

Conflicts of Interest Policy

COMMUNITY ADVOCACY RESEARCH & EVALUATION CONSULTING GROUP, INC.

Policy on Conflicts of Interest of Investigators Involved in Public Health Service ("PHS")

Funded Research

Updated: August 2017

1. Purpose

Interactions and collaborations between industries or with academia are beneficial for the public by providing means for effective and efficient translation of research findings. However, in certain cases a conflict of interest may occur in which a financial relationship potentially inappropriately affects an Investigator's research. Such Financial Conflicts of Interest may arise even though no improper conduct or unethical behavior has occurred. This Policy has been adopted by Community Advocacy Research & Evaluation Consulting Group, Inc. ("C.A.R.E. CONSULTING GROUP") to promote the objectivity and integrity of PHS-Funded Research conducted at or by C.A.R.E. CONSULTING GROUP. This Policy applies to all Investigators who engage in PHS-Funded Research and to non-research staff at C.A.R.E. CONSULTING GROUP who contribute to the design, conduct, or reporting of PHS-Funded Research. A Financial Conflict of Interest in PHS-Funded Research exists when C.A.R.E. CONSULTING GROUP, through the procedures described below, reasonably determines that a Significant Financial Interest reported by an Investigator could affect the design, conduct, or reporting of PHS-Funded Research conducted at C.A.R.E. CONSULTING GROUP. C.A.R.E. CONSULTING GROUP and Investigators have the responsibility to identify, manage, reduce, or eliminate such Financial Conflicts of Interest in a way that ensures the integrity of research findings and prudent stewardship of public funds.

Each Investigator shares responsibility in assuring that the highest standards of integrity and objectivity have been applied to the design, conduct and reporting of PHS-Funded Research at C.A.R.E. CONSULTING GROUP. To this end, it is essential that the integrity and objectivity of PHS-Funded Research at C.A.R.E. CONSULTING GROUP is not compromised by any potential, actual or apparent Financial Conflict of Interest. To achieve this goal, and to comply with PHS requirements, C.A.R.E. CONSULTING GROUP has implemented specific procedures for the disclosure and review of an Investigator's Significant Financial Interests, applicable to each Investigator, as described below. Accordingly, all such individuals are required to become familiar with this Policy and its mandatory reporting procedures.

This Policy applies to all PHS-Funded Research, including that funded by the National Institutes of Health ("NIH"). The purpose of this Policy is to implement the requirements of the Federal regulations set forth in 42 CFR Part 50 and 45 CFR Part 94, and any additional regulations that may be in effect from time to time, governing Investigators' responsibilities for promoting objectivity in PHS-Funded Research. This Policy shall be construed in accordance with such regulations and shall be deemed to include any requirements set forth in such regulations that are not expressly set forth below as may be updated from time to time. Where more stringent requirements and regulations relating to conflicts of interest of any funding agency or sponsor conflict with this Policy, the requirements and regulations of that funding agency or sponsor will take precedence.

2. Definitions

For the purposes of this Policy, the following terms will have the meanings described below:

- a. **"Financial Conflict of Interest" or "FCOI"** exists when the C.A.R.E. CONSULTING GROUP COI Official or COI Committee reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-Funded Research.
- b. **"Investigator"** means the principal investigator, co-principal investigator(s) and any other person who is responsible for the design, conduct, or reporting of research funded by the PHS-Funded Research, or proposed for PHS funding, which may include, for example, collaborators or consultants.
- c. **"Institutional Responsibilities"** means an Investigator's professional responsibilities on behalf of C.A.R.E. CONSULTING GROUP including but not limited to research, research consultation, teaching, professional practice, and administration such as service on committees, boards and panels.

- d. **"Manage"** means acting 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.
- e. **"PHS Awarding Component"** means the organizational unit of the PHS that funds the PHS-Funded Research.
- f. **"PHS-Funded Research"** means Research funded by or proposed to be funded by the PHS, including without limitation NIH awards. The term includes any Research for which funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the Public Health Service 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. For purposes of this Policy, the term shall not include Phase 1 Small Business Innovative Research or Small Business Technology Transfer applications or awards.
- g. **"Research"** means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health or agriculture, and encompasses basic and applied research. Research includes any activity for which research funding is available regardless of source.
- h. **"Senior/Key Personnel"** means the project director or principal investigator and any other person identified as senior/key personnel in the grant application, contract proposal, contract, progress report, or any other report submitted to the PHS for PHS-Funded Research.
- i. "Significant Financial Interest" or "SFI" means:
1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - i With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition:
 - remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); and
 - equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - ii With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - iii Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The COI Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a 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 to the Investigator by C.A.R.E. CONSULTING GROUP if the Investigator is currently employed or otherwise appointed by C.A.R.E. CONSULTING GROUP, including intellectual property rights assigned to C.A.R.E. CONSULTING GROUP and agreements to share in royalties related to such rights);

- any ownership interest in C.A.R.E. CONSULTING GROUP held by the Investigator;
- 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.

3. The Policy

a. Investigator Responsibilities

This Policy requires Investigators to (i) disclose Significant Financial Interests (including financial interests of the Investigator's spouse and dependent children), (ii) comply with the review process described below, and (iii) complete training with respect to PHS-Funded Research.

1. **Disclosure.** Every Investigator must disclose all of his or her Significant Financial Interests on a disclosure form ("**Disclosure Form**"), as well as those of the Investigator's spouse and dependent children, that reasonably appear to be related to the Investigator's Institutional Responsibilities. The Investigator is not charged with making a determination as to whether a Significant Financial Interest constitutes a FCOI or could affect the design, conduct or reporting of the PHS-Funded Research. That determination is made by the COI Official or COI Committee as further described below. Investigator disclosures are required as follows:
 - i **Upon Application.** Each Investigator who is planning to participate in PHS-Funded Research must disclose Significant Financial Interests on the Disclosure Form to the COI Official and COI Committee no later than the time of application or submission of a formal proposal for the PHS-Funded Research. With respect to Significant Financial Interests concerning reimbursed or sponsored travel, Investigators' disclosures will include travel received in the preceding twelve (12) months and will list, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip.
 - ii **Annually.** Each Investigator who is participating in PHS-Funded Research must submit an updated Disclosure Form at least annually during the period of the award. Such disclosure shall include any information that was not previously disclosed to C.A.R.E. CONSULTING GROUP pursuant to paragraph (a) above or in any subsequent disclosure of Significant Financial Interests, and shall include updated information regarding any previously disclosed Significant Financial Interests (e.g., the updated value of a previously disclosed equity interest).
 - iii **New Significant Financial Interests.** Each Investigator who is participating in PHS-Funded Research must submit a Disclosure Form within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new Significant Financial Interests.

b. Process for Reviewing Investigator Significant Financial Interests

1. COI Official and Committee
 - i C.A.R.E. CONSULTING GROUP's Conflict of Interest Official ("**COI Official**") and the Conflicts of Interest Committee ("**COI Committee**") are charged with administering this policy and ensuring compliance with all PHS requirements, including review of Disclosure Forms, timely identification, reporting and management of all FCOIs, and providing guidance to Investigators.
 - ii The COI Official is responsible for reviewing and analyzing all Disclosure Forms to identify real or apparent FCOIs, recommending management plans, and reporting all such FCOIs and management plans to the COI Committee for comment, approval, or any further action necessary to manage, reduce, or eliminate the conflict.

iii The COI Official and the COI Committee are appointed by the CEO of C.A.R.E. CONSULTING GROUP, in consultation with C.A.R.E. CONSULTING GROUP's Executive Director of Research, and shall consist of members of the C.A.R.E. CONSULTING GROUP Research Division, the COI Official, and any others who may be appointed by C.A.R.E. CONSULTING GROUP's CEO. The COI Committee shall provide guidelines consistent with PHS requirements and this Policy for the COI Official and the COI Committee to use in identifying FCOIs and to take such actions as are necessary to ensure that any such FCOIs will be managed, reduced, or eliminated as appropriate.

2. **Notification of Policy to Investigators.** C.A.R.E. CONSULTING GROUP will ensure that all Investigators have been notified of the PHS requirements and their disclosure responsibilities under those requirements and this Policy. A reminder of these requirements and the need to complete a Disclosure Form will be distributed annually within 60 days of October 1st to each Investigator conducting, or planning to conduct, PHS-Funded Research. C.A.R.E. CONSULTING GROUP will take reasonable steps to ensure that Investigators working for sub recipients comply with the regulations by requiring those Investigators to comply with this Policy or by requiring the entities to provide assurances to C.A.R.E. CONSULTING GROUP that will enable C.A.R.E. CONSULTING GROUP to comply with the regulations.

3. **Review of Conflicts of Interest**

- i The COI Official will be responsible for circulating and collecting the Disclosure Forms. Disclosure Forms are to be completed by Investigators and returned to the COI Official for review. The COI Official will conduct an initial review of Disclosure Forms to identify any potential or actual FCOIs according to guidelines that have been approved by the COI Committee, taking into account such factors as the nature of an Investigator's relationship to an outside entity, the dollar value of that relationship, and the overlap between that relationship and the Investigator's PHS-Funded Research. A FCOI will be deemed to exist when the COI Official reasonably determines that a SFI disclosed by an Investigator could bias the design, conduct, or reporting of the Investigator's PHS-Funded Research.
- ii The COI Official will review each FCOI, meet with the Investigator if necessary and make an initial recommendation to the COI Committee as to the management, reduction, or elimination of the FCOI. Simple conflicts may be managed through a standard management plan, requiring the Investigator take certain steps according to guidelines approved by the COI Committee. The implementation of such management plans will be promptly reported to the COI Committee. The COI Committee may accept, modify or reject such plans, and return any changes to the COI Official for reporting to the PHS Awarding Component, if and as required.
- iii The COI Official shall refer all complex conflicts to the COI Committee, which will take appropriate action to develop a custom management plan to manage, reduce or eliminate the conflict. As appropriate, the COI Committee may appoint a designated official ("**Designated Official**") to meet with the affected Investigator to design a management plan or mechanism appropriate for the specific situation. If the Designated Official reaches an agreement with the Investigator on a management plan the Designated Official will forward the agreement to the COI Committee. The COI Committee as necessary may accept, modify, or reject such plans. Upon approval, the Designated Official will forward the management plan to the Investigator for written acknowledgement and final implementation. The COI Official will receive a copy of the final management plan for reporting to the PHS Awarding Component, if and as required.
- iv If the Designated Official or the COI Committee is unable to reach agreement with the Investigator on a management plan, a letter will be sent to the Investigator summarizing the proceedings and the findings of the COI Committee. The Investigator may appeal the Designated Official's findings to the COI Committee and the CEO of C.A.R.E. CONSULTING GROUP by forwarding a request for reconsideration of those findings to the CEO's office within ten (10) days of the date of the letter. A copy of the letter sent to the Investigator from the Designated Official will be forwarded to the COI Committee and the CEO, who will determine whether a FCOI exists and the appropriate plan for managing the conflict. The CEO and/or the COI Committee may consult with the C.A.R.E. CONSULTING GROUP Board of Directors as needed. The CEO will have final review and authority regarding the management of all FCOI cases. A report on such determination and a plan for managing the FCOI will be promptly provided to the appropriate officials of the PHS Awarding Component, if and as required.

4. **Submission of the Research Application.** C.A.R.E. CONSULTING GROUP will certify in the PHS-Funded Research application as to C.A.R.E. CONSULTING GROUP's effective, implemented policy and full compliance with the federal regulations at 42 CFR Part 50 and 45 CFR Part 94.
5. **C.A.R.E. CONSULTING GROUP Remedies.**
 - i Investigators are required to comply with the final decision of the COI Official, COI Committee, or CEO (as applicable). If an Investigator fails to comply, the COI Committee will develop a corrective action plan for final review and approval by the CEO.
 - ii An Investigator will be considered non-compliant and in violation of this Policy if an Investigator:
 - Fails to submit a Disclosure Form or provide an update to his/her Disclosure Form in advance of those deadlines established by the COI Official and/or COI Committee for such submissions.
 - Fails to provide the COI Official and/or COI Committee with written acknowledgement of a management plan.
 - Fails to provide the COI Official and/or COI Committee with requested documentation regarding compliance with a management plan.
 - Fails to comply with the requirements of a current management plan applicable to Investigator's PHS-Funded Research.
 - iii C.A.R.E. CONSULTING GROUP will establish written procedures for resolving any alleged violation of this Policy and for enforcement action against Investigators who do not comply with this Policy. Violations of this Policy may result in the progressive disciplinary action consistent with C.A.R.E. CONSULTING GROUP policies, including without limitation placing a hold on the processing of any new grant application from a non-compliant Investigator and/or withholding disbursement or distribution of project-specific funding to the Investigator's laboratory.
 - iv If an Investigator fails to comply with this Policy or a management plan in a way that could have biased the design, conduct, or reporting of PHS-Funded Research, C.A.R.E. CONSULTING GROUP shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken (e.g., a mitigation report for the PHS-Funded Research, as further described below) and implement such corrective action.

c. Management of Financial Conflict of Interests

1. **Management Plans.** Each management plan shall specify the actions that have been, and shall be, taken to manage the FCOI.
2. **Conditions or Restrictions.** Examples of conditions or restrictions that might be imposed to Manage an FCOI include, but are not limited to:
 - i Public disclosure of the FCOI (e.g., when presenting or publishing the research);
 - ii Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the PHS-Funded Research against bias resulting from the FCOI;
 - iii Modification of the research plan;
 - iv Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the PHS-Funded Research;
 - v Reduction or elimination of a financial interest (e.g., sale of an equity interest); and
 - vi Severance of relationships that create the FCOI.
3. **Monitoring Compliance with the Management Plan.** Monitoring of the FCOI and an Investigator's compliance with a management plan will be required whenever a management plan has been instituted for a documented FCOI until completion of the relevant PHS-Funded Research. Initial monitoring will be conducted by the COI Officer, who at least annually, or whenever an Investigator updates his/her Disclosure Form, will review any updated information, review compliance with the management plan, and report to the COI Committee. As necessary, the COI Committee may require and develop a project-specific monitoring process, which may include appointing a Designated Official to assist with monitoring the FCOI and the Investigator's compliance with the management plan and to report on such monitoring to the COI Official and/or COI Committee.

- d. **New SFIs During Ongoing PHS-Funded Research.** In the course of ongoing PHS-Funded Research, whenever an Investigator who is new to participating in the PHS-Funded Research discloses a SFI or an existing Investigator discloses a new SFI, the COI Official will do the following, acting directly or in conjunction with the COI Committee, within sixty (60) days:
1. review the Significant Financial Interest;
 2. determine whether it is related to PHS-Funded Research;
 3. determine whether a FCOI exists, and, if so; and
 4. implement a management plan that shall specify the actions that have been, and will be, taken to Manage such FCOI.
- e. **Review of Existing SFIs and Retrospective Review during ongoing PHS-Funded Research.** The COI Official, acting directly or in conjunction with the COI Committee, will take the following actions with respect to a FCOI in ongoing PHS-Funded Research:
1. **Review of Existing SFIs.** Whenever C.A.R.E. CONSULTING GROUP identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during ongoing PHS-Funded Research (e.g., was not timely reviewed or reported by a sub recipient), the COI Official will, within sixty (60) days, undertake the same review, determinations, and management plan implementation set forth in Section III.D, above.
 2. **Retrospective Review.** 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 the COI Official or COI Committee to constitute a FCOI, failure by C.A.R.E. CONSULTING GROUP to review or manage such a FCOI, or failure by the Investigator to comply with a FCOI management plan, the COI Official will, within one hundred twenty (120) days of C.A.R.E. CONSULTING GROUP's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-Funded Research to determine whether any PHS-Funded Research or portion thereof, conducted during the time period of the noncompliance, was biased in design, conduct, or reporting of such PHS-Funded Research.

The COI Official, acting directly or in conjunction with the COI Committee, will document the retrospective review in accordance with Federal requirements set in 42 CFR, Part 50, Subpart F, §50.605(a)(3)(ii)(B)(1)-(9), for PHS-funded research grants or cooperative agreements, or 45 CFR Part 94, §94.5(a)(3)(ii)(B)(1)-(9), for PHS-funded research contracts, and if appropriate will update the previously submitted FCOI report, describing the new management plan.
 3. **Notification and Mitigation Report.** If the COI Official finds bias in the design, conduct, or reporting of PHS-Funded Research, the COI Official, acting directly or in conjunction with the COI Committee, will notify the PHS Awarding Component promptly and submit a mitigation report, as required by and including all key elements specified in 42 CFR, Part 50, Subpart F, §50.605(a)(3) (iii) and 45 CFR, Part 94, §94.5(a)(3)(iii), described further in Section III.H.3 below.
 4. **Interim Measures.** At any time, the COI Official may determine that interim measures are necessary to Manage the FCOI with regard to the Investigator's participation in the PHS-Funded Research.
- f. **Training.** Every Investigator will complete training on this Policy, the associated Federal regulations and Investigator responsibilities regarding disclosure of SFIs. Such training will be provided at the following times:
1. Prior to engaging in PHS-Funded Research and at least once every four (4) years thereafter;
 2. Immediately upon any of the following:
 - i when this Policy is revised in any manner that affects the requirements of Investigators;
 - ii
 - iii when an Investigator is new to C.A.R.E. CONSULTING GROUP, even if the PHS-Funded Research has already begun; and
 - iv
 - v when an Investigator is not in compliance with this Policy or a management plan, as determined by the COI Official.

3. **Sub recipients.** If C.A.R.E. CONSULTING GROUP is the awardee and conducts PHS-Funded Research through a sub recipient (e.g. subcontractors or consortium members), the COI Official will take reasonable steps to ensure that sub recipient Investigators comply with this Policy, as follows:
- i C.A.R.E. CONSULTING GROUP's written agreement with the sub recipient will establish whether this Policy or the sub recipient's Financial Conflicts of Interest policy will apply to the sub recipient's Investigators. The written agreement will state either that:
 - The sub recipient certifies that its Financial Conflicts of Interest policy complies with the applicable Federal regulations, and that the sub recipient's Investigators will comply with the sub recipient's policy; or
 - If the sub recipient cannot provide such certification, that sub recipient Investigators are subject to this Policy.
 - ii If the sub recipient's policy applies, the written agreement will specify the time period(s) for the sub recipient to report all identified FCOIs initially and annually thereafter to C.A.R.E. CONSULTING GROUP. The time period(s) will be sufficient to enable C.A.R.E. CONSULTING GROUP to provide FCOI reports to the PHS Awarding Component prior to the expenditure of any PHS funds and within sixty (60) days of finding any additional FCOI.
 - iii If this Policy applies, the sub recipient Investigators will disclose all Significant Financial Interests that are directly related to the sub recipient's work for C.A.R.E. CONSULTING GROUP. The written agreement with the sub recipient will specify the time period in which to comply, sufficiently allowing C.A.R.E. CONSULTING GROUP enough time to comply timely with its review, management and reporting obligations of providing FCOI reports to the PHS prior to the expenditure of funds, within sixty (60) days of finding any additional FCOI and annually thereafter.

4. **Reporting Requirements to PHS**

- i Prior to C.A.R.E. CONSULTING GROUP's expenditure of any funds under PHS-Funded Research, the COI Official shall provide to the PHS Awarding Component, as required, a FCOI report regarding any Investigator's FCOI ("**FCOI Report**"), unless the FCOI has been eliminated, and ensure that a management plan has been implemented. The FCOI Report will contain all the information required under federal regulations at 42 CFR, Part 50, Subpart F, §50.605(b)(3) and 45 CFR, Part 94, §94.5(b)(3), as applicable.
- ii For FCOIs acquired during ongoing PHS-Funded Research, described in Section III.D above, the COI Official shall provide to the PHS Awarding Component, within sixty (60) days, a FCOI Report ensuring that C.A.R.E. CONSULTING GROUP has implemented a management plan.
- iii For FCOIs not previously disclosed, reviewed or managed during ongoing PHS-Funded Research, described in Section III.E above, the COI Official shall, if the retrospective review results in a finding of bias in the design, conduct or reporting of the PHS-Funded Research, promptly submit its mitigation report to the PHS Awarding Component. In accordance with 42 CFR, Part 50, Subpart F, §50.605(a)(3)(iii) and 45 CFR, Part 94, §94.5(a)(3)(iii), the mitigation report shall include the key elements documented in the retrospective review and a description of the impact of the bias on the PHS-Funded Research and C.A.R.E. CONSULTING GROUP's plan of action or actions taken to eliminate or mitigate the effects of the bias.
- iv Such FCOI Reports will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. FCOI reports sent to NIH will be submitted through the eRA Commons FCOI Module. Annual FCOI reports will be submitted at the same time as when the annual progress report or multi-year progress report is due (as applicable) or at the time of extension of the funding period and/or as otherwise requested by the PHS Awarding Component.
- v Upon request of the PHS, C.A.R.E. CONSULTING GROUP will make information available to the PHS relating to any Investigator disclosure of SFIs and C.A.R.E. CONSULTING GROUP's review of, and response to, such disclosure, whether or not the disclosure resulted in C.A.R.E. CONSULTING GROUP's determination of a FCOI.
- vi In the event that the U.S. Department of Health and Human Services determines that PHS-Funded Research, whose purpose was to evaluate the safety or effectiveness of a drug, medical device or treatment, was designed, conducted or reported by an Investigator with a FCOI that was not managed or reported by C.A.R.E. CONSULTING GROUP, as mandated, C.A.R.E. CONSULTING GROUP will require the Investigator to disclose the FCOI in each public presentation of the PHS-

Funded Research results and to request an addendum to any previously published presentations of such PHS-Funded Research.

5. **Maintenance of Records.** C.A.R.E. CONSULTING GROUP will maintain records relating to all Investigator SFI disclosures, including the review of and response to such disclosures (whether or not resulting in a FCOI finding), and any other action under this Policy, for at least three (3) years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53 (b) and 92.42(b), relating to records retention.
6. **Public Accessibility.** C.A.R.E. CONSULTING GROUP will post this Policy on C.A.R.E. CONSULTING GROUP's public website. In addition, C.A.R.E. CONSULTING GROUP will provide by written response to any requestor, within five (5) business days of a request, information on SFIs: that were disclosed and are still held by Senior/Key Personnel; that C.A.R.E. CONSULTING GROUP has determined relate to PHS-Funded Research; and that C.A.R.E. CONSULTING GROUP has determined constitute a FCOI. The information provided will include the following: the Investigator's name, title, and role in the PHS-Funded Research; the name of the entity in which the SFI is held; the nature of the SFI and the dollar amount range of the SFI (\$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 response to the requestor will also note 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 Institution's identification of a new FCOI, which should be requested subsequently by the requestor. This information will remain available for three (3) years from the date the information was most recently updated.

4. Additional Procedures

The COI Committee may establish additional procedures relating to the implementation of this Policy, including procedures for reviewing Disclosure Forms and for managing, reducing, or eliminating conflicts of interest.