

Chief Research Compliance Officer New York State Psychiatric Institute New York, NY

THE SEARCH

The New York State Psychiatric Institute (NYSPI) seeks a strategic and collaborative leader to serve as its inaugural Chief Research Compliance Officer (CRCO). Reporting directly to the Director of Research, the CRCO will oversee compliance activities related to human subjects protections, animal welfare, conflicts of interest, biosafety, research privacy and security, investigational drugs and devices, export controls, and research integrity.

Since its inception, NYSPI has been at the forefront of psychiatry. Among its accomplishments are: the discovery of the spirochetal origin of general paresis; the earliest use of lithium in the United States; the first data describing a genetic predisposition to schizophrenia; leadership in the discovery of the genes causing Huntington's and Wilson's disease; and the development of the DSM-III, DSM III-R, DSM-IV, and DSM-5-TR. This is an incredible opportunity to help create strong regulatory systems to support and contribute to the vital work and research at one of the oldest and largest institutes of its kind in the country.

The successful candidate will be ready to partner across the Institute to ensure the fastidious oversight of the full complement of NYSPI's research operations and all HRPP and IRB activities. The CRCO will work to optimize research operations, improve compliance, and support infrastructure improvements, including the identification and implementation of best practices to help restart and reinvigorate NYSPI's research enterprise. To ensure the compliance and longevity of NYSPI's research apparatus, the CRCO will act as an advisor and a visible leader across the full research portfolio, guiding best practices and creating an institution-wide culture of compliance that is collaborative rather than punitive. Further, this leader will need to keep themselves informed about the changing federal and state regulatory landscape and anticipate shifts in policy to keep NYSPI at the forefront of compliance. This is an exciting opportunity for a leader to help create a strong and attentive compliance infrastructure in order for NYSPI's important research to continue unimpeded.

The New York State Psychiatric Institute has retained Isaacson, Miller, a national executive search firm, to assist in this recruitment. All inquiries, nominations, and applications should be directed to the search firm as indicated at the end of this document.

ABOUT NEW YORK STATE PSYCHIATRIC INSTITUTE

The New York State Psychiatric Institute, established in 1895, was one of the first institutions in the United States to integrate teaching, research, and therapeutic approaches to the care of patients with mental illnesses. In 1921, the Presbyterian Hospital formed an alliance with Columbia University's College of Physicians and Surgeons, leading to the formation of the Columbia University Medical Center. This affiliation allowed for coordinating the care of the sick with the educational and research programs of the College. Following that alliance, in 1925, NYSPI became affiliated with Presbyterian Hospital and Columbia University, adding general hospital facilities to the Institute's psychiatric services and research laboratories. Today, NYSPI is owned and operated by the State of New York under the supervision of the Office of Mental Health.

The NYSPI treatment, training, and research facilities were supplemented in 1983 by a 14-floor Psychiatric Research Building, the Kolb Annex. NYSPI was further modernized in 1998 by the opening of a new hospital building to replace the original one. Overlooking the Hudson River and George Washington Bridge, the new Herbert Pardes Building of the Psychiatric Institute provides a state-of-the art environment for patient care, education, and research. The approximately 320,000 square feet offer space for 55 inpatient beds, specialized outpatient research clinics, educational facilities, and research laboratories. Walkway bridges to and from the Kolb Annex and New York-Presbyterian Hospital provide comfortable and efficient all-weather avenues for patient and staff travel within the Columbia University Irving Medical Center.

Through the years, distinguished figures in American psychiatry have served as directors of the Psychiatric Institute, including Drs. Ira Van Gieson, Adolph Meyer, August Hoch, Lawrence Kolb, Edward Sachar, and Herbert Pardes. The Institute is the flagship for the Columbia University Department of Psychiatry, for which it is the primary location of research and educational activities.

The New York State Psychiatric Institute consists of more than 400 faculty, many of whom are part of Columbia University's Department of Psychiatry, and more than 2,000 professional staff. The NYSPI offers a diverse set of clinical services for individuals with schizophrenia, depression, eating disorders, substance abuse, anxiety disorders, trauma and stressor-related disorders, and other conditions. The NYSPI also offers a wide range of educational and training programs for medical students, residents, fellows, practicing physicians as well as professionals in related disciplines such as clinical psychology, nursing, and social work.

RESEARCH AT NYSPI

Research at NYSPI covers a wealth of subjects ranging from basic neurobiology to clinical, epidemiological, child psychiatry, and services-related studies. In addition, there are a wide variety of ongoing clinical trials in disorders ranging from depression to schizophrenia to borderline personality disorder. These clinical trials provide treatment in the context of ongoing research studies, generally at no cost to the patient.

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There are also numerous human research studies that examine patterns, risk factors, cognitive function, and the neurobiology of mental illness but do not provide treatment.

Currently almost 500 externally funded studies with budgets totaling \$86 million are underway, most of them supported by the federal government.

You can view some current research studies here.

NYSPI LEADERSHIP

Dr. Joshua Gordon, Director

Joshua A. Gordon, MD, PhD, has been named the next chair of the Department of Psychiatry at Columbia University Vagelos College of Physicians and Surgeons (VP&S), director of the New York State Psychiatric Institute, and psychiatrist-in-chief of the New York-Presbyterian campus at CUIMC. His appointments are effective as of Aug. 15, 2024.

This appointment is a homecoming for Gordon, who served on the Columbia faculty from 2004 to 2016, when he was named director of the National Institute of Mental Health (NIMH). A respected neuroscientist, psychiatrist, educator, and administrator with an international reputation, Gordon also is chief of the integrative neuroscience section at the National Institute of Neurological Disorders and Stroke. Gordon initially joined VP&S in 2004 following completion of his medical residency and research fellowship at Columbia. While at Columbia, he directed an active, NIH-funded research program in basic neuroscience relevant to mental illness, taught students and residents, and maintained a part-time practice in clinical psychiatry. He also served as associate director of the adult psychiatry residency program, where he oversaw the neuroscience curriculum and administered research programs for residents, including the Leon Levy Foundation Psychiatric Neuroscience Fellowship Program.

In September 2016, Gordon was appointed director of NIMH, where he oversaw an institution of more than 1,000 employees and a \$2 billion annual budget, developed national scientific priorities in mental health research, and expanded efforts to support and mentor early career scientists from diverse backgrounds. Gordon has received numerous awards and honors and was elected to the National Academy of Medicine in 2018. He earned his MD and PhD degrees at the University of California, San Francisco.

You can read more about NYSPI's administrative leadership here.

THE ROLE OF THE CHIEF RESEARCH COMPLIANCE OFFICER

The main objective of the Chief Research Compliance Officer is to educate and guide researchers, faculty, and staff in the compliant conduct of human subject research and to monitor and evaluate the

coordination of internal and external government compliance and privacy investigations or reviews to create a culture of effortless compliance. In compliance with recent federal oversight and guidance, most of NYSPI's human research is currently on pause. As such, in both the short- and long-term, the CRCO must be diligent in assessing and identifying potential areas of system-wide compliance risk, help set priorities for internal reviews, assist representatives from sponsors and federal agencies conducting audits, and review and approve identified corrective action as a result. To be successful, the CRCO will quickly need to build and maintain credibility as a trusted partner and advisor to all members of the NYSPI community and, at the same time, be regarded as an objective, impartial, and determined steward of the Institute's research mission and obligations. Additionally, the CRCO will act as a representative for NYSPI's Director of Research to coordinate with institutional units regarding the research compliance program responsibilities and obligations.

As a visible institutional leader, the CRCO will mentor and monitor NYSPI's IRB and HRPP directors in steering operations and reviewing the protocol review processes, HRPP/IRB policies and procedures, and protocol tracking integrity performed by the IRB to ensure full compliance with federal regulations and guidance. In partnership with other HRPP leaders, the CRCO will work to develop and implement written policies and procedures that foster and enhance compliance in research involving human subjects. Once established, the CRCO will proactively continue to develop new policies, programs, and procedures as needed to ensure that research compliance keeps pace with a dynamic regulatory environment and that the administration and constituents are kept aware of regulatory changes to mitigate unnecessary exposure to risk. Inherent to this work will be monitoring changes in federal regulations and state laws and, in turn, advising and educating institutional leadership, investigators, and staff on their impact on research compliance and human subject protection. The CRCO will ensure that research leaders and managers maintain continuously updated knowledge of current federal, state, and local regulations regarding research, including compliance with all required training and/or certifications. Further, they will evaluate compliance data requests, dashboards, and scorecards, and implement new systems and potentially new technologies to help guide, improve upon, and leverage compliance data including reports requested by federal agencies.

KEY OPPORTUNITIES AND CHALLENGES

In particular, the Chief Research Compliance Officer will be charged with addressing the following opportunities and challenges:

- Collaboratively lead and manage the necessary changes and corrective actions to reinstate human research activity at NYSPI, including compliance with the OHRP, federal and state regulatory requirements, and institutional policies and procedures.
- Identify potential areas of system-wide research compliance risk and set priorities for internal reviews
- Ensure that research leaders and managers maintain continuously updated knowledge of current federal, state, and local regulations regarding research, including compliance with all required

trainings and/or certifications.

- Advise on the development and implementation of policies and procedures that best facilitate
 the oversight and compliance of research and human subject protections.
- Build and maintain collegial relationships with leaders and researchers across NYSPI, RFMH, OMH,
 Columbia, and beyond to create a culture of effortless compliance.

QUALIFICATIONS AND CHARACTERISTICS

The successful candidate will bring many of the following qualifications and qualities:

- An M.A./M.S. Degree or equivalent related experience;
- A minimum of seven years of experience in research compliance oversight in an academic medical center;
- At least one of the following: Certified IRB Professional (CIP), Certified Research Associate (CRA), Certified Clinical Research Associate (CCRA), or equivalent training or experience (such as an attorney or auditor with the necessary experience);
- Comprehensive knowledge of the ethical issues, state laws, policies, and regulations pertaining to the protection of human research subjects;
- Demonstrated experience in guiding organizational compliance strategy including implementing new initiatives and protocols;
- Prior experience and proven success in establishing a culture of compliance across research units:
- Demonstrated understanding of, and commitment to, working as a member of the NYSPI's leadership team;
- Effective interpersonal skills and ability to build strong inter-organizational relationships;
- Excellent analytical and independent problem-solving skills, organizational, coordination, and prioritization skills;
- Ability to synthesize information from multiple sources to produce succinct, detail-oriented, and accurate documents, policies, reports, and announcements.

LOCATION AND COMPENSATION

The Chief Research Compliance Officer will work onsite at NYSPI located at 1051 Riverside Drive, New York, NY 10032. The compensation range for this role is set between \$167,905 - \$210,000.

APPLICATIONS, INQUIRIES, AND NOMINATIONS

Confidential inquiries, nominations/referrals, and/or resumes with cover letters may be submitted electronically to:

Rebecca Kennedy (she/her), Partner Angelo Alexander (they/them), Senior Associate

Cortnee Bollard (they/them), Senior Search Coordinator

https://www.imsearch.com/open-searches/new-york-state-psychiatric-institute/chief-researchcompliance-officer

Applicants with lived mental health experience are encouraged to apply. RFMH is deeply committed to supporting underserved individuals, organizations, and communities. To this end, RFMH is focused on implementing activities and initiatives to reduce disparities in access, quality, and treatment outcomes for underserved populations. A critical component of these efforts is ensuring that RFMH is a diverse and inclusive workplace where all employees' unique attributes and skills are valued and utilized to support the mission of the Agency. RFMH is an equal opportunity/affirmative action employer.