Special Associate Compliance Officer – Human Subjects Research and Academic Affairs

Nuvance Health has a network of convenient hospital and outpatient locations —Danbury Hospital, New Milford Hospital, Norwalk Hospital, and Sharon Hospital in Connecticut, and Northern Dutchess Hospital, Putnam Hospital Center, and Vassar Brothers Medical Center in New York —plus multiple primary and specialty care physician practices locations, including The Heart Center, a leading provider of cardiology care, and two urgent care offices. Non-acute care is offered through various affiliates, including the Thompson House for rehabilitation and skilled nursing services, and the Home Care organizations.

Summary:

Purpose: The Special Associate Compliance Officer ("SACO") – Human Subjects Research and Academic Affairs role will support compliance primarily with respect to all research conducted at or supported by Nuvance Health and all medical education activities within Nuvance Health. The role will also support hospital compliance at a regional hospital. The role is necessary to ensure: (i) integrity and compliance with regulatory requirements and internal policies and procedures as they relate to clinical and non-clinical research and academic affairs activities (*e.g.*, Graduate and Undergraduate Medical Education); and (ii) the ongoing development, implementation, and continuous improvement of effective human subjects research compliance program aimed at preventing, detecting, and responding appropriately to clinical and non-clinical research and academic compliance-related risks.

Responsibilities:

The SACO shall be responsible for, among other compliance-related functions, the following:

1. Manage compliance matters and provide day-to-day compliance support and oversight in assigned areas of responsibility. For example (i) implementation and monitoring of the eight (8) elements of the Nuvance Health Corporate Compliance Program; (ii) developing and conducting compliance training and education initiatives; (iii) conducting internal investigations; (iv) performing auditing and monitoring activities; (v) performing risk identification and assessment activities; (vi) writing compliance policies and procedures; and (vii) documenting, monitoring, and responding to compliance reports, issues, incidents, complaints, queries, and requests for guidance.
2. Support the implementation of applicable laws, regulations, guidelines, policies, and procedures with respect to the operations of a compliance program covering the conduct of human subjects research and other scientific research related activities throughout Nuvance Health in the following specific areas and topics: (i) Office for Human Research Protections regulatory compliance ("OHRP"); (ii) Institutional Review Board ("IRB") compliance; (iii) IRB Authorization Agreement Standards & Monitoring; (iv) human subjects research protections program compliance; (v) research compliance and vulnerable subjects' protections; (vi) U.S. Food and Drug Administration ("FDA") compliance; (vii) clinical trials compliance; (viii)

biosafety and recombinant DNA; (ix) radiation safety; (x) genetic research including predisposition genetic testing; (xi) internal investigations (research-related reports); (xii) human subjects privacy and certificates of confidentiality; (xiii) research billing; (xiv) financial conflicts of interest in the research context; (xv) research grants compliance; (xvi) biological agents and toxins; (xvii) research integrity and research misconduct; (xviii) invention reporting; and (ix) export controls.

3. Support the implementation of applicable laws, regulations, guidelines, policies, and procedures with respect to the operations of a compliance program covering medical education throughout Nuvance Health in the following specific areas: (i) Accreditation Council for Graduate Medical Education requirements; (ii) Medical Teaching Rule compliance; and (iii) academic or student misconduct.

4. Write or support the writing and/or review of reports and communications for submission to regulatory agencies (*e.g.*, U.S. Department of Health & Human Services ("HHS"), FDA), Industries (*e.g.*, pharmaceutical and medical devices), federal sponsors (*e.g.*, National Institutes of Health, National Cancer Institute, Department of Defense, or other federal agencies that have adopted the Common Rule), and/or cooperative groups (*e.g.*, Eastern Cooperative Oncology Group, NRG Oncology).

5. Lead and/or conduct complex investigations from initiation to completion and demonstrate critical thinking and analytical skills. For example, layout investigatory scope and plan for the execution of investigation, apply the correct regulatory standards, spot gaps in study records, apply proper logic to analyses, synthesize evidence from multiple sources, and draw evidence-based inferences.

6. Write or assist the SCO with writing memoranda, developing PowerPoint presentations, and interim and final investigative reports for presentation to executives.

7. Support Nuvance Health's standards concerning the dissemination of scientific communications to ensure compliance with the International Committee of Medical Journal Editors (ICJME) standards, the CARE Guidelines for Case Reports, and Nuvance Health's policy regarding proprietary information and data derived through Nuvance Health-funded or supported research and development.

8. Support the SCO by working with key stakeholders to conduct periodic reviews of policies and procedures associated with medical education and the conduct of clinical and non-clinical research to ensure continued compliance with applicable legal and regulatory requirements and other applicable standards.

9. Develop or support the development of training materials and conduct training of Nuvance Health Workforce Members.

10. Support the Executive Compliance Committee - Subcommittee on Human Subjects Research ("ECC-HSR"). For example, prepare meeting agenda, take minutes at meetings and

perform operational or administrative tasks to support the operations of the ECC-HSR Subcommittee.

11. Develop reporting on key compliance indicators, benchmarks, scorecards, and dashboards related to research compliance and integrity.

12. Develop controls that foster an environment that promotes the responsible conduct of research in compliance with standards set forth by the Office of Research Integrity ("ORI").

13. Work with a cross-functional team (e.g., Marketing, Legal, Risk Management) to support review of research-related press releases and other externally-facing materials prior to dissemination.

14. Assist the SCO with preparing written memoranda, PowerPoint presentations, dashboards, and other compliance metrics regarding Nuvance Health's human subjects research, academic activities, and hospital compliance program.

15. Perform other compliance-related tasks as directed by the SCO or other supervising compliance officer.

16. Maintain and model Nuvance Health values.

17. Demonstrate regular, reliable, and predictable attendance.

18. Perform other duties as required.

Leadership Competencies:

·**Influencing skills –** The SACO must: (i) effectively communicate a culture of compliance, ethics, professionalism, and zero tolerance for retaliatory conduct; (ii) engage the Nuvance Health workforce, business affiliates, and agents in a collaborative manner to facilitate the development of internal controls, encourage the reporting of compliance issues and concerns, (iii) assist the SCO with developing Nuvance Health-wide training and education initiatives; and (iii) display independence and an ability to lead others when conducting job functions.

·**Managing complexity –** The latitude of decision-making with regard to projects assigned to the SACO will range from a fair amount to a considerable amount depending on the task at hand and the corresponding input and consultation required by the SCO. The SACO will have considerable control over results, which will be reviewed by the SCO.

·**Relationship-building through integrity and trust –** the SACO shall carry out his/her responsibilities and functions in a manner that:

ØBuilds trust and confidence throughout the Corporate Compliance Office and Nuvance Health;

ØExemplifies the highest level of integrity, independence, competence, and diligence in carrying out his/her responsibilities;

ØMaintains open lines of communication with fellow Corporate Compliance Office staff members, as well as Nuvance Health workforce members, business affiliates, and agents;

ØDemonstrates the ability to work in a collaborative manner with fellow compliance team members and Nuvance Health leadership.

Functional/Technical Skills Requirements:

·***Health Care Expertise***- Through a combination of prior transferable work experience, professional development activities, and education, the SACO must be able to fully satisfy the following requirements:

ØPossess a significant level of knowledge and understanding of compliance program legal requirements and best practices;

ØPossess knowledge of federal and state regulations concerning human subjects research (e.g., regulations from HHS, FDA, ORI, Good Clinical Practice (ICH-GCP E6-R2), and related compliance program best practices; and

ØPossess a substantial level of knowledge and understanding of how to appropriately conduct and document internal investigations.

- Strategic/Analytical Capability- The SACO shall have the following key skills:
  ØExperience conducting clinical research investigations, including interviewing fact witnesses and investigatory subjects and reviewing regulatory binders and source documents;

  ØAbility to independently assess regulatory and other reporting requirements and support operational partners in preparing applicable reports to parties (*e.g.*, FDA, OHRP, ORI, states, industry sponsors, cooperatives, grantors).

  ØExcellent written and verbal communication skills, analytical and critical thinking skills, attention to detail, and project management skills.

- Information Technology – The SACO shall have advanced computer skills including a substantial understanding of and ability to use: Microsoft PowerPoint, Excel, and Word.

Education and Experience:

A Bachelor's Degree with at least four (4) years of job-related experience or a Master's Degree with at least three (3) years of job-related experience is required. A Bachelor's, Master's, or Doctorate Degree in healthcare compliance, clinical trial management, health sciences, public

health or health services administration, public administration, human resources management, business administration, organizational effectiveness, or management is a plus.

License, Registration, or Certification Requirements:

The successful candidate shall hold the following certifications and/or licenses within twelve (12) months of appointment:

- Certification in Healthcare Research Compliance ("CHRC") from the Compliance Certification Board or Certification as a clinical research professional from the Association of Clinical Research Professionals ("ACRP-CP").

Location: Summit-100 Reserve Rd

Work Type: Full-Time

Standard Hours: 40.00

FTE: 1.000000

Work Schedule: Day 8

Work Shift: Monday through Friday (hybrid remote)

Org Unit: 239

Department: Corporate Compliance

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(518) 487-8258 or send your resume to recruitment@hccconnections.com