JOB DESCRIPTION

Title: **Compliance Investigator, Human Subjects Research & Academic Affairs**

Reports To: **Senior Compliance Officer ("SCO"), Human Subjects Research & Academic Affairs**

Department: **Corporate Compliance**

FLSA Status: **Non-employee (Contingent Worker)**

Purpose: The Compliance Investigator ("CI") will support the Nuvance Health Corporate Compliance Program, Division of Human Subjects Research & Academic Affairs with primarily performing regulatory reviews and conducting required compliance investigations with respect to assigned sponsored and/or investigator-initiated clinical trials, other scientific research studies, and/or research-related activities that are either conducted at or supported by any Nuvance Health affiliate. Compliance reviews and investigations may also include activities in the Graduate Medical Education program within the Nuvance Health Learning Institute, the Nuvance Health Global Health Program, and the Nuvance Health Undergraduate Medical Education in Medical Affairs. The role is necessary to ensure: (i) compliance with regulatory requirements and internal policies and procedures related to clinical and non-clinical research and academic affairs activities; and (ii) the prompt and effective investigation of potential offenses and the development of corrective action plans in response to confirmed violations.

Essential Responsibilities

At the direction and under the oversight of the SCO, perform the following:

1. Apply proficient knowledge of and experience in interpreting applicable ethical principles, regulations, guidelines, policies, procedures related to conducting research and academic affairs compliance investigations to ensure that the integrity of investigations is preserved and analysis and interpretation of information collected yield to outcomes that support evidence-based findings.

2. Carry out investigations from initiation to completion. This includes, but is not limited to:
   a. investigation planning;
   b. creation and maintenance of interview notes and witness logs;

c. preparation of notices of investigation to workforce members;
d. preparation of hold and preservation notices;
e. scheduling of witness interviews;
f. reviewing of regulatory binders, source documents (where applicable), and study participant files;
g. using advanced interviewing skills to develop interview questions and conduct interviews of workforce members; and
h. collection and analysis of data from multiple sources and analysis and assessment of information.

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

4. Write or support the writing and/or review of reports and communications for submission to regulatory agencies (e.g., HHS, FDA), Industry (e.g., pharmaceutical and medical device), federal sponsors (e.g., NIH, NCI, DOD), and/or cooperative groups (e.g., ECOG, NRG).

5. Develop or support the development of notices to participants in research (as necessary).

6. Engage and collaborate with IT, HR, and other cross-functional operational partners (as necessary).

7. Engage Subject Matter Experts in cross-functional departments to discuss specific topics and gather meaningful information or secure written evidence to support investigatory activities.

8. Demonstrate critical thinking and analytical skills. For example, lay out investigatory scope and plan for 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.

9. Perform other compliance-related tasks related to investigative matters as directed by the Chief Compliance Officer (CCO) and/or the SCO.

10. Demonstrate discretion and ability to maintain confidentiality of sensitive matters.

11. Maintain and model Nuvance Health's values.

12. Demonstrate regular, reliable, and predictable attendance.

13. Perform other duties related to research compliance reviews and investigations as required.

Education and Experience Requirements:

Bachelor's Degree with at least three (3) years of work-related experience or a master's degree with at least two (2) years of job-related experience is required (preferably in research or business administration/management, public health or health services administration), or equivalent experience. Previous experience conducting research compliance investigations at a research site within a health care system setting or within the Quality Compliance or Clinical Operations function of a pharmaceutical or medical device company or comparable setting(s) is required. Completion of paralegal studies is a plus.

Minimum Knowledge, Skills and Abilities Requirements:

The ideal candidate possesses the following:

- Excellent writing skills, the ability to think critically, demonstrates sound judgment, and approaches work strategically with the goal of reducing inefficiencies, maximizing effectiveness, and delivering high quality work products.

- Proficient knowledge of ethical principles related to human subjects research.

- Proficient knowledge of federal and state regulations concerning human subjects research (e.g., regulations from the U.S. Department of Health & Human Services-Office for Human Research Protections, the U.S. Food and Drug Administration, the New York State Department of Health, and Good Clinical Practice (ICH-GCP E6-R2), and related compliance programs best practices.

- Knowledge about how a research study is conducted and associated risk areas (e.g., study management, IRB process, informed consent, vulnerable subjects, conflicts of

interest, IRB approval lapses, reporting of unanticipated problems, serious or continuing noncompliance, HIPAA privacy and confidential rule).

- Advanced knowledge in and experience with using MS Office Suite.

License, Registration, or Certification Requirements:

- Certification in Healthcare Research Compliance ("CHRC" designation) from the Compliance Certification Board or Certification as a clinical research professional from the Association of Clinical Research Professional (ACRP) is desirable but not required.