

VACANCY ANNOUNCEMENT

Department of Health and Human Services National Institutes of Health Clinical Center

Physician (Regulatory Affairs) Senior Clinician/Senior Clinician (HS) GP-602-15

Clinical Center: The NIH Clinical Center (CC) is the research hospital of the NIH. It provides medical and support services for patients participating in human subjects research protocols. In addition to the primary role of supporting intramural Institute clinical research and patient care, CC staff conduct both collaborative and independent research and support a variety of training programs. The NIH CC supports the NIH intramural clinical research program hosting over 100,000 outpatient visits and 6,600 inpatient admissions a year.

The NIH Clinical Center's mission requires the use of a number of investigational drugs and biologics as well as investigational devices. Use of investigational drugs or biologics is regulated by the Food and Drug Administration (FDA) and sponsors have specific detailed documentation and reporting requirements. The CC is currently the sponsor for 24 Investigational New Drug (IND). INDs are an essential research resource requiring detailed preparation and maintenance. Maintaining an IND involves multiple requirements including submission of research protocol and information amendments, safety reports, and annual reports to the FDA and Institutional Review Board. Thus, INDs are essential to the success of the intramural clinical research program for multiple Institutes and Centers as well as the CC. Medical supervision of all reporting and documentation requirements for CC INDs is a critical responsibility only to be entrusted to an experienced Senior Clinician.

Investigational devices (IDEs) are also regulated by the FDA. The NIH Clinical Center is currently the sponsor for 15 IDEs. The incumbent must be familiar with all aspects of FDA oversight and regulatory requirements for investigational devices, both those associated with significant risk and those determined to be no significant risk (NSR).

The position is located within the Warren G. Magnuson Clinical Center, a major research component of the NIH and the Department of Health and Human Services. The incumbent in this position supports the Chief Medical Officer, the Chief Operating Officer, and the Chief Executive Officer of the NIH Clinical Center. Furthermore, since the NIH Deputy Director for Intramural Research (DDIR) is the Institutional Official accountable to the US Food and Drug Agency (FDA) for regulatory compliance with all FDA regulations, the incumbent in this position has a critical role in support of the DDIR as well as the senior leaders of the CC. In fulfilling these responsibilities, the incumbent works closely with the Office of Research Support and Compliance that also supports the CC as well as the DDIR. While IND and IDE management and compliance represent the critical institutional entities associated with this position, the incumbent is also expected to participate in clinical care and research. An independent research program is desirable but not mandatory. The incumbent may also serve in a leadership or supervisory capacity in one of the CC's Clinical Departments, depending on training, experience, and demonstrated leadership ability.

LOCATION: Bethesda, Maryland

REQUIRED QUALIFICATIONS: Applicants must possess a M.D. or an equivalent doctoral degree and an established record of outstanding research accomplishments, scientific leadership, mentorship, and service within the basic and/or clinical scientific community. The incumbent may supervise their own research laboratory, supported by resources commensurate with the size and scope of their program.

SALARY/BENEFITS: Salary is competitive and will be commensurate with the experience of the candidate. A full package of Federal Civil Service benefits is available, including retirement, health and life insurance, leave, and a Thrift Savings Plan (401K equivalent). A recruitment and/or relocation incentive may be available, and relocation expenses may be paid.

Please read the following guidance on [Selective Service](#) requirements.

Diversity, Equity, Inclusion, and Accessibility (DEIA): Diversity, equity, inclusion, and accessibility (DEIA) is a core competency for the Clinical Center (CC) so candidates are required to submit a diversity statement describing their commitment to promoting DEIA as evident in a track record of activities within their resume/cover letter. If invited for an interview the candidate will be required to describe their record of promoting diversity and inclusion such as, but not limited to, mentoring individuals from underrepresented groups, participating in mentoring programs designed to promote diversity, and DEIA-related outreach activities.

EQUAL OPPORTUNITY EMPLOYMENT: Selection for this position will be based solely on merit, with no discrimination for non-merit reasons such as race, color, religion, gender, sexual orientation, national origin, political affiliation, marital status, disability, age, or membership or non-membership in an employee organization. NIH encourages the application and nomination of qualified women, minorities, and individuals with disabilities.

STANDARDS OF CONDUCT/FINANCIAL DISCLOSURE: NIH inspires public confidence in our science by maintaining high ethical principles. NIH employees are subject to Federal Government-wide regulations and statutes as well as agency-specific regulations described at the [NIH ethics website](#). We encourage you to review this information. The position is subject to a background investigation and requires the incumbent to complete a public financial disclosure report prior to the effective date of the appointment.

FOREIGN EDUCATION: Applicants who have completed part or all of their education outside of the United States must have their foreign education evaluated by an accredited organization to ensure that the foreign education is equivalent to education received in accredited educational institutions in the United States. **We will only accept the completed foreign education evaluation.** For more information on foreign education verification, visit the <https://www.naces.org> website. **Verification must be received prior to the effective date of the appointment.**

ADDITIONAL INFORMATION: HHS has a critical preparedness and response mission: HHS protects the American people from health threats, studies emerging diseases, and mobilizes public health programs with domestic and international partners. In support of this mission, HHS offers its employees the opportunity to volunteer to become Federal Civilian Detailees and contribute their unique skills through voluntary temporary assignments to humanitarian emergencies or Departmental priorities countering new and emerging health, safety, and security threats.

REASONABLE ACCOMMODATION: NIH provides reasonable accommodations to applicants with disabilities. If you require reasonable accommodation during any part of the application and hiring process, please notify us. The decision on granting reasonable accommodation will be made on a case-by-case basis.

HOW TO APPLY: Applications must be submitted via the www.usajobs.gov website, job announcement NIH-CC-DH-24-12515228, that will be open from September 25, 2024 to midnight on October 4, 2024. Please include in your CV a description of your mentoring and outreach activities, especially those involving women and persons from racial/ethnic and other groups that are underrepresented in biomedical research. If you have questions about this position, please contact Cris Leite at cc_recruits@cc.nih.gov. For questions about the application process, please contact Jacaranda Guzman-Vargas at jacaranda.guzman-vargas@nih.gov. Applicants are subject to a background investigation and pre-employment medical examination.

PLEASE DO NOT INCLUDE YOUR BIRTH DATE OR SOCIAL SECURITY NUMBER ON APPLICATION MATERIALS