

# VNS HEALTH CORPORATE POLICY & PROCEDURE

**TITLE: PUBLIC HEALTH SERVICE (PHS) FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY**

**APPLIES TO:** All VNS Health Entities, but only to VNS Health personnel who are Investigators on PHS-funded research, and to externally employed individuals who are Investigators on PHS-funded research projects awarded to VNS Health, and to Institutions that are sub-recipients on PHS-funded research projects awarded to VNS Health

**RESPONSIBLE OFFICES:** VNS Health

**APPROVED:** 12/7/2018

**POSTED TO WEBSITE:** December 2018

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## **PURPOSE:**

The following sections detail the content and implementation of the Policy on Financial Conflict of Interest (Objectivity in Research) at VNS Health. The primary purpose of this Policy is to preserve the credibility of VNS Health research through a transparent policy and procedure for conflict disclosure and resolution.

This policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOIs).

## **POLICY**

The policy applies to VNS Health employees and contractors (“Staff”) who are responsible for the design, conduct or reporting of research funded under Public Health Service (PHS) grants or cooperative agreements. The term “Investigator”, as defined in this Policy, will apply to all Staff who are designated as “Investigators” by a VNS Health Primary Investigator or equivalent for a given PHS-funded application or project.

The basic principle guiding this Policy is that VNS Health shall conduct its research and related academic activities in an ethical manner. Therefore, situations in which the general public may reasonably expect the possibility of conflict of interest shall be disclosed and managed to reduce or dispel any perception of lack of objectivity on the part of an Investigator.

For their own protection and the protection of VNS Health, pursuant to this Policy all Investigators are expected to disclose any Significant Financial Interests (SFI) related to their organizational responsibilities for any PHS funded research project.

This Policy is guided by U.S. Code of Federal Regulations (Title 42 CFR Part 50, Subpart F) that promotes “objectivity in research by establishing standards to ensure that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will not be biased by any conflicting financial interest of an Investigator.”

## **DEFINITIONS**

- 1. FCOI:** exists when VNS Health, through the process outlined herein, reasonably determines that a SFI (defined below) could directly and significantly affect the design, conduct, or reporting of PHS- funded research.
- 2. INVESTIGATOR** is a Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research on a PHS-funded project. The Investigator status of all Center for Home Care Policy & Research at VNS Health staff will be tracked on Center Compliance Tracking sheet. A Responsible Executive will determine the Investigator status of all new hires, and confirm change(s) in Investigator status for current staff. Additionally, all non-VNS Health personnel, as well as VNS Health personnel from other departments, who are Investigators on VNS Health PHS-funded Research will be tracked on the Center Compliance Tracking sheet, unless their contributions to the VNS Health PHS-funded research are bound under a sub-awardee Agreement with an institution that certifies that they have a compliant PHS FCOI policy that the Investigator(s) will comply with.
- 3. INSTITUTIONAL RESPONSIBILITIES:** An Investigator’s professional responsibilities on behalf of VNS Health including activities such as research, teaching, clinical or other professional practice, academic/instructional activities, scholarly events, institutional committee memberships, and service on panels such as the Institutional Review Board.

**4. PHS (PUBLIC HEALTH SERVICE)**, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

**5. PHS AWARDING COMPONENT** means the organizational unit of the PHS that funds the research that is subject to 42CFR Part 50, Subpart F. This includes, without limitation, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ).

**6. PHS - SIGNIFICANT FINANCIAL INTEREST (SFI)** means 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:

- 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); 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;
- 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
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 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 VNS Health, and/or 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.

SFI does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by VNS Health to the Investigator if the Investigator is currently employed by VNS Health, including intellectual property rights assigned to VNS Health and agreements to share in royalties related to such rights;
- 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.

**7. 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). As used in this Policy, 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.

**8. RESPONSIBLE EXECUTIVES:** The Vice President of Research, the Associate Director of Research, and the Vice President of Compliance and Regulatory Affairs (“VP of Compliance”) are the VNS Health employees responsible for ensuring VNS Health’s compliance with this Policy, among other duties specified below, and will be referred to collectively as the “Responsible Executives”.

**9. REVIEWERS:** VNS Health employees within the Center for Home Care Policy & Research at VNS Health (“The Center”) who are designated on an as-needed basis by a Responsible Executive.

**10. VNS HEALTH FCOI ADMINISTRATOR (ADMIN):** The VNS Health employee who has been officially designated (as specified in Part IV, Section A of this Policy) to be the VNS Health employee responsible for ensuring implementation of and compliance with all administrative requirements of this Policy.

## PROCEDURES

### ORGANIZATIONAL AND INVESTIGATOR RESPONSIBILITIES:

The following procedures will be used to comply with the expectations of 42 CFR Part 50, Subpart F, and this Policy.

#### A. Administrative roles of VNS Health Staff

(1) The Responsible Executives will be responsible for ensuring VNS Health's compliance with this Policy. A Responsible Executive may delegate on-going PHS FCOI compliance administration, review and monitoring to a subordinate. Compliance with this policy will be reviewed at least two (2) times per calendar year by a Responsible Executive or his or her delegate. A Responsible Executive must approve any change(s) to this policy prior to implementation of the change(s).

(2) The Reviewers shall make determinations and implement procedures as specified below and in Part IV, section D. of this Policy.

(3) The Reviewers will be responsible for ensuring that the role of ADMIN has been assigned to a VNS Health Staff member via the *Designation of VNS Health PHS FCOI Administrator* form. In cases in which there is not currently an assigned ADMIN, the Reviewers are responsible for ensuring that all administrative procedures required for compliance with this Policy are implemented.

- The ADMIN will be required to keep the completed *Designation of VNS Health PHS FCOI Administrator* form that designates him or her as ADMIN on file at all times.

(4) The ADMIN is responsible for ensuring that all administrative requirements of this Policy are implemented, and that the biannual review of the Research Center's compliance with this Policy by a Responsible Executive or his or her delegate is documented.

#### B. Training

(1) The ADMIN shall be responsible for ensuring that each Investigator is informed about this Policy, the Investigator's responsibilities regarding disclosure of SFI, and that the PHS FCOI regulations are met.

(2) The ADMIN shall require each Investigator to complete training on FCOI and SFI. If an Investigator is planning to participate in a PHS-funded project as an Investigator (as opposed to a role with less responsibility) for the first time, the Investigator must complete training prior to the submission of the application. In general, all Investigators must complete training prior to engaging, as an

Investigator, in research related to any PHS-funded grant and cooperative agreement or contract. Without limiting the foregoing, each Investigator must complete this training at least every four years. Further, if an Investigator is new to VNS Health or is not in compliance with this Policy or his/her management plan, as described in Section 5 below, then he or she must complete the training on FCOI immediately and in any event before he or she conducts PHS-funded Research or expends PHS funds.

In addition, if this Policy, the *VNS Health PHS Significant Financial Interest Disclosure* form or the VNS Health procedures are revised in any manner that affects the PHS FCOI requirements of the investigators, all VNS Health Investigators will be required to complete training before any further PHS-funded Research is conducted and/or PHS-funds are expended.

(3) Each Investigator will be required to acknowledge by signing and dating the *Acknowledgment of VNS Health FCOI Training Completion* form that he/she has completed VNS Health's FCOI training, has no outstanding questions regarding this Policy, and agrees to abide by all procedures in the Policy.

- The training and acknowledgment must be completed prior to the Investigator participating in a PHS-funded project, and prior to the submission of any application for PHS-funding that includes the given staffer as Investigator-level project personnel.

(4) The *VNS Health Significant Financial Interest Disclosure (SFID)* form shall be distributed to the Investigator during the training and must be completed by the Investigator and returned to the ADMIN prior to the Investigator participating in a PHS-funded project at VNS Health, and prior to the submission of any application for PHS-funding that includes the given staffer as Investigator-level project personnel.

### **C. Disclosure of SFI: Responsibilities of VNS Health Investigators**

(1) All VNS Health Investigators are required to comply with this Policy and to inform the ADMIN in ALL cases in which the Investigator suspects non-compliance with this Policy by any VNS Health employee and/or Investigator.

(2) A Responsible Executive will designate each VNS Health Research Center staffer upon hire as either an "Investigator-level Staffer" or as a "non-Investigator level staffer". This designation will be documented in the VNS Health Research Center Compliance Tracking Sheet Staff List. Changes to a Staffer's designation must be confirmed by the Responsible Executive in writing, and will be documented in the tracking sheet named above. Only Investigator-level staffers will be subject to this Policy.

- If a person who meets any of the criteria below is to be included as project personnel on a PHS application submitted by the Research Center, the

Principal Investigator for the application must, prior to the submission of the application, inform the ADMIN or a Responsible Executive that the person is to be considered an Investigator should the application be funded. All persons who will be considered Investigators subject to VNS Health's PHS FCOI Policy will be documented on the VNS Health Research Compliance Tracking Sheet Staff list. Under all circumstances, all persons who are both 1) designated as Investigators for at least 1 PHS application and 2) not employees of Sub-awardee institutions that have certified prior to application submission that the Institution has a compliant PHS FCOI policy that their Investigator(s) will comply with over the course of the PHS-funded project, must complete training and submit an SFID form prior to submission of the application per the procedures delineated above.

Criteria:

- a. A VNS Health staffer from another VNS Health department for whom a biosketch will be submitted with the application for PHS funding.
- b. A VNS Health Center staffer who has never while at VNS Health had their biosketch submitted with an application for PHS-funding, but whose biosketch will be submitted with the current application
- c. A consultant or other external person for whom a biosketch will be submitted (unless this person's contributions will be bound under a sub-awardee agreement)

(3) Any VNS Health employee who would like to officially undertake the responsibilities of an Investigator on a PHS-funded project in which VNS Health is *not or will not* be the Primary Institutional recipient of PHS-funding must inform the ADMIN *before* committing in any official capacity to serve on the project and before the Primary Institutional grantee submits the application for PHS-funding, unless that employee has already served in an Investigator role on PHS-funding at VNS Health and is in current compliance with VNS Health PHS FCOI Policy SFI disclosure and training requirements.

(4) On the SFID form, the Investigator shall list all of the Investigator's SFIs (and those of the Investigator's spouse, domestic partner and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities. The form will include a link to the PHS FCOI regulations and the NIH FCOI Web site.

Investigators are required to disclose their SFIs:

- Prior to the time of application for PHS-funded research;
- At least annually during the period of award; and
- Within thirty (30) days of a) discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI and/or b) any substantive changes to SFIs already disclosed to VNS Health.

If an Investigator already has a completed SFID form on file with the ADMIN that is less than 365 days old, and does not have a new SFI to disclose, he or she will not be required to submit a new SFID form to the ADMIN prior to applications for PHS-funding or prior to engaging in PHS-funded Research.

(5) Investigators are required to abide by all relevant protocols and policies provided in Management Plans, Mitigation and Non-Compliance reports (see section E below).

#### **D. Review and Management of Financial Conflicts of Interests**

(1) The ADMIN will collect the completed SFID forms from each Investigator planning to participate, or participating, in PHS-funded research activities. All completed SFID forms will be stored and tracked electronically by the ADMIN. All completed SFID forms that include a disclosed SFI will be subject to the procedures immediately below:

(2) A Reviewer may determine whether an Investigator's disclosed SFI is related to the specific PHS-funded research project and, if so related, whether the SFI is a FCOI, except in the cases specified below:

- When the Reviewer also is an Investigator on the same project
- When the Reviewer is unable to make the determination, or has a concern regarding the accuracy of the determination

In the event that all Reviewers in the Center are unable to make the determination, the determination will be made by the VNS Health Vice-President of Compliance & Regulatory Affairs, or a person he or she delegates (via a written email to the ADMIN) to make the determination in this specific instance.

A determination of an actual conflict of interest must meet the following criteria for an FCOI:

- i. An Investigator's SFI is related to PHS-funded Research when the Reviewer reasonably determines that the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the PHS-funded Research.
- ii. A FCOI exists when the Reviewer reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.

(3) If an SFI is determined to be an FCOI, a Reviewer will develop and implement a management plan per Section 5 below.



- In the event that any Reviewer has any concerns about the sufficiency of the management plan, the VNS Health Vice-President of Compliance & Regulatory Affairs or a person he or she delegates (via a written email to the ADMIN), will confirm, or revise as necessary, the management plan.

Recommendations for management, reduction or elimination of the FCOI may include but are not limited to:

- Disclosure of FCOIs (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institutional Review Board(s));
- For research projects involving human subjects Research, disclosure of the FCOI directly to participants;
- 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts

(4) The management plan will be a written document that includes but is not limited to the following:

- The role and planned principal duties of the conflicted Investigator in the Research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- How the management plan will be monitored to ensure Investigator compliance;
- Other information as needed; and
- Confirmation of the Investigator's signature to confirm his/her agreement with the management plan.

(5) The ADMIN will monitor adherence to the management plan and notify the Responsible Executives in any case of suspected or confirmed non-compliance.

#### **E. Reporting of an FCOI(s) to PHS**

(1) When an SFI is determined to constitute an FCOI, a Reviewer must review and ensure the reporting to the applicable PHS funding agency of a management plan in accordance with the procedures listed below, and with this FCOI Policy and the PHS FCOI Regulations in general.

- The ADMIN will submit an initial FCOI report prior to expenditure of the funds under a PHS-funded grant or cooperative agreement for every SFI determined by the Reviewer to constitute an FCOI.
- The ADMIN will submit an FCOI report within sixty (60) days of disclosure of a new SFI that is determined to be an FCOI by the Reviewer or VP of Compliance and/or the SVP of Clinical Transformation.

The elements of all FCOI reports shall include sufficient information to enable PHS to understand the nature and extent of the FCOI and to assess the appropriateness of the management plan.

- The ADMIN at least annually will provide PHS an update of the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.

(2) Required Elements of the FCOI Report:

The following key elements that must be included in the FCOI report to PHS. These include but are not necessarily limited to the following:

- i. Project number or equivalent;
- ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- iii. Name of the Investigator with the FCOI;
- iv. Name of the entity with which the Investigator has a FCOI;
- v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- vi. 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;
- vii. A description of how the SFI relates to the PHS- funded research and why VNS Health determined that the financial interest conflicts with such research.
- viii. The ADMIN will provide a description of the key elements of the Management Plan.

- ix. The ADMIN within the Center must prepare and gain approval in writing from the SVP of Clinical Transformation or designee to submit the report.
- x. The ADMIN will submit all FCOI reports, and check the Notice of Grant Award (NOGA) for the project in question to ensure that all FCOI management requirements other than those stated in this Policy are met as specified in the NOGA.

#### **F. Enforcement Mechanism, Remedies and Non-Compliance**

- (1) Instances of noncompliance include the following:
    - (2) Failure by the Investigator to disclose a SFI that VNS Health determines constitutes a FCOI;
    - (3) Failure by VNS Health to review or manage such a FCOI; or
    - (4) Failure by the Investigator to comply with this Policy or Management Plan.
  - (5) VNS Health will ensure compliance with the new regulations for retrospective review and prepare a mitigation report, if needed, for submission to the funding agency as required under the FCOI new regulations.
  - (6) If an Investigator violates or is suspected to have violated the FCOI Policy, for example by a failure to disclose a new SFI within 30 days of its acquisition, the ADMIN will notify the Responsible Executives who may recommend disciplinary or other appropriate actions.
  - (7) In cases where an Investigator has violated this Policy, no further PHS funds will be expended until the ADMIN and a Responsible Executive have confirmed compliance with this Policy, and if the project is still in the application phase, the application will not be submitted to the awarding agency for consideration until a Responsible Executive has confirmed compliance with this Policy.
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- (2) Process for Reporting Non-Compliance & Conducting Retrospective Reviews:
    - (3) For any SFI that VNS Health identifies as an FCOI subsequent to VNS Health's initial FCOI report under the award, a report shall be prepared and approved by a Responsible Executive and submitted by the ADMIN within sixty (60) days of the identification of noncompliance.
    - (4) Upon the determination of noncompliance involving a SFI(s) not previously reviewed, disclosed, identified or managed in a timely manner, a

Retrospective Review must occur within 120 days of VNS Health's determination and include the following key elements:

- i. Project number;
- ii. Project title;
- iii. PD/PI or contact PD/PI (if a multiple PD/PI model);
- iv. Name of the Investigator with the FCOI;
- v. Name of the entity with which the Investigator has a FCOI
- vi. Reason(s) for the retrospective review;
- vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- viii. Findings of the review; and
- ix. Conclusions of the review.

### (3) Process for when Retrospective Reviews Find Bias and for Submitting Mitigation Reports

If during the course of the review, a bias is found, the ADMIN will 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 VNS Health'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, VNS Health will submit FCOI reports annually. Depending on the nature of the FCOI, VNS Health 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 the VNS Health's retrospective review.

- A Responsible Executive must approve the Mitigation Report prior to its submission to the PHS Awarding Component by the ADMIN.

(4) In cases of Non-Compliance:

In cases of non-compliance, PHS, the awarding agency, VNS Health, and the Responsible Executives reserve the right to:

- a. Impose special award conditions;
- b. Suspend funding;
- c. Remove an Investigator or Investigators from a specific project; and/or
- d. Impose other enforcement mechanisms until the matter is resolved and VNS Health is in compliance with this Policy.

#### **G. Responsibilities of the Sub-recipients**

If VNS Health carries out PHS-funded research through a sub-recipient, VNS Health must take the following reasonable steps to ensure that all sub-recipient Investigators comply with PHS FCOI regulations:

- a. VNS Health will require, prior to the submission of the application, each sub-recipient institution with Investigator-level staff on the application to certify whether i) the sub-recipient's Investigators will follow VNS Health's PHS FCOI policy; or, ii), that the sub-recipient institution has an FCOI policy compliant with all current PHS FCOI regulations, and that its Investigators will follow this Policy for the duration of the project, should the application be funded.
  - If the sub-recipient selects option i. above, all sub-recipient Investigators, whose Investigator status must first be confirmed by a VNS Health Responsible Executive, will be required to complete VNS Health's PHS FCOI training, and submit completed *SFID* forms prior to the submission of the application.
  - If the sub-recipient selects option ii. above, they will be required to certify, prior to the submission of the application, that they have a FCOI policy compliant with relevant PHS regulations that their investigators will follow should the application be funded.
- b. Upon awarding of funds, the sub-recipient and VNS Health will provide final confirmation of which FCOI policy the sub-recipient Investigators will follow in the sub-recipient contract established between VNS Health and the sub-recipient.

- c. The sub-recipient contract must specify the time period for sub-recipient disclosure of any FCOIs to VNS Health to allow for VNS Health to report to PHS in a timely manner. In no case will this period be greater than thirty (30) days.

## **H. Public Accessibility**

(1) VNS Health will maintain an up-to-date written, enforced policy on FCOI and will make its policy available on its website (<https://www.vnshealth.org/for-professionals/research-center/>), via a link on the website's "About the Research Center" page.

(2) VNS Health shall ensure public accessibility. The ADMIN will provide a written response within five (5) business days of a request for information concerning any SFI disclosed to VNS Health that meets the following three criteria:

- The SFI was disclosed and is still held by an Investigator identified by VNS Health as a senior/key personnel in the application for the PHS-funded research project its progress reports, or any other required report submitted to the NIH;
- VNS Health determines that the SFI is related to the PHS-funded research; and
- VNS Health determines that the SFI is a FCOI.

(3) The SFI information that VNS Health makes available via written response shall include the following:

- i. Project number or equivalent;
- ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- iii. Name of the Investigator with the FCOI;
- iv. Name of the entity with which the Investigator has a FCOI;
- v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- vi. Value of the financial interest (dollar ranges [as set forth above] are permissible), 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;
- vii. 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 sixty (60) days of the VNS Health's identification of a new FCOI, which should be requested subsequently by the requestor.

## **I. Maintenance of Records**

(1) VNS Health's ADMIN is required pursuant to the FCOI Regulations to maintain all *SFID* forms and all related records of actions taken by VNS Health with respect to disclosures of financial interests for a period of three (3) years from the date of submission of the final expenditures report to PHS or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report.

(2) Information concerning the Investigators' SFI must remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated.

(3) Questions about this policy should be directed to either:

- a. Margaret McDonald, Associate Director for the Center for Home Care Policy & Research, via email at [Margaret.McDonald@vnsny.org](mailto:Margaret.McDonald@vnsny.org) and phone at: (212)-609-5761 or;
- b. Greg Horton, Business Manager for the Center, via email at [Greg.Horton@vnsny.org](mailto:Greg.Horton@vnsny.org) and phone at: (212) 609-5782 or;
- c. VNS Health's current ADMIN at [FCOIadmin@vnsny.org](mailto:FCOIadmin@vnsny.org)

## **J. Related Documents, Forms, and Complete Policy Acknowledgment**

### **(1) Internal Forms**

The following forms are used by VNS Health to ensure compliance with this Policy:

- a. Designation of VNS Health PHS FCOI Administrator Form
- b. Acknowledgement of VNS Health PHS FCOI Training Completion Form
- c. Significant Financial Interest Disclosure Form

To view any of these forms, please contact the ADMIN.

**REVIEWED: 12/7/2018**

**REVISED: 12/7/2018**

**POLICY OWNER:** Vice President and Director of Research

**RESPONSIBLE PARTIES:** Margaret McDonald, Associate Vice President, Center for Home Care Policy & Research; Kathryn Bowles, Vice President and Director, Center for Home Care Policy & Research

**REFERENCES:**

This policy is guided by the following federal and state regulations and reports:

42 CFR Part 50, Subpart F: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding Is sought.

**NIH checklist:**

[http://grants.nih.gov/grants/policy/coi/checklist\\_policy\\_dev\\_20120412.pdf](http://grants.nih.gov/grants/policy/coi/checklist_policy_dev_20120412.pdf)

**Research Center at VNS Health Website:**

<https://www.vnshealth.org/for-professionals/research-center/>