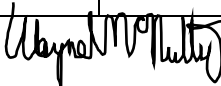




<b>Title:</b> Financial Conflicts of Interest in Public Health Service Funded Research – Nuvance Health	<b>Location/Owner:</b> Compliance
<b>Approved by:</b> Chief Compliance, Audit and Privacy Officer	<b>Version Effective Date:</b> October 6, 2021 <sup>1</sup>
<b>For Use At:</b>	<b>ID #s if needed:</b> COMP 5-1-21
<input checked="" type="checkbox"/> Nuvance Health System <sup>2</sup> <input checked="" type="checkbox"/> Danbury Hospital and New Milford (Campus) <input checked="" type="checkbox"/> Northern Dutchess Hospital <input checked="" type="checkbox"/> The Norwalk Hospital Association <input checked="" type="checkbox"/> Putnam Hospital Center <input checked="" type="checkbox"/> Sharon Hospital <input checked="" type="checkbox"/> Vassar Brothers Medical Center  <input checked="" type="checkbox"/> Nuvance Health Medical Practice CT, Inc. <input checked="" type="checkbox"/> Nuvance Health Medical Practice, P.C.	<input checked="" type="checkbox"/> Health Quest Systems, Inc. (“HQSI”) <input checked="" type="checkbox"/> Health Quest Home Care, Inc. <input checked="" type="checkbox"/> Hudson Valley Cardiovascular Practice, P.C. (“the Heart Center”) <input checked="" type="checkbox"/> Taconic ACO  <input checked="" type="checkbox"/> Eastern New York Medical Services, P.C. <input checked="" type="checkbox"/> Vassar Health Quest Medical Practice of Connecticut, Inc. <input checked="" type="checkbox"/> Northern Dutchess Residential Health Care Facility, Inc.
<input checked="" type="checkbox"/> Western Connecticut Health Network, Inc. (“WCHN”) <input checked="" type="checkbox"/> Western Connecticut Home Care, Inc. <input checked="" type="checkbox"/> Western Connecticut Health Network Physician Hospital Organization ACO, Inc.  <input type="checkbox"/> Other Entities Not Listed	
<b>Subject:</b> Policy on Financial Conflicts of Interest in Public Health Service Funded Research	<b>Page #:</b> Page 1 of 12
<b>Signature:</b> Chief Compliance, Audit and Privacy Officer  10/19/21	

**I. PURPOSE**

The purpose of this Policy on Financial Conflicts of Interest in Public Health Service Funded Research (the “Policy”)<sup>3</sup> is:

- A. To establish a written policy and procedural controls that enable Nuvance Health to identify, manage, and/or eliminate Financial Conflicts of Interest (“FCOI”) in research (“Research”) conducted at or on behalf of Nuvance Health when such Research is funded by the Public Health Service (“PHS”) of the U.S. Department of Health and Human Services (“HHS”). Establishing internal controls and enforcing such controls will enable reduction and/or elimination of FCOI so that the design, conduct, and reporting of Research at Nuvance Health will be free from bias that could result from an FCOI.

<sup>1</sup> This Policy was initially approved and deemed effective on October 6, 2021. On October 19, 2021, the Policy Face Sheet was amended for internal formatting, document management, and record keeping purposes. Except for: (i) this footnote and the footnotes 2 & 13, *infra*; (ii) the Nuvance logo being added to each page; and (iii) the final page number of the Policy changing from 11 pages to 12 pages as a result of the formatting mentioned herein, all other provisions set forth in this Policy remain unchanged.

<sup>2</sup> This Policy: (i) governs all PHS funded research at all Nuvance Health facilities, units, and entities as: (a) highlighted by this and the other marked checkboxes first provided above; and (b) set forth in Section III of this Policy; and (ii) applies to all Covered Individuals as set forth in Section IV of this Policy.

<sup>3</sup> This Policy does not replace any other Nuvance Health policy on Conflicts of Interest.

- B. To set organizational standards for compliance with the requirements set forth under 42 C.F.R. 50 §§ 601.1-607 (Promoting Objectivity in Research), 42 C.F.R. §§ 94.1-94.6 (Responsible Prospective Contractors), other applicable Federal and State laws, rules, regulations, standards, and other applicable Nuvance Health policies and procedures.

## II. POLICY STATEMENT

It is Nuvance Health’s policy to ensure compliance with all Federal and State laws, rules, regulations, and standards and adhere to established ethical principles governing scientific research. Nuvance Health believes that scientific discovery contributes to improved health care. In that regard, Nuvance Health promotes and encourages engagement in Research. Nuvance Health also believes that objectivity in the design, conduct, and reporting of Research is essential to ensuring that information health care providers rely upon to make critical decisions in caring for patients is free from bias resulting from an investigator’s FCOI.

Consistent with Nuvance Health’s policy enunciated above in this section, Nuvance Health promulgates its position concerning objectivity in Research by establishing this Policy. Nuvance Health also establishes this Policy to provide guidelines to Covered Individuals (defined in Section IV of this Policy (Applicability)) for compliance with related laws, rules, and regulations governing Research. Implementation of this Policy supports a reasonable expectation that Research conducted at or on behalf of Nuvance Health will be free from bias resulting from an investigator’s FCOI.

All Covered Individuals, who intend on engaging in Research at or on behalf of Nuvance Health, must adhere to this Policy and departmental standard operating procedures (“SOPs”) that implement the Policy. Adherence to this Policy will ensure compliance with regulations adopted by the federal PHS concerning grants, cooperative agreements, and research contracts.

## III. SCOPE

The procedures set forth in this Policy may be applied to non-PHS funded Research. This Policy covers all Nuvance Health facilities, units, and entities including, without limitation, the following as listed below:

- Nuvance Health
- Health Quest Systems, Inc. (“HQSI”)
- Western Connecticut Health Network, Inc. (“WCHN”)
- Danbury Hospital and its New Milford campus
- Eastern New York Medical Services, P.C.
- Health Quest Home Care, Inc.

- Nuvance Health Medical Practice, P.C.
- Hudson Valley Cardiovascular Practice, P.C. (“the Heart Center”)
- Vassar Health Quest Medical Practice of Connecticut, Inc.
- Northern Dutchess Hospital
- Northern Dutchess Residential Health Care Facility, Inc.
- The Norwalk Hospital Association
- Putnam Hospital
- Sharon Hospital
- Vassar Brothers Medical Center
- Western Connecticut Home Care, Inc.
- Western Connecticut Health Network Physician Hospital Organization ACO, Inc.
- Nuvance Health Medical Practice CT, Inc.
- Taconic ACO

#### IV. APPLICABILITY

A. This Policy applies to all Nuvance Health Workforce Members as well as Research Affiliates (hereinafter Workforce Members and Research Affiliates are collectively referred to as “Covered Individuals”) who apply for or receive on behalf of Nuvance Health, PHS Research funding. Covered Individuals under this Policy must also comply with the Nuvance Health Human Subjects Research Protections Policy (Policy Reference Number: COMP4-1-20) (“HSRP Policy”) when PHS-funded Research involves Human Subjects Research.<sup>4</sup> The HSRP Policy is available at the following [link](#).

- (i) *Workforce Member* – For purposes of this Policy, workforce members include any of the following individuals at Nuvance Health:
- Members of the Nuvance Health Board of Directors and the Boards of any Nuvance Health related entity listed in Section III (Scope) of this Policy;
  - Officers;
  - Employees;
  - Affiliates;

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<sup>4</sup> Human Subjects Research is defined in the HSRP Policy.

- Medical Staff Members;
  - Appointees;
  - Volunteers;
  - Personnel;
  - Interns;
  - Students;
  - Trainees; and
  - Any individual whose conduct is under the direct control of Nuvance Health, whether Nuvance Health pays such individual or not.
- (ii) *Research Affiliate* – For purposes of this Policy, this term means any non-workforce member contractor, subcontractor, vendor, agent or other third party that Nuvance Health engages to carryout, facilitate, assist, advise on or conduct PHS-funded Research or Research-related activities.
- (iii) *Covered Individual* – For purposes of this Policy, this term means any individual or entity that meets the definition of Workforce Member or Research Affiliate as described hereinabove and that intends on engaging in, conducting, or supporting Research at or on behalf of Nuvance Health.
- B. This Policy also applies whether Nuvance Health conducts or supports the conduct of Research funded or supported through an award or sub-award from a PHS agency (*e.g.*, cooperative research).

## V. DEFINITIONS

As used in this Policy, the terms provided in this section shall have the following meaning unless otherwise specifically defined elsewhere in the Policy:<sup>5</sup>

**Conflict of Interest:** A divergence between a Covered Individual’s private interests and his or her professional obligations to Nuvance Health such that an independent observer might reasonably question whether the Covered Individual’s professional actions or decisions are

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<sup>5</sup> The definition of certain terms is adapted from 42 C.F.R. 50.603.

determined by considerations of personal gain - financial or otherwise. An actual conflict of interest depends on the situation and the potential for the appearance of impropriety. It does not necessarily depend on the character or actions of the Covered Individual.

**Disclosure of Significant Financial Interests:** An investigator's disclosure to Nuvance Health of a financial interest that meets the definition of significant financial interests as defined in this Policy.

**eRACommons:** An online platform provided by the National Institutes of Health (“NIH”) Office of Extramural Research that contains information and resources to help grant applicants and grantees during the grants lifecycle, as well as help reviewers during the application review process. The platform can be accessed at the following [link](#).

**Financial Conflict of Interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

**Financial Conflict of Interests Report (FCOI Report):** A report submitted to the PHS Awarding Component using the eRACommons (for NIH-sponsored projects) or through the respective federal grantee portal (for all other PHS sponsored projects). The report provides a description of the nature of a Covered Individual’s Significant Financial Interest(s) (“SFI”), the SFI’s relationship to the Covered Research, and key elements of the Nuvance Health Management Plan.

**Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable.

**Investigator:** The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

**Institutional Responsibilities:** A Covered Individual’s professional responsibility towards Nuvance Health and as defined by Nuvance Health in this Policy, which may include 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.

**Manage:** Taking action(s) to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of Research will be free from bias.

**Management Plan:** An action plan to address an FCOI, which can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct, and reporting of Research will be free from bias.

**Management Plan Report:** A document that contains details of the Management Plan, including the conditions or restrictions imposed upon the Covered Individual in the conduct of the Research or in the relationship with the PHS Awarding Component.

**PHS:** The Public Health Service of the U.S. Department of Health and Human Services and any component thereof to which the authority of the Public Health Service may be delegated (*e.g.*, the NIH).

**PHS Awarding Component:** The organizational unit of the PHS that funds the Research.

**Research:** As defined at 2 C.F.R. Part 200, Subpart A, § 200.1,<sup>6</sup> it is a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. Research under this Policy also adopts the definition found at 42 C.F.R. § 50.603: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (*e.g.*, a published article, book or book chapter) and product development (*e.g.*, a diagnostic test or drug). The term also 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.

**Research Financial Conflicts of Interest Review Committee (“Research FCOI Review Committee”):** A Nuvance Health committee constituted for the purpose and functions of providing advice, guidance, and counsel to Research Leaders<sup>7</sup> on adjudication of actual or potential FCOI arising from disclosed SFI as defined in this Policy.

**Significant Financial Interest (“SFI”):** As adapted from 42 C.F.R. §50.603, this term is defined as a financial interest consisting of one or more of the following interests of the Covered Individual (and those of the Covered Individual’s spouse and dependent children) that reasonably appears to be related to the Covered Individual’s institutional responsibilities:

- With regard to any publicly traded entity, an 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

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<sup>6</sup> For purposes of this Policy, the definition of Research also encompasses the definition of *Human Subjects Research* and/or *Human Research* as defined in the Nuvance Health Human Subjects Research Policy available at the following [link](#).

<sup>7</sup> The term *Research Leaders* is defined in Section VII (Roles and Responsibilities) of this Policy.

authorship); equity interest (*e.g.*, 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, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure of an FCOI, when aggregated, exceeds \$5,000, or when the Covered Individual (or the Covered Individual'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.

The term “*significant financial interest*” does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by Nuvance Health to the Covered Individual if the Covered Individual is employed or otherwise appointed to a position by Nuvance Health. This includes:
  - Intellectual property rights assigned to Nuvance 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 Covered Individual 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;
  - 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.

**Subrecipient:** Another party who is assigned part of the obligations and tasks under a PHS grant, cooperative agreement, or research contract.



## VI. LIST OF ACRONYMS

C.F.R: Code of Federal Regulations  
FCOI: Financial Conflicts of Interest  
HHS: The U.S. Department of Health and Human Services  
HSRP: Human Subjects Research Protections  
PHS: Public Health Service  
SFI: Significant financial interest  
SOP: Standard operating procedures  
SCO: Senior Compliance Officer, Human Subjects Research and Academic Affairs  
HPA: Human Protections Administrator

## VII. ROLES AND RESPONSIBILITIES

Nuvance Health engages in Research in several clinical areas and has established leaders (“Research Leaders”) with responsibilities to oversee the conduct and administration of Research in assigned clinical area(s). Research Leaders are responsible for developing internal controls for implementation of this Policy. In collaboration with Nuvance Health’s Information Technology Administration, Research Leaders will also ensure adequacy of systems for supporting the administration of federal grants. More specifically, Research Leaders are responsible for oversight, management, and implementation of this Policy and associated procedures in their assigned area(s). Research Leaders may delegate certain responsibilities to qualified individuals within their department. Accountability for delegated responsibilities, however, remains with each Research Leader in each assigned area. The Research Leaders’ responsibilities include, but are not limited to, the following:

- A. Establishing and leading a Research Financial Conflicts of Interest Review Committee to advise Research Leaders on matters related to oversight and management of FCOI in PHS-funded Research.
- B. Clearly defining the role(s) of each Covered Individual and effectively assigning responsibilities in accordance with Element 8 of the Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards available at the following [link](#).
- C. Providing the Human Protections Administrator (“HPA”) with full and unfettered access to all documents, systems, and information to allow the HPA to perform his/her responsibilities - pursuant to the Terms of Nuvance Health’s FWAs and under applicable requirements of the Office for Human Research Protections of the U.S. Department of Health and Human Services. Such responsibilities include, but are not limited to, the HPA having comprehensive knowledge of all aspects of Nuvance Health’s system of protections for human subjects, as well as familiarity with the Nuvance Health’s commitments under the FWAs, and playing a key role in ensuring that Nuvance Health fulfill its responsibilities under the FWAs.



## VIII. PROCEDURES

- A. Each Research Leader will develop and distribute written SOPs to implement this Policy and the procedures set forth herein for assigned clinical area(s). The SOPs are part of the internal controls to assist Nuvance Health with complying consistently with rules and standards that apply to PHS extramural research awards. The Office of Inspector General has identified three major potential risk areas for recipients of NIH research awards: (1) Time and effort reporting, (2) properly allocating charges to award projects, and (3) reporting of financial support from other sources. The Research Leaders will ensure that the SOPs provide standardized processes for ensuring compliance with these risk areas. In addition, although not exhaustive of all potential risk areas, the SOPs must, at a minimum, also cover the following:
- (i) Development and implementation of regular, effective education and training for Covered Individuals;
  - (ii) Disclosure, review, monitoring, and auditing of perceived or actual FCOI;
  - (iii) Determination of conflict;
  - (iv) Management of perceived or actual FCOI;
  - (v) Reporting Requirements as required under 42 C.F.R. 50.604(h) and 42 C.F.R. 50.605(b);
  - (vi) Maintenance of Records;
  - (vii) Subrecipients monitoring; and
  - (viii) Confidentiality of disclosed information and documents.<sup>8</sup>
- B. Each Research Leader must provide an electronic copy of this Policy to all Covered Individuals both retrospectively and upon hire/affiliation.
- C. Nuvance Health is responsible to make the Policy available on the Nuvance Health Policy Manager Intranet site at the following [link](#).
- D. Each Research Leader will ensure that prior to applying for PHS funds, all Covered Individuals disclose to Nuvance Health any SFI related to their institutional responsibilities. Any new Covered Individual who plans to participate in Research subsequent to application for PHS funding or during the conduct of Research, must likewise disclose any SFI to Nuvance Health.
- E. At least annually thereafter, each Covered Individual must submit an updated disclosure of SFI to Nuvance Health or within thirty (30) days of a change, addition, or elimination of an SFI disclosed previously.

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<sup>8</sup> To the extent permitted by law, all disclosure forms, conflict management plans, and related information are to be kept confidential.

- F. Each Research Leader will ensure Covered Individuals continue to disclose any SFI related to their institutional responsibilities that might arise during the conduct of Research.
- G. Each Research Leader will ensure that Covered Individuals disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Covered Individual and not reimbursed to the Covered Individual so that the exact monetary value may not be readily ascertainable), related to the Covered Individual's 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.
- H. The SOPs must specify the details to be included in the disclosure of reimbursed or sponsored travel. The details will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Each Research Leader or his/her designee 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.

## **IX. PUBLIC POSTING OF POLICY**

In compliance with applicable federal regulations,<sup>9</sup> Nuvance Health will make this Policy publicly accessible on its Internet website.

## **X. RESPONDING TO PUBLIC REQUESTS FOR INFORMATION**

Prior to expending any fund under a PHS award, Research Leaders must respond to requests for public access to information about any perceived or actual FCOI with respect to a Research Leader's assigned research area of responsibilities. Research Leaders must respond in writing within five (5) business days from the receipt of such requests if: (i) the SFI was disclosed and is still held by the Covered Individual; (ii) Nuvance Health determines that the SFI is related to the PHS-funded Research; and (iii) Nuvance Health determines that the SFI is a FCOI. The response must be in writing, postmarked within five (5) business days, and include the Covered Individual's name, a description of the interest, and its dollar value range as required under applicable regulations.

## **XI. DISCIPLINARY ACTION AND OTHER SANCTIONS**

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<sup>9</sup> 42 C.F.R. §50.604.

The Compliance Office is responsible for enforcement of this Policy. Covered Individuals who fail to disclose a SFI that could be an FCOI under this Policy, fail to adhere to a prescribed Management Plan, or otherwise violate this Policy, shall be subject to progressive disciplinary action and other sanctions up to, and including, termination of employment, contract or other affiliation with Nuvance Health.<sup>10</sup>

## **XII. REPORTING**

Each Research Leader must ensure that, in addition to required reporting to the PHS Awarding Component and/or any other government agency, all suspected, reported,<sup>11</sup> or actual violations of this Policy and Procedures and associated SOPs are reported to the Senior Compliance Officer for Human Subjects Research and Academic Affairs (“SCO”),<sup>12</sup> as soon as practicable. In any event, all such violations must be reported to the SCO/HPA no later than two (2) business days after the violations were first reported to or discovered by any member of a Research Leader’s Department.

The SCO/HPA is responsible for prompt and proper response to detected offenses, such as the initiation of appropriate corrective action and preventive measures in accordance with the OIG’s Draft Compliance Program Guidance for Recipients of PHS Research Awards available at the following [link](#).

## **POLICY HISTORY**

**Originator:** Nuvance Health, Corporate Compliance and Ethics

**Supersedes:** None

**Original Implementation Date:** October 6, 2021

**Date Reviewed:** Not Applicable

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<sup>10</sup> The implementation of disciplinary action and other sanctions must be in accordance with applicable collective bargaining agreements, employment contracts, third-party contracts, medical staff bylaws, and internal human resources policies and procedures.


<sup>11</sup> This refers to any report made directly to anyone in a Research Leader’s department or of which a Research Leader becomes aware through any other means.

<sup>12</sup> The SCO also serves as HPA.

**Date Revised:** Not Applicable

**Note:** The authorized signature of the Chief Compliance, Audit and Privacy Officer on the first page of this document covers the entire Policy.

Wayne McNulty



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Chief Compliance, Audit & Privacy Officer &  
Policy Owner

October 19, 2021<sup>13</sup>  
Date

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<sup>13</sup> The Effective Date of this Policy is 10/6/21. See footnote 1, *supra*, for details.