators, whether employees or contractors, who are responsible for the design, conduct and reporting of research work under grants and contracts with PHS Organizations.

**C. Definitions**

1. **Conflict of Interest Official (COI Official):** Federal regulations require PHS-funded institutions to appoint a COI Official, with the potential assistance of a COI Committee, whose aggregate charge is to review financial interests in sponsored research projects. The Company’s Board of Directors shall appoint the COI Official, who will form the COI Committee as needed. The COI Official, or their COI Committee designee, serves as the signature authority for the Company regarding FCOI.
2. **Covered Individual (“CI”):** A CI is any employee or contractor of the Company who is responsible for the design, conduct or reporting of a PHS-Funded Research project or proposed for such project, including any project director, principal investigator and any other key personnel designated as such in a PHS-Funded grant application or contract.
3. **Covered Individual Responsibilities:** A CI’s professional responsibilities performed on behalf of an entity that proposes to undertake or undertakes PHS-Funded Research.
4. **Equity Interest:** Any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
5. **Financial Conflict of Interest (“FCOI”):**A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.
6. **Financial Interest:** Any interest of monetary value, whether or not the value is readily ascertainable.
7. **Immediate Family:** A CI’s spouse or domestic partner and dependent children.
8. **Non-Significant Financial Interests (“Non-SFI”):** include the following types of Financial Interests: (i) remuneration paid by an entity to which a CI owes non-conflicting CI Responsibilities, if the CI is currently employed or otherwise appointed by such entity, including intellectual property rights assigned to such entity and any agreement to share in royalties related to such rights; or (ii) any ownership interest in an entity held by the CI or income from investment vehicles, such as mutual funds and retirement accounts, as long as the CI does not directly control the investment decisions made in these vehicles; or (iii) income from seminars, lectures, or teaching engagements sponsored by a US 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 (iv) income from service on advisory committees or review panels for a US 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.
9. **PHS:** 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, among others, the NIH. A listing of the PHS agencies and their offices may be located on the U.S. Department of Health and Human Services Organizational Chart.
10. **PHS-Funded Research:** any Research funded by way of a grant from, or a contract with, a PHS Organization.
11. **PHS Organization**: (i) an agency that is part of the PHS or (ii) an organization that has adopted the PHS Regulations, but not a non-governmental non-profit organization.
12. **PHS Regulations**: U.S. 42 CFR Part 50, Subpart F and 45 CFR Part 94
13. **Remuneration:** (i) salary and any payment for services including consulting fees and honoraria; (ii) any Equity Interest; and (iii) travel reimbursement related to the CI Responsibilities.
14. **Research:** 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, including basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
15. **Significant Financial Interest (“SFI”):** A Financial Interest consisting of one or more of the following interests of a CI (and those of the CI’s Immediate Family) that reasonably appear to be related to CI Responsibilities, but specifically excludes any Non-SFI: (i) any Remuneration received from any publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds $5,000; or (ii) any Remuneration received from any non-publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds $5,000; or (iii) intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

CIs must also disclose the occurrence of any reimbursed or sponsored travel (*i.e.,* that which is paid on behalf of the CI and not reimbursed to the CI so that the exact monetary value may not be readily available), related to their Company 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)](https://www.govinfo.gov/link/uscode/20/1001), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. The Company'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 Company's FCOI policy, the Company’s 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.

Covered individuals must also disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

Significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Company to the CI if the CI is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights; any ownership interest in the Company held by the Investigator, if the Company is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the CI 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.

**D. Responsibilities of the Company Regarding FCOI**

The Company maintains an up to date, written, enforced policy on financial conflicts of interest that complies with 42 CFR Part 50 Subpart F and such policy is found at www.Compsit3.com.

The Company has established a process to inform each CI of the Company’s FCOI Policy, the CI Responsibilities, and the PHS Regulations. In addition, the Company has established a process that requires each CI to complete FCOI training:

1. within 60 days of joining the Company;
2. prior to engaging in PHS-Funded Research;
3. at least every four years; and
4. immediately, if: (a) the Company revises the FCOI Policy that affects requirements of CIs, or; (b) when a CI is not in compliance with the FCOI Policy or a management plan.

The Company has designated a Company COI Official to solicit and review disclosures of significant financial interests from each Covered Individual who is planning to participate in, or is participating in, the PHS-funded research.

The Company requires that each CI who is planning to participate in the PHS-funded research disclose to the Company's designated COI Official the CI's significant financial interests (and those of the CI's spouse and dependent children) no later than the time of application for PHS-funded research.

A CI who is participating in the PHS-funded research at the Company is required to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Company, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Company, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another institution or company), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

Each CI who is participating in the PHS-funded research must submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

The Company provides guidelines consistent with 42 CFR Part 50 Subpart F for the designated Company COI Official to determine whether a CI's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. A CI's significant financial interest is related to PHS-funded research when the Company, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Company may involve the Covered Individual in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Company, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

The Company must take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient investigator pursuant to [paragraph (c)](https://www.ecfr.gov/current/title-42/section-50.604#p-50.604(c)) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report.

the Company provides initial and ongoing FCOI reports to the PHS as required. In view of this, the Company maintains records relating to all CI disclosures of financial interests and the Company's review of, and response to, such disclosures (whether or not a disclosure resulted in the Company's determination of a financial conflict of interest) and all actions under the Company's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in [45 CFR 75.361](https://www.ecfr.gov/current/title-45/section-75.361) for different situations. Adequate enforcement mechanisms have been put in place and provide for employee sanctions or other administrative actions to ensure CI compliance as appropriate.

The Company must certify, in each application for funding to which 42 CFR Part 50 Subpart F applies, that the Company: (1) Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS; (2) Shall promote and enforce a CI’s compliance with 42 CFR Part 50 Subpart F requirements including those pertaining to disclosure of significant financial interests; (3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with 42 CFR Part 50 Subpart F; (4) Agrees to make information available, promptly upon request, to the HHS relating to any CI’s disclosure of financial interests and the Company’s review of, and response to, such disclosure, whether or not the disclosure resulted in the Company's determination of a financial conflict of interest; and (5) Shall fully comply with the requirements of 42 CFR Part 50 Subpart F.

Additionally, if the Company carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with 42 CFR Part 50 Subpart F by incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with 42 CFR Part 50 Subpart F. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution.

Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by 42 CFR Part 50 Subpart F.

Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests 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 42 CFR Part 50 Subpart F.

Furthermore, the Company shall provide FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with 42 CFR Part 50 Subpart F, *i.e.,* prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

**E. Management of FCOI**

Prior to the Company's expenditure of any funds under a PHS-funded research project, the designated official(s) of the Company shall, consistent with [Section](https://www.ecfr.gov/current/title-42/section-50.604#p-50.604(f)) C, paragraph f: review all CI disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest 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 financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to: (1) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research); (2) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants; (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 financial conflict of interest; (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; (6) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or (7) Severance of relationships that create financial conflicts.

Whenever, in the course of an ongoing PHS-funded research project, a CI who is new to participating in the research project discloses a significant financial interest or an existing Covered Individual discloses a new significant financial interest to the Company, the designated COI Official of the Company shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, 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 financial conflict of interest. Depending on the nature of the significant financial interest, the Company may determine that additional interim measures are necessary with regard to the CI's participation in the PHS-funded research project between the date of disclosure and the completion of the Company's review.

Whenever the Company identifies a significant financial interest that was not disclosed timely by an CI or, for whatever reason, was not previously reviewed by the Company 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 significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists.

If it is determined that a financial conflict of interest exists, the Company must 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 financial conflict of interest going forward.

In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Covered Individual to disclose a significant financial interest that is determined by the Company to constitute a financial conflict of interest; failure by the Company to review or manage such a financial conflict of interest; or failure by the CI to comply with a financial conflict of interest management plan, the Company shall, within 120 days of the Company's determination of noncompliance, complete a retrospective review of the CI'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.

The retrospective review and 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 CI with the FCOI;
5. Name of the entity with which the CI has a financial conflict of interest;
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.

Based on the results of the retrospective review, if appropriate, the Company shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Company 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 the Company'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, the Company will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, the Company may determine that additional interim measures are necessary with regard to the Covered Individual's participation in the PHS-funded research project between the date that the financial conflict of interest or the Covered Individual's noncompliance is determined and the completion of the Company's retrospective review.

Whenever the Company implements a management plan pursuant to 42 CFR Part 50 Subpart F, the Company shall monitor CI compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Prior to the Company's expenditure of any funds under a PHS-funded research project, the Company shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Company that meets the following three criteria:

1. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by 42 CFR Part 50 Subpart F;
2. The Company determines that the significant financial interest is related to the PHS-funded research; and
3. The Company determines that the significant financial interest is a financial conflict of interest.

The information that the Company makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the CI's name; the CI's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant 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.

If the Company uses a publicly accessible Web site for the purposes of this subsection, the information that the Company posts shall be updated at least annually. In addition, the Company shall update the Web site within sixty days of the Company's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Company determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Company's identification of a new financial conflict of interest. If the Company responds to written requests for the purposes of this subsection, the Company will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Company's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Company's publicly accessible Web site for at least three years from the date that the information was most recently updated.

In addition to the types of financial conflicts of interest as defined in 42 CFR Part 50 Subpart F that must be managed pursuant to this section, the Company may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Company deems appropriate.

**E. Reporting of Financial Conflicts of Interest**

Prior to the Company's expenditure of any funds under a PHS-funded research project, the Company provides to the PHS Awarding Component an FCOI report regarding any CI's significant financial interest found by the Company to be conflicting and ensure that the Company has implemented a management plan in accordance with 42 CFR Part 50 Subpart F. In cases in which the Company identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Company shall not submit an FCOI report to the PHS Awarding Component.

For any significant financial interest that the Company identifies as conflicting subsequent to the Company's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an CI who is new to the research project), the Company shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Company has implemented a management plan in accordance with 42 CFR Part 50 Subpart F. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by a CI or, for whatever reason, was not previously reviewed or managed by the Company (e.g., was not timely reviewed or reported by a subrecipient), the Company also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the Company is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section 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 Company's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

1. Project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. Name of the CI with the financial conflict of interest;
4. Name of the entity with which the Covered Individual has a financial conflict of interest;
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 Company's determination that the financial interest conflicts with such research; and
8. A description of the key elements of the Company's management plan, including:

(a) Role and principal duties of the conflicted CI 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 CI's agreement to the management plan;

(e) How the management plan will be monitored to ensure CI compliance; and

(f) Other information as needed.

For any financial conflict of interest previously reported by the Company with regard to an ongoing PHS-funded research project, the Company shall 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 shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Company 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.

In addition to the types of financial conflicts of interest as defined in 42 CFR Part 50 Subpart F that must be reported pursuant to this section, the Company may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Company deems appropriate.

**F. FCOI in Research Involving Human Subjects**

Additional consideration will be given to conflicts of interest when the research involves human participants. In addition to the process outlined above, any significant financial conflict identified will be disclosed to the Institutional Review Board (IRB) responsible for review and approval of the associated protocols. Research will not begin/resume until the IRB has confirmed that appropriate steps have been taken to ameliorate any potential harm or potential harm to participants due to the significant financial conflict.

**G. Maintenance of Records**

Records of CI SFI disclosure forms, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Company for three (3) years from the date the final expenditure report is submitted to the sponsor or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

**H.  Enforcement**

The Company ensures the existence of adequate enforcement mechanisms and provides for corrective action to ensure CI compliance. the Company has established a policy requirement to complete and document retrospective reviews within 120 days of the Company’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 and to document the reviews consistent with the regulation.

If the failure of a CI to comply with the Company's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Company shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Company for further action, which may include directions to the Company on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Company’s employing such a CI to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such a CI.

The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Covered Individual disclosure of financial interests and the Company's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Company's determination of a financial conflict of interest. The Company is required to submit, or permit on site review of, all records pertinent to compliance with 42 CFR Part 50 Subpart F. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Company has not managed the financial conflict of interest in accordance with 42 CFR Part 50 Subpart F. The PHS Awarding Component may determine that imposition of specific award conditions or suspension of funding or other enforcement action is necessary until the matter is resolved.

In any case in which HHS 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 a Covered Individual with an FCOI that was not managed or reported by the Company as required, the Company shall require the CI to disclose the FCOI in each public presentation of the results of the research, and request an addendum to previously published presentations and publications.

**I. Third Party Requirements**

Any individual or organization acting as a consultant, subcontractor, or subrecipient (“External Partner”) to the Company on a PHS-funded award must either: (1) have a FCOI policy that meets the requirements of the PHS FCOI Rules or (2) follow this policy.

Organizations with their own policy will certify that the policy meets the requirements of the PHS FCOI Rules by submitting an External Partner Financial Conflict of Interest Disclosure form or registering with the FDP Clearinghouse, <https://fdpclearinghouse.org/>, before submission of the Government Award.  The COI Official will verify registration with the FDP Clearinghouse before submission.  The contract with the Company will contain language requiring compliance with the organization’s FCOI Policy.

Individuals and organizations without their own FCOI policy are required to follow this policy. The contract with the Company will contain language requiring compliance with the Company’s FCOI Policy.

**J.  Accessibility of Documentation**

The Company must make the FCOI policy publicly accessible by ensuring the most recent version of this FCOI Policy is accessible to the public on the Company’s website.

**K. COI Official:**

Joshua M. Thurman, MD, President, Compsit3, Inc.