

Institutional Review Board Director New York State Psychiatric Institute New York, NY

## THE SEARCH

The New York State Psychiatric Institute (NYSPI) seeks a collaborative, strategic, and systems-oriented leader to serve as its next Institutional Review Board (IRB) Director (Director). Reporting to the Director of Research at NYSPI and Chief Medical Officer of the Office of Mental Health (OMH), the Director will be responsible for designing, establishing, and maintaining the IRB staffing and organizational structure to effectively accomplish the HRPP program function. This is an incredible opportunity to help create robust and lasting regulatory systems to support and contribute to the future of clinical care for those with mental illness.

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.

As a part of the larger New York State Office of Mental Health (OMH) Human Research Protection Program (HRPP), the Director and, by extension, the NYSPI IRB, is responsible for assessing all downstate OMH human subject projects requiring expedited or full board review. The incumbent will: direct the IRB staff and office; provide regulatory guidance to the IRB Chair, members, investigators, and Institute leadership; provide support and guidance to investigators in the design and submission of research protocols; and oversee the electronic protocol submission and management system. In coordinator with other directors, this individual will be responsible for the coordination of education and training to promote the highest standards for the conduct of human subjects research. Additionally, the Director will work closely with the Director of Regulatory Policy and the Nathan S. Kline Institute for Psychiatric Research's (NKI) IRB management to assume responsibility for the interpretation and deployment of policies that govern the OMH IRBs at NKI and NYSPI.

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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.

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#### **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. 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, Incoming 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 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 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.

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

#### THE ROLE OF THE IRB DIRECTOR

In compliance with recent federal oversight and guidance, NYSPI leadership has recently reconstituted its IRB, although most NYSPI human research is currently on pause. Until a long-term structure is in place, NYSPI is reliant on strong shared oversight and governance across the entire organization. Given that, the Director will need to be a strong communicator who can translate information across different constituency groups to maintain and promote an ethics-centered research climate at NYSPI. In the short term, the Director will work alongside institutional leaders to achieve the proper auditing and compliance measures in order to resume regular research activity. As such, the Director will need to be an adept change manager with the ability to maintain the core IRB work while being responsive to internal and external organizational needs. In the long term, they will work closely with IRB analysts, chairs, and the newly reconstituted board to ensure that review processes align with Good Clinical Practice (GCP), and institutional, state, and federal regulations. An adept convener and collaborator, the Director must be able to lead discussions among the board while maintaining a focus on the research and regulatory issues at hand.

The IRB Director will lead a team of 6 IRB analysts and a newly reconstituted Board who support and serve the research mission and activities of the Human Research Protections Program, ensuring the safety and welfare of all human participants in NYSPI research. In order to do so, they must invest in the professional development and growth of their team to ensure that IRB processes are on the cutting edge of the practice and responsive to the current and future regulatory landscape. Further, the Director also serves as the primary regulatory resource for clinicians, sponsors, and study teams in providing guidance on regulatory statuses, approvals, and instructions regarding patient consent. Working with the Director of the Human Research Protections Program, they will help to create, instill, and maintain a culture of mutual trust, effortless compliance, and continuous improvement across the entire institution.

#### **KEY OPPORTUNITIES AND CHALLENGES**

In particular, the next IRB Director will be charged with addressing the following opportunities and challenges:

- Collaboratively help 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.
- Build, support, and retain a team high-performing IRB Analysts.
- Convene and guide a rigorous and process-minded Institutional Review Board.
- Optimize the operations and systems that support the protection of human research participants, including the development and implementation of IRB policies and procedures in partnership with the Director of HRPP.

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- Build and maintain collegial relationships with leaders and researchers across NYSPI, RFMH, OMH, Columbia, and beyond, cultivating a culture of compliance.
- Proactively monitor, identify, and respond to emerging challenges in the field of human research protection and maintain updated knowledge of guidance and regulations.

# 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 a Human Research Protections Program setting at an academic medical center, with supervisory or management experience;
- Prior experience and proven success in leading an Institutional Review Board;
- Prior success leading and managing staff within a complex organization;
- Demonstrated understanding of, and commitment to, working as a member of the NYSPI's leadership team;
- Demonstrated knowledge of the ethical issues, state laws, policies, and regulations pertaining to the protection of human research subjects;
- 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 IRB Director will work onsite at NYSPI located at 1051 Riverside Drive, New York, NY 10032. The compensation range for this role is set between \$120,675 – \$143,496.

## **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 Isaacson, Miller 263 Summer St. Boston, MA 02210

https://www.imsearch.com/open-searches/new-york-state-psychiatric-institute/institutional-reviewboard-director IRB Director NYSPI Page 6 of 6

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.