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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement of Organization, Functions, and Delegations of Authority

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health has modified its organizational structure.

SUPPLEMENTARY INFORMATION: Part N, National Institutes of Health (NIH), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) is amended as set forth below to reflect the reorganization of the National Institute of Health, National Institute of Allergy and Infectious Diseases (NIAID), by retitling and updating the functional statement (1) the Office of the Chief of Staff for the Immediate Office of the Director to the Office of the Clinical Director within NIAID, (2) establishing the Intramural Clinical Management and Operations Branch, and the Office of Clinical Research Policy and Regulatory Operations within the Office of the Clinical Director, (3) establishing the Office of Biostatistics Research within NIAID, the Biostatistics Research Branch, and the Clinical Trials Research and Statistics Branch within the Office of Biostatistics Research, establishing the Laboratory of Viral Zoonoses and IRF-Frederick Comparative Medicine Branch within the Division of Intramural Research of NIAID, (4) Abolishing all of the Division of Clinical Research within NIAID.

Section N, *Organization and Functions,* is amended as follows:

(1) In the *National Institute of Allergy and Infectious Diseases (NM, formerly HNM)* retitle the following:

Office of the Chief of Staff for the Immediate Office of the Director (NM1J, formerly HNM1J) to *Office of the Clinical Director (NM1J, formerly HNM1J).* (1) Develops, implements, and evaluates policies and practices related to the conduct of human subjects research within NIAID; (2) Advises the Director, NIAID, on the portfolio of clinical research conducted and sponsored by NIAID and reviews research protocols for relevance to the mission of the Institute, priority to meet the needs of the public health of the nation, ethics in human use, and appropriateness of scientific design; (3) Oversees the OCD branches; (4) Provides oversight of clinical research and all related clinical operations of intramural laboratories conducting clinical research programs; (5) Manages several clinical research projects involving national programs of clinical research in areas of the highest public health priorities; (6) Oversees Clinical Research Oversight Management (CROM) for intramural clinical research operations in NIAID including logistical and technical support for the NIAID Data and Safety Monitoring Board (DSMB); (7) Maintains regulatory surveillance over intramural clinical trials and protocols to ensure compliance with FDA regulations to establish and monitor regulatory policies for clinical trials and to monitor quality assurance standards and standard operating procedures regarding regulatory matters; (8) Provides expert policy analysis with regard to the management, coordination, and integration of all OCD programs and predicts and responds to the changing needs of a program for on-site and off-site domestic and international clinical research in developing countries and collaborative efforts with industry and international foundations; (9) Oversees design and conduct of studies in collaboration and consultation with NIAID intramural and extramural programs including data management and study coordination, analyses, and reporting of clinical, population and laboratory investigations; and (10) Supervises medical staff appointments, fellowship programs, and other clinical training programs.

(2) In the *Office of the Clinical Director (NM1J, formerly HNM1J)* establish the following:

Intramural Clinical Management and Operations Branch (NM1J2, formerly HNM1J2). (1) Provides oversight of clinical research and all related clinical operations for intramural laboratories conducting clinical research; (2) Provides oversight of: (a) inpatient units and outpatient clinics in concert with the Clinical Center; (b) clinical protocol review and approval including assurance of scientific quality; (c) the quality of care delivered to NIAID patients and the quality of professional performance of NIAID health care providers for the intramural patient population; (d) continuing medical education; and (e) graduate physician training in allergy, immunology, and infectious diseases.

Office of Clinical Research Policy and Regulatory Operations (NM1J3, formerly HNM1J3). (1) Provides support and logistical services for intramural clinical research operations in NIAID to include the provision of a protocol navigator / protocol development program; (2) Coordinates the support and logistical services for NIAID clinical research projects; (3) Maintains regulatory surveillance over DIR supported clinical trials and protocols to ensure compliance with FDA regulations; (4) Establishes and coordinates trans-NIAID clinical research policies on behalf of the NIAID Clinical Research Subcommittee and harmonizes best practices across NIAID Divisions; (5) Coordinates the development of the OCD response to inquiries from HHS, other Agencies, and NIH regarding a wide-array of legislative and policy issues pertaining to clinical research; (6) Establishes and monitors regulatory policies for DIR-conducted clinical trials and supports the NIAID Clinical Director in the harmonization of a coherent NIAID response based on input from other NIAID Divisions; (7) Establishes and monitors quality assurance standards and standard operating procedures regarding regulatory matters; (8) Coordinates with investigators on the appropriate utilization of available clinical data management systems; (9) Develops, assembles, maintains, and submits investigational new drug (IND) applications to the FDA, authorizes sites for clinical trials, reviews adverse experience reports for DIR sponsored trials, and prepares safety reports and IND interim and annual reports for the FDA; (10) Ensures that sponsor responsibilities for IND/IDE applications held by the

Office are either fulfilled or that appropriate documentation transferring responsibilities of those regulatory obligations to include responsibility for maintenance and evaluation of clinical safety data; (11) Provides logistical and technical support for the NIAID intramural Data and Safety Monitoring Board; (12) Provides logistical and technical support for safety monitoring committees and independent medical monitors required for NIAID intramural clinical research; (13) Serves as liaison to the FDA, the pharmaceutical industry, the Office of Human Subjects Research Protections for regulatory issues during the initiation and conduct of clinical trials; (14) In conjunction with pharmaceutical collaborators, reviews the regulatory components of DIR Clinical Trial Agreements and Cooperative Research and Development Agreements; (15) Implements and maintains management information systems required to support regulatory and policy responsibilities; (16) Provides information and training relative to regulatory issues and logistical coordination of trials; (17) Provides consultation to NIAID officials and programs developing clinical trial protocols concerning scientific merit and protection of human subjects; and (18) Coordinates and communicates with other domestic and international government agencies and with other NIH and NIAID components to ensure accurate and timely exchange of information on regulatory issues.

(3) In the *National Institute of Allergy and Infectious Diseases (NM, formerly HNM)* establish the following:

Office of Biostatistics Research (NM1K, formerly HNM1K) (1) Provides institute-wide leadership, expertise, and strategic support in biostatistics to advance NIAID's scientific mission; (2) Advises NIAID leadership on policies and programmatic priorities to ensure statistical rigor, reproducibility, data integrity, and analytic accuracy; (3) Supports NIAID's rapid, adaptive, and data-driven response to emerging scientific and public health needs; (4) Facilitates the coordination, oversight, and administration of Data and Safety Monitoring Boards (DSMBs); and

(5) Ensures the timely, accurate, and transparent communication and dissemination of research data and results.

Biostatistics Research Branch (NM1K2, formerly HNM1K2) (1) Collaborates with intramural and extramural investigators to design, analyze, and report scientifically rigorous clinical, population-based, and laboratory studies; (2) Provides statistical leadership for safety monitoring activities and research protocol development and review; (3) Directs and conducts an independent research program focused on advancing innovative biostatistical methods; (4) Provides subject matter expertise and leadership for NIAID and cross-institutional Data and Safety Monitoring Boards; (5) Establishes program priorities and recommends funding levels within the biostatistics research portfolio; and (6) Identifies and mentors high-potential biostatisticians developing novel statistical methodologies, and supports early-career investigators in grant submissions to foster the next generation of NIAID researchers.

Clinical Trials Research and Statistics Branch (NM1K3, formerly HNM1K3) (1) Serves as the central resource for the design, coordination, and conduct of high-priority infectious disease clinical trials through innovative trial designs, advanced statistical methodologies, and robust data management and operations; (2) Functions as an operational hub that integrates and augments existing NIAID clinical research resources to enhance adaptability and responsiveness for special initiatives and rapid-response missions; and (3) Provides a turnkey clinical trials capability during outbreaks or urgent research responses, ensuring coordinated trial implementation, high-quality data management and analysis, and a flexible, nimble, and cost-effective operational model.

Laboratory of Viral Zoonoses (NM2Z13, formerly HNM2Z13)(1) Work in the Laboratory of Viral Zoonoses at the Integrated Research Facility-Frederick may include: (1) In vitro work using

standard and innovative cell culture and organoid models; (2) In vivo work using conventional laboratory and unconventional exotic animal species to develop surrogate models for emerging/re-emerging zoonotic infectious diseases; (3) Use cutting edge methods and state-of-the-art technologies in high/maximum biocontainment, at field sites, and for clinical trials; (4) Evaluate medical countermeasures to prevent or treat (re)emerging infectious diseases; and (5) Establish a world-renowned training site for researchers in high/maximum biocontainment.

IRF-Frederick Comparative Medicine Branch (NM2Z14), formerly HNM2Z14) (1) Provides support to the IRF-Frederick through centralized animal care, including animal husbandry, clinical care, breeding, shipping and receiving, disease surveillance, and technical scientific support that includes performance of surgeries, experiments, administration of experimental materials, collection of tissue samples and necropsies; (2) Ensures compliance with the Animal Welfare Act, PHS and NIH Animal Care and Use Policies, DHHS Guide for the Care and Use of Laboratory Animals, and accreditation standards for the Association for Assessment and Accreditation of Laboratory Animal Care; (3) Provides training for animal care technicians, laboratory technicians, and investigators; (4) Supports high and maximum containment animal experimental protocols for DIR Principal Investigators, including special animal models of emerging and re-emerging biodefense related infectious disease agents requiring Animal Biosafety Level-3 and Animal Biosafety Level-4 containment; (5) Provides detailed summary reports of experiments; and (6) Optimizes facility resources, monitors facilities, and establishes standard operating procedures.

(4) In the *National Institute of Allergy and Infectious Diseases (NM, formerly HNM)* remove the following:

- *Division of Clinical Research (NM9, formerly HNM9)*
- *Office of Biostatistics Research (NM93, formerly HNM93)*

- *Mathematical Biology Section (NM932, formerly HNM932)*
- *Clinical Trials Research and Statistics Branch (NM933, formerly HNM933)*
- *Biostatistics Research Branch (NM934, formerly HNM934)*
- *Collaborative Clinical Research Branch (NM94, formerly HNM94)*
- *Science Section (NM942, formerly HNM942)*
- *Operations and Strategy Management Section (NM943, formerly HNM943)*
- *Intramural Clinical Management and Operations Branch (NM95, formerly HNM95)*
- *Program Planning and Analysis Branch (NM96, formerly HNM96)*
- *Office of Clinical Research Policy and Regulatory Operations (NM97, formerly HNM97)*
- *Office of the Chief Scientist for the Integrated Research Facility at Ft. Detrick (NM99, formerly HNM99)*

Authority: 42 U.S. Code 281(d) (4)

Robert F. Kennedy, Jr.

Secretary,

Department of Health and Human Services.

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