

Department of Health and Human Services
National Institutes of Health
National Institute of Diabetes and Digestive and Kidney Diseases
Bethesda, MD

Director, Biostatistics Program Office

This person will serve as the Director of the Biostatistics Program Office (BPO) and will oversee a team of biostatisticians that collaborate with and provide support for clinical and translational research in both the intramural and extramural programs of the National Institutes of Diabetes Digestive and Kidney Diseases (NIDDK). The position is within the NIDDK Office of the Director (OD) and is a direct report to the Deputy Director, NIDDK. The Office of the Director is composed of the Biostatistics Program Office , Regulatory Support Program, NIDDK Central Repository and the Technology Advancement office (TAO). These independent programs collaborate to serve as important components that make up the Office of Clinical Research Support (OCRS). The OCRS is responsible for coordinating the development of policies and procedures to guide extramural NIDDK-funded clinical studies and clinical trials, for ensuring that such research is compliant with all NIH and HHS human subjects research policies, and that planning for, and management of clinical and translational research is consistent, rigorous, effective, and efficient across all divisions.

The Biostatistics Program Office is a new component of the NIDDK OD. Historically, NIDDK has had individual Biostatistics staff supporting intramural and extramural activities with multiple, separate reporting structures. NIDDK has now brought its senior biostatisticians (currently 3) into a single team in the Biostatistics Program Office that will work cooperatively to provide more strategic and comprehensive support to both our intramural investigators and our extramural research program under the leadership and supervision of this new Director.

Specific Responsibilities

The Director will be responsible for building the Biostatistics Program Office and providing leadership and supervisory oversight to at least three senior biostatisticians engaged in Biostatistics Program Office activities to meet the needs of NIDDK intramural and extramural research endeavors. Given that this is a new office, the Director will engage with NIDDK leadership, working closely with the Deputy Director, the Clinical Director of our Intramural program, and other senior leaders of the Institute to identify the NIDDK biostatistics needs and set the future direction of the Biostatistics Program Office and any new hiring for this group to meet those needs. Frequent communication with intramural and extramural staff and periodic assessment of success in meeting their biostatistics needs are expected from the Biostatistics Program Office Director.

The Biostatistics Program Office Director is responsible for ensuring that the Biostatistics Program Office addresses biostatistics needs of NIDDK intramural and extramural staff and directly assist with these activities, as needed. On the intramural side, the Biostatistics Program Office will provide expert advice to NIDDK intramural investigators on design, implementation, and statistical analysis of research studies; provide training and updates on newer statistical methods to both junior and senior investigators; and oversee ClinicalTrials.gov reporting. On the extramural side, the Office will be responsible for providing

strategic direction and advice to senior NIDDK extramural staff from the Divisions of Diabetes, Endocrinology, and Metabolic diseases (DEM), Digestive Diseases and Nutrition (DDN), and Kidney, Urologic, and Hematologic Diseases (KUH), and the Office of Obesity Research on the design and feasibility of proposed research studies (initiatives planned by division scientific staff) and the conduct and analyses of ongoing studies. The Biostatistics Program Office will similarly provide training and updates on emerging new statistical methods to our Extramural Program staff, advise on ClinicalTrials.gov reporting, and participate more broadly in OCRS-support of extramural activities.

The Biostatistics Program Office director will serve as an expert advisor to NIDDK and to other governmental and non-governmental research groups in areas relating to the development and application of statistical techniques to research in the biological and medical sciences and may interface with other governmental and non-governmental research groups, if appropriate. Governmental groups include the CDC, FDA, NIH Offices including Disease Prevention and Nutrition Research, the NIH Clinical Trials Operations Workgroup, and NIH biostatistics groups at NCI, NHLBI, NIAID, NICHD and other institutes and centers. Non-governmental research groups include academic institutions and research institutes such as the Patient-Centered Outcomes Research Institute (PCORI). The individual will advise the institute and our collaborators/partners on study design and study execution, where appropriate.

In addition to high level expertise in biostatistics, the position requires an individual with excellent communication and organizational skills and the ability to lead the work of a team on a large number of varied and diverse projects. The individual must also have extensive knowledge and experience in the design and analysis of clinical and translational research studies. They must have a wide range of skills and knowledge to support a Biostatistics Program Office that covers all areas of statistics and study design for clinical studies that range in size from smaller intramural research protocols to large extramural multi-center longitudinal studies and clinical trials and analytic approaches for a variety of data types ranging from qualitative data to large-scale -omics data. The position also requires the incumbent to have extensive experience and expertise in the area of trial design, analysis, and data coordinating center functions, including definitions of outcomes, methods for sample size estimation, preparation of data and safety monitoring plans, development of instruments for data capture and documentation, knowledge of systems for data entry and quality control, randomization procedures, statistical analysis of study data including modeling and graphical techniques, the preparation of reports for and familiarity with data and safety monitoring boards, and expertise in standard statistical software and database management programs. It is also anticipated that the Director will develop familiarity and possible working relationships with statistical program offices at other NIH Institutes and Centers including NHLBI, NIAID, and NCI.

Supervisory Responsibilities

The Biostatistics Program Office Director serves as a first line supervisor and exercises the full range of supervisor responsibilities. These responsibilities include monitoring and evaluating performance of Biostatistics Program Office staff; making recommendations for personnel actions including promotions, reassignments, awards and adverse/disciplinary actions; interviewing candidates for positions; hearing and resolving complaints from employees; identifying developmental and training needs; reviewing and discussing evaluations; and recommending performance awards and salary/bonus distribution for exceptional employees. The Biostatistics Program Office Director actively supports and promotes

acceptance and adherence to provisions of special programs such as Equal Employment Opportunity, safety, and internal controls.

LOCATION: Bethesda, MD

REQUIRED QUALIFICATIONS: Applicants must possess a doctoral degree in biostatistics, statistics or a related field. Also required is the extensive knowledge and experience in the design and analysis of clinical research studies; experience with Data Coordinating Centers, extensive teaching or mentoring experience, and demonstrated activities related to advancing the biomedical data ecosystem; and experience in managing personnel including Masters- and PhD-level biostatisticians. The applicant should have excellent communication and organizational skills with the ability to lead and work collaboratively on numerous and unique projects to solve problems and to make informed decisions.

SALARY/BENEFITS: This position will be filled under The Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS), SBR2 appointment. *The Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS) is a mechanism to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment.* Salary is competitive and will be commensurate with the qualifications and experience of the candidate. Full Federal benefits will be provided, including retirement, health and life insurance, long-term care insurance, leave, and a Thrift Savings Plan (401K equivalent). A recruitment or relocation bonus may be available, and relocation expenses may be paid.

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. The NIH encourages the application and nomination of qualified women, minorities, and individuals with disabilities.

STANDARDS OF CONDUCT/FINANCIAL DISCLOSURE: The 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 <http://ethics.od.nih.gov/default.htm>. We encourage applicants 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 U.S. must have their foreign education evaluated by an accredited organization to ensure that the foreign education is equivalent to education received in accredited education institutions in the United States. **We will only accept the completed foreign education evaluation.** For more information on foreign education verification, visit the National Association of Credential Evaluation Services (NACES) website. **Verification must be received prior to the effective date of the appointment.**

REASONABLE ACCOMMODATION: NIH provides reasonable accommodations to applicants with disabilities. If you require reasonable accommodations 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: Interested candidates should submit a curriculum vitae and bibliography, and full contact information for three references. Application packages should be sent via e-mail to Katie Tucker Katie.tucker@nih.gov. For further information about the position, please contact the Search Committee Chair: Theo Heller, M.D., theoh@intra.niddk.nih.gov

Review of applications will begin on or about August 8, 2022, but applications will be accepted until the position is filled.

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

DHHS and NIH are Equal Opportunity Employers and encourage application from women and minorities.