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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions,

and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 81 FR 66284-66285, dated September 27, 2016) is amended to reflect the reorganization of the Division of Scientific Resources, National Center for Emerging and Zoonotic Infectious Diseases, Office of Infectious Diseases, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete and replace the title and the mission and function statements for the Division of Scientific Resources (CVLH) and insert the following:

Division of Scientific Resources (CVLH). The Division of Scientific Resources (DSR) provides products, services, and specialized expertise to CDC staff and activities in support of research and service activities: In carrying out its mission, DSR:

- (1) provides animals, laboratory supplies, animal and human blood products, glassware, mammalian tissue cultures, microbiological media, special reagents, and other laboratory materials in support of research and service activities to laboratories and investigators at CDC;
- (2) develops and implements applied research programs to expand and enhance the use of animal models necessary to support research and diagnostic programs and to

improve breeding and husbandry procedures; (3) conducts applied research in cell biology and in the expansion of tissue culture technology as a research and diagnostic tool for infectious disease activities; (4) provides services for laboratory investigators in protein and DNA synthesis and sequencing, genomic sequencing, microarrays, proteomics, and molecular modeling; (5) maintains a bank of serum and other biological specimens of epidemiological and special significance to CDC's research and diagnostic activities; (6) obtains and distributes experimental and orphaned vaccines, drugs, antisera, antitoxins, and immune globulins; (7) manages and distributes the inventory, maintains the computerized system database, and provides general technical service support for the dispensing, lyophilizing, capping, and labeling of CDC reference reagents; (8) receives, triages, processes, and distributes specimens to CDC laboratories for reference diagnostic testing, research studies, and epidemics and reports diagnostic test results to submitting organizations; (9) manages all CDC exports and ensures compliance with regulations and serves as CDC liaison with the Department of Commerce for export related issues; (10) produces and distributes specialized reagents and kits for the detection of select agents to members of the Laboratory Response Network; (11) provides services and expertise in development of quality systems to support compliance with the Food and Drug Administration regulations on production, distribution, and use of laboratory diagnostic reagents; (12) provides liaison activities, resources, and expertise for inquiries related to animals and zoonotic diseases; and (13) provides a centralized activity for tracking requests for and distributing select agents to investigators outside of CDC in compliance with federal regulations.

Office of the Director (CVLH1). (1) Manages, directs, and coordinates the

activities of DSR; (2) provides leadership and guidance on policy, budget, program planning and development, program management, and operations; (3) provides DSR-wide administrative and program services and coordinates or ensures coordination with the appropriate CIOs, OID, and CDC staff offices on administrative and program matters; (4) provides liaison with other governmental agencies, international organizations, and other outside groups; (5) coordinates, in collaboration with the appropriate CIOs, OID, and CDC components, laboratory activities relating to support of outbreak investigations or laboratory-based research including but not limited to specimen management, biological reagents, and laboratory supplies; (6) maintains a formulary of investigational and licensed drugs and biologicals that are distributed to approved physicians for the prevention, control, and/or treatment of rare, tropical, or exceptional diseases; (7) advises the Director, NCEZID, on policy matters concerning DSR activities; and (8) coordinates technical services for laboratory activities of CDC programs including procurement of glassware and laboratory supplies.

Comparative Medicine Branch (CVLHB). (1) Acquires and distributes laboratory animals for research; (2) provides appropriate housing, husbandry, and psychological enrichment for all research animals; (3) provides veterinary services, including clinical and surgical support, for the laboratory animals; (4) develops standard operating procedures for animal care and use in accordance with the policies established by the American Association for Accreditation of Laboratory Animal Care, the Animal Welfare Act, The Guide for the Care & Use of Laboratory Animals, and the CDC International Animal Care & Use Committee; (5) conducts applied research to improve the care and use of animals in research and collaborates on research projects that use laboratory

animals; (6) provides consultation and laboratory animal technology training to investigators, technical staff and animal care personnel; (7) provides oversight, support and investigator training for the graphical animal information technology protocol development and animal tracking database; (8) coordinates technical services for laboratory activities of CDC programs including processing and distribution of glassware and related items, laboratory waste decontamination and disposal, laundry services, and materiel management; and (9) provides autoclave label production services.

Biotechnology Core Facility Branch (CVLHD). (1) provides state-of-the-art next-generation genomic sequencing and metagenomics analysis of infectious and biothreat agents; (2) provides optical mapping to produce high resolution whole-genome maps for strain typing, molecular epidemiology, comparative genomics, and quality control for whole genome sequence assembly; (3) provides computational analysis of genomics sequencing data, bioinformatics, and biological computing; (4) provides qualitative and quantitative proteomic analyses (identification of expressed proteins by mass spectrometry); analysis of functionally-relevant post-translational modifications of proteins; (5) provides mass spectrometry-based positive identification of bacteria and fungi (BioTyper™, Bruker Daltonics); (6) provides synthetic oligonucleotide chemistry in support of development of rapid diagnostic tests and characterization of pathogens and their hosts; (7) provides synthetic peptide chemistry in support of studies of immune response and antigen-antibody interactions; (8) provides biotechnology seminars and methods evaluation; (9) provides laboratory equipment design and repair services to all CDC; and (10) collaborates on research related to STD transmitted infections as chronic infectious diseases.

Reagent and Diagnostic Services Branch (CVLHG). (1) maintains laboratory water treatment systems to ensure quality of CDC reagent grade laboratory water; (2) produces, develops, evaluates and distributes custom microbiological and cell culture media, buffers and chemical reagent, mammalian and insect cell cultures, hybridomas, monoclonal and polyclonal antibodies, and in vitro diagnostic products for diagnostic research purposes, proficiency testing, pandemic preparedness, outbreak response and surveillance activities; (3) collaborates with subject matter experts in regulatory compliant development, production, packaging, storing and distribution of BSL2/BSL3 reagents, select agents, novel immuno- chemical reagents and reference diagnostic reagents; (4) provides dispensing, lyophilizing, label production, and device assembly services; (5) improves the process of bench-top development and in-house pilot scale production providing immediate availability for distribution, preventing backorders and streamlining commercialization; (6) maintains CDC's Biological Reference Reagent Inventory, mammalian cell line repository and a serviceable inventory at the DSR Continuity of Operations storage facility; (7) provides centralized specimen management services for diagnostic, reference, and outbreak investigations; maintains a bank of biological specimens of epidemiological significance to CDC's research and diagnostic activities; manages and tracks systems of specimen collections; (8) receives, triages, processes, stores and distributes specimens to CDC laboratories for reference diagnostic testing, research studies, and reports diagnostic and surveillance test results to submitting organizations; (9) serves as central facility for acquisition and distribution of fresh human blood, blood products, and serum in bulk; (10) packages and ships infectious substances and other materials, ensuring compliance with regulations for shipping clinical

specimens, infectious substances, and other materials; (11) manages all CDC exports and ensures compliance with regulations and serves as CDC liaison with Department of Commerce for export related issues; and (12) provides consultation in all of the above technical services;

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