

Director, Human Research Protections Program New York State Psychiatric Institute New York, New York

THE SEARCH

The New York State Psychiatric Institute (NYSPI) seeks an experienced and highly motivated leader to serve as the next Director of its Human Research Protections Program (HRPP). This is an incredible opportunity to manage, oversee, and ensure the highest standards of compliance within a leading research institute contributing to the clinical care and understanding of patients with mental illness. Reporting to the Director of Research at NYSPI and Chief Medical Officer of the Office of Mental Health (OMH), the HRPP Director will lead all administrative and compliance activities for NYSPI's HRPP and will be responsible for fulfilling NYSPI's obligations to promote ethical conduct of research and protect the rights of human research subjects. The ideal individual will have experience operating human research protection activities in a similar environment to NYSPI, a deep understanding of current and emerging regulatory requirements, and a proven ability to build and maintain collegial relationships with a diverse group of stakeholders.

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 Director will be a well-respected leader in research administration and a strategic thinker who displays a passion for supporting research. The Director will work closely with other leaders within NYSPI, the Research Foundation for Mental Hygiene (RFMH), Columbia University (CU), the academic partner of NYSPI, and the Office of Mental Health to oversee all aspects of human research and inspire a culture of high attention to and prioritization of compliance. This individual will be an experienced manager, ready to inspire change within the organization, and build and shape a robust human research protections program within NYSPI. The mission of the NYSPI Human Research Protections Program is to promote the welfare and rights of human research participants; to facilitate excellence in the conduct of all human research activities regardless of regulatory risk; to provide timely and high-quality IRB review in partnership with the IRB Director; to oversee monitoring of ongoing studies; and to manage ongoing education and training of investigators and HRPP staff. In fulfilling this mission, the Director will lead the charge in meeting all regulatory and ethical obligations pertaining to human research participants, and routinely collaborate across other institutional offices on this important work.

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. 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.

A list of some current research studies is available <u>here</u>.

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.

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

THE ROLE OF THE DIRECTOR

The HRPP Director will collaboratively lead all employees who support and serve the research protection mission and activities of the Human Research Protections Program, ensuring the safety and welfare of all human participants in NYSPI research. Most NYSPI human research is currently on pause, and the Director's first undertaking will be to achieve the proper auditing and compliance measures in order to resume regular research activity. Overall, the Director will be called to help move complex issues to resolution, often by consulting with multiple units across the organization and by complying with state and national policies and laws. By taking responsibility for the overall development, implementation, and continuous quality improvement of human research protection compliance, the Director will coordinate all HRPP activities across all offices and staff within NYSPI and RFMH that have roles in protecting human research participants. As such, the Director will manage and oversee all research protection activities, including compliance reporting; data security and privacy protection (HIPAA); monitoring of approved research studies; education and training of IRB personnel and research investigators; HRPP policy development; and IRB operations pertaining to the review and approval of research. A well-respected leader who will work within the leadership matrix of NYSPI, the Director will oversee a team of 20 administrative professionals and will be tasked with building the unit to ensure all human research compliance activities are properly supported. The successful candidate will leverage the skills and expertise of their team, enhance the human research protections program, establish best practices, and guide the NYSPI to achieve AAHRPP accreditation in the near future.

OPPORTUNITIES AND CHALLENGES

The success of the next HRPP Director will be determined by how well they meet the following opportunities and challenges:

- Lead and manage the necessary changes and corrective actions to reinstate human research activity at NYSPI, including compliance with the Office for Human Research Protections, federal and state regulatory requirements, and institutional policies and procedures.
- Build, support, and retain a high-performing HRPP team.
- Optimize the operations and systems that support the protection of human research participants, including overseeing the development and implementation of IRB policies and procedures in partnership with the IRB Director and IRB Chair.
- Oversee and maintain quality assurance, improvement, and monitoring functions of the HRPP, including for-cause audits of research protocols and investigation of potential non-compliance.
- Ensure that comprehensive human research protection education and training are available and completed by investigators, key study personnel, the Institutional Signatory Official, and all employees who participate in the HRPP.
- 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.
- Provide guidance to the IRB, researchers, research staff, and administrators regarding the interpretation and application of regulations, laws, and policies and communicate pertinent information and changes to staff and institutional leadership in a timely manner.

QUALIFICATIONS AND EXPERIENCE

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

- An M.A./M.S. Degree or equivalent related experience, with certified IRB Professional (CIP) certification preferred;
- A minimum of seven years of experience in a Human Research Protections Program setting at an academic medical center, with supervisory or management experience;
- Demonstrated understanding of federal regulations and agency guidelines for human subjects, including HHS, FDA, HIPAA, FERPA, and other agency-specific regulations (such as DOD, DoED, NIH, etc.);
- Managerial experience and proven success in leading an Institutional Review Board;
- Proven leadership and management skills, including establishing and measuring goals and objectives, optimizing and monitoring work assignments, facilitating career development, prioritizing staff retention, and managing change;
- Ability to formulate broad policy recommendations for NYSPI and RFHM regarding human research protection issues, including educational and training requirements for IRB members, staff, and investigators;
- Ability to apply flexibility and creativity to a complex array of compliance issues;
- Skill in establishing relationships with human subjects and regulatory agencies on state and federal levels;
- Excellent analytical and independent problem-solving skills as well as 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 HRPP Director 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 - \$190,003.

ISAACSON, MILLER

TO APPLY

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

Rebecca Kennedy, Partner (she/her) Lauren Wilkes, Senior Associate (she/her) Cortnee Bollard, Senior Search Coordinator (they/them) Isaacson, Miller 263 Summer St. Boston, MA 02210 <u>https://www.imsearch.com/open-searches/new-york-state-psychiatric-institute/director-human-research-protections-program</u>

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.