Viocare's Financial Conflict of Interest (FCOI) Policy

Purpose:
The purpose of this FCOI policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of NIH-related research carried out at Viocare, Inc. (Company) and to comply with specific regulations (**42 CFR Part 50 Subpart F**; the "Regulations"). The FCOI policy has been developed to ensure compliance with the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research. This regulation was developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring that the design, conduct, and reporting of research funded under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. An electronic version of the regulation is found at **http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf**. To be eligible for NIH funding, Viocare must maintain and enforce an FCOI policy that meets or exceeds the regulatory requirements.

Definitions:
The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI. A complete list of official definitions can be found at 42 CFR 50.603.

Investigator – means the project director or principal investigator and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the NIH, which may include, for example, collaborators or consultants.

Institution – means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for or receiving NIH research funding.

Financial conflict of interest (FCOI) – means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Significant Financial Interest (SFI) – means:

a. 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 (company) 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
    (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 in excess of $5,000.

b. Investigators also must disclose the occurrence of any reimbursed or sponsored travel in excess of $5,000 related to their company responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by Federal, state, or local government agency located in the United States, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education. Note: Reimbursed or sponsored travel from a foreign government, which includes local, provincial, or equivalent governments of another country or foreign institutions of higher education must be disclosed when such income is more than $5,000. The details of the disclosure will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

c. The term *significant financial interest* does not include the following types of financial interests:
   (i) salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution
   (ii) intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights
   (iii) any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization
   (iv) 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
   (v) income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency located in the United States, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education
   (vi) income from any service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education.

   Note: Income from seminars, lectures, or teaching engagements and from service on advisory committees or review panels received from a foreign

government, which includes local, provincial, or equivalent governments of another country or foreign institutions of higher education must be disclosed when such income meets the threshold for disclosure.

Institutional responsibilities – means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial interest – means anything of monetary value, whether or not the value is readily ascertainable.

Manage – means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Senior/Key Personnel – means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the regulation.

Procedure:

1. Training Requirements

i. All Investigators who plan to participate in or are participating in NIH-funded research must be informed of Viocare's FCOI policy, the Federal regulation 42 CFR Part 50 Subpart F, and the responsibility to disclose FCOIs. It shall be the responsibility of the Principal Investigator of a Research project to identify all Investigators who have a SFI requiring disclosure under this policy and to ensure that a SFI Disclosure Form is prepared and submitted.

ii. Investigators must be trained to 42 CFR Part 50 Subpart F and Viocare's FCOI policy:
a. Prior to engaging in NIH-funded research.
b. Every four years, thereafter.
c. Immediately, if:
- Viocare's FCOI policy is revised.
- Investigator is new to the company
- Investigator does not comply with the FCOI policy or management plan.

iii. Training constitutes Investigators certifying they have read and reviewed:
a. Viocare Financial Conflict of Interest Policy
b. NIH's "FCOI Training" on Regulation 42 CFR Part 50 Subpart F. The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health

(NIH) to provide educational training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH funded project, which includes all Investigators, consultants, and employees of Viocare engaged in NIH-funded research or its compliance. Upon completion of the training, a certificate of completion must be stored in the Company's financial records. This training is required prior to engaging in research relating to any NIH-funded grant or as deemed necessary by the Company due to changes in the FCOI policy, non-compliance of the Investigator/Key Personnel, or new to the Company. At a minimum, the FCOI training shall be taken every four (4) years. The course is accessible at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html, or another equivalent course provided through an institution.

iv. The FCOI Policy has been implemented in the following ways:

a. Each Investigator has been provided a written copy;

b. The FCOI Policy has been added to the company shared secure drive and on a publicly available website.

2. Disclosure, Review, and Monitoring Requirements

i. Each Investigator has a responsibility to disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigator's company responsibilities that meet or exceed the definition of SFI as provided in this policy using the company's Significant Financial Interest Form.

a. No later than at the time of application for NIH-funded research

b. At least annually during the period of the award

c. Within 30 days of discovering or acquiring a new SFI

ii. Viocare's Chief Executive Officer (CEO), as the company's designated institutional official, will solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to the Investigator's company responsibilities for determination of FCOI.

a. An SFI is related to NIH-funded research if the CEO reasonably determines that the SFI:

- Could be affected by the NIH-funded research; or
- Is in an entity whose financial interest could be affected by the research.

b. An Investigator may be involved in making the determination of whether the SFI is related to NIH-funded research.

c. An FCOI exists when the CEO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. If so, then steps will be taken to determine what measures are needed to address the SFI identified in the SFI Disclosure Form. A management plan may be required to outline the terms, conditions, and restrictions, if any, to ensure compliance with this policy (see under *Enforcement Mechanisms*).

iii. In the case an SFI is determined to be an FCOI, the company will manage the FCOI at its discretion. This may include full public disclosure, appointment of an independent monitor, modification of the research plan, removal of the Investigator from the NIH-funded research, etc.

iv. Prior to the company's expenditure of NIH funds, the CEO must:

a. Review all Investigator SFI disclosures.
b. Determine if any SFIs are related to the NIH-funded research.
c. Determine if an FCOI exists, and if so
d. Develop and implement a management plan to manage the FCOI(s).

v. In the case a new Investigator begins to work on the NIH-funded research project or an existing Investigator discloses a new SFI, the CEO shall within 60 days review the SFI disclosures, determine whether an FCOI exists, and, if so, implement a management plan that specifies the actions that have been and will be taken to manage the FCOI.

vi. In the case the company identifies an SFI that was not disclosed timely by an Investigator or was not previously reviewed by the company during an ongoing NIH-funded research project, the CEO shall within 60 days review the SFI disclosures, determine whether an FCOI exists, and, if so, implement a management plan that specifies the actions that have been and will be taken to manage the FCOI going forward.

vii. The company will manage FCOIs of all Investigators, including those of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

3. Reporting Requirements to NIH

i. Viocare must send initial, annual, and revised FCOI reports, including all required information defined in 42 CFR Part 50 Subpart F, to the NIH via the eRA Commons FCOI Module for the Institution and its subrecipients, if applicable, as follows:

a. Prior to the expenditure of funds.
b. Within 60 days of identification for an Investigator who is newly participating in the project.
c. Within 60 days for new, or newly identified, FCOIs for existing Investigators.
d. At least annually, at the same time as when the company is required to submit the annual progress report. The annual report will provide the status of the FCOI and any changes to the management plan until completion of the project.
e. After a retrospective review to update a previously submitted report if new information is discovered following completion of the review.

ii. Viocare must notify NIH promptly if bias is found with the design, conduct, or reporting of NIH funded research. A Mitigation Report will be submitted to detail the action(s) taken to mitigate the effects of the bias in accordance with 42 CFR Part 50

Subpart F. The company will report all elements (e.g., entity name, Investigator with the FCOI, nature of the SFI(s), value of the SFI(s), etc.) as required by 42 CFR Part 50 Subpart F.

iii. Viocare must notify NIH promptly if an Investigator fails to comply with Viocare's FCOI policy or if an FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research. The company will take corrective action for noncompliance with Viocare's FCOI policy or the management plan.

4. Maintenance of Records

Viocare will maintain all FCOI-related records relating to all Investigator disclosures of financial interests and the company's review of and response to such disclosures (regardless of whether a disclosure resulted in the Institution's determination of an FCOI) and all actions under the Institution's policy or retrospective review, if applicable:

a. For at least 3 years from the date the final expenditure report is submitted to NIH. b. Or, where applicable, from other dates specified in 45 CFR 75.361.

5. Enforcement Mechanisms and Remedies and Noncompliance

i. The management plan may require one or more of the following actions (but not limited to) to be taken to manage, reduce, or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests
- Review of research protocols by independent reviewers
- Monitoring of research by independent reviewers
- Modification of research plan
- Disqualification from participation in all or a portion of the research funded
- Divesture of significant financial interests
- Severance of relationships that create actual or potential conflicts

All management plans are required to be signed by the Investigator and the CEO.
In the case an Investigator fails to comply with Viocare's FCOI policy or an FCOI management plan, employee sanctions, or other administrative actions will be implemented. These may include a letter of reprimand, restriction on the use of funds, loss of wages, or termination from the company.

ii. Viocare will perform a retrospective review within 120 days of a determination of noncompliance when either an SFI is not disclosed timely or not previously reviewed or when an FCOI is not identified or managed in a timely manner, including:

a. Failure by the Investigator to disclose a significant financial interest that is determined by the company to constitute an FCOI.
b. Failure by the company to review or manage an FCOI.
c. Failure by the Investigator to comply with the FCOI management plan.

iii. The retrospective review will be documented and will include, at minimum, the following:

a. Project number
b. Project title
c. PD/PI and contact information
d. Name of Investigator with the FCOI
e. Name of the entity with which the Investigator has an FCOI
f. Reasons for the retrospective review
g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed)
h. Findings of the review
i. Conclusions of the review

iv. In the case where a NIH-funded project includes clinical research with the purpose to evaluate the safety or effectiveness of Viocare's medical device or treatment and said NIH-funded project was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the company as required by 42 CFR Part 50 Subpart F, Viocare will require the Investigator involved to:

a. Disclose the FCOI in each public presentation of the results of the research, and b. Request an addendum to previously published presentations.

6. Subrecipient Requirements

i. When applicable, Viocare will comply with all subrecipient requirements according to 42 CFR 50.604(c) and NIH Grants Policy Statement 15.2.1.

ii. Viocare will establish, via a written agreement, whether the subrecipient will follow Viocare's FCOI policy or the FCOI policy of the subrecipient. In the case of the latter:

a. Viocare will obtain a certification from the subrecipient that its FCOI policy complies with 42 CFR Part 50 Subpart F.
b. Viocare will include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the company to report identified FCOIs to the NIH as required by 42 CFR Part 50 Subpart F.
c. Alternatively, Viocare will include in the written subrecipient agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the company to identify, manage, and report identified FCOIs to the NIH.

7. Public Accessibility Requirements

Viocare's FCOI policy will be stored on the Company's shared drive and on a publicly available website and will:

a. Include the minimum elements as provided in 42 CFR Part 50 Subpart F.
b. Be made available within 5 business days of a written request.
c. Be updated at least annually, but a response to a written request must be current.
d. Be updated within 60 days of a newly identified FCOI, but a response to a written request must be current.
e. Remain available for 3 years from the date the information was most recently updated.