National Institute of Allergy and Infectious Diseases - HNM

Conducts, fosters, and supports research and research training programs directed at finding the cause of and improved methods for diagnosing, treating, and preventing immunologic and infectious diseases through: (1) research performed in its own laboratories; (2) research grants to scientific institutions and individuals; (3) individual and institutional research training awards; (4) a contract program aimed at the adaptation and application of laboratory and clinical findings to the development of specific disease control measures and solutions to infectious and immunological disease problems; and (5) collection and dissemination of research findings and related information.

Office of the Director - HNM1

(1) Determines Institute programs, plans, and policies; and (2) provides management, program analysis, and scientific program reporting services to the Institute.

Office of Science Management and Operations - HNM1A

(1) Provides mission and values-based business leadership, direction, support and assistance to NIAID's national and international scientific programs and activities to: (a) enhance NIAID's strategic position in related areas of biomedical research; (b) ensure responsible stewardship of resources in support of the research enterprise; (c) maintain core values; (d) optimize operational effectiveness of scientific and business services; and (e) institutionalize accountability for achieving Presidential, Departmental, and NIH management goals and initiatives including continuous improvement and reengineering in a comprehensive and integrated manner; (2) advises the Institute Director and senior staff on scientific management, business management and administrative management of the Institute and its programs; (3) plans, directs and coordinates scientific management, business management and administrative functions of the Institute including strategic and mission planning/integration and evaluation; knowledge management; budget and financial management; government relations and communications; legislative analysis and public information including access under the Freedom of Information Act; and technology information systems support to NIAID programs; (4) oversees and provides operational leadership and support for the coordination of the overall NIAID global research effort; (5) oversees the management of the Institute Technology Development Program; (6) oversees the coordination, planning and implementation of biodefense research supported by various Divisions of the Institute; (7) oversees and provides direction for the NIAID ethics program; (8) oversees development of and administers Institute policies and procedures for scientific business and program management activities, including the Institute's competitive sourcing program activities; (9) provides assistance to NIAID senior officials to assure that NIAID staff are sufficient in numbers, training, and diversity to effectively conduct the biomedical research mission of NIAID; (10) participates in and brings both a scientific and a business management perspective to the development of NIAID program goals and objectives; (11) interacts with Institute advisory groups on matters concerning NIAID scientific and business management issues; (12) maintains liaison with and represents the Institute to NIH and Departmental officials responsible for the leadership and policy direction of overall scientific program support and business management functions; and (13) serves as the NIAID focal point for the Institute's real property management responsibilities.

Office of Client Solutions - HNM1A94

Provides NIAID divisions and offices with a simplified path to integrated, holistic human capital (HC) solutions by (1) facilitating transparency of OWER's resources and providing a single point contact for NIAID organizations to access those resources; (2) providing resources and client data for use by OWER SME's to increase efficiency and knowledge sharing; and (3) coordinatingsupport across the OWER community to help NIAID managers and staff address human capital complexities in all phases of the human capital lifecycle.

Workforce Management Branch - HNM1A95

Assists senior leaders and managers in the areas of (1) strategic workforce planning to enhance overall organizational capability and performance by developing and implementing strategies and interventions to ensure that the Institute has a total workforce with the necessary capabilities and competencies to successfully deliver on NIAID's mission now and in the future; (2) implementing and encouraging proactive and continuous succession management practices; (3) supporting and fostering healthy employee engagement and retention; (4) providing analytics on the NIAID workforce to inform decisions on human capital management; and (5) managing the development or enhancement of NIAID's primary workforce management system.

Human Capital Automation Branch - HNM1A97

Supports efficient human capital management to NIAID divisions and offices through streamlined and standardized automated processes by (1) serving as the business owner of human capital applications and workflows; (2) fostering partnerships internal and external to NIAID to innovate and integrate systems and stakeholders; and (3) leading comprehensive data quality, operations and maintenance and communications of the applications and workflows.

Office of Mission Integration and Financial Management - HNM1AC

The NIAID Office of Mission Integration and Financial Management (OMIFM) formulates, presents, justifies, defends and executes the Institute's budget, conducts long-range analyses, creates plans and modeling to assess, project, and attain the Institute's critical resource needs as a whole and for critical research areas including the Institutes three major missions: Biodefense, HIV/AIDS, and Immunological and Infectious Diseases (IID)."Additionally, OMIFM manages a large portfolio of projects which are not funded via appropriations (e.g., gift funds, CRADAs, royalties and other non-appropriated accounts). The appropriated and non-appropriated programs and projects total about \$6.0 billion per year. OMIFM (1) manages, plans and directs all financial management activities of NIAID and its programs; (2) serves as the focal point budget for the identification and integration of long-range critical resource requirements to meet the Institute's strategic priorities; (3) provides financial reports, trend analyses, historical data, and financial modeling to inform and improve funding and policy decisions; (4) works with partners within NIAID, NIH, and HHS to facilitate the development, integration and deployment of new business systems for finance and budgeting; (5) partners with Institute and trans-NIH collaborators to improve financial information for the institute to ensure more reliable and predictable decision making; (6) allocates resources for over 300 major research programs to achieve NIAID's long-range strategic objectives, goals and milestones; (7) directs and coordinates all phases of trans-NIAID budgeting and financial management to ensure that they are integrated, effective, and mutually supportive; and (8) serves as the principal advisor to NIAID's leadership on the strategic management of NIAID resources.

AIDS Budget & Financial Management Branch - HNM1AC4

The HIV/AIDS Budget and Financial Management Branch is approximately one-third of the total annual appropriation (between \$1.6-2.2B per year). Specific functions include: (1) performing formulation, presentation and execution budgetary tasks and activities in HIV/AIDS; (2) developing mission-specific operating plans which will be integrated into an overall NIAID budget operating plan; (3) processing, establishing, and tracking vehicles transferring funds within NIH or to other government organizations; and (4) maintaining funds control to ensure proper stewardship, reconciliation, and end-of-year close outs.

Bio Defense Budget & Financial Management Branch - HNM1AC5

The Bio Defense Budget and Financial Management Branch is approximately one-third of the total annual appropriation (between \$1.6-2.2B per year). Specific functions include: (1) performing formulation, presentation and execution budgetary tasks and activities in Bio Defense; (2) developing mission-specific operating plans which will be integrated into an overall NIAID budget operating plan; (3) processing, establishing, and tracking vehicles transferring funds within NIH or to other government organizations; and (4) maintaining funds control to ensure proper stewardship, reconciliation, and end-of-year close outs.

Immunologic & Infectious Diseases Budget & Financial Management Branch - HNM1AC6

The Immunologic & Infectious Diseases Budget and Financial Management Branch is approximately onethird of the total annual appropriation (between \$1.6-2.2B per year). Specific functions include: (1) performing formulation, presentation and execution budgetary tasks and activities in IID; (2) developing mission-specific operating plans which will be integrated into an overall NIAID budget operating plan; (3) processing, establishing, and tracking vehicles transferring funds within NIH or to other government organizations; and (4) maintaining funds control to ensure proper stewardship, reconciliation, and endof-year close outs.

Office of Workplace Solutions- HNM1AA

(1) Serves as the NIAID focal point for Institute space and facility matters, advising the Deputy Director for Science Management and the Director, NIAID' on NIAID occupied space and facilities issues overall; biocontainment facility issues and NIAID facility planning, development, internal management and quality assurance of intramural, extramural and international facilities for NIAID infectious diseases research programs; (2) oversees and conducts specific facility-related technical and non-technical studies for more informed decision making and planning of facility programs based on specific NIAID program mission requirements; (3) develops and administers key data bases for NIAID facilities program management, evaluation and continuity of operations; (4) develops and maintains a NIAID space plan and represents NIAID in the development and maintenance of the NIH Master Plan; (5) coordinates the NIAID role in support of NIH construction or acquisition of space and facilities; (6) provides support to the NIAID program divisions in planning, implementation and sustained management of the facility aspects of international research programs including clinical trials; (7) provides comprehensive and customized conference and meeting support services for NIAID and acts as a surrogate for NIH conference facilities at the 5601 Fishers Lane location; (8) mitigates the operational and managerial risk associated with operating and sustaining mission critical facilities occupied and operated by the NIAID; (9) provides various services associated with maintenance and implementation of small work efforts via handy-man services in both office and laboratory environments; (10) provides program and project management oversight of various projects and relocation actions for all facets of the NIAID program within the intramural and extramural divisions as well as the Office of the Director; (11) manages logistics and assets necessary to support office, laboratory and cyber facilities throughout the Institute.

Space Resources and Asset Management Branch – HNM1AA2

(1) Provides comprehensive strategic planning and project management for all capital projects and interior renovations; (2) provides cost estimating, interior design, facilities and systems evaluation, building code evaluation, contracts management and building planning and programming for office, data centers, lab, clinical and vivaria efforts; (3) captures the supply and demand data for space resources and assets, prepares space allocation plans, and implements the plans within many federal mandates; (4) assists NIAID program leaders with developing space planning solutions to address space resource needs in the areas of office space, data centers, laboratory, vivaria and clinical work settings; (5) maintains current the NIAID space program inventory consistent with federal real property resource management requirements; (6) manages key data bases associated with space management, facility drawings, and workflow management within the organization.

Facilities Services and Operations Branch – HNM1AA3

(1) Manages building systems oversight of heating, ventilating, air conditioning, electrical, plumbing, security, mission critical spaces such as data centers laboratories and clinical areas; (2) has lead responsibility for relocation of NIAID staff on and off campus; (3) maintains warehouse for furniture and equipment asset management and storage; (4) integrates with OSMO offices on matters of change management and communications efforts to aid staff in assimilating ease of adjustment with regard to the changing workplace as enhanced by technology andflexible work schedules and locations; (5) handles multi-phased relocation of laboratory, office and cyber functions as called upon; (6) provides facility management services within office, cyber, clinical and laboratory settings to ensure NIAID needs are satisfied in the capacity of a liaison to the NIlli office of Research Facilities; (7) handles small work efforts via in-house handy man services.

Conference Services and Events Management Branch – HNM1AA4

(1) Offers direct meeting support services to NIAID staff with regard to recurring or special event meetings to include full service in the areas of technology support, logistics, planning, and associated graphics or catering functions; (2) integrates trans-NIAID, trans-Nlli operational matters and with other government agencies nationally and internationally on matters of facility security and clearance as related to conference attendance requirements; (3) oversees the full operations of the Conference Center at Fishers Lane designed to support internal scientific meetings (4) responsible for logistical staging of furniture within designated areas to ensure that the related meeting room requirements, logistics and layout meet the needs and intentions of the conference/meetings plans; and (5) provides technical audio-visual support and maintenance for the Conference Center, as well as basic support for all meeting and resource libraries for NIAID throughout their Fishers Lane location; (6) works collaboratively with NIAID scientific program leaders to foster communication outreach and engagement on science topics as discussed within the Conference Center at Fishers Lane.

Office of Administrative Services - HNM1A2

(1) Exercises the key responsibilities of the Executive Officer, NIAID; (2) directs, coordinates, and conducts administrative activities of the Institute by providing advice, guidance and services in the areas of: (a) administrative management for the extramural, intramural, and Office of the Director organizations of the Institute; and (b) management analysis; (3) advises the Director, Deputy Director, Deputy Director for Science Management and Operations, and Division Directors on developments in management and their implications and effects on program management; and (4) develops policies on administrative management and prepares and issues procedures and guidelines for implementation of administrative policies and requirements.

OD and Extramural Administrative Branch - HNM1A23

(1) Provides advice to the Director, Deputy Director, Executive Officer, and Extramural Division Directors, and other management staff on general management and administrative issues and policies for the Institute; (2) Advises the staff of administrative policies and practices and provides overall administrative management services to the NIAID Office of the Director and Extramural Programs, including budget, personnel, procurement, space management, travel, property accountability and financial monitoring and control; (3) Develops, implements, and provides advice on the development and implementation of regulations, policies, procedures and administrative tools for the Institute; (4) Analyzes the impact of changes to administrative policies and practices and advises the Executive Officer of these effects; and (5) Serves as the coordinating point in handling administrative or management issues that cross program lines.

Intramural Administrative Management Branch - HNM1A24

(1) Serves as the coordinating point in handling all administrative, management, and facility support problems associated with the Division of Intramural Research; (2) advises the staff of the Director, Division of Intramural Research, and other key officials of administrative policies and practices; and (3) provides overall administrative support services to the Division of Intramural Research including budget, management and program analysis, personnel, space management, procurement, and contract management, facilities management and related support services.

Office of Property and General Services - HNM1A25

(1) Maintains property accountability records to effectively control NIAID property; (2) Provides oversight and distribution of inventory and inventory levels of property; (3) Interprets, analyzes, evaluates and implements management and administrative information affecting Telework and time and attendance policies and practices; (4) Serves as the NIAID liaison to NIH on various administrative systems and functions; (5) Prepares staff papers and reports on general management issues at the request of Institute staff and in response to requirements from NIH and DHHS; (6) Designs and conducts management studies and surveys including staff utilization, workload measurement, work simplification, etc., for all parts of the Institute; (7) Coordinates, analyzes, and provides advice on all organization change proposals for the Institute.

Office of Administrative Excellence & Information Integration - HNM1A27

(1) Facilitates collaboration among administrative services, business partners and the NIAID community to align administrative functions with OSMO mission priorities; (2) Initiates harmonized communication strategies for the administrative community and stakeholders to ensure transparency and clarity of operations; (3) Analyze, facilitate and develop harmonized administrative processes with automated solutions when applicable (4) Assesses the impact of change on administrative operations, advises leadership of the effect and utilizes change management strategies to implement appropriate process improvements; (S) Develops and oversees framework for updating and maintaining administrative documents to increase efficient and effective business operations; (6) Designs, develops and implements task-based training and programs that combine administrative policies, procedures and tools with critical thinking and technical skills to empower staff to achieve administrative excellence.

Office of Travel and Conference Policy - HNM1A28

(1) Provides guidance and advice to management and staff on travel and conference regulations, policies, and procedures; (2) Develops, implements, and evaluates policies and practices relating to travel and conference management; (3) provides internal controls, audits travel actions, and develops best practices and supporting tools for planners and administrative staff; (4) develops, deploys, and coordinates the use and management of electronic information systems utilized by NIAID staff in the execution of travel and conference activities; (S) Provides review and clearance of travel and conferences requiring the Executive Officer or NIH STO approval; (6) provides business management services related to NIAID wide conference logistical support contract; (7) Represents the Institute on trans-NIH travel & conference program policy committees and coordinates such policy within the Institute and with other NIH institutes.

Vaccine Research Center Administrative Management Branch - HNM1A26

(1) Serves as the coordinating point in handling all administrative, management, and facility support problems associated with the Vaccine Research Center; (2) advises the staff of the Director, Vaccine Research Center, and other key official of administrative policies and practices; and (3) provides overall administrative support services to the Vaccine Research Center, including budget, management and program analysis, personnel, space management, procurement, contract management, facilities management and related support services.

Office of Biodefense Research and Surety- HNM1A3

(1) Serves as the NIAID focal point for coordinating, planning, and implementing biodefense research supported by the various Divisions of the Institute and serves as coordinating body for NIAID for biosurety practices, physical and personnel surety and accountability and the official repository for clearances, classified information and Federal Security/Suitability Clearances within NIAID; (2) maintains a comprehensive knowledge of the Institute's biodefense research programs and policies, and identifies relevant programs of other government and non-government agencies involved in biodefense activities in order to advise the Institute Director on program relationships and opportunities for collaboration; (3) supports the NIH Biodefense Research Coordinating Committee, which serves as a focal point for trans-NIH communication and planning of biodefense activities; (4) organizes and disseminates information on NIAID biodefense research activities, programs, and funding opportunities; (5) serves as the point of contact or liaison with a diverse array of federal and non-federal agencies and organizations involved in biodefense research: (6) serves a focal point for coordinating information on NIAID and trans-NIH Surety and Biosurety systems and procedures; (7) plans, manages and executes the Emergency Preparedness planning (EP) and Continuity of Operations planning (COOP) offices; (8) develops, administers and maintains key databases for NIAID management, evaluation, continuity of operations physical security and personnel reliability repository; such data bases will include an up-to date inventory on all biosafety practices for researchers and national and international functional biosafety level (BSL) 3/4 facilities and staff clearance and levels; (9) develops NIAID procedures and coordinates institute activities regarding access to, and use and protection of classified national security information and sensitive related to instate biodefense research; and (10) participates in the governance of the high-containment taskforce; and (11) serves as the NIAID liaison with the NIH OD, the Department of HHS, and other Federal departments and agencies regarding intelligence gathering and analysis which may impact NIH programs and operations

Biodefense Research Countermeasures Branch- HNM1A32

(1) Serves as the NIAID focal point for coordinating, planning, and implementing biodefense research supported by the various Divisions of the Institute; (2) maintains a comprehensive knowledge of the Institute's biodefense research programs and policies, and identifies relevant programs of other government and non-government agencies involved in biodefense activities in order to advise the Institute Director on program relationships and opportunities for collaboration; (3) supports the NIH Biodefense Research Coordinating Committee, which serves as a focal point for trans-NIH communication and planning of biodefense activities; (4) organizes and disseminates information on NIAID biodefense research activities, programs, and funding opportunities;(5) serves as the point of contact or liaison with a diverse array of federal and non-federal agencies and organizations involved in biodefense research and (6) serves as the NIAID liaison with the NIH OD, the Department of HHS, and other Federal departments and agencies regarding intelligence gathering and analysis which may impact NIH programs and operations.

Surety and Preparedness Coordination Branch- HNM1A33

(1) Serves as the NIAID central governance and coordinating body for biosurety efforts across the Institute; (2) serves as focal point for coordinating information on NIAID and trans-NIH surety and biosurety systems and procedures; (3) plans, manages and executes the NIAID Emergency Preparedness planning (EP) and Continuity of Operations planning (COOP) functions; (4) develops, administers and maintains key data- bases for NIAID management, evaluation, continuity of operations, personnel/physical security, security clearances and personnel reliability repositories; such data bases will include an up-to date inventory on all biosafety practices for researchers and national and international functional biosafety level (BSL) 3/4 facilities and staff clearance and levels; (5) develops NIAID procedures and coordinates institute activities regarding access to, and use and protection of classified national security information and sensitive related to instate biodefense research; and (6) participates in the governance of the high-containment taskforce and other associated related taskforces and workgroups.

Office of Communications and Government Relations - HNM1A4

(1) Serves as a focal point for the Institute's efforts to interpret and disseminate the goals and results of NIAID research programs and projects to the biomedical community, Congress, the media, constituents and other specialized groups, physicians and healthcare providers and the general public, at the national and international level; (2) Coordinates and supports collaborative international research programs which focus upon selected infectious diseases of substantial health importance in developing countries; (3) Coordinates NIAID intramural and extramural world-wide biomedical research on infectious and immunological diseases, advising the Institute Director on program relationships and opportunities for collaboration; (4) Provides epidemiology services and technical support to NIAID international research projects and staff assigned overseas; (5) Develops short- and long-term communications policies, goals, objectives, and strategies in support of the mission and priorities of the Institute; (6) Serves as the liaison and point of contact for all legislative matters, providing critical legislative analysis and Congressional testimony preparation; (7) Coordinates responses to all NIAID-directed media inquiries; writes news releases and statements directed to the media, including requests for information and records submitted under the Freedom of Information Act (FOIA) and Privacy Act (PA) programs; (8) Responds to public inquiries regarding NIAID-related research and health topics, for example, bio-defense, HIV/AIDS and infectious, allergic, and immunologic diseases; (9) Writes content for and produces pamphlets, fact sheets and Web-based information materials for the public; (10) Manages the NIAID Web site including content, policies, standards and guidelines and uses the Internet as a primary tool in communications efforts; (11) Serves as the Institute's liaison with appropriate voluntary, advocacy, and professional societies, providing information exchange and building understanding partnerships; and (12) Utilizes and integrates new communication technologies.

Immediate Office of the Director - HNM1A41

1)Develops short- and long-term communications policies, goals, objectives, and strategies in support of the mission and priorities of the Institute; 2) Serves as the main point of contact for all media inquiries about NIAID's research programs and activities; 3) Writes news releases, statements, and other materials directed to the media; 4) conducts media briefings to disseminate results of Institute research; 5) Establishes and maintains professional relationships with international, national and local news media representatives, and with communications staff in government and on-government organizations; 7) Develops and implements internal communications products and activities, including creating standard operating procedures, writing newsletters, creating and maintaining intranet sites, and establishing collaboration sites for the Institute; 8) Develops various communication resources and advises institute staff on internal communications matters; 9) Oversees the development of information channels and strategies for disseminating information internally and externally; 10) Writes content, obtains clearances, and produces pamphlets, fact sheets and Web-based information materials for the various target audiences; 11) Designs and creates visual materials and products; 12) Maintains a repository of images for use by OCGR and the Institute; 13) Plans and executes select special events for the Institute.

Freedom of Information Act Office - HNM1A43

(1) Manages and coordinates all activities associated with requests to the NIAID for information and records submitted under the Freedom of Information Act (FOIA) and Privacy Act (PA) programs; (2) Analyzes the nature and scope of all requests and determines the appropriate NIAID and NIH officials to be involved in preparing and/or coordinating the response; (3) Reviews all records to determine the information and documents that can be released under current law and regulations; (4) Designs and providing training to NIAID staff involved in responding to FOIA cases with respect to requirements, policies, regulations and procedures; and (5) Ensures organizational compliance with the legal requirements of these Acts.

Legislative Affairs and Correspondence Management Branch - HNM1A45

(1) Directs and coordinates legislative liaison, tracking, and analysis for the Institute; (2) prepares, edits, compiles, and/or reviews material for numerous policy, legislative, and budget-related briefings; and (3) manages the Executive Secretariat (controlled correspondence) and public inquiry functions for the Institute.

New Media and Web Policy Branch - HNM1A48

(1) Develops, implements, and maintains a communications technology infrastructure, inter- and intranet, and new media designed to enhance, maintain, and deliver information covering NIAID research initiative and accomplishments as well as information important to the general public; (2) develops Institute-wide guidelines, standards, metrics, policies, and procedures related to the creation and maintenance of new media products and ensures 508 Compliance and support; (3) provides for product development counselors to obtain business requirements from users on Internet, Intranet and new media and provide for translation of those requirements to New Media Service Support staff; (4) establishes content standards for new media that ensure that the tone and organization of the content of NIAID's products are appropriate both for the Institute's image and for the audiences NIAID serves; (5) serves as the Business Owner of and manages the redesign of NIAID web sites based on new information architecture, usability testing and guidelines, Web site user satisfaction survey information, and Web site statistics and NIAID content development strategic planning; (6) seeks opportunities for promoting NIAID's new media products to all appropriate audiences (citizens, business partners, employees, researchers, media, etc.); (7) serves as the principal interface with the NIAID Office of Technology Information Systems (OTIS) and other technical services providers to maintain and build upon Web-based information services, features, and future systems capabilities; and (8) serves as a resource to the Institute including the divisions and offices regarding Web and new media matters.

News and Science Writing Branch - HNM1A49

(1) Plans, directs, and manages proactive, comprehensive news and science writing programs and interactions that convey information on NIAID's research programs, activities, priorities, and accomplishments; (2) develops and recommends long-range strategic plans and strategies regarding the development and dissemination of news and science content; (3) serves as the focal point for NIAID's relationship with international, national, and local news media and trade press; (4) oversees media activities regarding NIAID's research programs and activities, including initiating news media contacts where appropriate, writing news releases and other materials for reporters, conducting media briefings, responding to media inquiries, and working collaboratively with NIH and HHS to ensure timely clearance of NIAID news products; and (5) oversees and manages media training for top level clinical, scientific, and administrative staff.

Communications Services Branch - HNM1A4A

(1) Plans, directs, and manages proactive, comprehensive communications services and initiatives that employ multimedia strategies to convey NIAID's leadership role in research in infectious and immune-mediated diseases, microbiology, immunology, and related disciplines; (2) develops and recommends long-range strategic plans and strategies regarding NIAID's communications initiatives and services; (3) serves as an authoritative resource and advisor on communications matters arising from information dissemination and new/social media issues; (4) oversees the development and execution of communication strategies for issues and program areas that span NIAID and/or do not fit into a single disease/research category; (5) oversees and manages internal NIAID communications initiatives; (6) oversees and manages social media campaigns and day-to-day activities; (7) plans, markets, and executes NIAID named lectures and other NIAID special events; (8) Provides broad editorial, design, and photography services; and (9) provides a broad range of turnkey video and animation services.

Office of Ethics - HNM1A5

(1) Administers a comprehensive NIAID ethics program that reflects statutory responsibilities and integrity in service to the public; (2) develops and recommends policies and procedures related to employee standards of conduct, financial interests and disclosure, and outside activities; (3) reviews and certifies financial disclosure reports; (4) reviews and approves requests for outside activities for conformance with regulations and policies; (5) maintains all records associated with the ethics functions; (6) provides advice and assistance to employees regarding the application of the ethics laws, regulations, and policies; (6) provides ethics training; (7) serves as the NIAID liaison to the DHHS Office of the General Counsel, and the Office of Government Ethics; and (8) provides advice to the Office of the Director regarding conflict of interest of individuals involved in the conduct of biomedical research, including Government employees, advisory committee members, and non-Government employees such as peer reviewers, DSMB members, or members of working groups.

Office of Strategic Planning, Initiative Development, and Analysis - HNM1A6

(1) Serves as a focal point for NIAID's strategic planning and evaluation, integration of longterm financial and capital asset resource requirements, budgeting, and financial management activities and knowledge management; (2) in collaboration with members of the Institute's scientific divisions and executive management, develops strategic plans, policies, goals, objectives, strategies and techniques in support of the Institute's missions; (3) directs and coordinates all phases of trans-NIAID strategic planning and financial management to ensure that they are integrated, effective, and mutually supportive; (4) serves as liaison, both internal and external, for all trans-NIAID planning and financial management activities; and (5) ensures that the Institute has a long-range, sustainable vision and program plan for carrying out its mandate based on (a) a sound understanding of trends in disease prevalence and treatment and of the general state of science, and (b) ongoing and effective assessment of its programs, both existing and proposed.

Policy, Planning and Evaluation Branch - HNM1A65

(1) Provides institutional leadership for systematic, trans-NIAID strategic planning and evaluation of all science research and clinical programs for which the Institute is responsible; (2) oversees the development and implementation of an ongoing strategic planning process, engaging all members of the Institute's scientific divisions and executive management; (3) directs ongoing and special assessments and evaluations of program performance that serve to guide the development of future Institute programs and initiatives and respond to requirements of the NIH Division of Program Coordination, Planning, and Strategic Initiatives; (4) ensures compliance with all applicable laws, regulations, and policies to include the Government Performance and Results Act (GPRA), the DHHS Agency Performance Report (APR), reporting requirements and OMB's Information Quality Bulletin for Peer Review; and (5) coordinates the preparation for meetings with and presentations to the NIH Director, Department Heads, members and staff of Congress, and representatives of scientific organizations and advocacy groups; (6) Oversees the Risk Management Program for NIAID.

Referral and Program Analysis Branch - HNM1A66

As the NIAID focal point for analytic data, the Branch is responsible for (1) the intra-institute program assignments of all research, training, career and fellowship grant applications; (2) the analysis, Interpretation and classification of the scientific content of research grants, contracts, and intramural research projects; (3) a variety of periodic and special reports and information displays to the Office of the Director, the Budget Officer, Division Directors, and review and Advisory groups; (4) program analysis and consultant services to senior staff for the collection, organization and analysis of scientific and programmatic data for current, historic and trend information, and (5) scientific information data management of the Multi-Axis Coding System (MACS), which the senior staff uses for decisions on program planning, policy determination, and evaluation of progress of the Institute's programs.

Office of Initiative Development - HNM1A67

(1) Provides direction, guidance, and support in the development of approved initiatives with NIAID; (2) provides advice and assistance to NIAID staff in the initiation, planning, management, quality control, and oversight of the initiative development process; (3) works closely with NIAID Divisions in the drafting of quality initiatives, including writing/editing, coordinating the review and quality control, negotiating content changes, and finalizing the scientific and programmatic text of initiatives; (4) works closely with program staff to provide direction and oversight to initiative development teams; (5) works collaboratively with NIAID staff to develop work assignments and timelines; (6) monitors adherence to and completion of work assignments; (7) evaluates quality of performance and efficiency and timelines of task completion; (8) resolves conflicts of differences of opinion in the initiative development process; (9) develops systems, procedures, policies, tools and training to support the quality and timely completion of NIAID-approved initiatives; (10) works closely with the Division of Extramural Activities (DEA) to ensure that acquisition packages and grant solicitations are executed in a timely manner; (11) coordinates with DEA, if needed, to DEA completes the release and awards process; (12) advises the Director of OSPFM on initiative development workload and process improvement; (13) provides advice on short and long term strategic planning for extramural research initiatives and participates in strategic planning activities; and (14) monitors, analyzes, and reports on the Institute's portfolio of approved initiatives.
Data Analytics Research Branch - HNM1A68

(1) Provides robust data and portfolio analytical capabilities for data-driven decision making; (2) performs short-and long-term portfolio analyses informed by analytical and data science research methodologies; (3) develops tools and applications for data mining, curation, manipulation, verification, cleansing, analysis, and visualization; (4) provides training on data and portfolio analysis tools and methodologies; (5) consults with program and other staff to produce portfolio analyses; (6) provides interpretations of data and portfolio analysis results; (7) disseminates findings, tools, data, etc. as appropriate; (8) informs NIAID leadership of key analyses to guide future policies and program direction; (9) coordinates with the NIAID Office of Data Science and Emerging Technologies regarding Institutional policies; and (10) informs and coordinates with counterparts and leadership in the Office of Extramural Research (OER) and the Office of Portfolio Analysis (OPA), and the NIH Institutes.

Technology Transfer and Intellectual Property Office – HNM1A7

(1) Serves as the NIAID focal point for implementing pertinent legislation, regulations, policies, and rules and administers activities relating to Cooperative Research and Development Agreements (CRADAs) and other agreements that govern research collaborations, Clinical Trial Agreements (CTAs), Material Transfer Agreements (MTAs), Conditional Gifts, inventions, patents, licenses, royalties, and associated matters; (2) provides advice, guidance, and assistance to NIAID staff on the development and management of intellectual property, including patents and trademarks, and the filing and prosecution of patent applications; the development of terms and the negotiation of licensing and agreements that govern research collaborations; the management, administration, and distribution of royalty income arising from licensing agreements; the transfer of research materials; and the interpretation of laws, policies, rules and regulations, especially those related to the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995; (3) proposes and assists in developing technology transfer policy for NIAID; prepares and disseminates operating procedures and guidelines to NIAID staff on matters relating to the functions of the Office; (4) reviews and analyzes planned collaborative agreements to ensure that they are consistent with the mission of NIAID and comply with applicable federal laws and the policies and procedures of NIAID, NIH, the Public Health Service, and; (5) advises and assists NIAID staff and extramural grantees and contractors with issues related to grantees' and contractors' intellectual property developed with NIAID support; (6) ensures NIAID receipt of funds due to NIAID through established CRADAs and Conditional Gifts; (7) develops, prepares, and coordinates the preparation of routine and special reports on matters within the purview of the Office; (8) serves as liaison with individuals, committees, and organizations within and outside of the Federal Government who are interested or involved in matters relating to the Office's assigned areas of responsibility; (9) provides an annual report to the Director, NIAID and other senior scientific management staff regarding the status of technology transfer; (10) may provide advice, guidance, assistance, and recommendations to other federal agencies, including the Centers for Disease Control and Prevention, on matters related to technology transfer, including intellectual property.

Office of the Director- HNM1A71

(1) Proposes and assists in developing technology transfer policy for NIAID; prepares and disseminates operating procedures and guidelines to NIAID staff on matters relating to the functions of the Office; (2) reviews and analyzes collaborative agreements to ensure that they are consistent with the mission of NIAID and comply with applicable federal laws and the policies and procedures of NIAID and NIH; (3) provides advice, guidance, and assistance to NIAID staff on the development and management of intellectual property; the development of terms and the negotiation of licenses and agreements that govern research collaborations; the management, administration, and distribution of royalty income arising from licensing agreements; the transfer of research materials; and the interpretation of laws, policies, rules and regulations, especially those related to the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995; (4) advises and assists NIAID staff and extramural grantees and contractors with issues related to grantees' and contractors' intellectual property developed with NIAID support; (5) ensures NIAID receipt of funds due to NIAID through established CRADAs and Conditional Gifts; (6) develops, prepares, and coordinates the preparation of routine and special reports on matters within the purview of the Office; (7) serves as liaison with organizations within and outside of the Federal Government related to technology transfer; (8) prepares an annual report on TTIPO activities to the Director, NIAID and other senior management; (9) promotes development, commercialization and public use of NIAID discoveries; (10) reviews annual reports from licensees, and coordinates audits of licensees, as appropriate; (11) provides support to the TTIPO Director through program planning, analysis, evaluation and reporting; (12) oversees TTIPO operations; (13) leads TTIPO's budget planning and execution; (14) develops and maintains TTIPO's standard operating policies, procedures, and templates; (15) develops and maintains content for TTIPO's intra- and inter-net sites; (16) acts as a liaison with OCICB (Office of Cyber Infrastructure and Computational Biology) to maintain and develop TTIPO digital information storage/sharing systems; (17) oversees employee performance management program; (18) manages NIAID's Technology Transfer Fellowship program; (19) organizes TTIPO staff training efforts; (20) manages and administers NIAID's Technology Evaluation Advisory Committee (TEAC); (21) leads efforts, tracks and reports to the TTIPO Director on all TTIPO human resource initiatives and activities; (22) assists TTIPO branches with special projects, including but not limited to NIAID requests for Determination of Exceptional Circumstances in grants and contracts; (23) manages FOIA requests directed to TTIPO; (24) prepares metrics-based reports and provides support to the TTIPO Director in answering enquiries from both within and outside of NIAID on matters in the purview of the Office; (25) monitors royalty arising from the licensing of NIAID inventions; (26) monitors expenditures associated with NIAID's patenting activities; (27) may provide advice, guidance, assistance, and recommendations to other federal agencies, including the Centers for Disease Control-and Prevention, on matters related to technology transfer, including intellectual property

Branch A- HNM1A72

(1) Serves- as a focal point for technology development and transfer for assigned intramural and extramural research programs of NIAID; (2) assists NIAID staff in identifying and evaluating discoveries that may constitute inventions; (3) proposes technology transfer and intellectual property policy pertinent to NIAID's intramural research programs that comports with federal laws, regulations and DID-IS and NIH policies; (4) protects inventions, consistent with applicable federal laws, regulations and DID-IS and NIH policies, by seeking intellectual property protection as appropriate to promote the development, commercialization and public use of the invention; (5) oversees NIAID's patenting and licensing activities as executed by contract law firms including directing and monitoring law firms in conducting U.S. and foreign patent application prosecution, patent law-related determinations of rights and inventorship analyses; (6) provides advice and recommendations on technology transfer and intellectual property; (7) promotes development, commercialization and public use of NIAID discoveries through the identification of qualified partners in the public and private sectors; (8) supports NIAID's programmatic objectives by drafting and negotiating transactional agreements including but not limited to MTAs, CRADAs, CDAs, Interagency Agreements, Memorandums of Understanding, Clinical Trial Agreements (CTAs), and Conditional Gifts; (9) provides training to assigned NIAID staff on matters relating to the functions of the Office; (10) monitors expenditures associated with NIAID's patenting activities; (11) enters appropriate legal correspondence and data into centralized databases to track, monitor and report on technology transfer activities; (12) conducts license and other technology transfer negotiations with the private sector and academia, reviews exclusive and non-exclusive license applications, executes licenses; (13) reviews annual progress reports, sales reports and attainment of benchmarks from licensees, and coordinates audits of licensees, as appropriate; (14) resolves disputes with licensees regarding non-- payment, infringement, and other issues that may result in amending licenses.

Branch B- HNM1A74

(1) Serves as a focal point for technology development and transfer for assigned intramural and extramural research programs of NIAID; (2) assists NIAID staff in identifying and evaluating discoveries that may constitute inventions; (3) proposes technology transfer and intellectual property policy pertinent to NIAID's intramural research programs that comports with federal laws, regulations and HHS and NIH policies; (4) protects inventions, consistent with applicable federal laws, regulations and HHS and NIH policies, by seeking intellectual property protection as appropriate to promote the development, commercialization and public use of the invention; (5) oversees NIAID's patenting and licensing activities as executed by contract law firms including directing and monitoring law firms in conducting U.S. and foreign patent application prosecution, patent law-related determinations of rights and inventorship analyses; (6) provides advice and recommendations on technology transfer and intellectual property; (7) promotes development, commercialization and public use of NIAID discoveries through the identification of qualified partners in the public and private sectors; (8) supports NIAID's programmatic objectives by drafting and negotiating transactional agreements including but not limited to MTAs, CRADAs, CDAs, Interagency Agreements, Memorandums of Understanding, Clinical Trial Agreements (CTAs), and Conditional Gifts; (9) provides training to assigned NIAID staff on matters relating to the functions of the Office; (10) monitors expenditures associated with NIAID's patenting activities; (11) enters appropriate legal correspondence and data into centralized databases to track, monitor and report on technology transfer activities; (12) conducts license and other technology transfer negotiations with the private sector and academia, reviews exclusive and non-exclusive license applications, executes licenses; (13) reviews annual progress reports, sales reports and attainment of benchmarks from licensees, and coordinates audits of licensees, as appropriate; (14) resolves disputes with licensees regarding non- payment, infringement, and other issues that may result in amending licenses.

Branch C – HNM1A75

(1) Serves as a focal point for technology development and transfer for assigned intramural and extramural research programs of NIAID; (2) assists NIAID staff in identifying and evaluating discoveries that may constitute inventions; (3) proposes technology transfer and intellectual property policy pertinent to NIAID's intramural research programs that comports with federal laws, regulations and HHS and Nlli policies; (4) protects inventions, consistent with applicable federal laws, regulations and HHS and Nlli policies, by seeking intellectual property protection as appropriate to promote the development, commercialization and public use of the invention; (5) oversees NIAID's patenting and licensing activities as executed by contract law firms including directing and monitoring law firms in conducting U.S. and foreign patent application prosecution, patent law-related determinations of rights and inventorship analyses; (6) provides advice and recommendations on technology transfer and intellectual property; (7) promotes development, commercialization and public use of NIAID discoveries through the identification of qualified partners in the public and private sectors; (8) supports NIAID's programmatic objectives by drafting and negotiating transactional agreements including but not limited to MTAs, CRADAs, CDAs, Interagency Agreements, Memorandums of Understanding, Clinical Trial Agreements (CTAs), and Conditional Gifts; (9) provides training to assigned NIAID staff on matters relating to the functions of the Office; (10) monitors expenditures associated with NIAID's patenting activities; (11) enters appropriate legal correspondence and data into centralized databases to track, monitor and report on technology transfer activities; (12) conducts license and other technology transfer negotiations with the private sector and academia, reviews exclusive and non-exclusive license applications, executes licenses; (13) reviews annual progress reports, sales reports and attainment of benchmarks from licensees, and coordinates audits of licensees, as appropriate; (14) resolves disputes with licensees regarding non- payment, infringement, and other issues that may result in amending licenses; (15) may provide advice, guidance, assistance, and recommendations to other federal agencies, including the Centers for Disease Control and Prevention, on matters related to technology transfer, including intellectual property.

Office of Cyber Infrastructure and Computational Biology - HNM1A8

(1) Provides technologies support to NIAID programs of research and research training involving causes, diagnoses, treatment and prevention of immunologic and infectious diseases; these technologies are programmatically planned, managed, and applied to support (a) research performed in NIAID laboratories; (b) research programs at scientific institutions; (c) institutional research-training; (d) contracts programming for implementing and using applied laboratory and clinical findings and development of specific disease control measures and solutions to infectious and immunological disease problems; and (e) collection, dissemination, and utilization of research findings and related information; (2) is responsible for oversight, policy, and guidance of Cyber Technologies (CT) Programs (CTP), including coordination of the CTP through strategic planning, knowledge management, cyber systems and software engineering, and bioinformatics throughout NIAID, coordinating with NIAID officials in the design and implementation of Cyber Technology (CT) solutions to meet NIAID needs; (3) provides technical and tactical CT management and support for NIAID intramural and extramural biomedical research programs, including technology support to NIAID biodefense areas through the use of performance standards and strict adherence to security assurance procedures and providing strategic planning and analyses for future needs by identification of major NIAID bioinformatics issues; (4) develops, conducts and reviews NIAID technologies and resource planning, programs and acquisitions to assure conformance with technology-related Federal laws, regulations, and policies and to ensure compliance with Governmental policy, Best Practices, and Federal Enterprise Architecture (FEA); (5) provides leadership and coordination for technology-related policy, program/project liaison, program/project collaboration, and resources administration for NIAID biomedical technologies programs; (6) provides guidance and coordination of technologies capital planning; (7) provides Systems Security Administration and Management, including defining standards and managing and implementing Information Systems Security measures; (8) manages the life-cycle program, governing and providing oversight for technologies maintenance and licensing agreements, controlling changes to configuration items and providing accurate status and current configuration data to NIAID management; (9) monitors and evaluates performed processes, work products, and services against established standards, for conformance to technologies, investment review, acquisitions, and evaluation policies and reports status to senior management; (10) provides essential and assured services to facilitate electronic systems processing communication and a collegial, authorized and accessible framework for automated information sharing and collaboration (shared network applications, Internet access, etc.); (11) analyzes, designs, develops, tests, implements, maintains, and manages software, client/server and web-enabled applications and systems, and applications that provide enhanced support for scientific and clinical research and bioinformatics in NIAID, including COTS, GOTS, and MOTS products, and systems designed to support specific areas (e.g. Scientific Coding and Referral System (SCORS) and Acquisitions Management Budget Information System (AMBIS 2000)); (12) determines and forecasts resources needed, negotiates commitments, and develops a schedule for all projects to be undertaken by rigorously following the project/program work management mechanism; (13) reviews all RFAs and RFPs containing IT or CT components and provides clearance for such, works with PO's and CO's during the execution of a grant or contract containing such components to ensure that NIAID's needs and requirements are met; (14) ensures that noncompliance issues are addressed and corrective actions taken; (15) enhances human resources

Office of Cyber Infrastructure and Computational Biology (ctd.)- HNM1A8

professional development through in-service training, professional development activity in the laboratories, and collaboration with interdisciplinary professionals; (16) ensures compliance with the Capability Maturity Model Integration (CMMI); (17) provides support for special access to extranet knowledge-information-data systems (KIDS) hosted on the NIAID Internet/Intranet/Extranet web servers; and (18) serves as intra/interagency liaison between the NIAID CT Program and the DHHS and NIH Chief Information Officers.

Operations and Engineering Branch - HNM1A82

(1) Provides technical and tactical cyber technologies (CT) management and support for the NIAID extramural biomedical research programs; (2) provides technology support to NIAID biodefense areas through the use of performance standards and strict adherence to security assurance procedures; (3) employs CT methodology comprising a consolidated integrated optimized systems approach, incorporating multidisciplinary teams of science program managers and technologists; (4) provides essential and assured services to facilitate electronic systems processing communication and a collegial, authorized and accessible framework for automated information sharing and collaboration (shared network applications, Internet access, etc.); (5) provides support for special access to extranet knowledge-information-data systems (KIDS) hosted on the NIAID Internet/Intranet/Extranet web servers; (6) ensures compliance with the Capability Maturity Model Integration (CMMI); and (7) throughout the Cyber Technologies Program (CTP): (a) manages the life-cycle program for the extramural community; (b) develops and implements standards for extramural configuration and workstations; (c) defines standards and manages and implements Information Systems Security measures; (d) identifies and estimates requisite tasks and attributes of the work products and tasks; (e) determines resources needed, negotiates commitments, and develops a schedule; and (f) controls changes to configuration items and provides accurate status and current configuration data.

Customer Services Branch - HNM1A83

(1) Provides technical and tactical cyber technologies (CT) management and intramural support for biomedical research programs in NIAID; (2) provides technology support to NIAID biodefense areas through the use of performance standards and strict adherence to security assurance procedures; (3) provides the cyber technologies infrastructure to facilitate electronic communication within NIAID through global scientific and clinical data exchange; (4) provides a framework for automated information sharing and collaboration; (5) promotes enhanced security, improved service and system availability, and timely deployment of new applications and services; (6) ensures compliance with the Capability Maturity Model Integration (CMMI); and (7) throughout the Cyber Technologies Program (CTP): (a) defines and establishes standards and processes; (b) identifies and analyzes requisite tasks and attributes of work products and tasks; (c) determines and projects resources needed, negotiates commitments, and develops a schedule; (d) develops and maintains the project/program plan mechanism for work management; (e) monitors and evaluates work products and services against established standards and reports status to senior management; (f) ensures that noncompliance issues are addressed and corrective actions taken; (g) controls changes to configuration items and provides accurate status and current configuration data; and (h) analyzes, designs, builds and tests rollout client/server and web-enabled applications and systems to support scientific and clinical research and bioinformatics mission in NIAID.

Program Management Branch - HNM1A84

(1) Is responsible for oversight, policy, and guidance of cyber technologies (CT) programs throughout NIAID; (2) provides leadership and coordination for technology-related policy, strategic planning, program/project liaison, program/project collaboration, and resources administration for NIAID biomedical technologies programs; serves as intra/interagency liaison between the NIAID CT Program and Chief Information Officer; (3) develops and reviews NIAID technologies planning, programs and acquisitions to assure conformance with technology-related Federal laws, regulations, and policies; (4) coordinates the CTP through h strategic planning, knowledge management, cyber systems and software engineering, and bioinformatics; (5) plans, monitors, and evaluates requirements and resources management, commitments, negotiation, and resolution of process-related issues in the Office of Technology Information Systems (OTIS), NIAID; (6) conducts technologies resource planning to ensure compliance with Governmental policy and Best Practices; (7) administers technology resources for OTIS missions; (8) governs and provides oversight for OTIS technologies maintenance and licensing agreements; (9) coordinates NIAID officials in the design and implementation of CT solutions to meet NIAID needs; (10) provides strategic planning and analyzes resources for future needs by identification of major NIAID bioinformatics issues; (11) enhances human resources professional development through in-service training, professional development activity in the laboratories, and collaboration with interdisciplinary professionals; (12) sponsors collaboration with biomedical researchers and information technologists to meet requirements in NIAID's programs effort; (13) monitors conformance with technologies, investment review, acquisitions, and evaluation policies; and (14) provides: (a) program quality assurance, performance assessment, and reporting guidance and oversight, (b) guidance and coordination of technologies capital planning, and (c) Systems Security Administration and Management.

Software Engineering Branch- HNM1A85

To effectively and efficiently develop and deliver high quality, customized software solutions to support the mission of NIAID.

Bioinformatics and Computational Bioscience Branch - HNM1A86

(1) Ensures that the BCBB manages, guides, and mentors all BCBB functions so that they are compliant and complementary with the strategic and tactical goals and direction of OCICB, NIAID, NIH, HHS and the Federal Government; (2) provides the tools, services, and infrastructure necessary to promote the use of bio-IT solutions that advance basic scientific research; (3) plays a lead role in developing bioinformatics tools and strategic directions within the NIAID and serves as a focal point for infectious diseases research informatics planning worldwide with a firm commitment to collaboration across disciplines, institution, and sections; (4) provides communication with, and education of, the NIAID scientific community in the areas of bioinformatics and computational biology; (5) provides direct assistance and training in areas that join biology with the computer sciences, engineering, mathematics, and statistics; (6) designs, develops, manages, and supports custom software application programs in computational biology, such as the generation of mathematical models of biological networks, the development of modeling and simulation tools, scientific workflows applications, data mining and visualization tools; (7) researches, evaluates, recommends, and implements new state-of-the-art bioinformatics and scientific IT tools and procedures, providing NIAID researchers with appropriate analytical bioinformatics tools; (8) evaluates and manages commercial scientific applications for site licensing, monitors scientific application license usage, and proactively plans for license acquisition and maintenance; (9) conducts basic theoretical studies related to biological network organizations and dynamic processes, and the development of methods for the analysis visualization, and biosimulation of complex biological processes; (10) researches, acquires, manages, and supports the NIAID High-Performance Bioinformatics Computing (HPBC) environment; (11) designs, develops and supports software applications, web services, and workflows for the HPBC; (12) develops, provides and fosters NIAID's Biomedical Informatics Infrastructure, making that informatics infrastructure available for use by the broader infectious disease and allergy and biomedical research communities; (13) partners with other NIH, DHHS, Federal Agencies, NIAID International programs, and the private sector to leverage combined strengths and collaboratively develop novel computational biology tools and services; (14) ensures the rigorous application of information security/information assurance policies, principles, and practices in the delivery of planning and management services; and (15) plans, develops, implements, tracks, manages, and evaluates policies and procedures to ensure that BCBB initiated/instituted functions embrace and implement as appropriate, the Capability Maturity Model Integration (CMMI®), Information Technology Infrastructure Library (ITIL®), and the Project Management Body of Knowledge (PMBOK®).

Business Process and Information Management Branch- HNM1A87

To develop and deliver high quality Electronic Content Management (ECM) and Business Process Management (BPM) solutions that increase effectiveness and efficiency for both internal and external NIAID collaborators.

Office of Workforce Effectiveness and Resources - HNM1A9

(1) Advises NIAID senior management officials regarding organizational performance, effectiveness, and efficiency; (2) serves as a catalyst for business and human capital strategies that ensure individual and team behaviors and performance are consistent with NIAID's mission and values; (3) works with NIAID leadership to develop their organizational infrastructure to enhance overall organizational capability and effectiveness; and (4) oversees various programs and initiatives to ensure NIAID has the depth and breadth of talent to achieve its organizational goals.

Human Capital Branch - HNM1A94

Develops and implements NIAID specific human capital programs and procedures that further support NIH OHR programs and initiatives or that respond to specific NIAID human capital needs by (1) interpreting policy and providing advice and developing written guidance regarding the application of various management authorities such as Title 42 pay and appointments, Senior Executive Service, Senior Biomedical Research Service, other executive level appointing authorities, Title 5, Title 38, Commissioned Corps and non-FTE programs; (2) assisting managers with the preparation and/or review of the necessary documentation to request personnel actions for submission, review, action and approval by OHR such as position descriptions, selection criteria, or incentive justification; and (3) providing advice and developing written guidance on performance management and awards.

Workforce Management Branch - HNM1A95

Assists senior managers in the areas of workforce planning, competency development, and employment outreach to enhance overall organizational capability and talent development by (1) developing the Institute's workforce plan and developing and implementing strategies and interventions to ensure that the Institute has a staff with the necessary competencies to achieve NIAID's mission and goals; (2) developing and executing strategies to target high quality candidates through marketing and outreach, and developing and implement equal employment opportunity and workforce diversity initiatives; and (3) managing the development or enhancement of NIAID human capital systems such as VEDS and Bizflow, and serving as the Institute liaison to OHR on such systems as Capital HR, WITS, QuickHire and QuickClass.

Workforce Development Branch - HNM1A96

Assists senior managers and staff in the areas of employee learning and development, leadership development, organizational development, and change management to enhance overall organizational capability by (1) advising on matters related to organizational effectiveness and performance measurement, to include organization structure and goals alignment, change management, and transition planning; and (2) providing leadership, oversight, and guidance for learning and development initiatives, conducting needs assessments and providing mandatory as well as targeted training programs and services to enhance the assimilation, retention, and productivity of the NIAID workforce.

Office of Global Research - HNM1AB

(1) Coordinates and supports collaborative international research programs which focus upon selected infectious diseases of substantial health importance in developing countries; (2) serves as the NIAID focal point with the Fogarty International Center, the World Health Organization, the State Department, and the Centers for Disease Control with respect to international research programs; (3) maintains a comprehensive knowledge of the Institute's research programs and policies and, in coordination with the Fogarty International Center, identifies relevant programs of other Federal domestic agencies, bilateral research agencies and organizations, multilateral research organizations, and voluntary agencies which are involved in international health activities; advises the Institute Director on program relationships and opportunities for collaboration; (4) coordinates NIAID intramural and extramural world-wide biomedical research on infectious and immunological diseases; (5) organizes and disseminates information on NIAID international research activities, programs, and funding opportunities; prepares reports and publications on the Institute's international activities and serves as the primary contact point for inquiries on international research; (6) advises and assists NIAID staff on international activities; provides information/orientations about the cultural and political dynamics of a region/country and how these may impact scientific research; this includes providing information about the priority health concerns of different regions/countries and information about the location/capacity/ongoing activities of research facilities in different countries; (7) organizes and coordinates cross-cutting NIAID international activities that complement Division activities and address unmet needs; (8) provides support and assistance to Divisions and OD/NIAID in the development, justification, negotiation and administrative support to NIAID staff assigned overseas; assists with the planning, justification, and coordination of Division and OD/NIAID international travel; (9) interacts with international scientists active in relevant areas of research and identifies scientists who may be potential participants in international collaborative research projects; (10) monitors and facilitates NIAID-supported foreign awards and domestic awards with a foreign component and serves as liaison with FIC and concerned Divisions to ensure requests are addressed in a timely manner; (11) provides epidemiology services and technical support to NIAID international research projects and staff assigned overseas, including hands-on assistance with study design, data management, analysis and interpretation. This service is extended to intramural as well as extramural components of the NIAID. Assures high scientific standards for all epidemiological work undertaken; and (12) engages in developing an epidemiology research portfolio, and epidemiologists will be expected to disseminate their results at scientific meetings and peer-reviewed journals.

Office of Mission Integration and Financial Management - HNM1AC

The NIAID Office of Mission Integration and Financial Management (OMIFM) formulates, presents, justifies, defends and executes the Institute's budget, conducts long-range analyses, creates plans and modeling to assess, project, and attain the Institute's critical resource needs as a whole and for critical research areas including the Institutes three major missions: Biodefense, HIV/AIDS, and Immunological and Infectious Diseases (IID)."Additionally, OMIFM manages a large portfolio of projects which are not funded via appropriations (e.g., gift funds, CRADAs, royalties and other non-appropriated accounts). The appropriated and non-appropriated programs and projects total about \$6.0 billion per year. OMIFM (1) manages, plans and directs all financial management activities of NIAID and its programs; (2) serves as the focal point budget for the identification and integration of long-range critical resource requirements to meet the Institute's strategic priorities; (3) provides financial reports, trend analyses, historical data, and financial modeling to inform and improve funding and policy decisions; (4) works with partners within NIAID, NIH, and HHS to facilitate the development, integration and deployment of new business systems for finance and budgeting; (5) partners with Institute and trans-NIH collaborators to improve financial information for the institute to ensure more reliable and predictable decision making; (6) allocates resources for over 300 major research programs to achieve NIAID's long-range strategic objectives, goals and milestones; (7) directs and coordinates all phases of trans-NIAID budgeting and financial management to ensure that they are integrated, effective, and mutually supportive; and (8) serves as the principal advisor to NIAID's leadership on the strategic management of NIAID resources.

AIDS Budget & Financial Management Branch (HIV/AIDS) - HNM1AC4

The HIV/AIDS Budget and Financial Management Branch is approximately one-third of the total annual appropriation (between \$1.6-2.2B per year). Specific functions include: (1) performing formulation, presentation and execution budgetary tasks and activities in HIV/AIDS; (2) developing mission-specific operating plans which will be integrated into an overall NIAID budget operating plan; (3) processing, establishing, and tracking vehicles transferring funds within NIH or to other government organizations; and (4) maintaining funds control to ensure proper stewardship, reconciliation, and end-of-year close outs.

Bio Defense Budget & Financial Management Branch (BioD) - HNM1AC5

The Bio Defense Budget and Financial Management Branch is approximately one-third of the total annual appropriation (between \$1.6-2.2B per year). Specific functions include: (1) performing formulation, presentation and execution budgetary tasks and activities in Bio Defense; (2) developing mission-specific operating plans which will be integrated into an overall NIAID budget operating plan; (3) processing, establishing, and tracking vehicles transferring funds within NIH or to other government organizations; and (4) maintaining funds control to ensure proper stewardship, reconciliation, and end-of-year close outs.

Immunologic & Infectious Diseases Budget & Financial Management Branch (IID) - HNM1AC6

The Immunologic & Infectious Diseases Budget and Financial Management Branch is approximately onethird of the total annual appropriation (between \$1.6-2.2B per year). Specific functions include: (1) performing formulation, presentation and execution budgetary tasks and activities in IID; (2) developing mission-specific operating plans which will be integrated into an overall NIAID budget operating plan; (3) processing, establishing, and tracking vehicles transferring funds within NIH or to other government organizations; and (4) maintaining funds control to ensure proper stewardship, reconciliation, and endof-year close outs.

Office of Data Science and Emerging Technologies - HNM1AD

Office of Data Science and Emerging Technologies (1) Serves as the principal advisor to the NIAID Director and senior leadership on bioinformatics and data science, data management, and emerging technologies; (2) Develops effective and innovative strategies that advance basic and applied research to understand, treat, and prevent infectious, immunologic, and allergic diseases by providing leadership, strategic guidance, planning and vision to the coordination, planning, and execution of bioinformatics and related omics and technology programs, initiatives, and activities across NIAID; (3) Enhances NIAID's capabilities to accelerate scientific discoveries and clinical research to facilitate translating discoveries into clinical applications; (4) Promotes data driven methods and strategies to better understand, treat, and prevent infectious, immunologic and allergic diseases to predict health outcomes; (5) Coordinates bioinformatics and related omics and technology programs, initiatives and activities across NIAID that encourages innovation, exploits emerging technologies, provides a big data readiness environment and promotes a framework to maximize collaborative efforts within intramural and extramural communities; (6) Coordinates and supports big data ready environment across NIAID for data management and supports data sharing by developing, implementing, and coordinating data platforms for housing and indexing data generated by NIAID extramural centers and intramural laboratories; (7) Builds novel public-private partnerships to develop innovative programs in bioinformatics, omics, and technology development; (8) Provides leadership in domestic and international data sharing efforts, initiatives, programs, and policies related to open access and FAIR principles with consideration of data security and privacy issues; (9) Provides leadership for programs developing innovative state of the art technologies and computational platforms, tools, building predictive models and identifying predictive signatures for health, treatment, and disease status-clinically actionable data/clinical use; (10) Oversees compliance of NIAID genomics and technology projects, programs, initiatives with US government directives, policies, regulations and guidelines; (11) Coordinates dissemination of data, open source software and computational tools, data standards from NIAID funded intramural and extramural programs including dissemination of clinical research data; and (12) Coordinates training efforts in bioinformatics and computational tools across NIAID staff and broad extramural community.

Office of the Chief of Staff for the Immediate Office of the Director - HNM1J

(1) Manages and directs executive level activities, functions, and priority setting for all tasks occurring within the Immediate Office of the Director (IOD), NIAID; (2) manages critical points of contact and related information flows to resolve and respond to external inquiries involving trans-NIAID and trans-NIH national, international and translational research issues involving HIV/AIDS, emerging infectious diseases including pandemic influenza, Biodefense research efforts and initiatives, and other unexpected program-related events; (3) represents the Institute in diplomatic matters related to international research; (4) addresses the political and cultural implications of current research and the initiation or expansion of research in specific areas by coordinating communications with outside lay, professional and other organizations; (5) brings the perspective of the Director, NIAID to the development of NIAID program goals and objectives; (6) advises and assists the Director, NIAID, the Chief Operating Officer, and other key officials on all aspects of the mission, activities and functions of the IOD; and (7) is responsible for overseeing the effective and efficient planning and coordination of executive operations within the IOD, NIAID.

Division of Intramural Research - HNM2

(1) Plans and conducts the Institute's laboratory and clinical research program, which encompasses allergic, immunologic, and infectious diseases, to insure maximum utilization of available resources in the attainment of Institute objectives; (2) evaluates research efforts and establishes program priorities; (3) allocates funds, space, and personnel ceilings and integrates ongoing and new research activities into the program structure; (4) collaborates with other Institute and NIH programs and maintains an awareness of national research efforts in program areas; (5) advises the Institute Director and staff of the intramural research and areas of science of interest and importance to the Institute; and (6) provides technical services related to scientific areas of technology, on a shared basis, to the laboratories of the Intramural Research Program.

Cytokine Biology Section - HNM2-7

(1) Conducts research on the structure and functions of immunologically relevant cultured cells and primary cell lines; 2) monitors modifications to cell structure and function mediated via interaction with infectious agents; 3) conducts studies which emphasize the effects of infection by retroviruses or tran~fection with cloned viral genes in modifying expression of cell surface receptors, susceptibility to apoptosis, patterns of cell signaling and other cell functions which depend on cell type and developmental stage; and 4) tests clones from retroviruses that cause disease and mediate asymptomatic infection; and 5) analyzes the correlation between viral pathogenesis and specific actions on cell parameters.

Viral Immunology Section- HNM2-A

(1) Investigates the interaction between host immunity and viruses; (2) Studies the biology and evolution of viruses with a primary emphasis on influenza virus evolution under immune (vaccination), partially immune and non-immune selection pressures in vitro and in vivo; (3) Studies innate and adaptive immunity with a focus on repertoire and the function of antiviral CD8+ T cells and B cells and their contribution to virus clearance and evolution; (4) Produces and uses monoclonal antibodies to probe the antigenic structure of viral proteins and to study antibody influence on infection and virus evolution in vivo and in vitro; (5) Investigates the cellular processing and presentation of viral antigens to major histocompatibility complex class I restricted CD8+ T cells.

Molecular HIV Host Interactions Section - HNM2-B

The major research focus of the Molecular HIV Host Interactions Section (MHHIS) is to investigate interactions between HIV-1 and host. In particular, children, adolescents and young adults, at molecular level, which inlcudes: 1) HIV-mediated chronic systematic immune activation, perturbation and deficiency in B-cells, T-cells and macrophages; 2) influance of recreational substance use, e.g. marijuana, tobacco product, and alcohol on HIV-modulated gene expression and functional pathways; and 3) HIV-1 call tropism, potency, reservoir, reactivation and molecular evolution of the HIV-1 genome over the course of infection with/without antiretroviral therapy.

Tuberculosis Imaging Program – HNM2-C

1)TB Research PET/CT Imaging Program (TBIP) is to support the use of medical imaging including:

PET/CT and sophisticated, quantitative image analysis within the conduct of experimental large animal models of TB diseases within NIAID IPR; 2) evaluates novel potential chemotherapeutics for tuberculosis treatment, evaluates potential vaccines for preventing clinical tuberculosis in humans and support expanding investigations into basic immunology of Mycobacterium tuberculosis infection; 3) provides the expertise to conduct large animal experiments including the application of medical imaging so that individual sections do not have to develop this expertise individually; 4) provides an efficient means of supporting multidisciplinary TB research efforts, facilitating interaction among investigators forwarding TB research and; 5) encouraging collaborations with other investigators.

Rocky Mountain Veterinary Branch - HNM22

(1) Provides support to the Rocky Mountain Laboratories 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; and (3) provides training for animal care technicians, laboratory technicians, and investigators.

Veterinary Pathology Section - HNM222

(1) Provides animal necropsy, tissue collection, and histopathology service for RML researchers (histology service includes tissue processing, paraffin embedding, cryosectioning, standard, special and immunohistochemical staining, and tissue and glass slide archiving); and (2) provides detailed summary report of necropsy, histopathology and immunohistochemistry examinations.

Laboratory of Parasitic Diseases - HNM25

(1) Conducts basic research on the prevention, control and treatment of parasitic diseases; (2) performs biochemical and molecular studies to discover the stages against which functional immunity acts, the way in which immunity affects the parasite, and the chemical and molecular structure of functional antigens; (3) determines the characteristics of parasitic organisms, including response to drugs; (4) studies the pathologic processes in parasitic diseases; (5) studies the epidemiology of parasitic infections; and (6) investigates the factors which influence the transmission capacity of vector insects, the genetic determinants for vector potential, and the population biology of these vector species.

Immunobiology Section - HNM255

(1) Studies the immunology of the host-parasite relationship with the aim of developing new strategies for immunologic intervention in parasitic and other infectious diseases, as we)l as new principles concerning the function and regulation of the immune system; 2) places a major emphasis on the examination of immune responses to parasites in experimental models, and conducts parallel studies on parasitic infections in humans where possible; in addition, focuses on the investigation of the role of the cytokine network in parasite immunity and immunopathology and the involvement of different T lymphocyte subsets in these responses; and 3) conducts pathogens studies which include parasitic helminths and protozoa, as well as other organisms (bacteria and fungi) responsible for opportunistic infection.

Helminth Immunology Section - HNM25A

Studies the host responses to infections with helminths, particularly the filarial infections, with the major focus on: a) determinants of resistance to infection and susceptibility to various clinical outcomes of filarial infection; b) regulation of the immune response to infection with helminthes with particular emphasis on 1gE and eosinophil activation; c) definition of the antigens responsible for the induction of pathology and resistance to infection; and d) understanding the pathogenetic mechanisms underlying infections with pathogenic nematodes (filariae, strongyloides, hookworm).

Intracellular Parasite Biology Section - HNM25B

(1) Engages in studies which correlate structures of parasites with their immunological and cell biological properties in both their vertebrate and invertebrate hosts; and 2) places emphasis on the study of protozoan parasites with an intracellular phase of existence.
Malaria Vaccines Section - HNM25H

(1) Conducts research on the development of transmission blocking vaccines for human malarias; and 2) uses a number of malaria species to identify antigens, clone the genes expressing these antigens, identify appropriate expression systems for recombinant proteins, and effective adjuvants where necessary to enhance immunogenicity, with emphasis on the sexual stages of the parasite critical for transmission to man through the mosquito vector.

Clinical Parasitology Section - HNM25K

To oversee the clinical and clinical research activities of the Laboratory of Parasitic Diseases (LPD);
 to be the administrative link between the NIH's Clinical Center and LPD and to coordinate the clinical training in tropical diseases of the physicians in the LPD and the NIAID;
 to focus on the definition of clinical syndromes associated with parasitic infection and hypereosinophilic conditions, the pathogenesis underlying them, and new ways to diagnose and treat them.

Immunopathogenesis Section -HNM25L

(1) Conducts basic research on the molecular and immunological mechanisms regulating the pathogenesis of diseases associated with persistent Th2-type cytokine responses, including schistosomiasis, asthma, and other chronic fibrotic diseases; (2) exploits emerging technologies such as gene and protein microarray technologies to further characterize the mechanisms of fibrosis and chronic inflammation in the gut, lung and liver; (3) uses experimental animal models such as genetically modified mice to study the pathogenesis of schistosomiasis, asthma, and other chronic Th2-associated diseases; (4) studies the pathologic processes of several important infectious diseases including toxoplasmosis, tuberculosis, schistosomiasis, and geohelminth infection so that successful intervention strategies might be developed for these and other infectious diseases; and (5) identifies and characterizes novel an-fibrotic drugs.

Microbial Pathogenesis Section - HNM25N

1) Studies the actions of bacterial protein toxins on animals cells, using methods of biochemistry, microbiology, genetics and cell biology; and 2) focuses on pathogenic bacteria, especially Bacillus anthracis, to include a) identification and analysis of bacterial virulence factors and their genetic regulation, b) structure-function analysis of bacterial toxin proteins and other virulence factors, and c) development of improved vaccines and therapeutics.

Molecular Parasitology Section - HNM25P

(1) Focus on the genetics of virulence among zoonotic parasites, specifically focusing on Toxoplasma gondii (T. gondii), a common food and water borne class B infectious agent of animals and people; (2) study how virulence emerges among eukaryotic pathogens, how it is propagated by parasite sexual cycles, and how it can be maintained in complex genetic populations circulating in the vast array of intermediate hosts these parasites infect; (3) directly deals with the genetic origins of outbreaks which occur among an extremely large and diverse group of eukaryotic pathogens, including Toxoplasma, Plasmodium species- the causative agent of malaria- Cryptosporidium, Leishmania species, and Giardia.

Human Eosinophil Section – HNM25Q

Conducts basic and translational research related to the role of the eosinophil and eosinophil activation in disease pathogenesis, with the major focus on: a)identification and characterization of new subtypes of hypereosinophilic syndromes (HES); b)elucidation of the role of the eosinophil in pathogenesis of eosinophilic disorders; c)assessment of the safety and efficacy of chemotherapeutic agents targeting eosinophils (or their precursors); d)prevention of post-treatment reactions in loiasis, a filarial infection associated with dramatic eosinophilia following anthelminthie therapy.

T Lymphocyte Biology Section – HNM25S

Studies the regulation of T-cell responses to infections relevant to global public health, with the goal of developing methods to both enhance pathogen control and prevent immune mediated pathology. 1. Immunoregulation by co-stimulatory and co-inhibitory molecules during infection with Mycobacterium tuberculosis in the murine model. 2. Discovery of novel anti-bacterial T cell effector mechanisms in murine model systems. 3. Mechanisms of host resistance to Mycobacterium tuberculosis and SARS-CoV-2 infection of rhesus macaques.

Type 2 Immunity Section – HNM25T

Studies the heterogeneity of type-2 immune responses during helminth infections. 1. Type 2 cytokine (IL-4 and IL-13) activated macrophages during helminth infections. 2. role of microbiota during helminth infections. 3. Genetic and environmental contributions towards immune variation between individuals. 4. Helminth infections, inflammatory bowel diseases, metabolic syndrome, atherosclerosis, chronic inflammation.

Systems Genomics Section – HNM25U

Studies systems analyses of host-pathogen interactions using both respiratory viruses and parasitic nematode models. 1. Performs multi-omics analyses of influenza- and SARS-CoV-2 in human infections and in animal models to identify predictors of disease severity. 2. Profiles the microbiome in respiratory infections through metagenomics and metatranscriptomics analyses to model microbial transmission and antibiotic resistance; 3. Applies novel high throughput tools and multi-mocs analyses to filarial nematodes, characterizing differences in filariae with and without symbionts.

Laboratory of Infectious Disease - HNM27

(1) Develops candidate vaccines for prevention of diseases due to virus infections emphasizing acute respiratory, enteric, neurologic, and hepatic diseases; (2) Studies the causes, epidemiology, prevention, diagnosis, and treatment of such infections; (3) Investigates the pathogenesis of such infections, including the role of genetic, host factors, and mechanisms of resistance.

RNA Viruses Section - HNM272

(1) Conducts fundamental molecular virologic and immunologic studies with paramyxoviruses, flaviviruses, and bunyaviruses; (2) develops live attenuated virus vaccine candidates for the indicated viruses; (3) uses live attenuated parainfluenza viruses as vectors for expression of foreign viral protective antigens such as the Ebola virus GP, the avian influenza virus H5, and the SARS spike protein; (4) oversees manufacture of clinical lots of vaccines for trials in humans; (5) generates INDs and conducts the clinical evaluation of the vaccine : candidates in volunteers; (6) develops intellectual property on the vaccines under study; and (7) interacts with industrial partners via CRADAs or other mechanisms, e.g., licensing, to foster commercial development of the vaccines.

Emerging Respiratory Viruses Section - HNM27B

(1) Develops pandemic influenza virus vaccines; (2) establishes CRADAs to continue development of pandemic influenza virus vaccines; (3) generates INDs to evaluate the vaccine candidates in humans; (4) oversees the clinical evaluation of the pandemic influenza virus vaccines in volunteers; (5) studies the molecular virology and immunology of the influenza viruses; and (6) responds to the emergence of new respiratory virus pathogens such as the SARS virus to study their pathogenesis and to evaluate candidate vaccines.

Viral Pathogenesis and Evolution Section - HNM27C

(1) Examines the mechanisms of interpandemic spread of influenza A and B viruses in humans; (2) examines the mechanisms of influenza virus spread from one host species to another; (3) studies the pathogenesis of influenza viruses by experimental studies in humans in which viruses with defined genetic properties are administered to human hosts; (4) uses reverse genetics to define the genetic determinants of host range of influenza viruses; (5) studies the evolution of influenza virus in humans and other hosts by recovering nucleic acid sequences/viruses present in pathological specimens; and (6) studies the molecular virology and immunology of the influenza viruses in their natural hosts.

Hepatic Pathogenesis Section - HNM27D

1) Conducts translational research in the field of human liver diseases; 2) applies global research procedures such a microarray analysis to studies of the pathogenesis of hepatitis viruses; 3) utilizes 'Tl0del systems such as animal models for the study of recognized and suspected viral agents; 4) searches for evidence of new etiologic agents in liver diseases of unknown etiology.

Caliciviruses Section - HNM27E

 Studies caliciviruses associated with human disease, including the noroviruses and sappoviruses; 2) develops models, including animal models for the study of these viruses; 3) studies the molecular biology of these viruses with the goal of establishing replication in cell culture; 4) studies animal caliciviruses as model systems for better understanding of human caliciviruses; 5) studies epidemiology of caliciviruses to better understand their disease impact;
 6) develops vaccines and .other preventive measures for calicivirus infections.

Neurotropic Flaviviruses Section - HNM27H

1) Studies f1aviviruses that affect the neurological system; 2) attenuates neurotropic flaviviruses to generate live attenuated virus vaccine candidates; 3) develops quantitative assays for evaluating virulence and attenuation of neurotropic viruses; 4) develops and utilizes modes, such as animal models, for the evaluation of candidate vaccines for neurotropic flaviviruses.

Medical Virology Section – HNM27J

(1) Studies the pathogenesis, diagnosis, and clinical aspects of human viruses, especially the herpes viruses; (2) Studies new components for the treatment of virus infections and develops candidate vaccines for prevention of herpes virus infections.

Structural Virology Section – HNM27K

Applies various biophysical and structural approaches: (1) to explore the mechanism of entry and replication of RNA viruses; (2) to understand how the cell distinguishes self from non-self; (3); to explore the immune response to RNA virus infections; (4) to contribute to the development of novel therapies to combat infection and spread of RNA viruses.

Laboratory of Viral Diseases - HNM28

(1) Conducts basic research on the structure, genetic organization, expression, replication, assembly, and pathogenicity of viruses; and (2) investigates the ability of viruses to cause disease, and the targets of protective host immune responses.

Molecular Genetics Section - HNM282

1) Investigates-the molecular biology of the human herpesviruses and their relationship to disease; and 2) studies the structure of herpesvirus genomes, the identification of virus encoded proteins, the regulatory mechanisms that control viral and host gene expression, cell tropism, latency, the mechanism of DNA packaging, and virus maturation.

Genetic Engineering Section - HNM287

1) Carries out fundamental research on the structure, replication, and expression of viral genomes; and 2) uses recombinant DNA technology to develop expression vectors for the preparation of subunit and modified live vaccines.

Cellular Biology Section - HNM289

1) Investigates the folding, assembly, and intracellular trafficking of viral and host cell proteins important in immune responses; 2) conducts other investigations directed towards understanding the cellular biology of processing and presentation of viral antigens to major histocompatibility complex class I restricted cytotoxic T cells.

DNA Tumor Virus Section - HNM28B

(1) Provides a comprehensive program of intramural research on the pathogenesis and biology of DNA tumor viruses, with emphasis on the papillomaviruses; and (2) provides advanced hands-on training in the principles and practices of scientific research to postdoctoral fellows, technical staff and students.

Viral Pathogenesis Section - HNM28C

(1) Conducts basic research on the structure, genetic organization, expression, replication, assembly, and pathogenicity of viruses including members of the flavivirus family; (2) investigates the ability of viruses including flaviviruses to cause disease; and (3) determines the targets of protective host immune responses to flaviviruses.

Barrier Immunity Section- HNM28D

(1) To understand better the mechanisms that underlie HIV and human disease progression. The immune system, particularly its T-cell arm, plays a central role in human disease pathogenesis; (2) Our long-term goal is to use the knowledge gained through these studies to develop novel therapeutic and vaccine approaches; (3) Use multiple nonhuman primate models with differing disease progression courses, and we study T-cell immunology in infected individuals or infected nonhuman primates in order to elucidate mechanisms of disease progression.

Laboratory of Malaria and Vector Research - HNM2A

(1) Conducts basic research on the prevention, control and treatment of malaria; (2) performs biochemical and molecular studies to discover the stages against which functional immunity acts, the way in which immunity affects the parasite, and the chemical and molecular structure of functional antigens; (3) determines the molecular, biochemical and physiological characteristics of the malaria Vparasite, including response to drugs; (4) studies the pathologic processes in malaria; (5) studies the epidemiology of malaria; and (6) investigates the factors which influence the transmission capacity of mosquito vectors, the genetic determinants for vector potential, and the population biology of these vector species.

International Studies of Malaria and Entomology Section - HNM2A2

(1) Supports a major program in Mali and collaborates in an NIAID program in Papua, New Guinea; (2) conducts research to understand human immune responses to malaria, genes that affect disease severity, drug resistance mechanisms, and parasite factors responsible for the transmission and pathogenesis of malaria; and (3) maintains close interactions with scientists in the Malaria Vaccine Development Unit who are developing field sites for the testing of candidate vaccine formulations.

Malaria Genetics Section - HNM2A3

(1) Conducts basic research on factors that govern the drug response, persistence, and severity of malaria; and (2) incorporates strategies of linkage mapping, field population surveys, and gene manipulation and gene product analysis with a view toward the discovery of fundamental biological information that will be of use in the development of new diagnostics, therapeutics and control measures against the disease.

Malaria Cell Biology Section - HNM2A4

Studies the pathogenesis of malaria, which includes studies on the mechanism by which malaria parasites invade erythrocytes (including the study of parasite ligands and erythrocyte receptors), the mechanism of antigenic variation, the molecular basis for cerebral malaria and rosetting, and the physiologic basis of vacuole formation.

Regulation of Growth and Development Section - HNM2A5

(1) Uses ribosomal RNA sequences to study the population distributions of different human malaria parasites (four *Plasmodium* species are responsible for nearly all human infections); and
(2) analyzes ribosomal RNA structures to determine functional differences between developmentally specific ribosomes that involve an alteration of a GTPase site.

Vector Biology Section - HNM2A6

(1) Focuses on the role of vector arthropod saliva in blood feeding and parasite transmission; and (2) conducts research on vectors of malaria (anopheline and culicine mosquitoes), American trypanosomiasis (*Rhodnius prolixus* and *Triatoma infestans*), leishmaniasis (*Phlebotomus papatas i* and *Lutzomyia longipalpos*), filariasis (*Culex quinquefasciatus*), and Lyme disease (*Ixodes scapularis*); this research includes (a) novel molecules with potent pharmacological activities are being discovered, (b) the role of saliva in the transmission of some pathogens (*Leishmania* and *Borrelia burgdorfen*) is being investigated, and (c) sand fly saliva is being investigated as a marker of human vector exposure and as a possible candidate for vaccine development against *Leishmania*.

Biochemical and Biophysical Parasitology Section - HNM2A7

(1) Studies basic cell biological and biophysical investigations of obligate intracellular parasites, with particular focus on Plasmodium falciparum; studies the contributions of both parts to the success (or failure) of the interaction; and (2) uses atomic force microscopy, video microscopy, and near field scanning optical microscopy (NSOM) to elucidate cellular and molecular biological aspects of disease processes.

Malaria Functional Genomics Section - HNM2A8

(1) Conducts basic research on the prevention, control and treatment of malaria; (2) performs biochemical and molecular studies to discover genes that control/affect various parasite development, drug resistance, and disease virulence; (3) studies the function and molecular interaction of the discovered genes; (4) determines the molecular, biochemical and physiological characteristics of the malaria parasite, including response to drugs; and (5) studies population biology and molecular evolution of malaria parasites.

Malaria Immunology Section - HNM2A9

(1) Conducts research that explores the complex interface between the immune system and the vertebrate host and the erythrocytic development stages of the malaria parasite; (2) studies the response of the humoral and cellular components of both the innate and adaptive immune systems to malaria parasite components; and (3) develops techniques to contribute to our understanding of host parasite interaction and evaluation of various intervention strategies designed to reduce the world-wide burden of the malaria disease.

Apicomplexan Molecular Physiology Section - HNM2AA

(1) Conducts basic research on the cell biology and physiology of malaria parasites; (2) studies transmembrane transport of organic and inorganic solutes. across various parasite and host membranes to identify mechanism and biological significance; (3) performs biochemical, molecular, genetic, pharmacological, and biophysical studies of parasite transport proteins; (4) determines whether parasite transport proteins are suitable targets for antimalarial discovery and development; and (5) develops and implements technologies for high-throughput screening of chemical libraries, with the aim of identifying basic research reagents and antimalarial drug leads.

Vector Molecular Biology Section - HNM2AB

1)The Vector Molecular Biology Section focuses on the molecular aspects of vector salivary and midgut proteins with emphasis on understanding vector/host and vector/parasite interactions; 2) emphasis in sand fly/Leishmania/mammalian host interactions; 3) Unit research combines basic approaches together with veterinary and clinical research broadening our understanding of the relationship between immune responses to vector salivary proteins in animal reservoirs and humans and disease outcome, and between the leishmania parasite and sand fly midgut proteins.
Mosquito Immunity and Vector Competence Section – HNM2AC

Laboratory of Immunogenetics - HNM2B

(1) Conducts research on the genetic control of the immune response with emphasis on the gene complexes which encode immunoglobulins and the major histocompatibility antigens in humans and experimental animals; (2) obtains structural information for molecules of immunogenetic interest, including membrane bound antigens of lymphoid cells, and relates the structural information to the function of the molecules and the genetic background of the donors; and (3) studies the role of the products of the major histocompatibility complex and other regulatory molecules in control of immune responsiveness to various antigens and infectious agents in laboratory model systems and by statistical studies which relate genetic typing data to occurrence and severity of human disease.

Lymphocyte Activation Section - HNM2B2

(1) Conducts research on the molecular mechanisms underlying the activation of B lymphocytes to proliferate and differentiate into ,clones of antibody producing cells; (2) B cell activation, which is triggered by the binding of foreign antigens to the B cell antigen receptor (BCR), initiates a signaling cascade that leads to the transcription of a variety of genes associated with B cell activation and targets antigens into the cell for processing and presentation to helper T cells - uses the tools of biology, biochemistry, and molecular biology to dissect these functions and to understand their regulation; and (3) uses knowledge gained from these studies to develop new strategies for enhancing antibody responses in the design of vaccines and to deactivate antibody responses in autoimmune disease.

Molecular and Cellular Immunology Section - HNM2B3

1) Explores the method in which microbial antigens are recognized by the human immune system; and 2) employs molecular techniques to study the manner in which antigens are presented to lymphocytes that will initiate immune responses.

Structural Immunology Section - HNM2B4

(1) Studies the molecular recognition between immuno-receptors and their ligands and the mechanism of the receptor activation; (2) using X-ray crystallography, delineates the atomic structures of immunoreceptors, their ligands, and the receptor-ligand complexes; (3) studies the functional recognition between the receptors and their ligands through mutational analysis and solution binding experiments of the receptor-ligand interface mutants; and (4) models the receptor aggregation and molecular formation of the immune synapses.

Chemotaxis Signal Section - HNM2B5

(1) Studies the manner in which cells detect chemical gradients and steer their movement towards their target sites; and (2) uses various techniques, including molecular genetics, biochemistry, and fluorescence and time-lapse microscopy, to elucidate the manner in which cells generate temporal and spatial responses when sensing gradients.

Autoimmunity and Functional Genomics Section - HNM2B7

(1) Studies the regulation of the immune response by inhibitory signaling pathways and its relevance to the development of autoimmunity; and (2) uses a combination of genomic, genetic, and microarray expression analyses in specific animal models to identify putative regulatory genes, and investigates the function and mechanism of action of these genes by targeted mutagenesis and molecular dissection of associated signaling pathways. Category: Intramural

Receptor Cell Biology - HNM2BA

(1) Conducts research on the natural killer (NK) cell activation and inhibitory receptors which serve to regulate the function of these key cells of the innate immune response; (2) studies the role that a newly described inhibitory receptor, LAIH-1, plays in regulating activation of immune cells in general; (3) determines how members of the CD94/NKG2 family of receptors effect target recognition and how post-recognition signals are transmitted that dictate lysis through. activation receptors (CD94/NKG2C, NKG2D, NKp46) or inhibition of lysis by CD94/NKG2A and other inhibitory receptors; (4) identifies the factors and processes that regulate tissue-specific and clonal expression of DAP-10, CD94 and NKG2 family of genes; and (5) examines the role of LAIR-1 and NKG2D in T-cell regulation.

Virology and Cellular Immunology Section - HNM2BB

1)Conducts research on mechanisms involved in normal hematopoietic differentiation and alterations associated with the development of lymphoma/leukemia and autoimmunity; 2) The major emphasis is on B cells including the contributions of T cell-B cell interactions, transcription factors, cytokines, and innate signaling pathways to normative and aberrant biology.

Molecular Pathology Section - HNM2BC

1)Focuses on (a) cancer genetics, mouse, and Drosophila embryogenesis, tumor suppressive genes, transgenic mice, transcriptional regulation and factors including Zn-finger proteins and nuclear receptors, and mechanics of DNA-protein and/or protein-protein recognition, and (b) studies of an evolutionarily conserved transcription factor called CTCF with multiple DNA sequence specificity, and a novel candidate tumor suppressor gene; 2) studies also include but are not limited to (a) expression regulation of CTCF and by CTCF, (b) mutational analyses of CTCF in human cancers, (c) characterization of embryogenesis and tumorigenesis using recently developed CTCF transgenic mice strains, (d) targeted in vivo mutagenesis in a variety of CTCF-target.

T Cell Tolerance and Memory Section - HNM2BD

Conducts experiments on: a) neonatal tolerance to determine if it is mediated by B cells; b) maternal tolerance to determine if it is mediated by the chimerism of fetal cells; c) adult tolerance induced by B cells to determine if it is in both the CD4+ and C08+ T cell compartments; d) Thymic Stem Cells to determine if they are precommitted and how long self renewal capacity lasts in the thymic microenvironment; amd d) T Cell Memory to determine if it requires the presence of B cells to develop.

Laboratory of Persistent Viral Diseases - HNM2C

(1) Plans and conducts research to study host factors related to the development of persistence of latency of viral infections in mammalian cells; (2) develops persistent viral disease animal models in which to quantitatively measure immune, biochemical, physiological, virological, and biological responses of the host to viruses which are capable of developing latent infections; (3) investigates genetic and molecular biological factors which may influence the ability of a virus to induce persistence in susceptible cells or individuals; and (4) studies the genetic basis of the host cell interaction in terms of the surface cell structure controlled by the major histocompatibility complex.

Retroviral Immunology Section - HNM2C2

(1) Discover mechanisms of natural and vaccine-induced immunity to retroviral infection; (2) discover mechanisms viruses use to escape immunity and establish chronic infections; (3) develop vaccines and immunotherapies to prevent acute and chronic infections; and (4) develop therapeutic vaccines and/or immunotherapies to cure chronic infections.

TSE/Prion Biochemistry Section - HNM2C6

(1) Understand the structure and propagation mechanism of TSE/prion infectivity; (2) define the pathways by which infectivity spreads within and between cells; (3) determine neuropathologic mechanisms of TSE/prion diseases; and (4) develop effective prophylaxes and therapeutics for TSE/prion diseases.

TSE/Prion Molecular Biology Section - HNM2C8

(1) Define the molecular mechanisms underlying TSE pathogenesis with particular regard to TSE strains and species barriers; (2) use recombinant DNA and eukaryotic/procaryotic protein expression technologies to understand the mechanisms of abnormal prion protein formation; (3) develop in vivo and in vitro systems to determine how the host influences susceptibility to TSE infection and disease pathology; and (4) develop in vitro systems to understand the molecular basis of heritable, amyloidogenic forms of TSE disease.

TSE/Prion and Retroviral Pathogenesis Section - HNM2C9

(1) Study and characterize the mechanisms of pathogenesis of brain diseases induced by prion/TSE agents and murine and human retroviruses using animal models, in vitro cell culture models and cell-free in vitro systems; (2) identify the host factors involved in causing or controlling the pathogenesis of the above diseases; (3) study the nature of the infectious prion/TSE agent using biological and biochemical approaches; and (4) study mechanisms and effects of prion/TSE cross-species infections.

Neuroimmunology Section — HNM2CA

(1) Studies the interactions between the immune and nervous systems in regulating viral pathogenesis with the goal of identifying targets for therapeutic treatment of viral-mediated neurological diseases. (2) Studies primarily focus on La Crosse Virus (LACV), an orthobunyavirus that is a primary cause of pediatric viral encephalitis in the United States. (3) Additional viruses studied in the lab include other California Serogroup of Orthobunyviruses such as Jamestown Canyon virus, Snowshoe hare virus, Tahyna virus or Inkoo virus as well as Zika virus, a flavivirus that has been associated with microcephaly. (4) Our studies focus on how the immune system influences the ability of viruses to gain access to the central nervous system (5) as well how the immune system influences virus mediated damage to neurons.

Research Technologies Branch - HNM2D

(1) Provides state-of-the-art biotechnology support to the Division of Intramural Research (DIR) scientists through supervision of Division wide resources including a facility for the structural analysis and sequencing of peptides and proteins, a flow cytometry facility, a microscope imaging facility, a transgenic knockout facility, and a research technologies development section; (2) provides advice and direction concerning new technologies relevant to DIR basic and clinical research programs and implements accounting procedures provided for these services.

Flow Cytometry Section - HNM2D2

(1) Provides state-of-the-art flow cytometric sorting and analysis services to Division of Intramural Research (DIR) scientists through the maintenance of a core flow cytometric facility which provides scientists with access to state-of-the-art instrumentation and a core of highly skilled personnel knowledgeable in all aspects of flow cytometry; 2) provides guidance to scientists in experimental design and; 3) provides a quarterly course in flow cytometry basics and the use of the FACScan flow cytometer.

Protein Chemistry Section - HNM2D3

(1) Conducts a peptide synthesis program for the NIAID which includes: a) the selection of peptides to be synthesized; b) automated solid phase synthesis or manual synthesis, if appropriate, of peptides; c) purification of the synthesized molecules by HPLC and other techniques; d) the analysis of the purity of the synthetic peptides; and e) the preparation of peptide-protein conjugates for use as immunogens for the preparation of antipeptide sera; 2) Conducts a protein analysis program for the NIAID that provides: a) a state-of-the-art protein sequencing facility for use by NIAID staff; b) expert advice for protein and peptide isolation and purification; c) mass spectrometric instrumentation and expertise for molecular analyses; and d) assistance with HPLC purification of proteins and peptides.

Genetically Modified Mice Section - HNM2D4

(1). Maintains a core transgenic mouse facility for NIAID intramural scientists; 2) provides assistance with various techniques including: a) the introduction of gene constructs into mouse embryos; b) molecular, biological, immunological, and biochemical detection of transgenes or their expressed protein products; c) cryopreservation of mouse embryos; and 2) provides advice on the design and production of transgenic mouse strains.

Research Technologies Development Section - HNM2D5

Facilitates the development of new technologies of interest to the DIR research community. Reviews new technologies and facilitates the implementation in DIR of those most appropriate for the research community.

Biological Imaging Section - HNM2D6

(1) Serves as a central resource for Division of Intramural Research (DIR) investigators with regards to biological imaging technology; 2) provides microscopy services via: a) a centralized Confocal Microscope and an imaging spectrophotometer; b) non-confocal microscopy image capture and analysis technologies; and 3) provides consultations, training, and technical user support services in the area of biological imaging.

Genomic Technologies Section - HNM2D7

(1) Serves as a central resource for DIR investigators regarding microarray technology; (2) provides microarray services; (3) provides consultations, training, and technical user support services in the area of microarrays; and (4) carries out research aimed at improvement of microarray technology.

RML Research Technologies Section (HNM2D8)

(1) Provides state-of-the-art research technologies to NIAID intramural laboratories; (2) provides technologies for High Throughput (HT) DNA sequencing, DNA sequence data storage, data retrieval and analysis, for projects ranging in scope from single clones to human gene sequencing of patient cohorts, up to complete pathogen genomes; (3) provides spotted and Affymetrix high density custom chip microarray support; (4) provides support on 4 RML·custom Affymetrix chips containing 62 different bacterial pathogen genomes; (5) provides support on HT TaqMan technologies for microarray data validation or de novo discovery; (6) provides support on HT SNP technologies for human patient cohorts; (7) provides support for HT robotics and liquid handling for AT sequencing, TaqMan, or SNP processing; (8) provides computationally intensive support for bioinformatics, statistical data analysis and figure generation of data generated from the above technologies; (9) provides support for statistically balanced experimental designs involving HT microarrays and TaqMan analysis; and (10) provides training on technologies described above and fosters close cooperation with NIAID intramural principal investigations (PIs) towards implementation of new technologies driven by PI needs and interests.

Laboratory of Immunoregulation - HNM2J

(1) Studies the immunobiology of normal and disease states in humans; (2) evaluates the mechanisms for activation and differentiation of human lymphoid cells and the methods by which they are modulated and immunoregulated; (3) investigates the relationship between non-specific and specific triggering of lymphoid cell activity; (4) studies human diseases characterized by hyperactivity of the immune system, such as autoimmune and corrective tissue diseases; (5) studies diseases characterized by hyporeactivity of the immune system, such as immunodeficiency diseases; and (6) utilizes new technologies that have become available for delineating specific cellular activity in order to more completely study the immunobiology of the human lymphoid system.

Immunopathogenesis Section - HNM2J2

 Conducts basic research on the molecular and cellular mechanisms of the immunopathogenesis of HIV infection; 2) studies the cellular and humoral immune responses against HIV infection focusing on the fine specificities of recognition of HIV epitopes by cytotoxic T cells; 3) conducts studies on the cellular and molecular mechanisms of neuropathogenesis of HIV infection; 4) studies the epidemiology and immunopathogenesis of HIV infection in selected population groups; 5) studies the immunopathogenesis of Chlamydia;
studies the cellular molecular mechanisms of the activation, proliferation, and differentiation of human B cells; 7) studies the mechanism of expression of B cell specific activation genes; 8) studies the molecular biological control of the T cell activation process and investigates the role of newly recognized T cell genes in the activation process; and 9) studies the immunopathogenic mechanisms of a number of immune mediated diseases.

Clinical and Molecular Retrovirology Section - HNM2J3

1) Conducts basic research on the role of gamma-delta T cells in the immunopathogenesis of HIV infection; 2) studies the role of regulatory genes of HIV on the normal function of human immune competent cells; 3) conducts clinical trials of antiretroviral agents as well as agents used to treat the opportunistic infections and neoplasms of HIV infected individuals; and 4) conducts clinical trials on candidate HIV vaccines.

B-Cell Molecular Immunology Section - HNM2J5

1) Conducts research on the mechanisms which regulate the activation, proliferation and differentiation of human B lymphocytes on both a cellular and molecular level; 2) isolates and characterizes genes expressed in B lymphocytes in a tissue or temporal specific manner; 3) determines the role of these genes in B-cell activation; 4) characterizes the proteins encoded by these genes to determine their role in normal B-cell physiology; 5) conducts mutagenesis studies to develop B-cell lines which no longer express specific B-cell genes to allow further characterization; 6) studies the human polyoma JC virus, the etiologic agent of progressive multifocal leukoencephalopathy, replication in B-cells; and 7) clarifies the role of B-cell specific factors in JC virus replication to understand the function and relate to normal physiology in B-cells.

Clinical Research Section - HNM2J7

(1) Provides the infrastructure and organization of a comprehensive program of intramural clinical research on the pathogenesis, treatment, and prevention of infectious diseases affecting the human immune system, with special emphasis on conducting clinical studies involving the human immunodeficiency virus and facilitating the development of novel therapeutic and preventative strategies for combating disease due to this infection; (2) oversees the implementation and performance of an extensive series of phase I-III research protocols centering on the immunopathogenesis of HIV-1 infection, the clinical testing of antiretroviral and immune-based treatments for infection with this virus, and explores the safety and efficacy of novel vaccine strategies against the virus; (3) manages a large clinical trials patient facility in the Clinical Center that is specifically dedicated to these trials; and (4) provides advanced hands-on training in clinical trials methodology and the principles and practices of infectious diseases research, which is an integral part of the section's mission.

HIV-Specific Immunity Section - HNM2J8

(1) Conducts basic research studies on the mechanisms of immunologic control or loss of control over HIV replication by the cellular immune response; (2) characterizes the neutralizing antibody response to HIV-1; and (3) conducts studies using experimental animals and humans to explore how immunologic control or broadly cross-neutralizing antibodies may be stimulated.

International HIV/STD Section - HNM2J9

(1) Defines the unique epidemiologic, clinical, virologic, and immunologic features of HIV infection in developing countries; (2) examines the viral kinetics and other biological and behavioral factors associated with HIV transmission; (3) characterizes the molecular strains of HIV by region for infectiousness, transmission, and immunologic response; (4) develops and evaluates novel interventions to prevent HIV transmission, including microbicides, circumcision and vaccines; (5) examines the efficacy of antiretroviral drugs in preventing transmission and increasing survival in developing countries; (6) defines the epidemiology, risk factors, and transmission of C. trachomatis genital tract infections in individuals internationally; (7) defines the immunopathogenesis of C. trachomatis infection in pelvic inflammatory diseases, infertility and blinding trachoma; and (8) implements clinical trials aimed at facilitation of more effective control of blinding trachoma in Africa.

Viral Pathogenesis Section - HNM2JA

(1)To investigate the pathogenesis of human viral diseases, particularly those caused by HIV-1 and herpes viruses; (2) to elucidate the early molecular interactions between pathogenic human viruses and their target cells; (3) to identify the cellular receptors utilized by pathogenic human viruses to gain access into their target cells; (4) to identify host factors, such as chemokines or other cytokines, that naturally binds viral receptors and thereby prevents infection by pathogenic human viruses; (5) to identify host factors produced by human immune cells that antagonize pathogenic human viruses by mechanisms other than receptor blockade; (6) to elucidate the role of chemokines and other natural antiviral factors in human viral diseases. particularly HIV-1 infections; (7) to elucidate the role immunomodulatory cytokines, such as IL-7, in the pathogenesis of human viral diseases, particularly AIDS; (8) to utilize the knowledge accrued by the study of viral receptors and host antiviral or immunomodulatory cytokines of the development of novel therapeutic approaches of HIV-1 infection and other human viral development of novel therapeutic approaches of HIV-1 infection and other human viral diseases; (9) to utilize the knowledge accrued by the study of the interaction between viral envelopes and cellular receptors for the development of novel vaccine strategies for the prevention of infection by HIV-1 and other human pathogenic viruses.

HIV Pathogenesis Section- HNM2JB

The HPS (1) investigates inflammatory complications in HIV with a special emphasis on immune reconstitution inflammatory syndrome (IRIS); (2) develops adjuvant immune-based therapies (IBT) to improve immune restoration in CD4 lymphopenic conditions such as HIV and idiopathic CD4 lymphopenia (ICL); (3) plans and conducts research on the pathogenesis of 2 major risk factors of IRIS: severe CD4 lymphopenia and the presence of opportunistic infections even if clinically silent (M. tuberculosis, M. avium complex, C. neoformans or other fungi, or viral pathogens) prior to antiretroviral therapy (ART) initiation; (4) pursues the development of immunomodulatory therapies, such as IL-7, with the objective to improve immune restoration and function and reduce inflammation in treated HIV infection; (5) investigates how residual immune activation and persistent lymphopenia associate or lead to dysregulated coagulation and inflammation that are linked to cardiovascular complications in HIV; (6) correlates mechanisms of ICL with T cell homeostasis and inflammation in HIV; (7) initiates and evaluates the clinical predictors, biomarkers and pathogenesis of IRIS by conducting large prospective, observational, clinical trials of ART-naive HIV⁺ patients with severe CD4 lymphopenia (<100 cells/L) who are followed prospectively after initiation of ART; (8) collaborates with other NIAID investigators to develop and elucidate a murine model of mycobacterial IRIS: (6) collaborates with international research sites (National Institute for Research in Tuberculosis (NIRT) Chennai, India, Shanghai Public Health Department (Fudan University) Shanghai, China, clinical networks (INSIGHT and ACTG) conducting multi-center clinical trials on IRIS and ICL.

Emerging Viral Pathogens Section - HNM2JC

(1) Conducts basic research to elucidate the pathogenesis of emerging viral diseases in animal models relevant to human infection; (2) identifies critical targets for therapeutic intervention based on viral processes in target cells and .host immune responses to infection; and (3) develops and tests therapeutic and preventative counter measures in animal models to affect disease outcomes.

Laboratory of Molecular Microbiology - HNM2K

(1) Studies the molecular structure and organization of animal virus genomes; (2) elucidates the role of viral gene products which mediate productive and transforming infections to mammalian cells; (3) identifies viral gene segments and viral encoded/induced proteins required for the oncogenic potential of DNA and RNA tumor viruses; (4) studies mechanisms of bacterial pathogenicity; (5) evaluates the contributions of plasmids to the virulence of bacterial pathogens; and (6) studies mechanisms of dissemination of genetic information among bacterial populations.
Viral Pathogenesis and Vaccine Section - HNM2K3

(1) Studies the manner in which viruses interact with their hosts/host cells to induce disease; (2) investigates the immunological responses of susceptible animals to infectious virions and virus encoded proteins; and (3) identifies correlates of protection applicable to the development of broadly acting prophylactic vaccines for lentiviral infections of animals and man.

Viral Biology Section - HNM2K6

1) Studies the interactions of animal viruses with permissive and non-permissive cells in culture and investigates mechanisms of viral pathogenicity in animal model systems; 2) develops tissue culture systems for the assay and propagation of animal viruses; 3) identifies and characterizes immunologic reagents used for the detection of viral genomes or virus-induced gene products in productively infected or transformed mammalian cells; and 4) elucidates the mechanisms associated with the establishment, maintenance, and rejection of virus-induced tumors in animal model systems.

Non-Human Primate Virology Section - HNM2K8

Non-Human Primate Virology Section (NM2K8) 1) Studies of the mechanisms of viral pathogenesis of simian immunodeficiency virus (SIV) in nonhuman primates, including both pathogenic models in Asian macaque species and nonpathogenic models in natural African host species; 2) studies of the phylogentic, and biologic evolution of SIV in nonhuman primates with a focus on evolution in the central nervous system; 3) proof of concept development of vaccines for AIDS using nonhuman primate models.

Viral Biochemistry Section - HNM2K9

(1) Studies the structure of viral gene products to identify functional domains and determine the biological and biochemical function of viral proteins; (2) investigates the molecular mechanisms involved in virus assembly/release and characterize postentry steps of virus replication; and (3) examines the interactions of host factors with viral proteins and assess the effect of virus-encoded proteins on general host-cell functions.

Comparative Medicine Branch - HNM2Q

(1) Provides technical support to the laboratories through centralized animal care, the performance of tests, experiments, autopsies, and pathologic examinations on animals, the administration of drugs and chemicals to animals, and the collection of animal tissues and fluids; (2) ensures compliance with the standards of the DHHS Guide for Care and Use of Laboratory Animals; (3) provides training for animal care personnel; (4) prevents, diagnoses, controls and treats diseases of laboratory animals; (5) prevents, alleviates, and minimizes animal pain and discomfort; (6) provides research, support, information, and services; (7) develops and manages animal husbandry programs; (8) designs and operates laboratory animal facilities; (9) participates in the design, interpretation, and reporting of research; (10) manages fiscal resources; (11) designs and develops a web-based information and database management system; and (12) ensures animal welfare.

Laboratory Animal Medicine Section - HNM2Q2

(1) Prevent, diagnose, control, and treat disease; (2) prevent, alleviate, and minimize pain and distress; (3) provide research support, information, and services; (4) develop and manage animal husbandry programs; (5) execute IACUC veterinary responsibilities; (6) design and operate laboratory animal facilities; (7) provide consultation governing the appropriate care and use of laboratory animals; (8) educate scientific, animal care and ancillary staff;. (9) collaborate on the selection and development of animal models; and (10) design and conduct research.

Laboratory Animal Science Section - HNM2Q3

(1) Animal husbandry, health, welfare, identification of animals, breeding, nutrition, husbandry practices, sanitation, disease prevention and control, animal health, clinical health, research procedures, and animal welfare; (2) facility administration and management, documentation and records maintenance, data collection, analysis, and interpretation, fiscal management, facility operations and management, occupational health and safety, employee management and training; (3) general knowledge, formulas and calculations, species specifics, and interpresonal relations;
 (4) optimizing facility resources, planning, renovating, and monitoring facilities, standard operating procedures, protecting assets and personnel-disaster planning and management; (5) managing fiscal resources, developing and monitoring budgets, grants and contracts, cost management; (6) achieving regulatory compliance, OSHA/safety/HAZMAT/BMBL, IACUC, FDA/USDA/EPA/PHS; (7) managing animal welfare, animal health, controlling disease and veterinary care, training personnel and handling incidents; and (8) assuring public trust, ethical considerations and euthanasia, public relations, customer service, and professionalism.

Infectious Disease Pathogenesis Section - HNM2Q4

(1) Provides acquisition, quarantine, transportation, housing, research subject management, and disposition for DIR nonhuman primates; (2) provides advice to the Director, DIR, concerning program direction for DIR nonhuman primate breeding colonies, Inter-Agency Agreements, and Cooperative Agreements; (3) represents DIR on NIH-wide committees and groups concerned with nonhuman primate research and animal biosafety matters; (4) provides collaborative-based, research program in integrative molecular pathology to design and characterize disease models critical to the advance of DIR research portfolios; (5) provides expertise in evaluating animal models for their relevance for human disease; (6) provides advice concerning the development of new animal laboratory facilities designed for use in biohazard pathogen research; and (7) acts as a resource to provide consultation and advice to DIR investigators, the Animal Care Branch, the DIR Animal Care and Use Committee, and the NIH Division of Safety on issues related to nonhuman primates.

Laboratory of Allergic Diseases - HNM2S

(1) Conducts research on the pathogenesis of allergic and immunologic inflammation including the regulation of IgE synthesis; determination of allergen structure; investigation of the biology of inflammatory cells including lymphocytes, mast cells, basophils, and eosinophils; identification of mediators of hypersensitivity and inflammation including lipid derived mediators, proteases, proteoglycans, and cytokines; exploration of late phase reactions; examination of immunologic and non-immunologic reactions in the respiratory tract, gastrointestinal tract, and skin; and the pharmacology of therapeutic agents employed in the treatment of allergic disease; (2) supervises clinical research on the pathophysiology and therapy of allergic and immunologic diseases in children and adults including asthma, allergic rhinitis and sinusitis, otitis media, urticaria, angioedema, food allergy, anaphylaxis, insect allergy, and disorders of mast cell activation and hyperplasia; and (3) coordinates the Allergy and Immunology training program under the direction of the Clinical Director, including assurance of implementation of the Residency Review Committee's program requirements in Allergy and Immunology and supervision of training requirements of the American Board of Allergy and Immunology for fellows in training.

Genetics and Pathogenesis of Allergy Section – HNM2S2

The lab is a basic, translational, and clinical lab focused on understanding the immunology of atopic disease through study of patients with genetic diseases associated with atopic manifestations, patients with immune deficiency and atopy, and patients with severe atopic dermatitis. Through studies of patients and mouse models of their diseases, we hope to gain better insights into the mechanisms of immunodysregulation that lead to atopic inflammatory disease, rare and common. The three major areas of research include 1) Search for novel genetic diseases associated with atopy; 2) Analysis of patients with known genetic diseases associated with atopy and 3) Investigation of defects in T-cell receptor signaling and repertoires.

Mast Cell Biology - HNM2S3

(1) Strives to understand the biology of mast cells so that this information can be applied to the understanding of the pathogenesis of allergic diseases, their diagnosis, and management; (2) focuses on understanding the regulation of mast cell differentiation, growth, and function; (3) emphasizes research that includes (a) identifying cytokines that regulate mast cell function, (b) understanding the interaction of mast cells with connective tissue matrix through specific adhesion receptors, (c) examining interactions between mast cells and other immune effector cells, and (d) identifying and characterizing molecules synthesized and released by antigenspecific stimuli; and (4) integrates studies on the basic biology of mast cells with clinical studies that examine the role of mast cells in allergic diseases, including asthma and anaphylaxis and systemic disorders of mast cell proliferation, the principle of which is mastocytosis.

Lung and Vascular Inflammation Section - HNM2S4

(1) Characterizes mechanisms of airway hyper-responsiveness in bronchial asthma (for example, interactions of lung cells with allergens; control of bronchoconstrictor responses by regulators of G protein signaling) and determines how such mechanisms drive clinical symptomatology. (2) Identifies mechanisms underlying vascular leakage occurring during anaphylaxis and/or systemic infections, with a particular emphasis on idiopathic systemic capillary leak syndrome (SCLS, Clarkson disease). (3) Characterizes natural history of SCLS and develops new treatment strategies based on basic science findings.

Inflammation Immunobiology Section - HNM2S6

(1) To examine the interactions of eosinophils and their secretory mediators with respiratory virus pathogens *in vivo*, with a specific focus on the mechanisms used by eosinophils to promote antiviral host defense; (2) to characterize the pathologic inflammatory responses to severe respiratory virus infection *in vivo* at the cellular and molecular levels and; (3) to use this information to develop creative strategies to circumvent the lethal inflammatory response.

Laboratory of Malaria Immunology and Vaccinology - HNM2X

(1) Conducts basic research to evaluate the potential of malaria problems as vaccine candidates;
(2) conducts basic research into immune effect or mechanisms of relevance to malaria vaccine development;
(3) conducts transitional research into the design of recombinant protein and other vaccine delivery systems with potential as malaria vaccines, including proof of principle testing in non-human models;
(4) develops methods of expression, purification and quality control of malaria vaccine candidates at a scale and purity required for pilot scale GMP production of antigens;
(5) investigates and tests methods of producing effective formulations of malaria vaccine antigens, including alternative delivery systems such as live viral vectors and replicons;
(6) undertakes Phase I trials of malaria vaccines in the United States and other developed countries;
(7) with collaborators, develops test sites for malaria vaccine trials; this includes the necessary pre-trial epidemiology, establishment of testing facilities and training of staff; and (8) with collaborators, undertakes Phases I, 2, and 3 testing of malaria vaccines in countries endemic for malaria.

Pathogenesis and Immunity Section – HNM2X2

The Pathogenesis and Immunity Section of the Laboratory of Malaria Immunology and Vaccinology (LMIV) (1) conducts human and animal studies of malaria pathogenesis and host immunity, including population-based studies in communities exposed to P. falciparum. Our research emphasizes pregnant women and children, the populations most susceptible to malaria morbidity and mortality, with collaborative cohort studies ongoing in Mali and Tanzania; (2) the over-arching goal of our basic, clinical and epidemiologic research is novel vaccine discovery and testing. Our group first described the distinct P. falciparum phenotype that causes placental malaria, and the findings have guided the design of a vaccine being manufactured at LMIV to prevent pregnancy malaria. We have recently extended this paradigm to severe malaria in African children, where efforts are underway to identify parasite forms and proteins involved in severe syndromes that may be targeted by protective antibodies; (3) we apply functional genomics tools, including microarray and RNA sequencing platforms, to identify surface proteins in blood-stage malaria parasites that may be targets of protective antibodies naturally acquired by individuals in malaria-endemic areas; (4) in addition to our studies of blood-stage parasites, we have a collaborative program to study liver-stage malaria parasites, which are the target for vaccines that will completely prevent infection. We have completed an initial characterization of the transcriptome of liver stage P. falciparum, and are assessing novel liver stage antigens as targets of immune responses that correlate with protection in animals or humans, including humans that are experimentally infected with the parasite; (5) the basic immunology and pathogenesis research of our section aligns with the broader LMIV focus on the development of vaccines to interrupt malaria transmission (transmission-blocking and anti-infection vaccines) and vaccines to prevent severe malaria in pregnant women and children; (6) consistent with the LMIV generally, the Pathogenesis and Immunity Section also emphasizes training for young American and African scientists, who conduct individual projects under the umbrella of a coherent synergistic program studying malaria pathogenesis and immunity.

Molecular Pathogenesis and Biomarkers Section – HNM2X3

The Molecular Pathogenesis and Biomarkers Section will: (1) Study malaria pathogenesis in naturally exposed individuals to identify protective immune responses against severe malaria in young children based on the model of pregnancy malaria including defining the adhesive properties of parasites associated with discrete clinical syndromes, and evaluating specific antibody responses that block parasite adhesion: (2) Identify and evaluate biomarkers for malaria disease and immunity that are urgently needed to guide interventions and monitor interventional trials and for vaccine development: (3) Continue collaboration efforts to produce pregnancy malaria vaccines and liver-stage vaccines by evaluating pregnancy malaria vaccine candidates and identifying targets of immunity to forward the development of a liver-stage vaccine and preerythrocytic vaccine candidates that might prove valuable for the overall effort of LMIV to accelerate development of malaria vaccines using functional genomic tools; (4) Develop the LMIV basic/clinical infrastructure in Mali and Tanzania and train Mali and Tanzania based scientists in malaria research; (5) Manage independent field-based basic research and molecular pathogenesis studies: (6) Establish collaborations with scientists within and outside the NIH and Mali and Tanzania; (7) Present research results at national and international meetings; (8) Monitor and manage LMIV ICER basic research budgets.

Human Immune Regulation Section - HNM2X4

Human Immune Regulation Section (1) works off the premise that in P. falciparum infections a sizeable proportion of red blood cells may harbor a parasite. Each parasite is several µm large, capable of expressing more than 5000 genes, the majority of which may act as antigens. This considerable parasite biomass constitutes a challenge to the immune system. While malaria induced cell-mediated immune effector mechanisms clearly contribute to parasite clearance, exacerbated immune responses are thought to cause immune-mediated pathology; (2) the ability to tailor the magnitude of malaria specific effector responses to a level that allow parasite clearance without causing immune pathology may thus be a determinant of immunity that protects against severe forms of malaria; (3) using samples obtained from naturally exposed individuals, the Human Immune Regulation Section at LMIV aims to elucidate the role different malaria-induced immune regulatory components may have on the outcome of subsequent malaria infections; (4) complementary in vitro experiments will explore how such mechanisms can be induced. Ultimately, the work of this section strives to inform the design of future vaccines to prevent severe disease.

Office of Research Training and Development - HNM2Y

(1) Develops, plans and conducts the Institute's training initiatives and programs for all trainee levels; (2) promotes and facilitates the inclusion of diverse populations in all DIR training programs in allergy, immunology, and infectious diseases; (3) engages underrepresented populations in order to fulfill the NIAID mission to encourage a diverse group of individuals to consider careers in the biomedical sciences; (4) tracks trainees who have participated in DIR training programs to evaluate the success of these programs and establish program priorities; (5) provides advice and guidance to the DIR Director and senior staff on all training matters; (6) participates with universities that serve targeted student populations to increase the visibility of DIR's training programs and to identify potential students for DIR's training programs; (7) recruits academically outstanding students for DIR laboratory training positions; (8) informs the scientific and medical communities and other government agencies of NIAID's research training programs to increase their visibility; (9) collaborates with training programs in other ICs to achieve training and diversity goals; (10) serves as the NIAID DIR focal point for the NIH Graduate Partnership Programs, the Undergraduate Scholarship Program, and the NIH Academy; (11) manages and evaluates the Summer Intern Program in Biomedical Research for the NIAID laboratories; and (12) develops and manages training programs for post baccalaureate IRTAs and postdoctoral fellows through career development activities.

Laboratory of Molecular Immunology - HNM2Z01

(1) Conducts basic and applied research on the immune system in health and disease; (2) studies molecular and cellular mechanisms of leukocyte trafficking, organization and function; (3) investigates the chemotaxis signal transduction pathway in leukocytes, including its effects on immune activation and effector responses; (4) studies mimics of chemotactic factors and their receptors in infectious agents, including HIV, herpesviruses and poxviruses; (5) investigates the structure and function of the mucosal immune system; and (6) studies the genetics of complex infectious and immunologic/inflammatory diseases in man and animal models, with the goal of identifying novel therapeutic and vaccine targets.

Mucosal Immunobiology Section - HNM2Z012

(1) Develops a fundamental understanding of how immune responses are induced and maintained at mucosal surfaces; and (2) applies this knowledge to the development of novel mucosal vaccine strategies and treatments for inflammatory bowel disease.

Inflammation Biology Section – HNM2Z013

(1) Identifies and characterizes novel proteins important for inflammation and host defense against infection; (2) studies the molecular biology and biochemistry of chemokines and chemokine receptors; and (3) studies the roles of chemokines and chemokine receptors in lymphocyte and macrophage biology and in HIV infection using human cells and mouse models as appropriate.

Molecular Signaling Section – HNM2Z014

(1) Delineates molecular mechanisms of host defense and inflammation, focusing on the molecular basis of leukocyte activation by chemoattractants, which includes the chemokine family of chemotactic cytokines; (2) recognizes that leukocyte subsets differentially traffic in homeostasis and emergency states, and accumulate preferentially according to the nature of the disturbance at local sites, where they are responsible for either host defense and repair or, if dysregulated, for pathologic inflammation; (3) isolates genes encoding chemokine and related chemoattractant receptors which are differentially expressed in blood leukocytes, including neutrophil-selective receptors important in acute inflammation, and monocyte-, lymphocyte- and eosinophil-selective receptors believed to play specific roles in chronic and allergic inflammation, with the belief that these receptors regulate the leukocyte composition seen in different forms of inflammatory pathology; examines the potential for these receptors to become targets for the development of novel anti-inflammatory drugs for many important diseases, such as asthma and multiple sclerosis; and tests this hypothesis by genetic loss of function experiments in gene knockout mice; (4) studies a subset of the family which is exploited by medically important pathogens to facilitate disease; (5) identifies taxonomically diverse obligate intracellular pathogens that use cellular chemoattractant receptors encoded by the host organism as essential factors for target cell entry; examples include Plasmodium vivax and HIV-1, the causative agents of malaria and AIDS, respectively, which exploit the chemokine receptors Duffy and CCR5, respectively; and (6) identifies virally-encoded chemoattractant receptors such as chemokine receptors encoded by three herpesviruses--human cytomegalovirus, Kaposi's sarcoma herpesvirus and Herpesvirus saimiri, whose corrresponding viral genes were apparently copied from host genes in a process analogous to the viral oncogenes.

Immune Activation Section - HNM2Z015

(1) Conducts research on the mechanisms involved in the activation of the immune system;
 (2) investigates the molecular mechanisms underlying the action of T-cells, a key step during an immune response;
 (3) isolates and characterizes mitogen- and antigen- inducible genes to identify those that are involved in gene activation;
 (4) determines the structure, function, and regulatory factors involved in controlling expression of these genes.

Laboratory of Virology - HNM2Z03

(1) Studies vector/reservoir transmission, pathogenesis, pathophysiology and host immune response of high containment viral pathogens; (2) utilizes in vitro and in vivo systems to study the interactions between either virus particles and/or viral components with human cells; (3) studies immune responses in animal models using modern technologies; (4) establishes links to collaborative partners in endemic viral hemorrhagic fever (VHF) areas to study immune responses in infected humans; (5) studies the efficacy of recombinant viruses expressing VHF virus surface glycoproteins as vaccine vectors; (6) determines the pathophysiological responses to infection using microarray technologies and state-of-the-art instrumentation; (7) studies the underlying mechanism of VHF virus pathogenesis using molecular, chemical and immunological tools and approaches; and (8) gains a better understanding of the mechanisms of virus replication and transmission in reservoir hosts and vectors.

Disease Modeling and Transmission Section - HNM2Z032

(1) Studies viral pathogens that cause viral hemorrhagic fevers (VHF) and other high biocontainment agents; (2) investigates the pathogenesis, immune, response, molecular epidemiology, cellular biology and molecular biology of VHF pathogens and other high biocontainment agents; (:,3) develops and utilizes standard and reverse genetics systems, including minigenomes and infectious molecular clones based on VHF pathogens and other high biocontainment agents; and (4) develops rapid, sensitive and specific diagnostic test systems including those that can be applied under field conditions.

Biology of Vector-Borne Viruses – HNM2Z033

1) Develop models in mammalian cells and intact animals to study the biology of arthropod vector-borne viruses, 2) Develop models in arthropod cells and intact arthropods to study the biology of arthropod vector-borne viruses, 3) Define viral and host determinants important in intra- and inter-species infection, persistence and transmission of arthropod vector-borne viruses.

Office of Scientific Management at Rocky Mountain Laboratories - HNM2Z04

(1) Actively coordinates with the RML scientific, administrative, ORS and ORF leadership staff to determine and resolve scientific program issues that require attention and decisions from the Director, DIR, NIAID; (2) actively coordinates with the RML, DIR, ORS and ORF leadership staff to manage and resolve scientific safety, emergency response, and containment issues; (3) communicates DIR and/or RML scientific goals and policies to RML staff; (4) provides scientific program input to construction and improvement projects, and to RML Campus Master Planning efforts; (5) manages and coordinates RML committees and recommends committee assignments to the Director, DIR, NIAID; (6) supervises and assures compliance with provisions of the NIH Lawsuit Settlement Agreement of 2004; (7) manages and coordinates RML seminar programs, RML Fellows Organization, RML Summer Internship Program, RML/NIH-University of Montana Graduate Program Partnership, and other programs designed to foster education and training programs at RML.

Office of Operations Management - HNM2Z05

(1) Supports the scientific infrastructure that sustains the biomedical research performed at the Rocky Mountain Laboratories including the management of campus-wide resources for the research laboratories and facilities; (2) plays a key role in master planning for the campus and serves as the Institute liaison with the Office of Research Facilities in planning for new buildings, road sidewalks, utilities and landscaping; (3) performs space management analyses and recommends reassignments and expansions; (4) provides oversight and quality assurance for campus support contracts; and (5) develops and/or analyses management policies and directives which apply to RML operations.

Research Support Services Branch - HNM2Z052

(1) Supports campus-wide laboratory research by providing central services such as laboratory media, glasswash support, medical library services and visual medical arts; (2) provides liaison with the Office of Research Services on all issues related to physical and personnel security and emergency response for the RML campus; and (3) develops and implements all procedures and policies related to the Homeland Security Presidential Directive - 12 (HSPD-12).

Operations Support Services Branch - HNM2Z053

(1) Manages operation support to the RML laboratories and branches in the areas of: (a) environmental and radiological compliance and waste management; (b) property; (c) central shipping and receiving; (d) central storeroom operations; and (e) management analysis, including human resources support to all RML staff members; (2) serves as NIAID DIR liaison for all issues related to the 20-year master plan for the RML campus; and (3) serves as NIAID representative for all construction and renovations projects.

Laboratory of Bacteriology – HNM2Z07

(1) Studies bacterial diseases, focusing on bacterial pathogens that cause important human infections to identify novel or improved strategies to control bacterial diseases; (2) researches bacterial pathogens listed as serious or urgent threats in the National Action Plan for Combating Antibiotic-Resistant Bacteria (The Plan), including methicillin-resistant *Staphylococcus aureus* (MRSA) and carbapenem-resistant *Klebsiella pneumoniae*; (3) investigates the molecular basis of host-pathogen interactions, with special attention to emerging and re-emerging pathogens (many of which are antibiotic-resistant); (4) studies the molecular genetic basis of bacterial pathogenesis; and (5) conducts research using animal models, human clinical material, and other in vivo and in vitro strategies to define cell biology of host-pathogen interactions.

Pathogen-Host Cell Biology Section – HNM2Z072

(1) Conducts a systematic molecular dissection of steps involved in the pathogen-host interaction, with specific emphasis on the interaction of bacterial pathogens with innate host defense (e.g., neutrophils); (2) investigates mechanisms mediating evasion of innate immunity by pathogens of special interest such as Staphylococcus aureus and Streptococcus pyogenes; (3) identifies new virulence genes involved in the pathogenesis of infections caused by pathogens of special interest; and (4) utilizes appropriate *ex vivo* assays, animal models (including knock-out mice), and (if possible) human specimens to test hypotheses developed from in vitro analyses.

Pathogen Molecular Genetics Section – HNM2Z073

(1) Identifies new virulence determinants involved in the pathogenesis of infections caused by bacteria such as Staphylococcus aureus and Staphylococcus epidermidis; (2) elucidates the role of new virulence genes in complex interactions between pathogen and host; (3) studies pathogen and host molecules and environmental factors that participate in regulating pathogen virulence genes; and (4) elucidates the molecular genetic basis of tissue tropism of bacterial pathogens.

Host-Parasite Interactions Section – HNM2Z074

(1) Elucidates mechanisms of parasite pathogenicity as it relates to parasite-host cell interactions;(2) defines and identifies penetration by organisms into eukaryotic cells; and (3) studies the role of gene products that regulate parasite intracellular differentiation and survival.

Coxiella Pathogenesis Section – HNM2Z075

(1) Investigates mechanisms by which the Q fever agent *Coxiella Bumetii* causes disease; (2) identifies pathogenic strategies that allow *Coxiella* to survive in host macrophages; (3) studies the molecular basis of morphological differentiation and the biological relevance or morphological forms; (4) develops strategies for genetic analysis and manipulation of *Coxiella*; (5) uses comparative genomics and Proteomics to define strain variants; (6) examines the virulence potential of strain variants and develops reagents for their detection; and (7) improves existing animal models of Q fever and uses those models to investigate virulence and potential vaccine candidates.

Salmonella-Host Cell Interaction Section – HNM2Z076

(1) Investigates the interactions between the facultative intracellular pathogen *Salmonella* and its mammalian hosts; (2) investigates the mechanisms by which *Salmonella* invade and survive within host cells; (3) characterizes the regulation of bacterial virulence factors and host cell proteins in infected cells; (4) characterizes the roles of individual bacterial virulence factors in host cells; (5) identifies host cell proteins and signaling pathways that are targeted by *Salmonella*; and (6) develops novel methods for studying pathogen-host cell interactions.
Immunity to Pulmonary Pathogens Section – HNM2Z077

(1) Develops relevant animal models of infection and immunity; (2) defines protective antigens and mechanisms of protective immune responses; and (3) develops new vaccines for the prevention of diseases caused by emerging and re-emerging pathogens and microorganisms of bio-defense interest.

Molecular Genetics Section - HNM2Z078

(1) Uses a molecular genetic approach to elucidate the mechanisms of adaptation and variation in *Borrelia burgdorferi* and their roles in the zoonotic infectious cycle; (2) understands the structure and function of plasmids in the unusual segmented genome of *B. burgdorferi* and the roles of plasmid-borne genes throughout .the infectious cycle; (3) determines how *B. burgdorferi* responds to environmental cues in order to persist in, and be transmitted between, the tick vector and mammalian host; and (4) develops basic genetic tools with which to identify and manipulate borrelial genes of interest.

Gene Regulation Section - HNM2Z079

(1) Conducts experiments to understand global gene regulation in the Lyme disease spirochete *Borrelia burgdorferi;* (2) analyzes environmental adaptations of the Lyme disease spirochete including the oxidative stress response; (3) characterizes antigens suitable for the development of an efficacious vaccine for protection against melioidosis and glanders, diseases caused by *Burkholderia pseudomallei* and *Burkholderia mallei*, respectively; and (4) identifies and characterizes genetic loci involved in the biosynthesis of lipopolysaccharide antigens in these *Burkholderia* species.

Plague Section - HNM2Z07A

(1) Uses molecular approaches to study the transmission of the plague bacterium, *Yersinia pestis*, by fleas; (2) identifies and characterizes Y. *pestis* genes required for flea-borne transmission; (3) utilizes molecular approaches to study the mechanisms of plague pathogenesis and host response following flea-borne transmission; and (4) uses comparative genomics to identify unique genes and pathways in the evolution of the plague bacterium.

Laboratory of Immune System Biology — HNM2Z09

(1)Conducts research in fundamental and applied aspects of immunology; (2) investigates the genetic, chemical, and cellular basis of specific immune responses and related aspects of developmental, cellular, and molecular biology as they related to the immune system; (3) investigates the interface of the host and the commensal microbiome; (4) in cooperation with other Institute units, develops approaches to the prevention, diagnosis, and therapy of immunologic, allergic, and infectious diseases and neoplastic disorders; (5) develops a broadly useful systems biology research paradigm and the necessary associated technological infrastructure, including tools for mathematical modeling, informatics analysis, and large-scale data acquisition using methods such as high-throughput genomic analysis, multiplex live and static imaging, proteomics, and high-throughput screening; (6) develops new ways to investigate, conceptualize, and model the fundamental organization and operation of genetic, biochemical, and cellular networks across biological scales; (7) utilizes these advances to develop a deeper [quantitative] understanding of host-pathogen and host-microbiome interactions and the operation of the immune system function in health and disease; (8) seeks opportunities to apply these new methods and tools in other key areas of biomedicine; (9) disseminates these new technologies, as well as the general concepts of systems biology, both within the NIH IRP and to the extramural community; and (10) fosters the concept of multidisciplinary team-science as a major paradigm for the future research enterprise.

Molecular and Cellular Immunoregulation Section - HNM2Z091

1) Conducts basic research on the mechanisms of the development, differentiation, activation and expansion of lymphocytes, particularly, CD4 T helper (Th) and innate lymphoid cell (ILC) subsets; 2) investigates gene regulatory network in Th and ILC subsets; 3) determines cellular and molecular mechanisms through which Th and ILC subsets together with other immune cells are involved in host defense and inflammation; 4) studies the effects of perturbations in particular components of the immune system on immune responses both in vitro and in vivo; and 5) in collaboration with other NIAID labs and labs in other NIH Institutes, gains new insights into immune regulation from various animal models and applies the new information to clinically relevant studies.

Lymphocyte Biology Section - HNM2Z092

(1)Conducts basic research in immunology; (2) investigates the molecular, cellular, and developmental events controlling immune recognition by lymphocytes; (3) studies the cell biology of lymphocytes and other cell types involved in immune responses; (4) analyses the regulation of immune responses at the organismal, cell, and molecular level; and (5) in collaboration with other Institutes and NIH units, applies newly gained insight or technology in the above areas to clinically relevant studies.

Computational Systems Biology Section- HNM2Z093

(1)Develops and applies mathematical and computational approaches and tools to explore cellular signaling processes and the role of the spatial organization of signaling components within and around cells; (2) acquires quantitative cell biological data; (3) develops and applies tools for analyzing high resolution data from various sources, including microscopy and high through put - proteomic sources; (5) contributes to the development of standards for encoding quantitative models of biological processes.

Cell Signaling and Immunity Section - HNM2Z094

(1) Plans and conducts research on signal transduction pathways focusing on signaling in the immune system and its contribution to normal cellular development and abnormal disease states; (2) uses a combination of genetic, genomic, biochemical, and cellular approaches including both transgenic and gene-targeting technology in mice to examine the function of tyrosine kinases and related signaling molecules involved in lymphocyte development, function and responses to infection and immunization; and (3) uses functional genomic, cellular and systems approaches to understand mechanisms of human immunity and immunemediated diseases, including genetic causes of primary immunodeficiencies.

Molecular Biology Section - HNM2Z095

(1)Uses molecular biological techniques to investigate the structure/function relationships of cell surface molecules involved in immune recognition; 2) examines the interactions of the major histocompatibility class I antigens with both antigenic peptides and T cell receptors, using molecularly engineered soluble counterparts of the class I molecules; 3) conducts molecular and functional analyses of naturally occurring mutant class I genes; and 4) conducts cellular studies of in vitro recombinant and mutant class I and class II/class I hybrids following their expression in transgenic mice.

Cellular Immunology Section - HNM2Z096

(1)Characterizes cell surface antigens on T and B lymphocytes which are involved in the process of lymphocyte activation; 2) develops monoclonal antibodies which exhibit agonistic or antagonistic effects on T cell triggering; and 3) develops model systems for the analysis of lymphocyte activation in vivo in order to evaluate the potential of drugs or monoclonal antibodies to modulate or abrogate an ongoing immune response.

Molecular Development Section - HNM2Z097

(1)Conducts basic research on the regulation of T lymphocyte growth, development, and antigen responsiveness; 2) studies the cellular and molecular factors that control programmed cell death in the immune system; 3) studies the molecular basis for cytokine gene regulation and investigates the effector activities of these immune system mediators;
4) develops novel therapeutic approaches to autoimmune diseases; and 5) utilizes new knowledge in collaborative efforts to prevent or treat clinically important diseases.

Integrative Immunobiology Section - HNM2Z098

(1)Conducts basic research on the regulation of gene expression programs in the hematopoietic and immune systems; (2) investigates the functions of RNA-binding protein and non-coding RNAs in health and disease using an integrative systems biology approach; (3) studies the basic properties and clinical relevance of fetal hematopoietic stem cells and their derivatives; and (4) in collaboration with other Institute and NIH units, applies newly gained insight or technology in the above areas to diagnose, prevent or treat clinical conditions including hematologic and immune system disorders.

Signaling Systems Section - HNM2Z099

(1) Research program is focused on the design, implementation, and interpretation of genetic screening efforts to identify and determine the interactions among the components in immune cell signaling networks. (2) Identification of new pathway regulators by high-throughout genetic screening, and implementation of cell biology, biochemistry, and molecular biology approaches to characterize their function. (3) Specific utilization of these approaches to develop a better understanding of how signaling pathway responses to pathogen infection control the macrophage inflammatory state. (4) Development of strategies to regulate these responses to treat human inflammatory diseases. (5) Dissemination of developed technologies and software applications both within the NIH IRP and the extramural research community.

Multiscale Systems Biology Section Functional Statement - HNM2Z09B

(1) Conducts research in fundamental systems immunology in both humans and animal models; (2) interrogates and develops quantitative and computational model of immune homeostatic and response processes in the context of infection, vaccination, immune-mediated diseases, and health maintenance; (3) invents and develops experimental and computational methodology to study biological systems by examining and integrating across multiple levels, spanning organismal, cellular, and molecular scales; (4) develops conceptual paradigms to understand biological system processes and functions.

Laboratory of Clinical Immunology and Microbiology - HNM2Z11

The Laboratory of Clinical Immunology and Microbiology (LCIM) integrates basic and clinical research of immune function and studies of pathogens, including those that infect the immunocompromised host. The laboratory has a comprehensive research program ranging from microorganisms to host defense, with a special emphasis on understanding the molecular pathophysiology and genetic determinants of disease in both microbe and host, as well as on developing novel therapeutic approaches to the treatment of immune disorders, including bone marrow transplant, gene therapy and new targeted pharmacological interventions. The LCIM trains fellows in the medical specialty of Infectious Diseases. In the laboratories and clinics the LCIM studies (1) the epidemiology, pathogenesis, pathophysiology, treatment and underlying risk factors of infectious diseases, including Aspergillus, Cryptococcus, and Candida; mycobacterial infections, including the nontuberculous mycobacteria and M. tuberculosis; as well as other bacterial infections that include gram negative and gram positive organisms, Chlamydia and Lyme disease; and (2) the pathogenesis, pathophysiology, and treatment of autoinnmune lymphoproliferative syndrome (ALPS) and related lymphoproliferative disorders, autoinflammatory diseases, and a broad range of inherited primary immunodeficiencies (PID), including PIDs with associated Omenn Syndrome or other severe immunodysregulation-mediated autoimmunity; and (3) application of stem cell and immune cell transplantation and/or gene transfer technologies for correction of disorders of immune function.

Translational Mycology Section - HNM2Z111

Conducts and supports research directed at understanding fungal infections to improve patient outcomes. The focus is on the AIDS-related pathogen, *Cryptococcus*, responsible for over a half a million deaths annually. Mouse modeling, fungal genetics and mammalian immunology are complemented by research protocols of human patients with cryptococcal meningitis to aid in the development of novel diagnostics and therapeutic approaches for these difficult infections.

Immunopathogenesis Section - HNM2Z112

(1) Identifies, characterizes, and molecularly dissects the genes and pathways involved in innate immunity and host defense; (2) identifies critical pathways in host defense through the treatment of patients with .infections resulting from inherited defects in the relevant pathways of the immune function; (3) studies patients with (a) immune defects leading to generalized or localized mycobacterial infections, (b) unusual recurrent or chronic pulmonary infections, (c) infections resulting from defects in the oxidative burst host defense system; and (4) examines the convergence of these pathways of innate immunity in the control of a variety of environmental organisms.

Molecular Microbiology Section – HNM2Z113

1) Conducts studies of the basic biology and pathogenesis of human microbial infections, including bacterial and fungal pathogens, with major emphasis on fungal pathogens; 2) designs and conducts rigorous and novel studies and develops new methods of analyses which lead to a better understanding of how these microbes grow, invade the human host, and cause disease; and how the immune system and the organism interact, and determines measures that may be developed to treat or prevent the infection; and 3) dissects microbial mechanisms with molecular and cellular tools of study.

Tuberculosis Research Section - HNM2Z114

(1) Focuses on the development of novel chemotherapeutics and immunotherapeutics for the treatment of tuberculosis and related diseases; because much of the inherent drug resistance of Mycobacterium tuberculosis is due to their highly impermeable cell wall, important targets for new drug development lie in the enzymatic pathways responsible for cell wall biosynthesis and assembly; (2) conducts studies to understand the pathways responsible for the synthesis and modification of mycolic acids, the major component of mycobacterial cell walls, using tools from both biochemistry and molecular genetics to foster a deeper understanding of the interactions between the various molecular components of the cell wall and create genetically engineered strains which are defective in cell wall synthesis and have utility as new improved vaccine strains; targets chemotherapeutic enzymes involved in the modification of such molecules through the construction of directed combinatorial libraries of known inhibitors of similar chemical reactions and by construction of libraries of analogs of known antituberculars; (3) studies biochemical mechanisms of survival under low-oxygen conditions, which has been correlated with survival in long-term or latent tuberculosis infections; and (4) identifies critical enzymatic functions which permit the development of novel chemotherapies for treatment of latently infected individuals.

Chlamydial Diseases Section - HNM2Z115

(1) Investigates the mechanisms by which intracellular pathogens cause disease; (2) identifies pathogen virulence factors that contribute to pathogenesis using modem molecular approaches; (3) studies the molecular basis of virulence factor host cell interactions; (4) studies the immunological properties of virulence factors; (5) constructs live-attenuated and recombinant protein based vaccines; (6) tests the immunogenicity and protective efficacy of vaccines in preclinical models of infection; (7) investigates methods and tool for the development of genetic systems for obligate intracellular pathogens; and (8) employs novel gene products in the development of new anti-infectives for intracellular prokaryotic pathogens.

Genetic Immunotherapy Section - HNM2Z116

(1) Focuses on basic, translational, and clinical aspects of phagocytic cells and delineation of the structure/function relationships as they pertain to phagocytic cell host defense; 2) develops novel genetic, cellular or protein therapies to treat infections, to correct inherited and acquired immune deficiencies, and/or to control excessive inflammation; 3) studies a) the biology of bone marrow stem cells which give rise to phagocytic cells; b) the differentiation program which results in the production of mature neutrophils, eosinophils, and monocytes from stem cells; the molecular biology and enzymology of critical host defense molecules found in phagocytic cells; and the trafficking of phagocytes to sites of immune responses to infection; c) gene therapy and allogeneic bone marrow transplant therapy for chronic ranulomatous disease, an inherited defect in the phagocytic cell NADPH oxidase; d) the physiology of eosinophils and their role in host defense against respiratory syncytial virus (RSV) and other respiratory viral pathogens, and consideration of the pharmacologic potential and mechanism of action of eosinophil-derived neurotoxin (EON) and related ribonucleases as antiviral agents; e) the development of monocytes, macrophages and dendritic cells from stem cells; includes determination of the trafficking of such cells into lymph nodes and other tissues and the determination of mechanisms for antigen presentation by these antigen presenting cells and the use of gene transfer techniques to modify immune responses by these cells; 4) conducts clinical trials of gene therapy and bone marrow transplantation; 5) studies the activation and regulation of the phagocytic cell NADPH oxidase and structure and regulation of the genes encoding the subunits of this essential host defense enzyme system, including consideration of the pharmacologic potential of inhibitors of this enzyme system for the purpose of controlling inflammation; 6) develops native or recombinant versions of phagocytic cell host defense molecules and enzyme systems as potential pharmaceutical agents to augment host defense against infection; to restore inherited or acquired defects in phagocytic host defense; or to inhibit phagocytic cell functions which contribute to pathology caused by excessive inflammation; and 7) develops clinical protocols for treatment of inherited immune deficiencies using bone marrow transplantation or gene therapy targeting the stem cells which give rise to the immune cells.

Clinical Pathophysiology Section - HNM2Z117

(1) Identifies, characterizes, and treats immune defects affecting phagocytes; 2) studies patients and animal models with diseases affecting phagocytes in order to better understand normal phagocyte function; and 3) studies patients and animal models with diseases and syndromes affecting phagocytes for several decades, focusing on chronic granulomatous disease, hyper IgE recurrent infection syndrome, and mycobacterial susceptibility.

Molecular Defenses Section - HNM2Z118

(1) Explores the biochemistry of innate anti-microbial defense mechanisms in man; (2) characterizes sources of reactive oxygen products that serve as effective microbicidal agents and mediate inflammatory responses to infection; (3) identifies phagocyte genes affected in chronic granulomatous disease (CGD) and characterizes functional domains involved in oxidase assembly and signaling intermediates involved in its activation; this leads to the development of strategies to augment oxidase activity to enhance host defense or inhibit the enzyme for controlling inflammation; and (4) characterizes related oxidases (Nox family) on epithelial surfaces that appear to function in host defense, which includes superoxide-generating oxidases of the colon and kidneys and hydrogen peroxide generating enzymes detected in airways, salivary glands, and the rectum that support the anti-microbial activity of lactoperoxidase on mucosal surfaces.

Mucosal Immunity Section - HNM2Z119

1) Studies the basic immunologic mechanisms characteristic of the mucosal immune system and diseases that primarily involve the mucosa; 2) investigates the regulation of IgA synthesis and secretion, the origin of cells mediating mucosa-associated cytotoxicity mechanisms, the traffic of cells in the mucosal system, and the regulatory T cells that are called into play during mucosal responses; 3) studies diseases involving the mucosa through investigation of the pathologic mechanisms underlying inflammatory bowel disease, hypersensitivity diseases of the GI mucosa, and infections of the GI and respiratory tract; and 4) investigates diseases involving mucosal surfaces of the liver.

Human Immunological Diseases Section - HNM2Z11A

(1)Works on two main projects. First, after discovering DOCK8 immunodeficiency, which is a combined immunodeficiency hallmarked by poorly controlled viral skin infections, we have continued to investigate DOCK8 function in health and human disease; (2) Exposes unexpected and interesting new facets of the molecular regulation of T lymphocyte migration in skin to provide immunity against viruses; (3) Collaborates their insight into the signaling pathway controlled by DOCK8, which keeps the lymphocytes intact and functioning as they migrate within the skin; (4) Defines the genetic etiology and biochemical consequences of several new combined immunodeficiencies, some of these resemble DOCK8 immunodeficiency in featuring viral skin infections, while others feature more prominent systemic viral infections; (5) Collaborates with NM Colleagues to become the major international referral center for the evaluation and treatment of DOCK8-immunodeficient patients; (6) Studies the natural history of this disease and relate it closely to basic science studies aimed at understanding how DOCK8 functions in the immune system; (7) Focuses primarily on investigating why patients have an unusual susceptibility to viral infections that target the skin, which can inform us about normal mechanisms of antiviral immunity in the skin.

Immune Deficiency Genetics Diseases Section - HNM2Z11B

(1)Studies the autoantibody profile observed in patients with RAG deficiency presenting with combined immune deficiency and autoimmunity (CID-G/A); (2) Demonstrates that these patients produce a broad spectrum of autoantibodies, with a characteristic anti-cytokine profile that includes antibodies to IFN- and IFN-0; (3) Explains RAG deficiency presenting with autoimmunity is often associated with hypomorphic mutations that affect the coding flanksensitive region at the C-terminus of the RAG1 protein; this region interacts not only with the RSS, but also with flanking nucleotides in the coding region of the V, D, and J genes; (4) Studies in vitro that had previously indicated that missense mutations in this region of RAG1 may favor rearrangement of some V. D, J genes over others-including skewing of the composition of T and B cell repertoire might also contribute to the autoimmunity observed in patients; (5) Utilizes CRISPR/Cas-mediated gene editing, and generated three new mouse models with missense mutations at contiguous residues (F971L, R972Q, and R972W) within the coding flank-sensitive region of Rag 1; (6) Analyzes mouse models and observes patients RAG deficiency presenting with CID-G/A; (7) Practices Hematopoietic cell transplantation that would potentially represent a curative option; because of the presence of autologous T and NK cells, conditioning is required, but fully myeloablative regimens may pose a significant risk, in light of the frequent concurrence of organ damage.

Fungal Pathogenesis Section - HNM2Z11C

1) Conducts basic studies to dissect the cellular and molecular factors that regulate the innate and adaptive immune response against mucosal and invasive fungal infections in clinically relevant animal models of fungal disease; 2) Performs clinical research studies to enhance our understanding of genetic and immune defects that underlie enhanced susceptibility to mucocutaneous and invasive fungal infections in humans; 3) Conducts clinical and basic research studies to improve our understanding of the genetics, phenotypic expression and pathogenesis of the inherited disorder APECED with a goal to develop mechanism-based preventive and therapeutic strategies for affected patients.

Laboratory of Host Immunity and Microbiome- HNM2Z

1). To examine the factors controlling immunity and inflammation, whether they are host intrinsic (e.g., tissue-specific or the consequence of tissue-tissue communication) or extrinsic (e.g., involving the microbiota, nutrition, or infection). 2). To assess the consequences of environmental stress, such as infection, nutrition, and pollution, on host immunity and predisposition to inflammatory disorders in the context of fetal development, early life, and in adults. 3). To explore novel microbiota-mediated and immunotherapeutic approaches to combat the increasing threat of antimicrobial resistance.

Metaorganism Immunity Section - HNM2Z2

1) To explore the role of the microbiota in the control of immunity and inflammation 2) To explore the factors controlling tissue specific immune regulation and protective immunity 3) To explore the long term consequence of altered relationship with pathogenic or commensal microbes 4) To explore the role of nutrition in the control of immune responses.

Division of AIDS - HNM3

(1) Increases basic knowledge of the pathogenesis, natural history, and transmission of HIV disease, and promotes progress in its detection, treatment, and prevention; and (2) accomplishes this by planning, implementing, and evaluating programs in: fundamental basic and clinical research, discovery and development of therapies for HIV infection and its complications, discovery and development of vaccines and other preventative interventions, and training of researchers in these activities.

Office of Clinical Site Oversight - HNM312

The Office of Clinical Site Oversight (OCSO): 1) coordinates and communicates with other DAIDS components and Networks to ensure timely, accurate information exchange and obtain requisite scientific and policy input to facilitate informed analysis and decision-making; 2) provides oversight for clinical trials units (CTU) and clinical research sites (CRS), including: a) overseeing the implementation of DAIDS harmonized clinical research standards, policies arid procedures across CTU & CRS participating in DAIDS-sponsored clinical trials; b) having primary responsibility as the DAIDS point of contact with sites for matters related to site assessment, preparation and approval; c) verifying site requirements to start studies; d) evaluating site capacity assessment for additional activities; e) overseeing site monitoring, site. oversight visits, site performance evaluation, site suspensions, and' study/site closures; and f) informing the DAIDS Management Group' of any issues that require prioritization and/or resolution; 3) assesses site resources and capacity to meet additional protocol requirements to determine adequacy of available resources and identify gaps and communicate these to DAIDS leadership as necessary; 4) provides pharmacy expertise and support for site development, protocol development and implementation, study product management, and site pharmacy oversight and guidance; 5) works in collaboration with Program staff to develop and implement plans for site monitoring, including: development of general and protocol specific site monitoring plans, resolution of findings, follow-up communications and documentation, as appropriate; 6) assumes lead responsibility for DAIDS to develop and implement harmonized site evaluation systems, in collaboration across Networks, and to use this information for analyses of clinical trials program progress, effectiveness and outputs; 7) assumes lead responsibility and authority for coordination of site oversight visits for CTU and CRS, including: prioritization of visits, staff selection, scheduling, planning and conduct of visits, and follow-up of issues identified; 8) performs fiscal and administrative responsibilities (as Program Officers) for Network CTU and CRS grants; 9) maintains a high level of awareness of cultural, political, and social developments which can affect clinical research activities at U.S. and non-U.S. sites, and develops recommended courses of action to facilitate DAIDS-sponsored research 10) monitors CTU and CRS progress toward enrollment of underserved populations and inclusion of community representation; and 11) facilitates, for' non-network studies, the preparation and oversight of performance of sites in collaboration with the scientific programs.

Pharmaceutical Affairs Branch - HNM3122

The Pharmaceutical Affairs Branch (PAB): 1) provides pharmaceutical expertise on all aspects of protocol development, implementation, and closure for DAIDS-sponsored clinical trials; 2) provides oversight and -guidance to research site pharmacies; 3) provides consultation, advice, support and expertise to address pharmaceutical issues and inquiries to appropriate stakeholders; 4) serves as subject matter expert for development of policies, standard operating procedures, guidances, training, and quality assurance standards in all matters related to the duties and responsibilities of the PAB; and 5) provides management and oversight for Clinical Research Products Management Center contract.

Monitoring Operations Branch – HNM3123

The Monitoring Operations Branch: 1). develops and manages division-wide clinical site monitoring activities to support DAIDS-funded and/or sponsored clinical research, including: a) developing and executing the Clinical Site Monitoring Contract, b) directing monitoring of all clinical investigations in compliance with 21 CRF §312.56 and ICH Good Clinical Practices Section 5.18, and c) evaluating the performance of the Branch's contractors including quality of work products and efficiency and timeliness of task completion; 2) serves as the DAIDS-wide technical resource in clinical trial oversight and support and provides support and expertise to the OPCRO and other DAIDS Directors and NIAID management for related issues; 3) coordinates with DAIDS' Scientific Programs to review resol1rce requirements for existing and upcoming clinical studies, develop general and protocol specific monitoring requirements, as applicable, and promote a harmonized Division-wide approach to the support and oversight of clinical research; 4) develops and implements tools to support risk-based approaches to site monitoring; 5) in conjunction with the Policy, Training, and Quality Assurance Branch, OPCRO, serves as subject matter expert for development of policies, .standard operating procedures, guidance, training, and quality assurance standards in clinical site monitoring matters; and 6) develops and implements tools designed to evaluate the efficiency/effectiveness of new monitoring strategies.

Asia and Americas Branch – HNM3124

The Asia and the Americas Branch: 1) serves as the DAIDS primary point of contact for clinical trials units and clinical research sites located in Asia and South America as well as a portfolio of North American sites and is responsible for: a) communicating with Principal Investigators, site staff, Networks and other NIAID and NIH offices and b) facilitating communications, problem identification and issue resolution to further safe, efficient conduct of NIAID-supported clinical research; 2) provides technical expertise on all aspects of site assessment, site establishment, protocol implementation and site closure; including: a) assessing capacity and infrastructure of sites to perform clinical research, b) facilitating site approval in accordance with OCSO requirements, c) coordinating with OPCRO to ensure site readiness and preparedness to conduct research in accordance with DAIDS' standards, d) overseeing site performance to ensure protocol compliance, adherence to Good Clinical Practices and ICH standards, DAIDS standards, and Network requirements, e) developing corrective action plans with sites to address deficiencies, and ensure compliance with required standards, and f) serving as primary point of contact for site personnel for all matters related to site establishment, protocol conduct and site closure; 3) develops and implements performance evaluation tools to complement Network evaluation processes; 4). serves as subject matter experts on cultural, political and economic issues in Asia, North and South America that may affect the ability of the regions to support and conduct clinical research; 5) provides programmatic oversight for assigned grants, working with Grants Management Program, Principal Investigator, and Institutional Officials as necessary to ensure responsibilities and rights of the awardees, applicable NIH and NIAID policy, and human subject protection requirements are understood; 6) monitors adequacy and use of grant resources, facilitating adjustments when appropriate; and 7) reviews annual progress reports and budgets and provides input to Grants management program.

Africa and the Domestic Partners Branch – HNM3125

The Africa and the Domestic Partners Branch: 1) serves as the DAIDS primary point of contact for clinical trials units and clinical research sites located in Africa and North America and is responsible for: a) communicating with Principal Investigators, site staff, Networks and other NIAID and NIH offices and b) facilitating communications, problem identification and issue resolution to further safe, efficient conduct of NIAID-supported clinical research; 2) provides technical expertise on all aspects of site assessment, site establishment, protocol implementation and site closure including: a) assessing capacity and infrastructure of sites to perform clinical research, b) facilitating site approval in accordance with OCSO requirements, c) coordinating with OPE:RO to ensure site readiness and preparedness to conduct research in accordance with DAIDS' standards, d) overseeing site performance to ensure protocol compliance, adherence to Good Clinical Practices and ICH standards, DAIDS standards, and Network requirements, e) developing corrective action plans with sites to address deficiencies, and ensure compliance with required standards, and f) serving as primary point of-contact for site personnel for all matters related to site establishment, protocol conduct and site closure; 3) develops and implements performance evaluation tools to complement Network evaluation processes; 4) serves as subject matter experts on cultural, political and economic issues in Africa and North America that may affect the ability of the regions' to support and conduct' clinical research; 5) provides programmatic oversight for assigned grants, working with Grants Management Program, Principal Investigator, and Institutional Officials as necessary to ensure responsibilities and rights of the awardees, applicable NIH and NIAID policy, and human subject protection requirements are understood; 6) monitors adequacy and use of grant resources, facilitating adjustments when appropriate; and 7) reviews annual progress .reports arid budgets and provides input to Grants' management program.
Vaccine Research Program - HNM3D

(1) Plans and directs a comprehensive program of research grants and contracts to foster the development of vaccines, chemoprophylactic agents, and other biomedical and behavioral interventions for prevention of the acquired immunodeficiency syndrome and its associated opportunistic infections; (2) fosters the evaluation of the safety and efficacy of the prevention modalities identified above and prepares analyses of needs and research efforts and recommends new and/or continuing program emphases; (3) maintains surveillance over national and international developments in vaccines, vaccine adjuvants, immunomodulators and chemoprophylactic and other biomedical agents; (4) prepares analyses of national needs and the outcome of research efforts to assist the National Institute of Allergy and Infectious Diseases (NIAID) and advisory groups in recommending new and/or continuing program emphases; (5) consults with voluntary and professional health organizations in identifying and meeting research needs in the development of relevant prevention modalities; (6) provides medical monitoring of Division of AIDS (DAIDS) sponsored vaccine clinical trials groups to ensure compliance with federal regulations; (7) establishes and fosters liaison with investigators, industry groups and the Food and Drug Administration (FDA) to facilitate obtaining regulatory approval for new vaccines; (8) coordinates and communicates with other DAIDS Programs to assure timely and accurate interchange and/or transfer of scientific information relevant to achieving the Division's mission; and (9) coordinates the Institute's program in these areas with other government agencies and other Institutes of the National Institutes of Health.

Vaccine Clinical Research Branch - HNM3D5

(1) Plans, develops, implements, and evaluates a comprehensive extramural program of research grants and contracts to foster evaluation of AIDS vaccines in Phase I, II and III clinical trials, both domestically and internationally; (2) promotes identification and prioritization of candidate AIDS vaccines to assist in expediting the clinical evaluation of experimental vaccines through DAIDS sponsored vaccine clinical trials network; (3) promotes, fosters, evaluates, and provides scientific leadership in the identification, validation, and standardization of immunologic and virologic markers for monitoring response to patients enrolled in vaccine clinical trials and develops new initiatives designed to support immunology, virology, laboratory research as it relates to the DAIDS clinical vaccine research agenda; (4) determines program priorities and recommends funding levels within program areas; (5) coordinates and communicates with other DAIDS components to assure timely and accurate interchange and/or transfer of scientific information relevant to achieving the DAIDS mission and collaborates with relevant preclinical and basic research programs within the DAIDS and other NIH Institutes; (6) maintains surveillance over developments in program areas of responsibility and prepares analyses of national and international needs and research efforts and recommends new and/or continuing program emphases; (7) consults with voluntary and professional health organizations in identifying and meeting research needs in the program areas described above; (8) serves as liaison with other NIAID components and other NIH Institutes regarding relevant clinical, preclinical and basic research activities related to HIV vaccines and for AIDS vaccine trials; and (9) develops and oversees quality assurance programs and accreditation policies for immunology, virology and pharmacology laboratories for inter- and intra-laboratory performance assessments.

Preclinical Research and Development Branch - HNM3D6

(1) Plans, develops, implements, and evaluates a comprehensive extramural contracts resource program to support the applied preclinical development and evaluation of candidate AIDS vaccines and adjuvants for the prevention of AIDS; (2) promotes and supports directed research to assess and overcome specific biomedical obstacles to HIV vaccine development, and develops and supplies characterized reagents, animal models, and other resources necessary for these tasks; (3) promotes, fosters, and evaluates safety and efficacy of the prevention modalities identified above in preclinical models and prepares analyses of needs and research efforts and recommends new and/or continuing program emphases; (4) determines program priorities and recommends funding levels within the program area; (5) coordinates and communicates with other DAIDS components to assure timely and accurate interchange and/or transfer of scientific information relevant to achieving the DAIDS mission; (6) maintains surveillance of both national and international efforts in preclinical AIDS vaccine development and recommends new and/or continuing program emphasis; (7) consults with and maintains liaison with academic institutions, research institutions, commercial organizations, other NIAID components, other NIH Institutes, and other governmental and non-governmental organizations to promote participation in the branch's program area by competent research groups; and (8) coordinates the DAIDS programs in these areas with other government agencies and other Institutes of the National Institutes of Health.

Vaccine Translational Research Branch - HNM3D9

(1) Plans, develops, implements, and evaluates a comprehensive extramural grant and contract resource program to support translational HIV vaccine research by efficiently managing and directing HIV prophylactic products through the vaccine development pipeline; (2) proactively identifies the most promising vaccine candidates based on the results of immunogen discovery research and/or preclinical and animal studies; (3) evaluates the feasibility of manufacturing and production scale-up of vaccine candidates; (4) implements/manages all IND-enabling studies and process development for manufacture of vaccine candidates; (5) determines program priorities and recommends funding levels within the program area; (6) coordinates and communicates with other DAIDS components to assure timely and accurate interchange and/or transfer of scientific information relevant to achieving the DAIDS mission; (7) maintains surveillance of both national and international efforts in preclinical AIDS vaccine development and recommends new and/or continuing program emphasis; (8) consults with and maintains liaison with academic institutions, research institutions, commercial organizations, other NIAID components, other NIH Institutes, and other governmental and non-governmental organizations to promote participation in the branch's program area by competent research groups; and (9) coordinates the DAIDS programs in these areas with other government agencies and other Institutes of the National Institutes of Health.

Basic Sciences Program - HNM3E

(1) Plans, develops, implements, and evaluates an extramural program of basic and applied preclinical research supported by grants and contracts; (2) determines program priorities and recommends funding levels within the program area; (3) promotes multidisciplinary research on the basic virology, immunology and pathobiology of HIV and related lentiviruses; (4) implements focused epidemiologic studies of HIV-related events in humans to define mechanisms of HIV transmission and disease to further future therapeutics and vaccine research; (5) fosters and supports a multidisciplinary program to utilize the information obtained on the mechanisms of viral and immune pathogenesis of HIV disease to discover novel therapeutic and vaccine strategies for the treatment and prevention of HIV disease; (6) coordinates and communicates with other Division of AIDS (DAIDS) components to assure timely and accurate interchange and/or transfer of scientific information relevant to achieving the DAIDS mission; (7) maintains surveillance over developments in program areas of responsibility and prepares analysis of national needs and research efforts and recommends new and/or continuing program emphasis; (8) consults with voluntary and professional organizations in identifying and meeting research needs in designated program areas; and (9) coordinates the DAIDS program in these areas with those of other government agencies and other Institutes of the National Institutes of Health.

Pathogenesis and Basic Research Branch - HNM3E2

(1) Plans, develops, implements, and evaluates an extramural program of research grants and contracts to acquire basic knowledge in the molecular and cellular biology, virology, and immunology of: (a) virus host interactions of HIV-1 and related lentiviruses, (b) mechanisms of disease progression, and (c) HIV transmission, to improve the basic understanding of the disease process and to improve diagnostic and prognostic capabilities; (2) determines program priorities and recommends funding levels within the program area; (3) utilizes information gained from the research to help define, implement, coordinate, and communicate the basic science studies within the Basic Sciences Program as well as the other Programs in the Division of AIDS (DAIDS); (4) maintains surveillance over developments in program areas of responsibility and prepares analyses of national needs and research efforts and recommends new and/or continuing program emphases; (5) consults with voluntary and professional health organizations in identifying and meeting research needs in the program areas identified above; (6) coordinates the DAIDS program in these areas with other government agencies and other Institutes of the National Institutes of Health; and (7) coordinates and communicates with other DAIDs components to assure timely and accurate interchange and/or transfer of scientific information relevant to achieving the DAIDS mission.

Targeted Interventions Branch - HNM3E3

(1) Plans, develops, implements, and evaluates an extramural program of grants and contracts for research directed toward the discovery of effective vaccines and therapies for the prevention and treatment and of HIV-1 infection and disease; (2) determines program priorities and recommends funding levels within the program area; (3) maintains surveillance over developments in program areas of responsibility and prepares analyses of national needs and research efforts and recommends new and/or continuing program emphases; (4) consults with voluntary and professional health organizations in identifying and meeting research needs in the program areas identified above; (5) coordinates the Division of AIDS (DAIDS) program in these areas with other government agencies and other Institutes of the National Institutes of Health; and (6) coordinates and communicates with other DAIDS components to assure timely and accurate interchange and/or transfer of scientific information relevant to the DAIDS mission.

Epidemiology Branch - HNM3E4

(1) Plans, develops, implements, and evaluates an extramural program of research grants and contracts to foster population-based research to advance the understanding of the biology and clinical course of HIV infection to serve as a foundation for advancing treatment and prevention; (2) determines program priorities and recommends funding levels with the program area; (3) coordinates and communicates with other Division of AIDS (DAIDS) components to assure timely and accurate interchange and/or transfer of knowledge of scientific information relevant to achieving the DAIDS mission; (4) maintains surveillance over developments in program areas identified above and prepares analyses of national needs and research efforts and recommends new and/or continuing programs emphases; (5) consults with voluntary and professional health organizations in identifying and meeting research needs in the program areas identified above; and (6) serves as a liaison with other NIAID components, other Institutes of the National Institutes of Health and other government agencies regarding epidemiologic studies of HIV.

Therapeutics Research Program - HNM3G

1) Develops the scientific agenda for clinical research of therapies to treat human HIV infection and AIDS, its co-infections (e.g. tuberculosis and hepatitis C) and comorbidities in adult populations; 2) plans, develops, implements and evaluates an extramural program of cooperative agreements, grants and contracts in these areas; 3) plans and supports a program of research grants and contracts for research into the preclinical development of therapies which have the potential for the treatment of HIV/AIDS, its co-infections and co-morbidities, including the development of new or existing antimicrobials, the screening and identification of antimicrobial drugs and immunomodulators related to therapy, the preclinical evaluation of toxicity, pharmacology and evaluation of the effectiveness of drugs, biologics, or devices; 4) maintains surveillance over developments in program areas of responsibility and prepares analyses of national needs and research efforts and recommends new and/or continuing program emphasis; 5) maintains liaison with the pharmaceutical industry and the Food and Drug Administration to facilitate the evaluation and approval of new therapeutics; 6) provides expert scientific guidance to grantees and contractors concerning interaction with other Federal agencies and pharmaceutical sponsors; 7) provides medical monitoring of Division-supported clinical trials; 8) consults with voluntary and professional health organizations, including community based organizations and health care providers, to identify and meet research needs in the program areas identified above; 9) coordinates the Division's programs in these areas with other public and private stakeholders; and 10) coordinates and communicates with other Division and Institute components to assure timely and accurate interchange and/or transfer of scientific and clinical trials.

Drug Development and Clinical Sciences Branch - HNM3G2

1) Plans, develops, implements, and evaluates the Division's IND-directed preclinical drug development effort; 2) facilitates preclinical development of experimental therapies by evaluating new therapies in appropriate in vitro systems and animals; 3) establishes and maintains a computerized database of HIV and opportunistic infection (OI) therapies in development to assure timely analysis and dissemination of information to stimulate and assist drug development efforts; 4) maintains a portfolio of grants and contracts relevant to pre-clinical drug development; 5) determines program priorities and recommends funding levels within the program area; 6) maintains surveillance and development in program area and prepares analyses of national needs and research efforts and recommends new and/or continuing program emphases; 7) maintains active programs to acquire promising compounds for development of high priority anti-OI agents and to facilitate clinical evaluation of anti-HIV and anti-OI agents and devices designed to diagnose and manage HIV and OI infections; 8) serves as liaison with other AIDS drug development resources; 9) provides scientific leadership and expertise in immunology, virology and pharmacology as relates to the design and conduct of Divisionsponsored clinical trials; I 0) provides scientific leadership in the identification, validation, and standardization of immunologic and virologic markers; 11) develops and oversees quality assurance programs and accreditation policies for immunology, virology and pharmacology laboratories for inter- and intra-laboratory performance assessments; 12) develops and fosters initiatives designed to support immunology, virology and pharmacology laboratory research related to the Division's clinical research agenda; and 13) coordinates and communicates with other Division and Institute components to assure timely and accurate transfer of scientific information.

Complications and Co-Infections Research Branch - HNM3G3

1) Plans, develops, implements and evaluates a program of research grants, contracts, and cooperative agreements for research into the preclinical and clinical development of improved therapies and therapeutic strategies for the treatment of infections and noninfectious complications of importance to HIV / AIDS (e.g. hepatitis C); 2) maintains surveillance over developments in program areas of responsibility and prepares analyses of national needs and research efforts and recommends new and/or continuing program emphases; 3) determines program priorities and recommends funding levels or support of specific clinical trials within the program area to ensure appropriate allocation and optimal utilization of available resources to attain program objectives; 4) formulates, implements and reviews a comprehensive research agenda to achieve efficient preclinical and clinical evaluation of promising therapeutic approaches in these areas; 5) provides medical monitoring of clinical trials under the purview of the Branch; 6) provides medical/scientific liaison with the Food and Drug Administration, other governmental agencies, collaborating clinical trials groups, pharmaceutical companies, Data Safety Monitoring Boards, and investigators on issues related to the development of therapies and therapeutic strategies for the program areas identified above; 7) coordinates eff01ts with other Division and Institute components in the planning and performance of preclinical and clinical research projects related to the program areas identified above; 8) consults with voluntary and professional research and health organizations in identifying and meeting research needs in the program areas identified above; and 9) facilitates dissemination of new research results and responds to requests for information for the program areas identified above.

HIV Research Branch - HNM3G4

1) Plans, develops, implements, and evaluates a program of clinical research into the evaluation of improved therapies and therapeutic strategies directed at the treatment of adult HIV infection, IDV -associated non-infectious co-morbidities, the augmentation of specific HIV immune responses and general host immunity in HIV infected individuals, and the neurological complications of HIV infection; 2) analyzes national needs and research efforts regarding the treatment of adult primary infection and recommends new and/or continuing program emphases; 3) determines program priorities and recommends funding levels or support of specific clinical trials within the program area to ensure appropriate allocation and optimal utilization of available resources to attain program objectives; 4) provides medical monitoring of clinical trials involvh1g HIV therapeutics in Division-sponsored research mechanisms; 5) formulates, implements and reviews a comprehensive HIV therapeutics research agenda to achieve efficient preclinical and clinical evaluation of promising approaches for improving HIV therapies; 6) provides medical/scientific liaison with the Food and Drug Administration, other government agencies, collaborating clinical trials groups, pharmaceutical companies, Data Safety Monitoring Boards, and investigators on issues related to the development of therapies for HIV; 7) coordinates efforts with other Division and Institute components in the planning and performance of HIV preclinical and clinical research projects; 8) facilitates dissemination of new research results and responds to requests for information about program areas of responsibility; 9) consults with voluntary and professional research and health/organizations in identifying and meeting research needs in the program areas identified above; and 1 0) maintains surveillance over developments in areas of responsibility and prepares analyses of national needs and research efforts and recommends new and/or continuing program emphases.

TB Clinical Research Branch - HNM3G8

1) Plans, develops, implements, and evaluates an extramural clinical research program on tuberculosis (TB), with and without HIV co-infection, to facilitate the development of: a) improved diagnostics/prognostic biomarkers, b) drugs and drug combinations for treating drugsensitive and drug-resistant TB, c) chemoprevention and vaccines for prophylactic and therapeutic uses, d) understanding of TB pathogenesis and host defenses; 2) analyzes national needs and research efforts in these areas and recommends new and/or continuing efforts; 3) determines program priorities in these areas and recommends funding levels for support of clinical research within areas to attainment of program objectives; 4) formulates implements, and updates a comprehensive research agenda for clinical evaluation of promising approaches for improving diagnosis, treatment and prevention of TB mono- and co-infection; 5) provides review and comment for relevant study concepts and draft protocols, 6) provides medical monitoring of all Division-sponsored adult clinical trials in these areas; 7) provides medical/scientific liaison with the Food and Drug Administration, other governmental agencies, collaborating clinical trials sponsors and groups, pharmaceutical and biotechnology companies, Data Safety Monitoring Boards, and investigators on issues related to the development of diagnostic, treatment, and prevention strategies for TB; 8) coordinates efforts in. these areas with other Division and Institute components; 9) consults with health and research organizations, the community, advocates, and other stakeholders in identifying and meeting research needs and conducts meetings/workshops to facilitate progress in critical areas; and 1 0) facilitates dissemination of new research results and responds to requests for information.

Office for Policy in Clinical Research Operations – HNM3H

The Office for Policy in Clinical Research Operations (OPCRO): 1) develops and maintains Division-wide clinical research polices and standard procedures, and performs quality assurance activities; 2) provides consultation and expertise to address complex human subjects protection regulatory issues; 3) develops and implements the safety monitoring and reporting system, related safety standards, and pharmacovigilance capacity; 4) manages a portfolio of contracts to provide clinical research support and oversight services; 5) performs investigational new drug (IND) management and other regulatory functions, including provision of related consultation and support, and serves as liaison to the FDA; 6) manages protocol registration and its policies, procedures, and related training and guidance activities; and 7) develops clinical trial agreements and other agreements for Division-sponsored clinical research and collaborative activities and provides consultation on related requirements and issues.

Clinical Research Resources Branch – HNM3H2

The Clinical Research Resources Branch (CRRB): 1) delivers critical Division-wide support services through the development and administration of large-scale contracts and serves as a technical resource in areas of clinical trial infrastructure support; 2) serves as the primary technical interface to contractors to ensure appropriate delivery of services according to contract requirements and interfaces with staff to review resource requirements for clinical trials, coordinate access to Division-wide resources, avoid duplicative clinical trial support activities, and encourage a standardized approach to clinical trials support; 3) provides resources for the development and implementation of clinical research training; and 4) provides scientific and program management expertise by making recommendations regarding proposals, actions and reports relative to the delive1y of infrastructure support services, developing contract initiative descriptors and other briefing materials.

Regulatory Affairs Branch - HNM3H4

The Regulatory Affairs Branch; 1) manages IND submissions to the FDA for DAIDS-sponsored clinical trials; 2) provides expertise to internal and external stakeholders on IND regulatory issues and inquiries by developing regulatory strategies for clinical trials, providing guidance on regulatory issues during the development and conduct of IND and non-IND studies, and performing regulatory review of protocols, amendments, and letters of amendment to ensure compliance with U.S. regulations; 3) provides Regulatory Support Center oversight in collaboration with the contracting officer's technical representative; 4) manages the protocol registration process to ensure that all sites conduct clinical research according to all applicable regulations and standards.

Protection of Participants, Evaluation and Policy Branch - HNM3H5

The Protection of Participants, Evaluation and Policy Branch (Pro PEP): 1) develops and maintains a coordinated set of policies, standard operating procedures, guidance, and other materials to foster harmonization of practices within the Division and to ensure that clinical research is conducted in accordance with applicable laws, regulations, guidelines, and policies; 2) participates in compliance-related activities; 3) performs quality assurance testing to gauge the level of compliance with established policies; 4) provides consultation regarding clinical research policies and standard procedures; training, and quality assurance to resolve questions and issues of interpretation and application; 5) protects the rights and well-being of subjects participating in Division-sponsored clinical research by ensuring that clinical research is conducted in accordance with all applicable human subjects protection laws, regulations, guidelines, policies, and procedures; 6) provides consultation and expertise to address complex human subjects protection regulatory issues; and 7) works with the contracting officer's technical representative to provide direction, oversight and evaluation of the contractor performing activities to support implementation of the Division's human subjects protection.

Prevention Sciences Program - HNM3J

The Prevention Sciences Program (PSP): 1) plans, develops, implements, and evaluates a comprehensive extramural program in support of HIV prevention research in adult and pediatric populations, including a portfolio of grants and contracts covering basic research, observational studies, and human clinical trials (domestic and international.) to evaluate prevention strategies, including, but not limited to, topical microbicides, pre-exposure prophylaxis using chemoprophylactic agents and other biomedical and behavioral interventions, alone and in combination; 2) collaborates with other Programs, Divisions, and Centers within DAIDS, NIAID, and across NIH, and with other government and non-government organizations; 3) provides oversight to three HIV/AIDS clinical trials networks, the I-IIV Prevention Trials Network, the Microbicide Trials (IMPAACT) Group; and 4) collaborates with the Therapeutics Research Program on selected studies performed by the AIDS Clinical Trials Group.

Clinical Prevention Research Branch - HNM3J2

The Clinical Prevention Research Branch (CPRB): 1) plans, develops; implements, and evaluates a comprehensive extramural program of research grants and contracts in support of domestic and international phase I, II, and III clinical trials to examine HIV/AIDS prevention strategies; 2) develops and evaluates chemoprophylactic agents alone and in combination, for prevention of HIV transmission and disease; 3) promotes and supports epidemiological and behavioral research in adolescents and adults to identify risk factors and to evaluate methods to prevent transmission of HIV by sexual and other routes; 4) promotes, fosters, and evaluates the safety and efficacy of the prevention modalities identified above; 5) oversees the HIV Prevention Trials Network; 6) prepares ongoing analyses of HIV prevention research, identifies gaps, dete1mines scientific priorities, proposes new initiatives, and recommends funding levels; 7) coordinates and communicates with DAIDS leadership and other DAIDS policy and program components to assure timely and accurate interchange and/or transfer of scientific information relevant to achieving the Division's mission; 8) engages community and professional health organizations to foster the development and evaluation of strategies for preventing HIV infection; and 9) communicates and partners with other NIAID components, other NIH Institutes and Centers, the Office of AIDS Research, appropriate HHS public health agencies, and other governmental and non-governmental ol ganizations and institutions, both domestically and internationally, regarding AIDS prevention strategies.

Clinical Microbicide Research Branch - HNM3J3

The Clinical Microbicide Research Branch (CMRB): 1) plans, develops, implements, and evaluates a comprehensive extramural program of research grants and contracts in; support of domestic and international phase I, II, and III clinical trials to examine HIV *I* AIDS microbicide prevention strategies; *2:*) develops and evaluates the safety and efficacy of topical microbicide agents alone and in. combination, for prevention of HIV transmission and disease; 3) oversees the Microbicides Trials Network; 4) prepares ongoing analyses of HIV topical microbicide prevention research, identifies gaps, determines scientific priorities, proposes new initiatives, and recommends funding levels; 5) coordinates and communicates with DAIDS leadership and other DAIDS policy and program components to assure timely and accurate interchange and/or transfer of scientific information relevant to achieving the Division's mission; 6) engages community and professional health organizations to foster the development and evaluation of strategies for preventing HIV infection; and 7) communicates and partners with other NIAID components, other NIH Institutes and Centers, the Office of AIDS Research, appropriate HHS public health agencies, and other governmental and non-governmental organizations and institutions, both domestically and internationally, regarding AIDS prevention strategies.

Preclinical Microbicide and Prevention Research Branch - HNM3J4

The Preclinical Microbicide and Prevention Research Branch (PMPRB): 1) plans, develops, implements, and evaluates a comprehensive extramural program in support of HIV topical microbicide research, including a portfolio of grants and contracts supporting discovery, preclinical, and clinical development of topical microbicides; 2) oversees basic, preclinical, and clinical research programs to evaluate the safety and efficacy of HIV topical microbicide candidates, identifying potential microbicide targets based on early steps in the infectious process, establishing new models of microbicide safety and efficacy, and optimizing topical formulations; 3) prepares analyses of gaps, needs, and research efforts and determines scientific priorities in order to recommend funding levels within the program area and propose new and/or continuing program initiatives; 4) coordinates and communicates with DAIDS leadership and other DAIDS policy and program components to assure timely and accurate interchange and/or transfer of scientific information relevant to achieving the Division's mission; 5) maintains surveillance over national and international developments in program areas of responsibility and prepares analyses of national and international needs and research efforts and recommends new and/or continuing program emphases; 6) engages community and professional health organizations to foster the development and evaluation of HIV topical microbicide strategies; and 7) communicates and partners with other NIAID components, other NIH Institutes and Centers, the Office of AIDS Research and appropriate HHS public health agencies, and other governmental and non-governmental organizations and institutions, both domestically and internationally, regarding topical microbicide research strategies.

Maternal, Adolescent and Pediatric Research Branch - HNM3J5

The Maternal, Adolescent and Pediatric Research Branch (MAPRB): 1) Plans, develops, implements, and evaluates an extramural research program of prevention, diagnostic, and therapeutic strategies directed against HIV and related infections in infants, children, adolescents, and pregnant/post-partum women; 2) analyzes public health needs and research efforts in these areas and recommends new, modified, expanded and/or continuing efforts; 3) determines scientific priorities and recommends appropriate funding levels or support for research within these program areas; 4) provides medical and safety monitoring of relevant clinical trials; 5) coordinates efforts, consults and provides medical/scientific liaison with partners and stakeholders on issues related to the development of and implementation of therapies for infants, children, adolescents and pregnant/post-partum women; and 6) facilitates dissemination of new research results and responds to requests for information regarding these areas.

Workforce Operations, Communications, and Reporting Branch – HNM3K

The Workforce Operations, Communications, and Reporting Branch is responsible for: 1) seeking, organizing, and coordinating communications activities for the Division's sponsored research, clinical trial results, and ongoing scientific programs to a variety of audiences. This is accomplished through the development and/or dissemination of written materials, correspondence, presentations, briefing documents, and scientific reports; 2) maintaining and updating of relevant internal and public websites/portals; 3) coordinating the NIAID scientific reporting processes, media requests, requests made under the Freedom of Information Act; and the review and/or clearance of a variety of documents; 4) coordinating Division-wide operational activities associated with human capital, workforce planning, and space management; 5) providing leadership and oversight to the Division-wide support contracts for meeting logistics and scientific/administrative support; 6) facilitating and coordinating Division-sponsored meetings and seminars; 7) leading the operations of the web-based Clinical Research Management System including release activities, change requests, and new technology developments; and 8) facilitating oversight for the Strategic Working Group, the HIV / AIDS Network Coordination project, and related community engagement, educational and outreach activities.

Science Planning and Operations Branch – HNM3L

The Science Planning and Operations Branch is responsible for: 1) facilitating integrated crossprogram strategic planning and evaluation activities; 2) facilitating and coordinating the scientific initiative planning and development process for the Division, to include: a) managing and coordinating the scientific, administrative and operational activities associated with the AIDS Subcommittee of the NIAID Advisory Council and the AIDS Research Advisory Committee, b) planning, developing and coordinating the DAIDS annual and strategic budget process, including oversight and tracking of DAIDS budget activities, c) providing guidance and operational support to Program staff on administrative and/or policy issues for grants and contracts, and d) overseeing bilateral research initiatives and other grants programs as required; 3) maintaining and updating referral guidelines for grants and contracts for the branches within DAIDS and between Divisions; 4) leading scientific coding activities for grants and contracts; 5) ensuring human subjects information is recorded in the population tracking system; 6) facilitating Division-wide management group meetings; and 7) facilitating training for DAIDS Program Officers and Contract Officer Representatives.

Division of Microbiology and Infectious Diseases - HNM5

(1) Plans and directs a program of research grants and contracts in microbiology and infectious diseases to insure maximum utilization of available resources to attain program objectives; (2) determines program priorities and recommends funding levels within the program area; (3) prepares analyses of national needs and research efforts to assist advisory groups in recommending new and/or continuing program emphases; (4) plans, directs, and coordinates international collaborative program in infectious diseases research; (5) maintains surveillance over developments in designated program areas and assesses need for research into the causes, diagnosis, prevention, and treatment of infectious diseases and for training related thereto; (6) consults with voluntary and professional health organizations in identifying and meeting research needs in microbiology and infectious diseases; and (7) coordinates the Institute's program in these areas with those of other government agencies and other institutes of the National Institutes of Health.

Bacteriology and Mycology Branch - HNM52

(1) Plans and conducts a program in bacteriology and mycology which includes research project grants, contracts, training grants, fellowships, and career awards; (2) coordinates the various support programs of grants and contracts and develops priorities within this scientific program area; (3) recommends the development of selected research centers in high priority program areas; (4) reviews and presents to the full National Advisory Allergy and Infectious Diseases Council applications in this program area; and (5) develops and maintains liaison with appropriate domestic organizations and scientists, and collaborates on international health programs via appropriate organizations.

Basic Sciences Section - HNM522

(1) Analyzes basic research on all pathogens within the Bacteriology and Mycology Branch (BMB), with responsibilities for both biodefense and non-biodefense scientific programs as they pertain to the research objectives of BMB, the Division of Microbiology an4 Infectious Diseases (DMID), and the National Institute of Allergy and Infectious Diseases (NIAID); (2) plans, - implements, administers and evaluates a program of basic research on fungal and select bacterial pathogens through grants, contracts and cooperative agreements; (3) recommends the development and/or augmentation of specific basic research and product management activities that are of high priority in meeting the goals of NIAID's biodefense and non-biodefense research agendas; (4) coordinates BMB's basic research activities with projects and programs in other DMID offices and branches, within the NIAID, within other Institutes and Centers of the National Institutes of Health, other Government agencies as well as with the private sector research and health organizations; and (5) promotes dissemination of advances in basic research to the professional and lay communities through conferences, workshops and publications.

Translational Sciences Section - HNM523

(1) Analyzes translational research on all pathogens within the Bacteriology and Mycology Branch (BMB), with responsibilities for both biodefense and non-biodefense scientific programs as they pertain to the research objectives of BMB, the Division of Microbiology and Infectious Diseases (DMID), and the National Institute of Allergy and Infectious Diseases (NIAID); (2) plans, implements, administers and evaluates a program of translational research on fungal and select bacterial pathogens through grants, contracts and cooperative agreements; (3) recommends the development and/or augmentation of specific translational research and product management activities that are of high priority in meeting the goals of NIAID's biodefense and non-biodefense research agendas; (4) coordinates BMB's translational research activities with projects and programs in other DMID offices and branches, within the NIAID, within other Institutes and Centers of the National Institutes of Health, other Government agencies aswell as the private sector research and health organizations; and (5) promotes dissemination of advances in translational research to the professional and lay communities through conferences, workshops and publications.

Parasitology and International Programs Branch - HNM53

(1) Plans and conducts programs in basic and applied research on parasitic and other tropical diseases and vector biology, utilizing research grants, program project grants, centers grants, cooperative agreements, contracts, training grants, fellowships, and research career development awards; (2) coordinates the various support programs of grants and contracts and develops funding priorities within scientific program areas; (3) identifies important problems or research opportunities in parasitic diseases, vector biology, and other aspects of international health and recommends the development of programs to address these areas; (4) reviews and presents to the National Advisory Allergy and Infectious Diseases Council applications relevant to the Branch's scientific program; (5) develops and maintains liaison and collaborations with appropriate domestic and international governmental agencies and private organizations; (6) administers the U.S. panel on Parasitic Diseases of the U.S.-Japan Cooperative Medical Sciences Program; and (7) promotes dissemination of research results to the professional and lay communities through conferences, workshops and publications.

Malaria Vaccine Development Section – HNM532

(1) Plans and conducts programs on discovery, development and evaluation of vaccines for the prevention of malaria and other parasitic diseases at both the preclinical and clinical levels, utilizing research grants, program project grants, centers grants, cooperative agreements, contracts, training mechanisms, fellowships, and research career development awards; (2) develops priorities within the Malaria Vaccine Development Section, coordinates the use of various mechanisms of support to provide a balanced program, and recommends development of new programs to address important problems or research opportunities; (3) provides scientific, clinical and technical management of vaccine production and clinical testing under contracts and interagency agreements; (4) reviews and presents to the National Advisory Allergy and Infectious Diseases Council applications and concepts relevant to the section's scientific program; (5) develops and maintains liaison and collaboration with other government agencies, biomedical research organizations, or private industry in the area of parasite vaccine development; and (6) promotes dissemination of research results and advances in vaccine development to the professional and lay communities through conferences, workshops and publications.

Enteric and Hepatic Diseases Branch - HNM55

(1) Identifies important enteric infectious disease problems, including hepatitis, with potential for control or prevention through the development of vaccines, hyperimmune sera, or therapeutic intervention; (2) plans, implements, and administers program research contracts, cooperative agreements, and grants in enteric diseases and hepatitis to support the research objective identified above; (3) recommends the development of research areas of high priority or opportunity in enteric diseases and hepatitis; (4) maintains surveillance over developments in designated areas of responsibility and assesses needs for research into the causes, diagnosis, prevention, and treatment of enteric diseases and hepatitis and for training related thereto; (5) coordinates the Institute's program in enteric diseases and hepatitis with those of other Government agencies and other institutes of the National Institutes of Health; and (7) promotes dissemination of research results to the professional and lay communities in enteric diseases and hepatitis.Respiratory Diseases Branch (HNM56)(1) Identifies important respiratory disease problems with potential for control or prevention through the development of vaccines, hyperimmune sera, or therapeutic intervention; (2) plans, implements, and administers a program of research contracts, cooperative agreements, and grants in respiratory diseases to support the research objective identified above; (3) recommends the development of research areas of high priority or opportunity in respiratory diseases; (4) maintains surveillance over developments in designated areas of responsibility and assesses needs for research into the causes, diagnosis, prevention, and treatment of respiratory diseases and for training related thereto; (5) coordinates the Institute's program in respiratory diseases with those of other government agencies and other institutes of the National Institutes of Health; and (6) promotes dissemination of research results to the professional and lay communities in respiratory diseases.

Respiratory Diseases Branch - HNM56

(1) Identifies important respiratory disease problems with potential for control or prevention through the development of vaccines, hyperimmune sera, or therapeutic intervention; (2) plans, implements, and administers a program of research contracts, cooperative agreements, and grants in respiratory diseases to support the research objective identified above; (3) recommends the development of research areas of high priority or opportunity in respiratory diseases; (4) maintains surveillance over developments in designated areas of responsibility and assesses needs for research into the causes, diagnosis, prevention, and treatment of respiratory diseases and for training related thereto; (5) coordinates the Institute's program in respiratory diseases with those of other government agencies and other institutes of the National Institutes of Health; and (6) promotes dissemination of research results to the professional and lay communities in respiratory diseases.

Tuberculosis and Other Mycobacterial Diseases Section - HNM562

(1) Plans, implements and administers a comprehensive and, strategically balanced program of research contracts, cooperative agreements, and grants in tuberculosis and other mycobacterial diseases; (2) monitors the status of and identifies new developments in tuberculosis and mycobacterial diseases research as they pertain to the research objectives of the Respiratory Diseases Branch; (3) recommends the development and/or augmentation of specific tuberculosis and other mycobacterial disease research areas that are of high priority, but currently understudied, or that present unique opportunities for fundamental, translational and clinical research; (4) identifies and implements training opportunities for investigators to newly enter or transition to the field of tuberculosis and other mycobacterial diseases research; (5) encourages participation and partnering with public and private/commercial entities to transition basic research knowledge in the development of products that will improve human health in the U.S. and globally; (6) coordinates programs in tuberculosis and other mycobacterial diseases with programs in other branches in the Division of Microbiology and Infectious Diseases, within the NIAID, with other Institutes and Centers of the National Institutes of Health, other Government agencies, and with private sector research and health organizations; and (7) disseminates tuberculosis and mycobacterial disease research results and knowledge to professional and lay communities through meetings, workshops and publications.

Viral Respiratory Diseases Section - HNM563

(1) Monitors the status and identifies new developments in influenza, severe acute respiratory syndrome (SARS), and other viral respiratory diseases as they pertain to the research objectives of the Respiratory Diseases Branch, Division of Microbiology and Infectious Diseases; (2) plan~, implements, administers, and evaluates a comprehensive program of research contracts, cooperative agreements, and grants addressing influenza, SARS, and other viral respiratory diseases; (3) recommends the development and/or augmentation of specific influenza, SARS, and other viral respiratory diseases research areas of high priority that are currently understudied or present unique opportunities for translational and clinical research; (5) participates with public and private-commercial entities to transition basic research knowledge into the development of products that will improve human health; (6) coordinates programs in influenza, SARS, and other viral respiratory diseases with programs in other NIAID offices, NIH ICs, Government agencies, and private research and health organizations; and (7) disseminates influenza, SARS, and other viral respiratory diseases research results and knowledge to the professional and lay community through meetings, workshops, and publications.

Enterics and Sexually Transmitted Infections Branch- HNM57

(1) Identifies important sexually transmitted disease (STD) problems with potential for control or prevention through the development of vaccines, hyperimmune sera, or therapeutic intervention; (2) plans and implements a program of research contracts, cooperative agreements, and grants in STD to support the research objective identified above; (3) recommends the development of research areas of high priority or opportunity in STD research (4) maintains surveillance over developments in designated area of responsibility and assesses needs for research into the causes, diagnosis, and prevention and treatment of STDs and for training related thereto; (5) coordinates the Institute's program in STDs with those of other government agencies and other institutes of the National Institutes of Health; and (6) promotes dissemination of research results to the professional and lay communities on STDs.

Sexually Transmitted Infections Section - HNM572

(1)Identifies important sexually transmitted infections (STIs) problems with potential for control or prevention through the development of vaccines, hyperimmune sera, or therapeutic intervention; (2)Plans and implements a program of research contracts, cooperative agreements, and grants in STIs as they pertain to the research objectives of the Enterics and Sexually Transmitted Infections Branch, Division of Microbiology and Infectious Diseases; (3) recommends the development of research areas of high priority or opportunity in STI research (4) maintains surveillance over developments in designated area of responsibility and assesses needs for research into the causes, diagnosis, and prevention and treatment of STIs and for training related thereto; (5) coordinates the Institute's program in STIs with those of other government agencies and other institutes of the National Institutes of Health; and (6) promotes dissemination of research results to the professional and lay communities on STis.
Enteric Diseases Section - HNM573

(1)Identifies important bacterial enteric infectious disease problems with potential for control or prevention through the development of vaccines, hyperimmune sera, or therapeutic intervention;(2)plans, implements, and administers program research contracts, cooperative agreements, and grants in enteric diseases as they pertain to the research objectives of the Enterics and Sexually Transmitted Infections Branch, Division of Microbiology and Infectious Diseases; (3) recommends the development of research areas of high priority or opportunity in enteric diseases; (4) maintains surveillance over developments in designated areas of responsibility and assesses needs for research into the causes, diagnosis, prevention, and treatment of enteric diseases and for training related thereto; (5) coordinates the Institute's program in enteric diseases with those of other Government agencies and other institutes of the National Institutes of Health; and (7) promotes dissemination of research results to the professional and lay communities in enteric diseases.

Virology Branch - HNM59

(1) Plans and conducts programs in basic and applied research on virology and viral diseases, including preclinical and clinical research on the discovery, development, and evaluation of prophylactic and therapeutic interventions, utilizing research project grants, program project grants, contracts, training grants, fellowships, and career awards; (2) coordinates the various support programs of grants and contracts and develops funding priorities within this scientific program area; (3) surveys and analyzes new developments in high priority program areas and recommends the development of new activities to address these areas; (4) reviews and presents to the National Advisory Allergy and Infectious Diseases Council applications relevant to the branch's scientific program; (5) develops and maintains liaison and collaborations with other components of the Division of Microbiology and Infectious Diseases, the NIAID, NIH, and other organizations and scientists, including collaboration on international health programs via appropriate organizations; (6) administers the U.S. Panel on Viral Diseases of the U.S.- Japan Cooperative Medical Sciences Program; and (7) promotes dissemination of research results to other investigators, government staff and the lay and professional public through conferences, workshops, and publications.

Translational Science Section - HNM592

Identifies and prioritizes preclinical translational development of promising vaccines, therapeutics and diagnostics reagents/tools emerging from the basic research grant and contract portfolios as well as candidates identified through the preclinical services contracts; (2) conducts in vitro preclinical screening of small molecule therapeutic compounds against a broad panel of viruses and recommends further testing and development (3) conducts in vivo small animal model screening of a diverse portfolio of promising vaccine and therapeutic products, resulting in handoff to downstream product developers (3) manages large contracts for clinical testing of cohort samples and development of diagnostic assays (4) coordinates information sharing and establishes annual meetings among all preclinical service contractors; (5) serves as programmatic lead for the Emerging Infectious Diseases Research Centers network; (6) serves as the Branch lead for NIAID wide pandemic preparedness planning; (7) interfaces with HHS agencies and outside funders to coordinate response to outbreaks.

Basic Research Section - HNM593

(1) Plans, implements, administers, and evaluates a comprehensive program of basic research grants, cooperative agreements and contracts addressing the full range of viruses and viral diseases under the purview of the Virology Branch (VB), Division of Microbiology and Infectious Diseases (DMID); (2) Develops strategies for addressing critical fundamental knowledge gaps and research opportunities across the spectrum of viral diseases; (3) Promotes early discovery of new vaccines, therapeutics and diagnostics for viral infections, including emerging infections and disease outbreaks; (4) Disseminates virology basic research results and knowledge to professional and lay communities through conferences, workshops and publications; (5) Identifies and implements training opportunities for investigators to newly enter or transition to the field of virology research; (6) Oversees VB's grant-supported activities, including managing Council and end-of-year actions, and developing and implementing grant policies and processes; and (7) Coordinates with the VB Translational and Clinical Research groups to facilitate seamless advancement of basic research findings into the development of products that will improve human health.

Office of Biodefense, Research Resources and Translational Research - HNM5C

(1) Determines biodefense research priorities and recommends funding levels to support the Division of Microbiology and Infectious Diseases (DMID) extramural biodefense research agenda; (2) analyzes biodefense research needs and maintains surveillance over developments in basic research diagnostics, drug discovery, vaccine development, and clinical research to assist the DMID Director and advisory groups in recommending new and continuing biodefense research emphasis; (3) coordinates the planning, implementation, and evaluation of DMID-wide biodefense research to ensure a coordinated research agenda and to facilitate the conduct of a broad and diverse range of biodefense research across the DMID branches; (4) oversees and ensures compliance of DMID biodefense research with government directives, policies, regulations and guidelines; (5) identifies and resolves scientific, fiscal, and administrative issues related to DMID biodefense research programs; (6) consults with professional and voluntary research and health organizations, pharmaceutical and biomedical industries, and constituency groups in identifying and addressing biodefense research needs; (7) coordinates the development of DMID biodefense research periodic and special reports; (8) solicits and oversees research resource contracts to support mission-related activities and provide services to the extramural community; (9) solicits and oversees medical countermeasure contracts; and (10) coordinates DMID biodefense research programs and activities within DMID and with other NIAID components, NIH Institutes, and with other government agencies.

Biodefense Vaccines and Other Biological Product Development Section - HNM5C2

(1) Analyzes biodefense research with emphasis on opportunities in biodefense product development and management as they pertain to the research objectives of the Office of Biodefense Research Affairs; (2) plans, implements, administers, and evaluates a program of biodefense product development and management research through interagency agreements and contracts; (3) recommends development and/or augmentation of specific biodefense product development and management activities of high priority in meeting the goals outlined in NIAID's biodefense research agenda; (4)coordinates biodefense product development and management activities with projects and programs in DMID and NIAID, other ICs, other Government agencies, and research and health organizations in the private sector; and (5) promotes dissemination of information regarding advances in biodefense research product development and management to professional and lay communities through conferences, workshops and publications.

Biodefense Drug Development Section - HNM5C3

(1) Analyzes Biodefense research with emphasis on opportunities in biodefense drug development and product management as they pertain to the research objectives of the Office of Biodefense Research Affairs (OBRA), Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID); (2) plan, implements, administers and evaluates a program of Biodefense drug development and product management research interagency agreements and contracts; (3) recommends the development and/or augmentation of specific biodefense drug development and product management activities that are of high priority in meeting the goals outlined in the NIAID biodefense research agenda; (4) coordinates biodefense drug development and product management activities with projects and programs in other DMID offices and branches, within the NIAID, within other Institutes and Centers of the National Institutes of Health, other government agencies as well as with the private sector research and health organizations; and (5) promotes dissemination of advances in biodefense drug development to the professional and lay communities through conferences, workshops and publications.

Extramural Biodefense Facilities Section - HNM5C4

(1) Analyzes biodefense research with emphasis on opportunities in biodefense vaccines and other biologicals product development and product management as they pertain to the research objectives of the Office of Biodefense Research Affairs (OBRA), Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID); (2) plans, implements, administers and evaluates a program of biodefense vaccines and other biologicals product development and product management research interagency agreements and contracts; (3) recommends the development and/or augmentation of specific biodefense vaccines and other biological product development and product management activities that are of high priority in meeting the goals outlined in the NIAID biodefense research agenda; (4) coordinates biodefense vaccines and other biologicals product development and product management activities with projects and programs in other DMID offices and branches, within the NIAID, within other Institutes and Centers of the National Institutes of Health, other Government agencies as well as with the private sector research and health organizations; and (5) promotes dissemination of advances in biodefense vaccines and other biological product development and product management to the professional and lay communities through conferences, workshops and publications.

Research Resources Section – HNM5C5

(1) Analyzes Biodefense research with emphasis on opportunities and needs for biodefense and emerging infectious diseases research resources as they pertain to the research objectives of the Office of Biodefense Research Affairs (OBRA), Division of .' Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID); (2) plans, implements, administers and evaluates a program of Biodefense and emerging infectious diseases research resources interagency agreements and contracts; (3) recommends the development and/or augmentation or specific Biodefense and emerging infectious diseases research resources activities that are of high priority in meeting the goals outlined in the NIAID biodefense and emerging infectious diseases research resources activities with projects and programs in other DMID offices and branches within the NIAID, within other Institutes and Centers of the National Institutes of Health, other Government agencies as well as with private sector research and health organizations; and (5) promotes dissemination of advances in Biodefense and emerging infectious diseases research resources to the professional and lay communities through conferences, workshops and publications.

Translational Centers of Excellence and Research Coordination Section - HNM5C6

(1) Analyzes biodefense research with emphasis on opportunities and needs for biodefense and emerging infectious diseases basic and translational research that pertain to the objectives of the Office of Biodefense Research Affairs (OBRA), Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID); (2) evaluates a Cooperative Agreement Centers grant program of Biodefense and emerging infectious diseases research and training; (3) recommends the development and/or augmentation of specific biodefense and emerging infectious diseases research activities that are of high priority in meeting the goals outline in the NIAID biodefense and emerging infectious diseases research agenda; (4) coordinates the Center and training activities with projects and programs in other DMID offices and branches, within the NIAID, within other Institutes and Centers of the National Institutes of Health, other Government agencies as well as with private sector research and health organizations; and (5) promotes dissemination of advances in Biodefense and emerging infectious diseases research and training to the professional and lay communities through conferences, workshops and publications.

Office of Clinical Research Affairs - HNM5E

(1) Determines biomedical clinical research priorities and recommends funding levels to support DMID extramural clinical research to control and prevent diseases caused by infectious agents, except HIV; (2) analyzes domestic and international clinical research needs and maintains surveillance over developments in clinical research in program area to assist Director, DMID, and advisory groups in recommending new and continuing program emphasis; (3) coordinates the planning, implementation, and evaluation of DMID-wide clinical research funding mechanisms to ensure a coordinated clinical research agenda and to facilitate the conduct of a broad and diverse range of domestic and international clinical research across DMID branches; (4) oversees and ensures compliance of DMID extramural clinical research with government policies, regulations, and guidelines, that mechanisms and procedures are in place to protect the safety of study participants, and the required clinical research reports are completed; (5) identifies and resolves scientific, policy, fiscal and administrative issues related to DMID clinical research studies; (6) coordinates and oversees all clinical research procedures for DMID supported domestic and international clinical trials; (7) consults with voluntary and professional health and research organizations, pharmaceutical and biomedical industries, and constituency groups in identifying and meeting clinical research needs; and (8) coordinates DMID clinical research programs with other NIAID components, other Institutes of the NIH, and with other government agencies.

Clinical Trials Management Section - HNM5E2

(1) Standardizes the development of clinical trial protocols for the Division of Microbiology and Infectious Diseases (DMID), assuring the highest levels of safety and quality procedures; (2) coordinates with the scientific programs in providing support for concept, protocol and informed consent development, including review, writing, editing, and site implementation coordination; (3) provides data management, case report form development, and statistical support for singlesite and multi-center clinical trials; (4) provides protocol team support and participates in protocol team discussions; (5) develops manuals of procedures for DMID protocols in a standardized fashion; (6) coordinates and manages pharmacovigilance and safety management for all DMID trials, including interventional and epidemiological trials as appropriate; (7) supports and manages safety oversight committees for clinical protocols; (8) implements and manages quality assurance systems for DMID clinical sites and protocols; (9) provides clinical trial conduct and Good Clinical Practices (GCP) training at DMID clinical sites and to DMID staff; (10) supports and coordinates DMID investigator meetings and other protocol-related meetings; (11) develops systems and procedures for implementing and communicating the section's functions; and (12) provides an organizational structure and staff expertise to enhance the capabilities of the Office of Clinical Research Affairs to manage, monitor, and evaluate DMID's large and complex clinical trials programs.

Office of Regulatory Affairs - HNM5G

(1) Maintains regulatory surveillance over all clinical trials and protocols supported by the Division of Microbiology and Infectious Diseases (DMID) to assure that trials are conducted in accordance with the Food and Drug Administration (FDA) regulations; (2) establishes and monitors DMID regulatory policies; (3) establishes and monitors quality assurance standards and standard operating procedures regarding regulatory matters; (4) assembles, submits to FDA, and maintains Investigational New Drug (IND) applications, authorizes sites for clinical trials, monitors adverse experiences reported for DMID-sponsored trials and prepares safety reports, IND interim and annual reports for the FDA; (5) develops and maintains liaison for regulatory issues with the FDA, pharmaceutical industry; Office of Protection for Research Risk (OPRR) during initiation and conduct of clinical trials; (6) negotiates for DMID Clinical Trials Agreements with pharmaceutical collaborators, negotiates Letters of Understanding and Interagency Agreements; (7) coordinates and communicates with other domestic and international government agencies and with other DMID components to assure accurate and timely exchange of information on regulatory issues; (8) provides information on regulatory issues and logistical coordination of clinical trials; and (9) provides consultation concerning protection of human subjects to DMID staff and to DMID extramural supported programs developing clinical trials protocols.

Clinical Regulatory and Investigational Products Section- HNM5G2

(1) Maintains regulatory surveillance over all clinical trials and protocols supported by the Division of Microbiology and Infectious Diseases (DMID) to assure that trials are conducted in accordance with the Food and Drug Administration (FDA) and international equivalents regulations; (2) establishes and monitors DMID regulatory policies and SOPs related to clinical trials; (3) assembles, submits to FDA, and maintains Investigational New Drug (IND), Investigational Device Exemption (IDE), Master File (MF), and other applications, and all subsequent amendments to the FDA; (4) develops and maintains liaison for regulatory issues with the FDA and international equivalents, pharmaceutical industry, and other partners during initiation and conduct of clinical trials; (5) coordinates and communicates with other domestic and international government agencies and with other DMID components to assure accurate and timely exchange of information on regulatory issues; (6) provides information and makes recommendations on regulatory issues and logistical coordination regarding clinical trials and product development both domestically and internationally; (8) maintains and manages efforts related to procurement, storage and shipping of clinical trial material, and storage and shipment of clinical samples; (9) coordinates efforts related to clinical trial site pharmacy activities.

Non-clinical Development and Pharmacokinetics Support Section- HNM5G3

(1) Maintains regulatory surveillance over non-clinical product development efforts, including cGMP manufacturing, non-clinical in vitro and GLP animal testing, bioanalytical and immunogenicity assays from clinical and non-clinical studies, and pharmacokinetic efforts supported by the Division of Microbiology and Infectious Diseases (DMID) that are submitted to the Food and Drug Administration (FDA); (2) establishes and monitors DMID regulatory policies and SOPs related to non-clinical efforts; (3) develops and maintains liaison for non-clinical regulatory issues with the FDA and international equivalents, pharmaceutical industry, and other partners; (4) coordinates and communicates with other domestic and international government agencies and with other DMID components to assure accurate and timely exchange of information on regulatory issues; (5) analyzes capabilities and regulatory compliance of non-clinical testing facilities whose work will be submitted to FDA; and (6) analyzes and provides recommendations on regulatory issues and logistical coordination regarding non-clinical product development efforts; (6) coordinates preparation of non-clinical sections of regulatory filings and briefing documents.

Office of Scientific Coordination and Program Operations - HNM5H

(1) Develops and coordinates the DMID annual scientific planning process, including the review of research initiative plans; (2) oversees research initiatives development and the DMID fiscal year phasing plan, and provides scientific and management oversight for the preparation, review, and approval of Requests for Applications, Program Announcements and Requests for Contracts; (3) maintains liaison with the NIAID Division of Extramural Activities, the NIH Division of Research Grants, and the NIH Office of Extramural Research related to the review, approval and administration of DMID grants, cooperative agreements, and contracts; (4) manages and coordinates the scientific and administrative activities associated with Microbiology and Infectious Diseases Subcommittee of the National Advisory Allergy and Infectious Diseases Council; (5) provides coordination and administrative support for grants and contracts within DMID, including preparation and updating of grants referral guidelines, coding of grants, and administration of Small Business Innovation Research solicitations and training grants; (6) provides DMID-wide grant and contract database sources; (7) oversees and manages DMID communications and public liaison activities with Congress, the media, general public constituency groups, and other groups; (8) works with the Institute's Office of Communications and Public Liaison, Office of Policy Analysis, and Office of Financial Management to develop and coordinate DMID scientific input for a wide variety of Institute periodic and special reports; and (9) prepares and coordinates DMID responses to Freedom of Information requests and other priority controlled correspondence requests.

Policy, Legislation and Communications Section - HNM5H2

(1) Plans and implements DMID communications and public liaison activities for Congress, the media, general public constituency groups, and other interested parties; (2) works with the Institute's Office of the Director, Office of Communications and Public Liaison (OCPL), Office of Policy Analysis, and the Office of Financial Management to develop and coordinate DMID scientific input for a wide variety of Institute and NIH activities; (3) develops and reviews web and print publications, coordinating communications strategies with OCPL; (4) develops and/or reviews NIAID and DMID Director briefing materials, testimony, and follow-up information for meetings and Congressional hearings, including appropriations; (5) coordinates and manages the development of strategic plans, priority-setting research agendas, scientific progress reports and up-to-date health communications materials covering the range of research supported by DMID, and promotes their dissemination; (6) coordinates and manages DMID performance evaluation activities such as GPRA and PART; and (7) prepares and coordinates DMID responses to Freedom of Information requests and other priority correspondence requests.

Office of Genomics and Advanced Technologies - HNM5J

1) Determines genomics and related omics priorities and recommends funding levels to support the Division of Microbiology and Infectious Diseases (DMID) extramural genomics research agenda; 2) analyzes genomics and related omics needs and maintains surveillance over developments in basic research, diagnostics, drug discovery, and vaccine development to assist the DMID Director and advisory groups in recommending new genomics technologies and strategies to study infectious diseases; 3) coordinates the planning, implementation, and evaluation of DMID-wide genomics initiatives and projects to ensure a coordinate research agenda and facilitates the conduct of use of genomics and related omics technologies across DMID branches; 4) oversees and ensures compliance of DMID genomics research with government directives, policies, regulations and guidelines; 5) identifies and resolves scientific, fiscal, and administrative issues related to DMID genomics research programs; 6) consults with domestic and international professional and voluntary research and health organizations, pharmaceutical, and biomedical industries and constituency groups in identifying and addressing needs to apply genomic technologies to study infectious diseases; 7) coordinates the development of DMID genomic research periodic and special reports; and coordinates DMID genomics program and activities within DMID and maintains liaison with other NIAID offices and divisions, NIH institutes and with other government agencies; 8) establishes DMID genomic and omics related guidelines and coordinates with other NIAID divisions and offices, NIH institutes, other US and international government agencies, biomedical industries and not for profit organizations; and 9) provides consultation concerning issues related to genomics data and technologies to DMID staff and DMID extramural supported programs and includes coordination of data release to DMID-funded databases and other internationally recognized data repositories as NCBI.

Office of Clinical Research Resources – HNM5K

(1) Provide a centralized and standardized coordination planning, implementation, and evaluation of clinical trials in the division wide clinical resources (e.g. Vaccine Trials Evaluation (VTEU) and Phase I Units) to ensure efficient management and implementation of clinical research across DMID; (2) provide clinical expertise to guide development, implementation and evaluation of all DMID clinical trials; (3) generate effective approaches to the execution of clinical trials to ensure quality and compliance with laws, regulations, government policies, and Good Clinical Practice; (4) promote successful investigation to discover or validate new diagnostics, therapeutic agents, and vaccines for infectious disease thorough DMID Division clinical resources; (5) facilitate the translation of DMID Office of Biodefense Research, Respiratory, Parasitic and International Disease, Virology, Sexually Transmitted Disease, Enteric and Hepatic Disease and Bacteriology and Mycology Branch concepts for therapeutics, diagnostics or vaccines into viable and productive clinical trials; (6) identify problems, analyze processes, and develop solutions to meet needs related to the development and implementation of clinical research within DMID; (7) promote the development and implementation of appropriate and targeted professional orientation, training and education and topical updates for DMID clinical personnel; (8) develop and maintain DMID clinical research enterprise SOPs, guidances, and standards; (9) provide expert clinical consultation on clinical research, design and implementation for internal and external partners; (10) provide a centralized coordinating entity to field clinical trials quickly in the event of public health emergency.

Division of Allergy, Immunology and Transplantation - HNM6

(1) Plans and directs a program of research grants and contracts in immunology and allergic diseases to insure maximum utilization of available resources to attain program objectives; (2) determines program priorities and recommends funding levels within the program area; (3) prepares analyses of national needs and research efforts to assist advisory groups in recommending new and/or continuing program emphases; (4) maintains surveillance over developments in designated program areas and assesses need for research into the causes, diagnosis, prevention, and treatment of allergic and immunologic diseases and for training related thereto; (5) consults with voluntary and professional health organizations in identifying and meeting research needs in immunologic and allergic diseases; and (6) coordinates the Institute's program in these areas with those of other Government agencies and other institutes of the National Institutes of Health.

Transplantation Branch - HNM63

(1) Plans and conducts programs of research related to the genetic control of immune functions and the interaction of genetic and immunologic mechanisms in organ transplantation and resistance to susceptibility to disease through research grants, program project grants, contracts, training grants, fellowships, and career awards; (2) identifies problem areas in organ transplantation and immunogenetics where initiatives by the Institute would increase the level of understanding and promote the translation and application of research findings into improved procedures and resources for diagnosis, prevention, and treatment; (3) designs and effects appropriate studies for development and evaluation of these procedures and resources; (4) coordinates various support programs of grants and contracts and develops priorities within this scientific program area; (5) identifies high priority areas for Institute support of research development and application; (6) reviews and presents relevant applications to the National Advisory Allergy and Infectious Diseases Council; and (7) develops and maintains liaison with appropriate organizations and scientists and, through such interactions, promotes dissemination of research results and information on technological advances that may be applicable to clinical organ transplantation or disease susceptibility.

Clinical Transplantation Section - HNM632

(1) Develops, implements and manages a program of grants and contracts dealing with the immunology of organ transplantation, particularly those processes leading to organ rejection and its prevention; 2) identifies new opportunities for research on the immunologic mechanisms involved in organ transplantation; and 3) designs and coordinates initiatives that would advance scientific knowledge concerning organ transplantation that would lead to the prevention of organ rejection by new and improved modalities of therapy.

Transplantation Basic Sciences Section - HNM633

(1) Develops, implements and manages a program of grants and contracts focused on the genetics of the immune system and the genetics of the histocompatibility system; 2) identifies new opportunities for research on the genetics of allorecognition; and 3) designs and coordinates initiatives that would advance scientific knowledge concerning the genetics of organ transplantation that would lead to the prevention of alloimmune responses.

Basic Immunology Branch - HNM64

(1) Plans and conducts programs of research in the biology and chemistry of the immune system and its products through research grants, program project grants, contracts, training grants, fellowships, and career awards; (2) collaborates with the Asthma and Allergy and the Genetic and Transplantation Biology branches in identifying promising research findings from the basic immunobiology and immunochemistry programs that could be translated and applied to areas of programmatic interest in allergy, clinical immunology, and transplantation; (3) designs and effects appropriate studies for development and evaluation of procedures and resources to facilitate research activities; (4) coordinates various support programs of grants and contracts and develops priorities within this scientific program area; (5) identifies high priority areas for Institute support of research development and application; (6) reviews and presents relevant applications to the National Advisory Allergy and Infectious Diseases Council; and (7) develops and maintains liaison with appropriate organizations and scientists and, through such interactions, promotes dissemination of research results and information on technological advances that may be applicable to disease diagnosis, prevention, and treatment.

Immunoregulation Section - HNM642

(1) Develops, implements, and manages a program of grants and contracts dealing with the regulation of the function of immune cells, particularly those processes involving immune mediators such as lymphokines and cytokines; 2) identifies new opportunities for research on immune regulatory processes; and 3) designs and coordinates initiatives that would advance scientific knowledge on immune regulation that could be applicable to the diagnosis, prevention and treatment of immune-mediated disease.

Innate Immunity Section - HNM643

1) Develops, implements and manages a program of grants and contracts dealing with the biologic and chemical structure and function of the immune system, particularly the body's basic cellular and molecular immune responses in health and disease; 2) identifies new opportunities for research in this scientific program area; 3) designs and coordinates initiatives to advance scientific knowledge and foster the application of new knowledge and technological advancements to disease diagnosis, prevention and treatment; and 4) develops and maintains liaison with relevant national and international professional societies, individual scientists, 'and lay organizations to enhance dissemination of research advances and foster their application in the clinical setting.

Autoimmunity and Mucosal Immunology Branch - HNM65

(1) Plans and conducts programs of research in clinical immunology and immunopathology to include basic mechanisms of immune system deficiencies and dysfunctions, the pathogenesis of immunologic diseases, and the pathophysiology of inflammation; (2) identifies problem areas in clinical immunology and immunopathology where initiatives by the NIAID would promote the translation and application of research findings into improved procedures and resources for diagnosis, prevention, and treatment; (3) designs and effects appropriate studies for development and evaluation of these procedures and resources; (4) coordinates various support programs of grants and contracts and develops priorities within this scientific program area; (5) identifies high priority areas for NIAID support of research development and application; (6) reviews and presents relevant applications to the National Advisory Allergy and Infectious Diseases Council; and (7) develops and maintains liaison with appropriate organizations and scientists and, through such interactions, promotes dissemination of research results and information on technological advances that may be applicable to the diagnosis, prevention, and treatment of disease.

Rheumatologic Autoimmune Disease Section - HNM652

(1) Develops, implements and manages a program of grants and contracts involving the mechanisms of autoimmunity in a wide variety of localized and systemic diseases; 2) identifies new opportunities for research on autoimmune processes; and 3) designs and coordinates initiatives that would advance scientific knowledge in this area that would be applicable to the diagnosis, prevention and treatment of autoimmune disease.

Autoimmune and Primary Immunodeficiency Diseases Section - HNM654

(1) Develops, implements, and manages a program of grants and contracts involving studies of immunodeficiencies and the immunopathology of a variety of disorders including inflammatory and infectious diseases; 2} identifies new opportunities for research on immunodeficiency and immunopathology; and 3} designs and coordinates initiatives to advance scientific knowledge in this area and foster the application of new knowledge and technologies to disease diagnosis, prevention and treatment; and 4} develops and maintains liaison with relevant national and international professional societies, individual scientists, and lay organizations to enhance dissemination of research advances and foster their application in the clinical setting.

Office of Program Planning, Operations and Scientific Information - HNM66

(1) Directs and coordinates scientific and programmatic planning activities, including the identification of research needs and opportunities, the development of short- and long-term research plans, and the preparation of proposals for support of new and continuing research initiatives and programs; (2) serves as the principal advisor to the Division Director on all matters pertaining to extramural policies and procedures for support of research grants, cooperative agreements and contracts and as liaison to the NIAID Division of Extramural Activities and the Office of Financial Management concerning the appropriate implementation and monitoring of such policies; (3) establishes priorities and criteria for the evaluation of major DAIT research grant, cooperative agreement, and contract programs, identifying the need for directing and/or conducting analyses of current research activities/programs; (4) directs and manages all aspects of the internal operations of the Division including fiscal planning and monitoring of research management and support, contract and grant funds, staff recruitment, training and performance evaluation, the development of guidelines, instructions, procedures and internal schedules to ensure compliance with fiscal and personnel requirements; (5) manages and coordinates all activities pertaining to the chartered National Advisory Allergy and Infectious Diseases Council and the Allergy, Immunology and Transplantation Subcommittee; (6) prepares and/or coordinates the preparation of multiple planning documents and scientific reports for the NIAID Office of the Director, the NIH Director's Office, and the Office of the DHHS Secretary; (7) responds to and requests information from Congressional and Executive Offices, professional societies, constituency groups, and the general public regarding the Division's research programs; (8) establishes and maintains liaison and develops collaborations with other NIH institutes, the OD/NIH, and with pharmaceutical companies and a broad array of constituency organizations, including professional societies, patent advocacy groups and private foundations; and (9) provides leadership and direction for the design, management and expansion of the Division's Demonstration and Education Research Projects in asthma and transplantation.

Allergy, Asthma, and Airway Biology Branch - HNM68

(1) Plans and conducts programs of research in asthma, allergic mechanisms, inflammation, and relevant hypersensitivity phenomena through research grant, program project grant, contract, training grant, fellowship and career awards; (2) identifies problem areas in asthma, allergic diseases, and inflammation where initiatives by the NIAID would promote the translation and application of research findings into improved procedures and resources for diagnosis, prevention, and treatment; (3) designs and effects appropriate studies for development and evaluation of these procedures and resources; (4) coordinates the various support programs of grants and contracts and develops priorities within this scientific program area; (5) identifies high priority areas for NIAID support of research, development, and application; (6) reviews and presents relevant applications to the National Advisory Allergy and Infections Diseases Council; and (7) develops and maintains liaison with appropriate organizations and scientists and, through such interactions, promotes dissemination of research results and information on technological advances that may be applicable to the diagnosis, prevention and treatment of disease.

Food, Allergy, Atopic Dermatitis and Allergic Mechanisms Section - HNM682

(1) Develops, implements, and manages a program of grants and contracts involving: a) studies of the initiation, regulation, prevention, and treatment of asthma, with a focus on the role of allergens and on immunologic and inflammatory components of allergic and non-allergic asthma; b) the role of antigens and allergens in immunologic lung diseases such as hypersensitivity pneumonitis and allergic bronchopulmonary aspergillosis; c) studies of the initiation, regulation, prevention and reversal of allergic diseases, including analysis of basic mechanisms of IgE antibody production, allergic inflammatory reactions and other components of immediate hypersensitivity reactions, including genetic and epidemiologic investigation; 2) identifies new opportunities for research that lead to advances in the diagnosis, prevention, and treatment of asthma and allergic diseases; and 3) designs and coordinates initiatives that would advance scientific knowledge concerning asthma and allergic diseases.

Asthma and Airway Biology Section - HNM683

(1) Develops, implements, and manages a program of grants and contract~ involving studies of asthma, host defenses and inflammation in a wide variety of disorders, including infectious, allergic, and inflammatory diseases; 2) identifies new opportunities for research on asthma, allergy, host defense and inflammation; 3) designs and coordinates initiatives to advance scientific knowledge in the area and foster the application of new knowledge and technologies to disease diagnosis, prevention and treatment; and 4) develops and maintains liaison with relevant national and international professional societies, individual scientists, and lay organizations to enhance dissemination or research advances and foster their application in the clinical setting.

Clinical Research Operations Program - HNM69

(1) Serves as primary advisor to the DAIT Director concerning support of new and continuing clinical research programs; (2) determines clinical research priorities and recommends associated funding levels; (3) analyzes domestic and international clinical research needs and maintains surveillance over developments in clinical research to assist the Director, DAIT, advisory groups, and DAIT staff in recommending new and continuing program emphasis; (4) coordinates the planning, implementation, and evaluation of DAIT-wide clinical research to ensure a coordinated clinical research agenda and to facilitate the conduct of a broad and diverse range of domestic and international clinical research across DAIT branches; (5) guides the design, development, and implementation of DAIT-supported clinical research directly or in collaboration with other senior level Division staff; (6) provides the scientific, technical, and administrative expertise to manage DAIT-supported clinical research directly or in collaboration with senior level Division staff; (7) provides scientific leadership and programmatic, budgetary, and administrative direction for the NIAID Collaborative Network for Clinical Research on Immune Tolerance and its Statistical and Clinical Coordinating Center; (8) manages the scientific, technical, fiscal, contractual, and administrative aspects of all activities associated with the co-sponsorship of DAIT clinical trials including the development and negotiation of various written documents to include, but not limited to clinical trial agreements, cooperative research and development agreements, material transfer agreements, memoranda of understanding, and other written agreements; (9) identifies and resolves scientific, policy, fiscal, and administrative issues related to DAIT clinical research; (10) serves as primary liaison to various Offices, Boards, and Institutes to assure the timely approval and implementation of scientifically sound and ethically acceptable research protocols; and (11) develops and maintains working relationships with pharmaceutical and biotechnology companies with respect to the development of new agents for the treatment of immune-mediated disorders, to include exposure to radiation.

Radiation and Nuclear Countermeasures Program - HNM6A

(1) Coordinates with other DAIT offices (Office of Regulatory Affairs, Office of Medical Affairs, and the Basic Immunology Branch) on the development and implementation of research, development, regulatory, and clinical strategies as part of the Radiation Countermeasures Program for the development of medical countermeasures of radiation injury; (2) develops and manages projects to: (a) screen for new drugs; (b) confirm proof of concept; (c) evaluate bioavailability, pharmacokinetics, and efficacy; (d) formulate products and establish route of administration, dosing, and schedules; (e) evaluate safety and efficacy in animal models; and, (f) develop regulatory strategy and regulatory documents for submission to the FDA for licensure (e.g., IND, New Drug Application [NDA], and Biologics License Application [BLA]); (3) coordinates with the NIAID Office of Technology Development on issues related to intellectual property, invention, clinical trial agreements, and material transfer agreements; and (4) participates, coordinates, and/or manages inter-agency working groups to develop a responsive Radiation Countermeasures Program.

Office of Regulatory Affiars - HNM6C

1)Serves as primary advisor to the DAIT Director concerning all communications with FDA and outside U.S. Health Authorities related to DAIT-sponsored clinical trials; 2)serves as the DAIT authorized representative to all Health Authorities (e.g., U.S. Food and Drug Administration, Health Canada, etc.) for communications regarding all DAIT-sponsored clinical trials to ensure accurate and timely exchange of information on regulatory issues; 3) provides strategic direction, guidance and oversight of regulatory affairs polices, rules, and regulations to all DAIT clinical programs and DAIT-sponsored investigators, maintaining consistency of approach across DAIT Branches and Programs to ensure continued compliance of the conduct of the trial with regulations and requirements for the safety of the patient and the integrity of the trial; 4) provides quality assurance oversight of manufacturing operations as needed (e.g., cellular therapies manufactured by investigators); 5)maintains Investigational New Drug applications and Drug Master Files by assembling and submitting to appropriate Health Authorities, all required documentation, throughout the course of the trial, as needed; 6)participate in Adverse Event reporting review process and makes submission to Health Authorities as needed; 7) develops and provides written guidance to facilitate overall program compliance with regulations governing clinical research; 8)establish, monitors, and maintains quality assurance and safety standards, and standard operating procedures pertaining to regulatory and clinical operations matters; 9)conducts training on International Congress of Harmonization guidelines, Good Clinical Practices, and other regulatory processes; 10)maintains budgetary and administrative oversight of the Contract Research Organization that provides regulatory support (which includes maintenance of the FDA Auditable Sponsor Essential Clinical Study Documents which are required for every clinical trial) for all DAITsponsored trials including those conducted by the NIAID Collaborative Network for Clinical Research on Immune Tolerance; 11)conducts periodic audits of DAIT Contract Research Organization performing data coordination and monitoring activities, as required by IND sponsors; and 12) develops and maintains working relationships with pharmaceutical and biotechnology companies with respect to their provision of agents to be used in DAITsponsored trials for the treatment of immune-mediated disorders, including exposure to radiation.
Division of Extramural Activities - HNM7

(1) Provides scientific leadership and oversight for the initial scientific merit review of Institute initiatives, grants, contracts, and cooperative agreements, and unsolicited program projects, training grants, and fellowships; (2) determines the scientific priorities for Institute initiatives through the process of scientific review, technical interpretation of policy, and professional judgment; (3) provides monitoring and oversight of the management of research grants and contracts to ensure NIAID/NIH/PHS/DHHS policies are adhered to; (4) performs a full range of activities that empower the four extramural divisions to complete all the activities necessary for final scientific and programmatic review of all initiatives by the National Advisory Council for Allergy and Infectious Diseases, and coordinates scientific and programmatic presentations, and other subcommittee activities of the Council; (5) advises the Institute Director on extramural program policies for research contracts, grants, cooperative agreements, and training programs; (6) represents the Institute on trans-NIH extramural program policy committees and coordinates such policy within the Institute and with other NIH institutes; (7) manages and conducts the scientific review of all applications submitted in response to all initiatives from the Institute; (8) manages the chartered scientific review committees and the National Advisory Allergy and Infectious Disease Council; (9) provides grant and contract management and processing services to all Institute programs; (10) prepares and issues awarding and encumbrance documents for all Institute extramural programs; and (11) prepares analyses and consults with voluntary and professional organizations in identifying and meeting the national needs and research efforts in all areas of staff development in research and training areas of interest to the Institute.

Office of Program Coordination and Operations - HNM72

(1) Leads and/or coordinates DEA operations, and as necessary, responses to correspondence, requests, and data calls from the NIAID Office of the Director and the NIH Office of Extramural Research; (2) Leads and/or coordinates the development, implementation and dissemination of policy, procedures, and other guidance related to extramural award activities; (3) Develops and implements systems, procedures, and operations aimed at improving the effectiveness and mitigating the risks that pertain to NIAID initiative development and the awarding of extramural research grants, cooperative agreements and contracts, including managing the NIAID Director's and DEA Director's extramural conflicts of interests and recusals; (4) Exercises oversight of and provides advice on extramural policies and standard operating procedures to the extramural community and NIAID staff, including peer review appeals, application submission and special grant programs; (5) Serves as the liaison with the NIH Office of Extramural Research and Center for Scientific Review, and coordinates with the program divisions and the NIAID Scientific Review Program with regard to receipt and referral of applications assigned to NIAID and resolution of issues related to initiative development and application submission; (6) Manages the assignment of eRA/IMPAC accounts to manage COI and maintain system and data security and performs audits and other reports related to NIH operational systems; (7) Provides technical leadership and expert consultation to maintain data integrity and resolve problems related to NIAID and NIH extramural awards and management systems; (8) Works with NIH extramural program leadership in the NIH Office of Extramural Research and Center for Information Technology, as well as NIAID staff in assessing needs and improving systems analysis, systems design and programming; (9) Coordinates and/or leads the planning of NIAID extramural grant, cooperative agreement and contract activities, including the phasing and review of research initiatives, with DEA offices and programs, other divisions within the Institute, and NIH Office of the Director; (10) Serves as the NIAID coordinator and liaison for the NIH Guide Publication System, including the Early Notification System; (11) Performs a full range of activities necessary for final scientific and programmatic review of all initiatives by the National Advisory Allergy and Infectious Disease Council and coordinates scientific and programmatic presentations, presentation and disposition of appeals and other subcommittee activities of the Council; and (12) Coordinates within DEA and NIAID program divisions to prepare for the final review of grant applications by the National Advisory Allergy and Infectious Disease Council.

Operations Branch - HNM723

(1) Monitors, updates, and serves as a control point for the NIAID RFA/RFP Phasing and Tracking Plans; (2) provides administrative and technical information to the extramural community regarding Requests for Applications (RFAs), Requests for Proposals (RFPs), and general grant and contract applications; (3) identifies grants requiring administrative or policy actions; (4) through interaction with other divisions, coordinates Council activities with respect to administrative problems, animal welfare concerns, research involving the use of human subjects, budgetary problems, and clearance of foreign applications; (5) serves as a control point for rebuttal letters from the other extramural divisions in the Institute; and (6) prepares documentation on various issues for discussion at NIAID Council meetings.

Office of Acquisitions - HNM74

(1) Manages and conducts a comprehensive program of all research and development contracting, non-research and development contracting, station support contracting, commercial item acquisitions using simplified acquisition procedures, GSA Federal Supply Schedule acquisitions and simplified acquisitions for customer ICs. (2) Provides advice and assistance regarding all phases of the acquisition cycle from planning to closeout with the purpose of accomplishing all acquisitions needed for the scientific mission and all related acquisitions required by its customers.

Acquisition Policy and Evaluation Branch – HNM742

(1) Is responsible for the interpretation, development, implementation, and evaluation of Federal policies, standards, and procedures pertaining to research and development contracting operations that support the NIAID mission; (2) provides business management services, legal advice, and interpretation for OA staff and NIAID senior management officials; and (3) provides internal controls, reviews OA staff work products, and develops best practices and supporting tools for OA and scientific program staff.

Acquisition Management and Policy Branch - HNM748

(1) Coordinates all OA operating and management activities; (2) ensures that the policies, procedures, and processes developed by the Acquisition Policy and Evaluation Branch are implemented consistently throughout the OA; (3) develops, deploys, and coordinates the use and management of electronic information systems utilized by OA staff in the execution of eCommerce activities; evaluates best practices, and develops reporting tools for use in monitoring the operation of the OA; (4) is responsible for all administrative functions of the OA including personnel recruitment, training, and allocation of resources; and (5) is responsible for all contract closeout activities.

AIDS Research Contracts Branch - HNM749

Microbiology and Infectious Diseases Research Contracts Branch A - HNM74A

Microbiology and Infectious Diseases Research Contracts Branch B - HNM74B

Allergy, Immunology, and Transplantation Research Contracts Branch - HNM74C

Acquisition Management and Operations Branch - HNM74D

(1) Develops innovative solutions for the planning and formulation of station support contracts, and all simplified acquisition procedures supporting the scientific mission of the Division of Intramural Research and Office of the Director NIAID; (2) identifies and implements best practices to negotiate, award, monitor and administer all business aspects of procurements for support services, equipment, and supplies; and (3) develops guidelines, procedures, and internal controls to implement Federal procurement policy related to small purchases and delegated procurement.

Grants Management Program - HNM75

(1) Advises the Director, Division of Extramural Activities, in the planning, development, implementation, and evaluation of Institute policies, procedures, and guidelines in the business management of grant programs; (2) collaborates with NIAID scientific staff to provide technical advice and consultation necessary to fulfill the objectives of the grant programs; (3) provides fiscal and administrative policy review of grant applications which includes attending committee meetings, sitevisits, council subcommittee meetings, etc.; (4) assists in negotiating budgets and terms of grant awards in accordance with recommendations of the scientific review groups and in compliance with established grants management policies and procedures; (5) reviews and analyzes progress and expenditure reports of active grants and assists Institute scientific staff and institutional officials in the resolution of problems; (6) provides assistance to individual recipients of grant awards and to grantee institutional business officials in the interpretation and application of NIAID, NIH, PHS, and DHHS policies and procedures relative to the business management aspects of the grant programs; (7) implements and executes the PHS National Research Service Award (NRSA) requirements, including payback, to ensure compliance by all trainees and fellows who have received NRSA support from the Institute; (8) creates, manages, and maintains a computerized Integrated Grants Management System to provide state-of-the-art grants administration to the Institute's grant constituency as well as internal organizational components; (9) reviews proposed audit exceptions and assists in the negotiation of their resolution; and (10) maintains liaison with other components of NIH, PHS, DHHS and officials of other Federal agencies.

Grants Management Regional Section C - HNM752

(1) Collaborates with the scientific program staff of the Division of Microbiology and Infectious Diseases (DMID), the Division of Allergy, Immunology and Transplantation (DAIT), and the Division of Acquired Immunodeficiency Syndrome (DAIDS) to provide technical advice and consultation necessary to fulfill the objectives of their grant programs in Region C as assigned; (2) provides fiscal and administrative policy review of assigned DMID, DAIT, and DAIDS grant applications; (3) assists in negotiating budgets and terms and conditions of assigned grant awards in accord with recommendations of the scientific review groups and grants management policies and procedures; (4) reviews and analyzes progress and expenditure reports of assigned active grants; (5) provides assistance to individual recipients of assigned grant awards and to grantee institutional business officials in the interpretation and application of DHHS, NIH and Institute policies and procedures relative to the business management aspects of the grant programs; and (6) provides coordination to Institute staff, enabling the Branch to fulfill its responsibilities in the administration and awarding of all NIAID grants.

Grants Management Regional Section A - HNM758

(1) Collaborates with the scientific program staff of the Division of Microbiology and Infectious Diseases (DMID), the Division of Allergy, Immunology and Transplantation (DAIT), and the Division of Acquired Immunodeficiency Syndrome (DAIDS) to provide technical advice and consultation necessary to fulfill the objectives of their grant programs in Region A as assigned; (2) provides fiscal and administrative policy review of assigned DMID, DAIT, and DAIDS grant applications; (3) assists in negotiating budgets and terms and conditions of assigned grant awards in accord with recommendations of the scientific review groups and grants management policies and procedures; (4) reviews and analyzes progress and expenditure reports of assigned active grants; (5) provides assistance to individual recipients of assigned grant awards and to grantee institutional business officials in the interpretation and application of DHHS, NIH and Institute, policies and procedures relative to the business management aspects of the grant programs; and (6) provides coordination to Institute staff, enabling the Branch to fulfill its responsibilities in the administration and awarding of all NIAID grants.

Grants Management Regional Section B - HNM759

(1) Collaborates with the scientific program staff of the Division of Microbiology and Infectious Diseases (DMID), the Division of Allergy, Immunology and Transplantation (DAIT), and the Division of Acquired Immunodeficiency Syndrome (DAIDS) to provide technical advice and consultation necessary to fulfill the objectives of their grant programs in Region B as assigned; (2) provides fiscal and administrative policy review of assigned DMID, DAIT, and DAIDS grant applications; (3) assists in negotiating budgets and terms and conditions of assigned grant awards in accord with recommendations of the scientific review groups and grants management policies and procedures; (4) reviews and analyzes progress and expenditure reports of assigned active grants; (5) provides assistance to individual recipients of assigned grant awards and to grantee institutional business officials in the interpretation and application of DHHS, NIH and Institute policies and procedures relative to the business management aspects of the grant programs; and (6) provides coordination to Institute staff, enabling the Branch to fulfill its responsibilities in the administration and awarding of all NIAID grants.

Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) and Training Grants Branch - HNM75A

(1) Advises the Director, NIAID Grants Management Program in the planning, development, implementation, and evaluation of Institute policies, procedures, and guidelines in the business management of grant programs; (2) collaborates with NIAID scientific staff to provide technical advice and consultation necessary to fulfill the objectives of the grant programs, with special focus on the SBIR/STTR grants program; (3) provides fiscal and administrative policy review of grant applications which includes attending committee meetings, site visits, working group meetings, etc.; (4) assists in negotiating budgets and terms of grant awards in accordance with recommendations of the scientific review groups and in compliance with established grants management policies and procedures; (5) reviews and analyzes progress and expenditure reports of active grants and assists Institute scientific staff and institutional officials in the resolution of problems; (6) provides assistance to individual recipients of grant awards and to grantee institutional business officials in the interpretation and application of NIAID, NIH, PHS, and DHHS policies and procedures relative to the business management aspects of the grant programs; (7) implements and executes Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) abbreviated together as SBIR/STTR grant programs, ensure compliance with program requirements including coordinating program within GMP; (8) creates, manages, and maintains a computerized Integrated Grants Management System to provide state-of-the-art grants administration to the Institute's grant constituency as well as internal organizational components, with special focus on the SBIR/STTR grants program; (9) reviews proposed audit exceptions and assists in the negotiation of their resolution; and (10) maintains liaison with other components of NIH, PHS, DHHS and officials of other Federal agencies.

Clinical Trials and NIH OD Grants Branch - HNM75B

(1) Advises the Director, NIAID Grants Management Program in the planning, development, implementation, and evaluation of Institute policies, procedures, and guidelines in the business management of grant programs; (2) collaborates with NIAID scientific staff to provide technical advice and consultation necessary to fulfill the objectives of the grant programs, with special focus on the grants programs with Clinical trials and grant programs coordinated by NIH Office of the Director (OD), e.g., Common Fund and Environmental influences on Child Health Outcomes (ECHO); (3) provides fiscal and administrative policy review of grant applications which includes attending committee meetings, site visits, working group meetings, etc.; (4) assists in negotiating budgets and terms of grant awards in accordance with recommendations of the scientific review groups and in compliance with established grants management policies and procedures; (5) reviews and analyzes progress and expenditure reports of active grants and assists Institute scientific staff and institutional officials in the resolution of problems; (6) provides assistance to individual recipients of grant awards and to grantee institutional business officials in the interpretation and application of NIAID, NIH, PHS, and DHHS policies and procedures relative to the business management aspects of the grant programs; (7) implements and executes with special focus on the grants programs with Clinical trials and grant programs coordinated by NIH OD; (8) creates, manages, and maintains a computerized Integrated Grants Management System to provide state-of-the-art grants administration to the Institute's grant constituency as well as internal organizational components, with special focus clinical trials grants and NIH OD programs; (9) reviews proposed audit exceptions and assists in the negotiation of their resolution; and (10) maintains liaison with other components of NIH, PHS, DHHS and officials of other Federal agencies.

Office of Knowledge Resources - HNM76

(1) Disseminates information on extramural policy, procedures, initiatives, and other administrative items targeted to the extramural research community and Institute staff; (2) provides policy and advice to NIAID's extramural research community and its scientific staff by creating major outreach vehicles for NIAID's extramural programs and directs new efforts to foster the Institute's scientific mission; (3) designs, creates, edits, and manages major information outreach vehicles, including the NIAID Council News newsletter and the NIAID Council News Extramural Information Center website, the DEA section of the NIAID intranet, and the DEA express newsletter; (4) coordinates and directs the design and content of other major writing and analytical functions of the Division; (5) prepares special projects for the DEA Director and collaborates with Institute staff and other ICs in areas of mutual interest; and (6) develops training programs for new staff members.

Scientific Review Program - HNM77

(1) Participates with the Director, Division of Extramural Activities, in the planning, development, implementation, and evaluation of Institute policies, procedures, and guidelines for Institute initiatives (Request for Applications [RFAs], Request for Proposals [RFPs] and Program Announcements [PAs] and the scientific evaluation of grant, contract, and cooperative agreement applications and proposals assigned to the Institute for primary review. These proposals consist of all competing contract proposals and all applications for program projects, centers, cooperative agreements, regular research grants in response to RFAs, all K programs, except the Research Career Development Awards [KO4s], Institutional Research Fellowship Awards [T32s], Conference grants [R13s], Demonstration projects [R18s] and selected interagency agreements, unsolicited contract proposals, and sole source proposals, either new or after a lapse of three to five years from the last peer review); (2) manages the scientific review of the aforementioned applications and proposals; (3) nominates members of the three chartered review committees of the NIAID and selects appropriate ad hoc reviews; (4) provides orientation for new scientific review group members; (5) explains and interprets NIH review policies and procedures to review group members, prospective applicants, and program staff; (6) assigns review responsibilities to review committee members and other consultants; (7) manages project site visits; (8) manages initial review group meetings; (9) prepares summary statements to aid Council members in making funding recommendations and program staff in making funding decisions; assists principal investigators in determining the next course of action for applications and to provide debriefing information to unsuccessful offerors; (10) attends Council meetings for applications, and source selection meetings for proposals to provide information in support of committee recommendations; (11) communicates with program staff on review matters; (12) manages the clearance of concepts brought before the committees for review and approval; (13) prepares detailed minutes of committee proceedings; and (14) participates in development of Institute initiatives, e.g., RFAs, RFPs and PAs.

Microbiology Review Branch - HNM773

(1) Performs a broad range of functions involving the development, implementation and evaluation of Institute policies, procedures and guidelines for Institute initiatives and for the scientific evaluation of research grant applications and contract proposals assigned to the Institute for primary review, with primary scientific focus on clinical and epidemiological research in microbiology (other than HIV/AIDS), and also performs functions in areas of HIV/AIDS and immunology as needed; (2) supports the mission of the NIAID by ensuring that the highest standards of scientific excellence, fairness, objectivity, and professionalism are brought to bear upon the process which leads to selection of the most promising research proposals for funding; customers include the extramural research community, including public and private research organizations, foreign and domestic, NIAID and NIH administrators and scientific staff, other federal agencies and the Congress, and the ultimate beneficiaries, the general public; (3) provides advice to the Director, Scientific Review Program (SRP) on the development, implementation and evaluation of Institute policies, procedures and guidelines for Institute initiatives and for the scientific evaluation of research proposals and applications for grants, contracts, and cooperative agreements assigned to the Institute for primary review; (4) manages the scientific review of clinical and epidemiological research grant and cooperative agreement applications and contract proposals for microbiology solicited by the NIAID, as well as fellowship and training grant applications; types of applications reviewed include: any of the R series single project applications, program projects, center grants, cooperative agreements, K series training awards, Institutional National Research Career Development Awards, Institutional National Research Service Awards, conference grants, demonstration projects, selected interagency agreements, competing contract proposals, unsolicited proposals and sole source proposals; (5) participates in the development of phasing plans for review workloads; (6) participates in the developmental phases of microbiology research initiatives and proposals to assist with the development of review criteria and statements of review procedures; (7) explains and interprets NIH policies and procedures to review group members and prospective applicants; (8) selects members for Special Emphasis Panel review committees, being cognizant of requirements for scientific expertise, geographic distribution, and representation by women and minorities; (9) schedules review meetings for applications and proposals received in response to Institute research initiatives; 10) assigns review responsibilities to review committee members and other consultants; (11) provides orientation for new review committee members; (12) keeps committee members apprised of review activities, policies and procedures, and related regulations and policies that may impact on review; (13) prepares summary statements and technical evaluation reports in a timely manner and prepares minutes of Committee proceedings for both open and closed sessions; (14) attends Council meetings and Source Selection meetings in support of review Committee recommendations for applications and proposals respectively; and (15) coordinates site visits with committee members, program staff, and principal investigators of grant applications and conducts site visits as necessary.

AIDS Review Branch - HNM775

(1) Performs a broad range of functions involving the development, implementation and evaluation of Institute policies, procedures and guidelines for Institute initiatives and for the scientific evaluation of research grant applications and contract proposals assigned to the Institute for primary review with primary scientific focus on clinical and epidemiological research on HIV and AIDS, and also performs functions in other areas of microbiology and immunology as needed; (2) supports the mission of the NIAID by ensuring that the highest standards of scientific excellence, fairness, objectivity, and professionalism are brought to bear upon the process which leads to selection of the most promising research proposals for funding; customers include the extramural research community, including public and private research organizations, foreign and domestic, NIAID and NIH administrators and scientific staff, other federal agencies and the Congress, and the ultimate beneficiaries, the general public; (3) provides advice to the Director, Scientific Review Program (SRP) on the development, implementation and evaluation of Institute policies, procedures and guidelines for Institute initiatives for the scientific evaluation of research proposals and applications for grants, contracts, and cooperative agreements assigned to the Institute for primary review; (4) manages the scientific review of clinical and epidemiological research grant and cooperative agreement applications and contract proposals for HIV and AIDS solicited by the NIAID, as well as fellowship and training grant applications; the types of applications reviewed include: any of the R series single project applications, program projects, center grants, cooperative agreements, K series training awards, Institutional National Research Career Development Awards, Institutional National Research Service Awards, conference grants, demonstration projects, selected interagency agreements, competing contract proposals, unsolicited proposals and sole source proposals; (5) participates in the development of phasing plans for review workloads; (6) participates in the developmental phases of HIV and AIDS research initiatives and proposals to assist with the development of review criteria and statements of review procedures; (7) explains and interprets NIH policies and procedures to review group members and prospective applicants; (8) selects members for Special Emphasis Panel review committees, being cognizant of requirements for scientific expertise, geographic distribution, and representation by women and minorities; (9) schedules review meetings for applications and proposals received in response to Institute research initiatives; 10) assigns review responsibilities to review committee members and other consultants; (11) provides orientation for new review committee members; (12) keeps committee members apprised of review activities, policies and procedures, and related regulations and policies that may impact review; (13) prepares summary statements and technical evaluation reports in a timely manner and prepares minutes of Committee proceedings for both open and closed sessions; (14) attends Council meetings and Source Selection meetings in support of review committee recommendations for applications and proposals respectively; and (15) coordinates site visits with committee members, program staff, and principal investigators of grant applications and conducts site visits as necessary.

Immunology Review Branch - HNM777

(1) Performs a broad range of functions involving the development, implementation and evaluation of Institute policies, procedures and guidelines for Institute initiatives and for the scientific evaluation of research grant applications and contract proposals assigned to the Institute for primary review, with primary scientific focus on clinical and epidemiological immunology research, and also performs functions in areas of microbiology as needed; (2) supports the mission of the NIAID by ensuring that the highest standards of scientific excellence, fairness, objectivity, and professionalism are brought to bear upon the process which leads to selection of the most promising research proposals for funding; customers include the extramural research community, including public and private research organizations, foreign and domestic, NIAID and NIH administrators and scientific staff, other federal agencies and the Congress, and the ultimate beneficiaries, the general public; (3) provides advice to the Director, Scientific Review Program (SRP) on the development, implementation and evaluation of Institute policies, procedures and guidelines for Institute initiatives and for the scientific evaluation of research proposals and applications for grants, contracts, and cooperative agreements assigned to the Institute for primary review; (4) manages the scientific review of clinical and epidemiological research grant and cooperative agreement applications and contract proposals for immunology solicited by NIAID, as well as fellowship and training grant applications; types of applications reviewed include: any of the R series single project applications, program projects, center grants, cooperative agreements, K series training awards, Institutional National Research Career Development Awards, Institutional National Research Service Awards, conference grants, demonstration projects, selected interagency agreements, competing contract proposals, unsolicited proposals and sole source proposals; (5) participates in the development of phasing plans for review workloads; (6) participates in the developmental phases of immunology research initiatives and proposals to assist with the development of review criteria and statements of review procedures; (7) explains and interprets NIH policies and procedures to review group members and prospective applicants; (8) selects members for Special Emphasis Panel review committees, being cognizant of requirements for scientific expertise, geographic distribution, and representation by women and minorities; (9) schedules review meetings for applications and proposals received in response to Institute research initiatives; 10) assigns review responsibilities to review committee members and other consultants; (11) provides orientation for new review committee members; (12) keeps committee members apprised of review activities, policies and procedures, and related regulations and policies that may impact on review; (13) prepares summary statements and technical evaluation reports in a timely manner and prepares minutes of Committee proceedings for both open and closed sessions; (14) attends Council meetings and Source Selection meetings in support of review Committee recommendations for applications and proposals respectively; and (15) coordinates site visits with committee members, program staff, and principal investigators of grant applications and conducts site visits as necessary.

Microbiology Review Branch - HNM778

(1) Performs a broad range of functions involving the development, implementation and evaluation of Institute policies, procedures and guidelines for Institute initiatives and for the scientific evaluation of research grant applications and contract proposals assigned to the Institute for primary review; (2) is responsible for the overall performance of the Scientific Review Program (SRP); (3) keeps abreast of changes in federal, NIH and NIAID policy impacting on activities within the larger context of extramural programs administration; (4) anticipates the need for adjustments in policy and procedure and proactively plans to meet those future needs; (5) designs, develops and maintains up-to-date information resources on peer review policies and procedures for use by SRP staff, including electronic shared-directory resources and accompanying manuals; (6) leads in translating new developments in policy and procedural requirements into every day practice, including development and distribution of resources, case studies and training; (7) designs, develops and delivers training modules to new SRP staff, and delivers updated/refresher training modules to experienced staff, as needed; (8) develops policy standards and maintains records on professional training and competencies of SRP staff; (9) maintains key liaison with NIH and DHHS offices of policy implementation and NIAID Committee Management Officer, Program Officers and Referral; Liaison; 10) monitors SRP compliance with Institute and Federal policies, tracking compliance with Department goals set for gender and minority inclusion on review committees, and for appropriate geographic representation of reviewers; develops approaches for identification of women and minority scientists as potential reviewers; (11) develops plans and schedules for phasing of reviews for current and future years, schedules review assignments based on the expertise, experience and workload of the Scientific Review Administrator staff, and coordinates assignments with Branch Chiefs and the SRP Director; (12) modifies assignments based on changes in workload or other unexpected variances in scheduling, and adapts staff schedules accordingly; (13) tracks the SRP workflow and prepares ad hoc reports in response to Institute management needs and GSA reporting requirements for SRP activities; (14) utilizes IT systems including County/Area Profile Program (CAPP), Electronic Research Administration (ERA) Commons, IMPACT II, Scientific Initiative Management System (SIMS) and other administrative applications available via the NIH intranet and internet resources to plan and track initiatives and assignments, and to prepare reports and analyses; (15) maintains liaison with the IMPAC II development team and keeps the SRP staff apprised of impending function changes in related IT review systems; (16) serves as coordinator for SRP senior management staff comments on Institute initiatives for identification of key issues and actions, and provides follow-up on action items and outcomes; (17) coordinates the nomination process for new members of the three NIAID chartered review committees; (18) maintains active databases for tracking records, submissions and assignments for the SRP Referral List and SEP Assignment List using a coding scheme with uniquely assigned Scientific Review Administrator flex codes; and (19) tracks assignments of grant applications for review to NIAID Special Review Groups and chartered communities via the IRG/SRG assignment/referral function of application administration in the IMPACT II Peer Review module.

Office of Special Population and Research Training - HNM79

(1) Provides the Director, NIAID, and his senior staff with advice and guidance on matters pertaining to minority and women's health as well as minority and women's participation in research; (2) serves as the focal point for establishing NIAID-wide goals for minority and women's research training programs; (3) develops and implements a trans-NIAID plan to improve research on minority populations and women on diseases and conditions that affect minority and women disproportionately; (4) creates initiatives to enhance the research efforts targeted to minority and women's health, increase the effectiveness of outreach and education programs, and develop the research infrastructure at minority institutions; (5) informs the scientific and medical communities and other Government agencies of NIAID minority and women's health activities and involves them in efforts to expand and encourage minority and women's health research and training programs; (6) assists the Director, NIAID in reviewing and assessing the Institute's activities with respect to clinical trials involving minorities and women, and collaborates with the Institute's Division Directors and other senior medical staff on the conception, design, development and implementation of clinical trials which are either exclusively focused on or include minorities and women; (7) in conjunction with the Director, Division of Extramural Activities (DEA) and senior staff within NIAID and NIH, leads in the planning, development, and implementation of programs and projects related to the training and development of new generations of scientists to conduct research in areas of interest to NIAID; (8) functions as the principal office within the Office of the Director, NIAID for carrying out policies for scientific training and manpower development; (9) is responsible for all policy and procedure related to extramural training grant and fellowships; (10) coordinates the development of statistical and budgetary data and other related information to project the scientific training and manpower needs relevant to the NIAID mission; (11) works with the Director, NIAID, to bring forward to Council and professional societies the NIAID efforts to enhance and strengthen the manpower needed to meet the mission of the Institute; and (12) maintains oversight and statistical data on all other manpower and training activities in the Institute.(1) Provides leadership for a national program in the major disease categories of arthritis and musculoskeletal and skin diseases; (2) plans, conducts, fosters, and supports an integrated and coordinated program of research, investigations, clinical tria

Office of International Extramural Activities - HNM7A

(1) Plays a key role in establishing and implementing the NIAID's global health and biodefense research policies and plans; (2) provides the NIH in general, and the NIAID specifically, with expertise on biodefense issues related to the use, possession, security, and transfer of select biological agents or toxins (Select Agents) deemed a threat to public, animal or plant health at NIH-funded foreign institutions; (3) provides expertise on international Select Agents policies through activities with senior government officials at DHHS, Department of State, Department of Justice, NIH, and NIAID; (4) develops procedures for managing international awards; (5) represents NIAID interest on several trans-NIH committees formed to review extramural international policy and coordinates the implementation of resulting policies within the Institute and with other NIH institutes; (6) responsible for planning, managing, reviewing, analyzing, evaluating, and reporting on NIAID international research funding and resource management; (7) responsible for assisting foreign institution official and researchers in their understanding of NIH research policies and NIAID scientific objectives; (8) identifies technical, administrative, and resource needs of NIAID-funded foreign research institutions; (9) coordinates the review, study and analysis of a variety of reports, statements, briefing papers, and other relevant documents from foreign countries; and (10) coordinates meetings with foreign institutional leaders to gain support and consensus on the best practices implementation of NIH funding policies.

Vaccine Research Center - HNM8

(1) Develops a vaccine against human immunodeficiency virus (HIV); (2) stimulates multidisciplinary research from basic and clinical immunology and virology through vaccine design and production; (3) integrates modern immunological science with a detailed understanding of the pathogenesis of HIV infection; (4) develops immunogens and vectors and new approaches to vaccination; (5) conducts research directed towards developing candidate HIV vaccines suitable for evaluation in large field trials for efficacy in blocking HIV including both laboratory and clinical research projects focused on developing vaccines to prevent HIV.

Immunology Laboratory - HNM82

(1) Investigates novel aspects of the cellular immune response to pathogens in support of the rational development of a vaccine against HIV; (2) advances current information on ways of manipulating the HIV immune response into practical applications in clinical trials of prophylactic and therapeutic vaccines; and (3) performs detailed analysis of the strength, breadth, plasticity, phenotype, and functional characteristics of the cellular immune response to HIV during natural infection, and determines how it differs from the immune response generated after vaccination.

Immunology Core Section - HNM822

(1) Develops, validates, and performs assays of the immune response to HIV and other pathogens on clinical samples derived from recipients of candidate vaccines; (2) performs sensitive and reliable assays as endpoints of phase one and two clinical trials carried out through the VRC clinical trials program or other collaborators; and (3) develops assays and improves existing assays to better understand the nature of the immune responses generated by candidate vaccines.

Human Immunology Section - HNM823

(1) Investigates the induction, maintenance and reconstitution of immunity in humans by studying the specificity and frequency of T cell clonotypes; (2) establishes correlates of effective and protective immunity by studying HIV disease and vaccination against HIV; and (3) studies immune reconstitution to explore mechanisms by which recovery from HIV disease can be enhanced.

ImmunoTechnology Section - HNM824

(1) Elucidates the complex heterogeneity of the immune system; defines the functional roles of each uniquely identifiable leukocyte subset in the healthy immune system to understand how imbalances in these subsets leads to disease; and (2) develops and applies highly sophisticated technologies required for this research; participates in the dissemination of these technologies to other researchers, and in the application of these tools to clinical medicine and vaccine trials.

Flow Cytometry Core Section - HNM825

(1) Supports the flow cytometry needs of VRC research laboratories and clinical trials; (2) brings in or develops new flow cytometry-based assays and technologies to support VRC efforts; (3) maintains and operates a range of instruments from basic bench top analyzers to the most sophisticated sorter extant; and (4) manages all flow cytometric data collected by researchers and clinical trials, and assists in the analysis and presentation of flow cytometric experiments.

Cellular Immunology Section - HNM826

(1) Develops infectious disease vaccines which require the cellular immune response to mediate protection (eg Leishmania major, Mycobacterium tuberculosis, HIV); (2) investigates cellular and molecular mechanisms by which cytokines and co-stimulatory molecules regulate cellular immunity in vivo, with emphasis on the regulation of memory Th 1 responses.

Biodefense Research Section - HNM827

(1) Conducts research on extraordinary biodefense research needs in Ebola and other viral hemorrhagic fevers (VHF) and develops multiple biodefense related vaccine products; (2) studies the innate and adaptive immune response to such agents, and their pathogenetic, viral, cellular, and immune components; (3) utilizes the potential of various animal models to predict pathogenetic and/or immune responses in humans; and (4) develops vaccine products and potential therapeutic agents.

Nonhuman Primate Immunogenicity Section - HNM828

(1) Consults on the design and implementation of NHP studies; (2) coordinates all studies, sample collection, and analysis with the VRC Laboratory of Animal Medicine, including writing and defending Animal Study Protocols before the Institutional ACUC; (3) develops standard operating procedures for, and validating, cellular and humoral immunogenicity assays; (4) implements all testing according to GLP guidelines; (5) collates, analyzes, and coordinates all data; (6) prepares oral and written presentations of studies for both internal and external use; and (7) coordinates with VRC Principal Investigators to design, implement, and analyze immunogenicity and immunopathogenesis experiments for basic research projects.

Immunology Section - HNM829

(1) Investigates how the immune response impacts upon virus acquisition and virus replication, in order to establish immune correlates of protection and inform appropriate vaccination strategies for various pathogens; (2) studies HIV/SIV replication in vivo in an effort to determine what cells are infected, what cells express viral proteins, and how strategies can be developed to eliminate infected cells from the host and; (3) investigates T follicular helper cells in HIV /SIV pathogenesis and vaccination with the goal of coming up with better strategies to induce the generation of hypermutated neutralizing antibodies to HIV through vaccination.

NIAID Vaccine Immune T-Cell and Antibody Laboratory Core – HNM82A

NVITAL is a Good Clinical Laboratory Practices (GCLP) accredited laboratory which: (1) performs high through-put end point immunogenicity testing for clinical trials performed by the VRC and other collaborators; (2) optimizes, qualifies, and implements new assay technology transfer from both intra and extramural NIAID labs and collaborators; (3) develops and utilizes new high-throughput immunological methodologies to facilitate generation of robust data sets to better understand the nature of immune responses generated by candidate vaccines; and (4) uses high-throughput neutralization assays for the identification and characterization of broadly neutralizing antibodies.
Tissue Analysis Core (TAC) HNM82B

To provide critical information to Vaccine Research Center groups who study (1) the development of neutralizing antibodies, (2) the localization and function of immune cells that could mediate novel "cure" strategies, (3) the complexity of phenotype-function-localization, and (4) the complex interactions between the virus and host immune cells at tissue level. Imaging technology is critically important for these studies since they provide information regarding the location of active and latent virus reservoirs in association with the dynamics of potential cytotoxic T lymphocytes (CTLs) within different areas of the lymph node. Furthermore, tissue-imaging methods can be of great interest monitoring these dynamics after *vivo* immunotherapies that target the T cell arm of the immune system.

Viral Pathogenesis Laboratory - HNM83

Includes both the Viral Pathogenesis Section and the Viral Pathogenesis Translational Science Core and; (1) Studies the virological and immunological basis for respiratory viral diseases; and (2) Defines approaches to prevent viral diseases through vaccine development or passive immunotherapy.

Viral Pathogenesis Section – HNM832

(1) Studies viral immunity and develops animal models of viral immunopathogenesis; (2) Studies the mechanisms of T cell mediated virus clearance and immunopathology, and mechanisms for regulating T cell function in both adult and neonatal mice; (3) Studies the mechanism of antibody-mediated neutralization of RSV and other respiratory viruses.

Viral Pathogenesis Translational Science Core - HNM833

Provides project management support for pre-clinical product development; 1) production of reagents including immunogens and antibodies to support vaccine development and collaborations; and 2) develops assays to support pre-clinical product evaluation.

Emerging Virus Section - HNM834

1) identifies virologic and immunological gaps in preparedness for emerging viruses that represent a pandemic threats; 2) develops vaccines for pandemic preparedness and response with an emphasis on coronaviruses; and 3) develops strategies to support general vaccine design solutions for virus families with an emphasis on a universal coronavirus vaccines.

Molecular Immunoengineering Section - HNM835

1) investigates basic aspects of protein antigenicity and immunogenicity; 2) uses molecular and single-cell technologies to define mechanistic basis for protective immunity that guides antigen design with an emphasis on influenza; 3) uses structural biology and protein engineering to design immunogens that improve the quality, breadth, and durability of immune responses with an emphasis on influenza; and 4)develops assays and tools that inform vaccine development.

Virology Laboratory – HNM84

The VRC Virology Laboratory comprises the Virology, Humoral Immunology, and Structural Biology Sections and related Cores. The goal of the Virology Laboratory is to conduct research to better understand the cellular and molecular regulation of viral gene expression, viral entry into the host cell, optimization of immune responses to gene-based vaccination and correlates of immune protection, assessment of active and passive approaches for HIV-1 vaccine development, and to apply structural biology techniques toward rational vaccine design for emerging and re-emerging infectious diseases. The work of the Virology Laboratory is closely integrated with other VRC basic and translational research Laboratories and Cores to facilitate research and development of novel vaccine candidates against pathogens threatening public health.

Virology Core Section - HNM842

(1) Designs vaccine candidates including vectors and inserts that function as gene-based and proteinbased immunogens to elicit cellular/humoral immune responses; (2) provides investigators with DNA vectors, viral-based vectors including adenoviral vectors, lentiviral vectors, and alternative Ad vectors and recombinant proteins for basic research, vaccine applications, and crystallographic studies of vaccine candidates, preclinical studies, and clinical trials; and (3) designs and examines the various vaccine delivery routes and vaccination platforms to enhance the immune responses.

Humoral Immunology Core Section - HNM843

(1) Accommodates VRC laboratory work requiring level 3 biosafety containment; (2) produces and characterizes viral stocks of SIV and HIV, including diverse viral strains representing multiple genetic subtypes; (3) performs studies of antibody-mediated neutralization of HIV and SIV, with a focus on primary virus strains and physiologically relevant target cells; and (4) ensures accurate measurement of neutralization of primary HIV-1 strains for the evaluation of immune responses to candidate vaccines; evaluates neutralizing antibody levels in serum from preclinical and clinical vaccine studies.

Structural Biology Section - HNM844

(1) Applies tools of atomic resolution structural analysis-,primarily X-ray crystallography-to the design of an effective HIV vaccine involving several components; (2) investigates the mechanisms by which viruses evade the humoral immune response; determines structures of relevant viral antigens; manipulates these antigens to produce immunogens with altered immunogenicity; (3) produces altered viral antigens that elicit a broadly neutralizing immune response; (4) collaborates with other VRC sections to decipher and exploite the virological, immunological, and biological implications of the atomic structures; and (5) Interacts with other structural biology sections to aid in establishing the infrastructure and developing the methodology necessary to attack these technically challenging structural projects.

Structural Bioinformatics Core - HNM846

1)The Structural Bioinformatics Core (SBIC) seeks to apply the tools of computational biology and structural bioinformatics to the design of effective vaccines against human immunodeficiency virus (HIV) and other viruses; 2) Specifically, the SBIC aims to use computational tools to bring efficient and cost-effective solutions to problems related to (i) efforts to enhance protein crystallization, (ii) structure -based immunogen design, and (iii) structural analysis, and design of probes for analysis of sera and isolation of monoclonal antibodies; 3) Based on atomic-level structural information of the target epitope provided by the SBS, the SBIS uses computational tools for designing appropriate crystallization constructs and structural analysis. Immunogens can be designed using computational tools relatively quickly and these can be evaluated by the BSL-3 Core Virology Laboratory and the Vector Core, thus increasing the overall efficiency of the immunogen design process. Computational design can also contribute to the development of antigenically specific probes useful in analyzing the neutralizing activity of sera and in deciphering the HIV-1 elements recognized by both binding and neutralizing antibodies. Such an understanding provides critical in vivo feedback for the iterative structure-based improvement of immunogens.

Humoral Immunology Branch - HNM847

1) The Vaccine Research Center Humoral Immunology Section focuses on understanding antibody-mediated protective immune responses against HIV-1 via studies of both the plasma antibody compartment and the B-cell compartment; 2) the goal of these studies is to elucidate mechanisms of virus neutralization and the viral epitopes targeted by neutralizing antibodies, and to translate this information into novel strategies for vaccine design; 3) new vaccine immunogens are designed based on the latest information from the atomic level structure of the HIV-1 Env glycoprotein complexed to neutralizing antibodies; 4) The Humoral Immunology Section evaluates the antibody specificities elicited by these vaccine, including the neutralizing activity of sera and the viral epitopes that are vulnerable to neutralizing antibodies.

Vaccine Production Program Laboratory - HNM85

(1) Advances candidate products from the laboratory to the clinic; (2) develops manufacturing processes and tests that provide material for Phase I/II clinical trials, with emphasis on techniques suitable for large-scale manufacture of vaccines; (3) produces vaccine components at VRC facilities and through contract agreements and a cGMP pilot plant that is currently under construction in Frederick, MD; and (4) ensures the timelines of vaccine projects selected for clinical trial evaluation, prepares regulatory submissions, and develops appropriate pre-clinical testing for all vaccine products.

Clinical Trials Program - HNM86

(1) Conducts clinical studies of candidate vaccines and monoclonal antibodies targeting HIV, influenza, malaria, filoviruses, alphaviruses, and other emerging infectious diseases; (2) performs translational immunology and vaccine research; and (3) manages advanced clinical development including strategic planning, facilitation, support, and oversight of external clinical trials involving VRC products.

Translational Research Program - HNM87

(1) Provides research and logistical support, relevant in vitro and in vivo information and services to assist in the planning, design and conduct of translational research leading to human clinical trials; (2) ensures the availability of relevant, high quality in vitro and in vivo; and (3) provides oversight of an accredited vivo research program that is fully compliant with all institutional, local, state and Federal laws, regulations and standards.

Division of Clinical Research - HNM9

(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 OCR branches: (4) provides oversight of clinical research and all related clinical operations of five intramural laboratories; (5) manages several clinical research projects involving national or international programs of basic and 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 intramural Institutional Review Board (IRB) and 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 OCR 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) collaborates and consults with NIAID intramural and extramural program officials with respect to biodefense research and guides independent Biodefense Clinical Research program research in biodefense; and (10) 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.

Biostatistics Research Branch - HNM93

(1) Collaborates and consults with NIAID intramural and extramural programs the with respect to study design and study conduct (including data management and study coordination), analyses, and reporting of clinical, population and laboratory investigations; (2) directs and conducts an independent research program in biostatistical methodology; (3) provides consultation to NIAID leadership in establishing policies involving the program areas defined above; (4) provides service on and in support of data and safety monitoring boards; (5) determines program priorities and recommends funding levels within the area of biostatistics; (6) plans and directs a program of grants for research in the design, development and utilization of statistical methodology, mathematical modeling and systems for the collection of data; (7) reviews developments in assigned program areas and assesses needs for additional support of program responsibilities; (8) consults with voluntary and professional research and health organizations in identifying and meeting research areas in the program areas defined above; and (9) ensures timely and accurate communication and interchange of information with other NIAID components.

Clinical Trials Research Section (CiTReS) – HNM933

Resource for the design and conduct of clinical trials through clinical trials methodological advances, statistical analysis and robust data operations and management; and operational hub that coordinates with existing resources to augment and tailor NIAID clinical research resources to be more adaptive and responsive to special projects and a rapid response mission.

Mathematical Biology Section - HNM932

1)The Mathematical Biology Section provides support to research studies that interface biology, virology, immunology and imaging; 2) The primary focus is the study of the dynamics of viral replication, lymphocyte turnover and immune active in HIV infected patients and related model systems.

Collaborative Clinical Research Branch - HNM94

(1) Is responsible for managing several high-profile clinical research projects that: (a) involve one or more public health issues; (b) are carried out by several scientists, medical officers or other health care professionals; (c) are financed through multiple funding mechanisms and have a multi-million dollar annual budget, and (d) involve national or international programs of basic and clinical research in areas of the highest public health priorities, and have high visibility in the political and scientific communities, as well as with the general public; (2) develops policy initiatives, goals, and objectives to achieve an appropriate balance of priorities among ongoing and planned research; (3) recommends intramural and extramural research priorities to the OCR Director and the NIAID Director; (4) coordinates policy initiatives with managers and professional staff throughout the Institute; (5) develops the budget, workforce plan and supporting resources to implement long-term plans; and (6) recommends priorities and resource allocations to achieve these goals.

Intramural Clinical Management and Operations Branch - HNM95

(1) Provides oversight of clinical research and all related clinical operations for the Laboratory of Immunoregulation, Laboratory of Host Defenses, Laboratory of Clinical Investigation, Laboratory of Parasitic Diseases, and Laboratory of Allergic Diseases; and (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.

Program Planning and Analysis Branch - HNM96

(1) Evaluates the efficiency and effectiveness of Office of Clinical Research (OCR) operations: (a) with expertise in operational and organizational development, 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, and (b) transfers management expertise to international and domestic collaborators on a longterm basis, taking into account the vast differences between the organizations; (2) provides policy analysis to the OCR Director regarding management, coordination, and integration of all programs for which the office is responsible; (3) advises the OCR Director in areas such as clinical funding and organizational strategies designed to manage international clinical trials; (4) coordinates the development of the strategic plan; (5) develops world-wide partnerships with domestic and international governmental and non-governmental organizations and private sector entities along with other leading industrial nations to support research efforts in developing countries, using its own resources to fight infectious diseases; (6) determines optimal means for funding new initiatives on-site and in other geographic locations; (7) develops strategies to meet changing staffing needs using mechanisms such as professional services contracts and outsourcing; (8) prepares the OCR business and functional plans and statements of work, and develops management strategies to accomplish the OCR mission in the most efficient manner possible; (9) develops resources for establishing and operating new areas such as staff, facilities, lab equipment, information technology and other support services; (10) coordinates efforts among OCR branches and with other NIAID organizations when projects cross branch or division lines; and (11) executes and expedites actions through delegated signature authority to meet OCR business priorities and to provide a "one-stop-shop" approach and comprehensive program planning and support.

Office of Clinical Research Policy and Regulatory Operations - HNM97

(1) Providing support and logistical services for intramural clinical research operations in NIAID to include the provision of a protocol navigator / protocol development program; (2) coordinating the support and logistical services for NIAID special projects clinical research and other DCR-supported research; (3) maintains regulatory surveillance over DCR and DIRsupported 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 DCR 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 DCR supported and 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) coordinate 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 DCR and 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 Institutional Review Board; (12) ensures that all federal and NIH human subject protection requirements as well as standards for AAHRPP accreditation are fulfilled for intramural clinical research; (13) coordinate with HHS and other government Agencies when the NIAID IRB serves as the Public Health Emergency Research Review Board; (14) provides logistical and technical support for the NIAID intramural Data and Safety Monitoring Board; (15) provide logistical and technical support for safety monitoring committees and independent medical monitors required for NIAID intramural clinical research; (16) 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; (17) in conjunction with pharmaceutical collaborators reviews the regulatory components of DIR Clinical Trial Agreements and Cooperative Research and Development Agreements; (18) implements and maintains management information systems required to support regulatory and policy responsibilities; (19) provides information and training relative to regulatory issues and logistical coordination of trials; (20) provides consultation to NIAID officials and programs developing clinical trial protocols concerning scientific merit and protection of human subjects; and (21) 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.

Office of Planning and Operations Support - HNM98

(1) Provide services and innovative solutions to optimize the facilitation of NIAID clinical research and special projects is directly aligned to the DCR mission and purpose; (2) directs initiatives and efforts towards the achievement of DCR's goals to: develop and maintain a leadership culture that advocates and advances the priorities of NIAID; facilitate the generation of new knowledge and insight from research; evaluate clinical research processes in order to optimize efficiency and effectiveness; (3) develops and maintains an innovative portfolio of services and solutions that include: organizational development including strategy management of clinical research special projects and DCR branches/offices; project management; learning and professional development; and technical solutions and development; (4) facilitates the assessment, evaluation, development, integration and alignment of processes into the day-to-day operations of DCR to promote better utilization of resources and enhance program results.

Office of the Chief Scientist for the Integrated Research Facility at Ft. Detrick - HNM99

(1) Develops and executes an intramural biodefense clinical research program utilizing the unique biocontainment resources of the IRF, to elucidate disease processes and develop and test therapeutic and preventative countermeasures in animal models to affect disease outcomes; (2) develops policy, goals, and objectives to achieve an appropriate balance of priorities among ongoing and planned research; (3) establishes collaborative partnerships with other NIAID programs, partners in the National Interagency Biodefense Campus at Fort Detrick, academia, biotechnology consortia, and other domestic and international agencies; (4) prioritizes and coordinates research proposals to maximize efficient utilization of the IRF resources; and (5) provides advice to the Director, NIAID, and other federal leadership in establishing and prioritizing biodefense research.