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THE INFECTIOUS DISEASE CLINICAL RESEARCH PROGRAM (IDCRP) was founded in 2005 under an interagency agreement between the Uniformed Services University of the Health Sciences (USU) and the National Institute of Allergy and Infectious Diseases (NIAID). The work of the program, executed through a unique, adaptive and collaborative clinical research network, has a direct impact on force readiness by advancing clinical practice and informing health policy for military personnel.

In collaboration with partners from the Department of Defense (DoD), academia, government and industry, IDCRP supports a broad clinical research portfolio within the Military Health System. From observational, longitudinal cohort studies to field-based interventional trials to evaluation of long-term health outcomes, IDCRP conducts protocols that address critical knowledge gaps in the control and prevention of infectious disease in the military. What is learned from these studies has far-reaching implications for public health and disease prevention beyond military communities.

VISION
To substantially reduce the impact of infectious diseases in the military population through collaborative clinical research

MISSION
To conduct infectious disease clinical research of importance to the military through a unique, adaptive and collaborative network to inform health policy and clinical practice and disseminate findings throughout the scientific community
As we end 2014, the Infectious Disease Clinical Research Program (IDCRP) remains positioned as the innovative leader in conducting military multi-center clinical research. Since its establishment in 2005, when the first interagency agreement was drafted between the National Institute of Allergy and Infectious Diseases (NIAID) and the Uniformed Services University (USU), the program has set a new standard for collaborative clinical research within the Military Health System (MHS). The program was built on a premise that regulatory processes for multi-center clinical research could be streamlined through a rigorous, centralized scientific review and human subjects protection process through the infectious disease-specific IRB at the University. Over the past nine years, the program has delivered on that potential and is poised to lead by example within the new Defense Health Agency Research, Development and Acquisition Directorate.

This past year has seen continued evolution of the program with enhanced focus on research management within seven research areas: war trauma related infections, deployment and travel related infections, human immunodeficiency virus infections, acute respiratory infections, skin and soft tissue infections, sexually transmitted infections and emerging infectious diseases/antimicrobial resistance. Research Area Directors have been appointed and clinical research strategic plans developed to define efforts complementary to our colleagues in public health surveillance and the Research and Development commands. These roadmaps will help guide the program for several years to come. The program not only continues to produce many publications in peer-reviewed journals, but also provides expert briefing materials and presentations to senior military leaders that inform and update best clinical practice standards.

2014 also brought an external review of our program by a team under the leadership of LTG (ret) James Peake. The panel stated the program “through its access to the military’s unprecedentedly large clinical cohorts, has been transformative in facilitating and enabling the conduct of high-caliber, high-impact militarily relevant research. The program is to be congratulated on its excellent productivity in conducting research and publishing findings in high-quality journals, which have begun to inform policy and are currently being implemented into clinical practice within the MHS.” They further recommended that the University pursue a Department of Defense (DoD) Charter Directive for the research program to ensure sustainability. This support was augmented by our first DoD core infrastructure funding from the Defense Health Program in FY14.

Many successes are outlined in the report that follows. I wish to thank our leadership at USU, guidance from our Steering Committee, the long-standing partnership of the NIAID, and the effective implementation of our plans through the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. I also want to thank our DoD funding partners through the Defense Health Program, the Military Infectious Diseases Research Program (MIDRP), the Navy Bureau of Medicine and Surgery (BUMED) and the Armed Forces Health Surveillance Center (AFHSC). Lastly, our accomplishments are borne out through the hard work of our military ID physicians, and the dedicated team of research professionals from USU and HJF at our central office and embedded in the hospital network across MHS. It is a privilege to serve with such a great team.

R. Scott Miller, MD
Colonel, US Army Medical Corps
Director
RESEARCH AND SURVEILLANCE PARTNERS

Armed Forces Health Surveillance Center  
Biomedical Advanced Research and Development Authority  
Centers for Disease Control and Prevention  
Defense Health Agency  
Defense Medical Research and Development Program  
Global Emerging Infections Surveillance and Response System  
Military Infectious Diseases Research Program  
Military Vaccine Agency  
National Institute of Allergy and Infectious Diseases  
National Institute of Mental Health  
National Institute of Neurological Disorders and Stroke  
Naval Health Research Center  
Naval Health Research Center San Diego  
Naval Medical Research Center  
Navy and Marine Corps Public Health Center  
Uniformed Services University of the Health Sciences  
US Army Congressionally Directed Medical Research Programs  
US Army Institute of Surgical Research  
US Army Medical Research and Materiel Command  
US Army Medical Research Institute of Infectious Diseases  
US Army Public Health Command  
US Department of Veterans Affairs  
US Military HIV Research Program  
US Navy Bureau of Medicine and Surgery  
Walter Reed Army Institute of Research

PARTNER MILITARY HEALTH COMMANDS

Armed Forces Research Institute of Medical Sciences, Thailand  
British Army Training Unit, Kenya  
Evans Army Community Hospital, Fort Carson  
Landstuhl Regional Medical Center, Germany  
Madigan Army Medical Center, Joint Base Lewis-McChord  
Martin Army Community Hospital, Fort Benning  
Naval Medical Center Portsmouth  
Naval Medical Center San Diego  
Naval Medical Research Unit 3, Egypt  
Naval Medical Research Unit 6, Peru  
Naval Medical Research Unit Asia, Singapore  
San Antonio Military Health System  
Soto Cano Air Base, Honduras  
Tripler Army Medical Center, Honolulu  
UK Role 3 Joint Force Hospital, Afghanistan  
US Army Medical Research Unit, Kenya  
US Army Medical Research Unit, Republic of Georgia  
US Naval Expeditionary Base, Djibouti  
Walter Reed National Military Medical Center  
Womack Army Medical Center, Fort Bragg

Arthur L Kellermann, MD, MPH, Dean of USU’s F. Edward Hébert School of Medicine, speaks at the American Institute of Biological Sciences review of IDCRP, June 9–10, 2014
Acute respiratory infections (ARI) remain a research priority for the military as outbreaks of ARI continue to pose a major threat to the health and operational readiness of military forces. The Acute Respiratory Infection Consortium (ARIC), established in 2009, is now actively engaged in the analysis of clinical and laboratory data from the ARIC Natural History Study. Numerous manuscripts are in development, with the major objectives to describe the epidemiology and clinical characteristics of influenza-like illness, to evaluate the sensitivity and specificity of new multiplex diagnostic panels, and to assess the impact of antiviral treatment, as well as vaccination, on the clinical course and outcome of influenza infection. The team is in the final stage of development of a standardized symptom severity scale for influenza. NIAID will seek qualifications of this patient-reported outcome scale with FDA for future use in influenza product development. Finally, the ARI research area continues its participation in a NIAID-sponsored, multi-center randomized controlled trial of hyperimmune plasma for the treatment of severe influenza.

Novel respiratory pathogens, such as the Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and avian influenza strains, also pose significant risk to military populations, as the deployment of military personnel into disease-endemic areas increases the risk of their acquisition and importation. The ARI research area recently submitted for IRB approval a contingency protocol for the epidemiologic and clinical investigation of emerging pathogens with pandemic potential. Early identification and characterization of these cases will be critical to improve our basic understanding of disease in military populations, as well as to provide insight for the development of needed diagnostic, treatment and prevention strategies.

The 2015–2016 ARI season will bring a strategic realignment of the ARI research area, namely an increased focus and initiation of new studies on the epidemiology, control and prevention of ARI among congregate military populations (i.e., recruits). The increased risk of ARI outbreaks among military trainees is well-known, and further epidemiologic studies in military training settings are needed to describe ARI transmission dynamics, to elucidate the impact of routine vaccination on long-term immunity and the risk and severity of subsequent infections, as well as to identify host factors that may predispose some recruits to severe clinical course and outcome of ARI.
Sexually transmitted infections (STI) remain of importance to the DoD, given that soldiers are at high risk of contracting STIs and continue to be infected. The IDCRP STI Research Area has expanded this past year as part of the scientific strategic plan. Three research aims have been established to advance the STI research area, taking into consideration not only their relevance to active duty members and their beneficiaries, but also the larger STI research landscape within the scientific community.

The first aim is to evaluate the impact of STIs due to multidrug-resistant gonorrhea (MDR-GC) and other common pathogens among active duty members. Drug-resistant *Neisseria gonorrhoeae* is considered an urgent threat based on the 2013 CDC report on antibiotic resistance threats in the United States. Surveillance continues at Fort Bragg, Fort Carson, Madigan Army Medical Center, Naval Medical Center San Diego and the San Antonio Military Health System, with key partners globally (IDCRP-067). A substudy to assess the prevalence of GC from three anatomic sites (uro-genital, pharyngeal and ano-rectal) among HIV-positive individuals will be recruiting in early 2015. Taking advantage of existing data, the GEIS funded STI Serosurvey Study and the STI Epi Study, a substudy of the DoD HIV Natural History Study (NHS), continue to be a rich resource for STI research. A manuscript on herpes simplex virus and human papillomavirus was recently submitted, and an oral presentation on the impact of permanent change of station (PCS) on syphilis incidence was accepted at this year’s CDC STD Prevention Conference.

The second aim is to develop and test STI prevention efforts among active duty members to inform DoD policy and impact STI clinical practice. To date, sexual risk behavior data are being collected in the GC resistance study as well as the DoD NHS. We are currently planning to study the impact of social networks on STI risk, starting at Fort Bragg and expanding thereafter to other GC resistance study sites.

The third aim is to improve STI treatment practices and outcomes. The emergence of drug-resistant strains of STI pathogens has spurred the development of new diagnostics and therapeutics. The IDCRP is currently evaluating the impact of same-day diagnostic GC and Chlamydia nucleic acid amplification testing on clinical treatment practices.

**HIGHLIGHTS**

- Established the DoD gonococcal reference lab and repository in partnership with Dr. Ann Jerse, USU Department of Microbiology and Immunology
- Established a network of gonococcal multidrug-resistance surveillance in the Military Health System
- Centers for Disease Control and Prevention (CDC) STD Prevention Conference featured presentation on the impact of permanent change of station (PCS) on syphilis incidence
- Trained and built capacity at Walter Reed Army Institute of Research (WRAIR) lab in Republic of Georgia to conduct gonococcal culture and drug-resistance testing
Our research area is focused on current concerns for HIV-positive military members, their care providers and their commanders. Strategic aims include:

1. Mitigate specific complications of HIV and highly active antiretroviral therapy (HAART) among military HIV-infected patients
2. Identify, treat and prevent HAND in the US military healthcare system
3. Develop and employ predictive models to optimize individual management of HIV
4. Improve therapeutic outcomes with the ultimate goal of functional cure of HIV infection
5. Assess acquisition among HIV-infected active duty troops and how to prevent new infections

Since the beginning of the HIV epidemic, over 10,000 active duty members have been diagnosed with HIV infection. Although the rate of new infections remains low, the increased risk of active duty members for other STI underscores the perennial threat of HIV infection in this population. The HIV research area is focused on the maintenance of health, longevity and function of HIV-positive individuals as well as prevention of new infections among active duty members. The centerpiece of this program is the long-standing US Military HIV Natural History Study (NHS). Since its establishment in 1986, the NHS has enrolled nearly 6,000 HIV-positive active duty members and beneficiaries, and their highly-valued clinical data and biological specimens have been maintained in repositories. In addition, a longitudinal cohort study of HAND was initiated at Walter Reed National Military Medical Center and Naval Medical Center San Diego, in partnership with the National Institute of Neurologic Disorders and Stroke (NINDS) and other National Institutes of Health (NIH) contributors, including NIAID, the National Institute on Mental Health, the National Institute on Aging and the NIH Clinical Center.

HIV-positive active duty members continue to serve in the military. However, in spite of virological and immunological response to antiretroviral therapy (ART), many will develop complications such as neurocognitive disorders (HAND) in partnership with the NIH Intramural NeuroHIV Research Consortium.

Submitted 19 manuscripts, 11 published/accepted and 8 under review

Followed HIV seroconverters and showed that 38% of those who started antiretroviral treatment within the first year of infection achieved a normal CD4+ T-cell count (>900 cells/μL), while only 28% of those who delayed treatment initiation reached this level (Journal of the American Medical Association Internal Medicine 2014 Nov 24)

Continued investigation of syphilis infection among HIV-positive military members, demonstrating equivalent response (92%) among those with early syphilis treated with a single or multiple doses of benzathine penicillin, reinforcing current treatment guidelines (single dose) (Clinical Infectious Diseases 2014 Dec 3)

Extended the use of a prognostic model to predict mortality among NHS participants treated with anti-retroviral therapy (Journal of Acquired Immune Deficiency Syndromes 2014 Feb 1)
disorders, cardiovascular and/or kidney diseases, and cancer. Nearly one in five HIV-positive individuals in the military met criteria for HIV-associated neurocognitive impairment (*Neurology* 2013 Jan 22). The high prevalence of this complication is concerning and remains the primary reason for limited duty status of HIV-positive active duty members, an issue not only for the infected individual, but also to the military. Our current study of HAND has a number of major objectives, including the evaluation of host and viral determinants of disease, the development of rapid and highly sensitive diagnostic methods, and the identification of at-risk subjects for participation in future prevention and/or treatment trials.

Ensuring the long-term health and function of HIV-positive individuals is essential, and warrants studies of interventions beyond universal use of ART. The planning of such studies is under way, with primary interest in novel immune therapies (e.g., broadly neutralizing HIV antibodies, therapeutic HIV vaccines and chimeric antigen receptors). The ultimate goal of these efforts is to achieve functional cure of HIV, that is, the elimination of all adverse effects of HIV infection, whether or not the virus is eradicated from the host. Because such interventions would be targeted to those most likely to benefit, studies to identify and understand host biomarkers and treatment strategies for individualized management of HIV infection are being conducted. Moreover, we are evaluating the impact of decades-long use of ART, including factors of adherence to medications as well as their adverse effects.

HIV testing in the military is mandatory and routine. As such, the active duty force is an intensely screened population in which the early events and the time course of HIV infection can be evaluated. In addition, the military population is healthy, racially diverse and educated, and has ready access to healthcare. Studies of HIV infection in the military are not confounded by factors such as illicit drug use, non-adherence to ART and loss to follow-up. Combined, these military-unique assets have resulted in hundreds of publications that have advanced the fields of HIV science and care. These same assets are now enhancing our understanding of long-term HIV infection and its role in the development and acceleration of a variety of chronic diseases.
Prevention and control of deployment and travel-related infections remain a priority for the military. Recent efforts in this research area include the development of a strategic plan focused on assessment of deployment-related infectious disease threats, as well as field-based evaluation of treatment and prevention strategies to minimize mission-compromising losses. Integral to this program is complementary efforts at WRAIR and Naval Medical Research Center. Investigators are utilizing the infrastructure, patient population and data from existing observational studies to support new clinical trials and treatment effectiveness studies on travelers’ diarrhea, vector-borne febrile illness, respiratory infections and emerging infectious diseases. Lastly, we have begun to address a number of newly emerging infectious disease threats, including Chikungunya virus and Ebola virus, the latter as part of the large-scale deployment of troops into West Africa as part of Operation United Assistance.

The central protocol in this area, TravMil, underwent significant restructuring to better address objectives in the strategic plan. As a result, the proportion of TravMil enrollees who were deploying active duty members increased significantly, while overall rates of enrollment and retention were maintained. To date, approximately 2,500 participants across four sites have been enrolled and two new sites have been added, one in the continental US (Madigan Army Medical Center) and one overseas (Landstuhl Regional Medical Center, Germany). The protocol was amended to allow post-deployment enrollments, and will capture critical data on malaria chemoprophylaxis compliance, rates of diarrheal disease and respiratory infections among troops returning from Operation United Assistance. Using the TravMil study platform, we launched a clinical trial for the prevention of travelers’ diarrhea during short-term deployments (Prevent TD). This study, conducted in collaboration with the United Kingdom (UK) military, is enrolling US troops deploying to the Philippines or Central and South America to evaluate the efficacy of rifaximin prophylaxis in reducing the risk of travelers’ diarrhea.

The Treatment of Travelers’ Diarrhea (TrEAT TD) study will be completed within the next fiscal year. This is a multi-site,
randomized, double-blind, controlled trial involving US and UK deployed forces to evaluate the efficacy of various single-dose drug regimens for the treatment of acute infectious diarrhea. Soto Cano Air Force Base in Honduras became a clinical trial site in June 2014. Findings from this study will be critical to the development of DoD clinical guidelines for the diagnosis and management of travelers’ diarrhea among deployed military personnel.

Current efforts in this research area include the development and evaluation of new diagnostic methods for travelers’ diarrhea. We are collaborating with investigators from the University of Virginia to assess the utility of diarrheal smears obtained on filter paper cards paired with a molecular assay for detection of enteropathogens. The University of Virginia team (Lead: Dr. Eric Houpt) has expertise in molecular assays development and validation for diarrheal diseases in the developing world. If successful, the method would allow for rapid detection of enteropathogens without the need for cumbersome and costly processes common to traditional testing methods.

The research area is evaluating the impact of deployment/travel medicine knowledge, attitudes and practices on clinical outcomes of infectious diseases. A project led by Lt Col Patrick Hickey will assess training of DoD providers in deployment and travel medicine; describe available resources and provider knowledge, attitudes and practices; and evaluate the impact on disease outcomes. Results from these initiatives will provide valuable data for DoD practice guidelines and will inform future research on a broad range of topics related to deployment and travel medicine.
Battlefield injuries and resultant complications, including infections, are prevalent among deployed military personnel and frequently result in extended periods of hospitalization, often with considerable morbidity or mortality. The nosocomial acquisition of multidrug-resistant organisms or virulent further complicated wound management. In addition, late onset or recurrent infections are associated with increased morbidity and healthcare costs.

The Trauma Related Infections research area has prioritized efforts to address these challenges, most notably with the continued support of the Department of Defense-Department of Veterans Affairs (DoD-VA) Trauma Infectious Disease Outcomes Study (TIDOS). Initiated in 2009, TIDOS is a multi-site, prospective, observational cohort study, using predefined standardized methodology to evaluate short- and long-term infectious outcomes among military personnel with deployment-related traumatic injuries. The success of TIDOS is due to the collaboration of investigators across various medical specialties (e.g., infectious disease, trauma surgery and orthopedics) and commands at Landstuhl Regional Medical Center (LRMC), Walter Reed National Military Medical Center (WRNMMC), San Antonio Military Medical Center (SAMMC), US Army Institute for Surgical Research (USAISR), WRAIR, Naval Medical Research Center, St. Louis Veterans Affairs (VA) Medical Center, and USU. Current microbiology projects include analyses of bacterial antagonism in wounds, anaerobic bacterial infections, presence of antibiotic resistance genes/virulence mechanisms and their association with antibiotics and clinical outcomes, and biofilm dispersal. In cooperation with the USAISR Joint Trauma System (JTS), the TIDOS team has continued efforts to develop and improve evidence-based clinical practice guidelines (CPGs).

Data from approximately 6,000 injured military personnel have been collected and analyzed. Over 1,370 patients have enrolled in the TIDOS cohort. Of the infections diagnosed at LRMC, approximately 46% were skin and soft tissue infections, 26% pneumonia, 12% bloodstream infections and 2% osteomyelitis. Among the patients who transferred to a US site, the distribution of infections was approximately 52% skin and soft tissue infections, 11% pneumonia, 15% bloodstream infections and 8%...
osteomyelitis. Over the past year, nine manuscripts were published in peer-reviewed journals and two were accepted for publication.

Lastly, the Infectious Disease-Orthopedic Surgery collaborative protocol investigating trauma-related osteomyelitis risk factors and management completed data collection for tibial and femur fractures, and analyses are projected for completion by the end of 2015.
Skin and soft tissue infections (SSTI) continue to be burdensome in the military setting, often leading to significant morbidity, and frequently affecting operational and training requirements. Outbreaks of SSTI may result in recycling of recruits in training, or the medical evacuation of military personnel from remote locations. Substudies of the SSTI prevention trial, IDCRP-055, yielded considerable data beyond the primary objectives, including enhancing our understanding of the molecular epidemiology of methicillin-resistant *Staphylococcus aureus* (MRSA), host microbiome and host immune response to SSTI. The follow-on investigation at Fort Benning, IDCRP-074, continues to capture epidemiological and microbiome data on participants, as well as expand surveillance for colonization to additional body sites and prospectively collect participants’ serum for more robust analysis of immune response to infection. The study, which launched in July 2012 and ended in December 2014, enrolled 2,025 cases and 1,275 non-cases of SSTI. These protocols have generated a wealth of data and provide a foundation for new initiatives. A longitudinal, cohort study at Fort Benning, funded by MIDRP, is planned for May 2015. Recruits will be enrolled when they arrive and followed through graduation, lending unique insight into the acquisition and transmission of MRSA and identifying risk factors for disease. Other SSTI initiatives include a study to investigate the burden of SSTI among submarine personnel, another military population known to be at increased risk for disease.

The overall goal of the research area is to further expand the scientific knowledge of the epidemiology, clinical characteristics, microbiome, and immunology of *S. aureus* colonization and infection. Although we have made progress toward this end, the relationship among *S. aureus*, other microbes and the immune response has not been fully elucidated. The research area is poised to make significant contributions to this field, owing to the unique study sites at Fort Benning and on submarines, and to its strong collaborative research team.
Infectious disease threats to military forces remain high due to deployment worldwide. Novel respiratory pathogens, such as the Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and avian influenza strains, pose significant risk to military populations, and the program has established a protocol to evaluate the etiology, clinical presentations and outcomes of infection with novel pathogens. Partnering with the DoD Global Emerging Infections Surveillance and Response System (DoD GEIS), the World Health Organization’s International Severe Acute Respiratory Infection Consortium (ISARIC) and state-of-the-art DoD diagnostic laboratories, such infections can be quickly identified and described within the Military Health System. Partnering with the US Army Medical Research Institute of Infectious Diseases, the viral hemorrhagic fever module will also help us evaluate the safety and impact of emergency investigational new drug treatment use of experimental products.

2014 also saw the launch of the Executive Order for Combating Antibiotic-Resistant Bacteria. IDCRP is leading the way to identify and assess the public health impact of multidrug-resistant gonococci, as well as defining the epidemiology of MRSA skin and soft tissue infections. Working with the DoD Multidrug-Resistance Surveillance Network (MRSN) at the WRAIR and Wounds Research programs at Naval Medical Research Center, we have launched a retrospective study to evaluate the clinical outcomes and costs associated with acquisition of gram-negative MDROs from war trauma.

**HIGHLIGHTS**

- IDCRP supported a Phase Ib study of the safety and immunogenicity of a DNA vaccine for Ebola virus and Marburg virus by the Makerere University Walter Reed Project in Uganda. Results from the first Ebola or Marburg vaccine trial in Africa (published in *The Lancet*) showed that, given separately or together, both investigational DNA vaccines, one (EBO vaccine) encoding Ebola virus Zaire and Sudan glycoproteins and one (MAR) encoding Marburg virus glycoprotein, were well tolerated and elicited antigen-specific humoral and cellular immune responses. These findings have contributed to the accelerated development of more potent Ebola virus vaccines that encode the same wild-type glycoprotein antigens as the EBO vaccine, which are being assessed during the 2014 Ebola virus disease outbreak in West Africa.
- Partnering with researchers from NIAID and the network of Ebola Treatment Units, IDCRP brought state-of-the-art experimental therapies and post-exposure prophylaxis protocols to DoD hospitals for the care of potentially exposed and infected active duty members.
- Initiated a retrospective case-control study to evaluate the clinical outcomes of infection with multidrug-resistant organisms (MDROs) in service members with combat-related traumatic injuries using the TIDOS cohort.

**EMERGING INFECTIOUS DISEASES AND ANTIMICROBIAL RESISTANCE**

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DATA COORDINATION CENTER AND BIOSTATISTICS

The Data Coordination Center (DCC) is the home of the IDCRP’s data system designers, data managers, data entry staff, and SAS and Oracle programmers. This group provides expertise to principal investigators for the conceptualization, design, collection, management, analysis and publication of research study data.

The DCC utilizes multiple systems that allow us to receive data in either paper or electronic format. Our primary system is ClinPlus, a traditional desktop/laptop based electronic data capture (EDC) system. In the past year, we greatly expanded use of our mobile-based data acquisition system, Mi-Forms. Our tablets have been used worldwide, allowing the IDCRP to extend its reach and enroll subjects who may seek medical care at places other than our US-based medical treatment facilities, as well as to conduct in-person surveys electronically. The IDCRP won several awards for its innovative use of Mi-Forms and the introduction of mobile technology to capture research data in challenging environments. The DCC also acquires survey data and other types of data via the Qualtrics website and via scanned standardized forms. Once data are in-house, the DCC’s programmer analysts produce tables, listings and figures; create analysis datasets; and support IDCRP biostatisticians in analyzing data, primarily using SAS and Oracle PL/SQL.

To fulfill its mission of supporting the program’s scientific goals, the DCC is improving the efficiency and efficacy of our processes and ensuring we are staffed appropriately. For example, we have significantly reduced the size of our in-house data entry staff in response to a reduction in the amount of paper-based data received, a decrease on average of 40% over each of the past three years. We are working to increase the scope and relevance of the program’s research by acquiring supplemental data from external sources, such as the Military Health System Data Repository. In 2015, we will be conducting a search to find a replacement for our current primary EDC system, which is reaching the end of its planned life cycle.

REGULATORY AFFAIRS, CLINICAL OPERATIONS, SCIENTIFIC REVIEW AND MONITORING

The IDCRP Regulatory Affairs team consists of staff at the network’s Military Treatment Facilities and the IDCRP Program Coordination Center (PCC). Working with the Regulatory Affairs Coordinator, clinical research staff develop protocols, evaluate Institutional Review Board (IRB) submissions, consult with investigators during IRB review, coordinate with IRB staff to address concerns, conduct on-site quality assurance and auditing, track study milestones such as publications and presentations, and maintain regulatory documents for the program.

IDCRP Clinical Operations has a strong team of clinical research managers (CRMs) who oversee multi-site projects centrally, coordinating and communicating among Principal Investigators, the DCC and with site managers accountable for study operations at military treatment facilities. IDCRP CRM capacity has recently expanded to support growing research areas, with opportunities for CRMs to cross-train across protocols.

An independent scientific review is required by the DoD for all greater-than-minimal-risk studies. The review is headed by the IDCRP program officer at NIAID. The USU Infectious Disease Institutional Review Board (ID IRB), established in 2008 via a Memorandum of Understanding among all of the Services, creates a single review pathway for multi-center ID research and eliminates the need for multiple and repetitive scientific, ethical and second level reviews at multiple medical treatment facilities. In 2014, six new protocols and almost 70 amendments were reviewed and approved.

IDCRP has a risk-management strategy to ensure quality management of protocols. NIAID’s Office of Clinical Research Policy and Regulatory Operations (OCRPRO) or pharmaceutical sponsors oversee clinical monitoring.
STATE OF THE ART SPECIMEN REPOSITORIES

The program maintains study-specific repositories of host (e.g., blood), diagnostic (e.g., nasal wash) and/or pathogen (e.g., bacterial culture) specimens. IDCRP partners in the maintenance and application of these collections with groups such as the Military HIV Research Program, USU Department of Microbiology and Immunology, and the San Antonio Military Medical Center. This vast collection of human and microbiologic specimens is invaluable for studies of disease pathogenesis, the host immune response, and the development and evaluation of novel diagnostic methods.

IDCRP EDUCATION PROGRAM

A core part of the IDCRP mission is to develop the next generation of military clinical researchers in infectious disease related fields. The IDCRP addresses this by providing educational and training opportunities at USU and throughout the IDCRP network of military training facilities that includes medical students, residents, fellows, graduate students and junior faculty. Main opportunities offered are research projects, an Introduction to Clinical Trials course in the USU Masters of Public Health (MPH) program, a USU School of Medicine (SOM) capstone rotation, a training grant for young investigators and a one-month rotation at our overseas clinical research site. The education program hosts internal education activities for IDCRP staff and externally supports the Armed Forces Infectious Disease Society (AFIDS) and Continuing Medical Education activities at Walter Reed National Military Medical Center (WRNMMC). IDCRP developed an Ebola Therapeutics and Vaccines reference document for AFIDS in 2014. The IDCRP recently established a partnership with the USU and AFHSC-GEIS Tropical Medicine Rotation for trainees, becoming a participating location.

CURRENT PROGRAM AND 2014 TOTALS AT A GLANCE

40 TRAINEES

- 30 trainees involved in ongoing research projects
- 10 trainees participated in an overseas rotation in 2014
- 23 presentations at national conferences in 2014
- 2014 publications: 6 accepted, 8 submitted, 8 in preparation
- 2014 awards: 3 IDSA travel grants (LT Tida Lee, Capt Dana Blyth, Maj Brian White), 3 paper competition wins (LT Louis Lewandowski), 1 podium presentation 1st place prize

20 MENTORS

- 13 study collaborators and 7 IDCRP staff involved in ongoing trainee projects
- LTC Jason Okulicz won USAF 2014 researcher of the year; LTC Michael Ellis won USU Department of Medicine Research Excellence Award
IDCRP ORGANIZATION

Governing Board

- Chief, Division of Clinical Research (DCR), National Institute of Allergy and Infectious Diseases (NIAID)
- President, Uniformed Services University of the Health Sciences (USU)
- Commanding General, US Army Medical Research and Materiel Command (MRMC)
- Director, Research, Development and Acquisition, Defense Health Agency

Steering Committee

- Surgeon General Infectious Disease Consultants—Army, Navy, Air Force
- Director, Armed Forces Health Surveillance Center
- Director, Military Infectious Diseases Research Program, MRMC
- Chief, Collaborative Clinical Research Branch, DCR, NIAID
- Chair, Department of Preventive Medicine and Biostatistics, USU
- HJF Representative (non-voting)
- VA Representative

Program Coordination Center

- Science Directorate
  - Science Director
  - Science Deputy Director
  - Research areas
    - Research area directors and lead clinical research managers
  - Data Coordination Center
    - Data configuration
    - Data management
    - SAS programming
    - Oracle programming
  - Education

- NIAID Liaison
  - Chair, Scientific Review Board

- Deputy Director
  - Research Administration
  - Regulatory Affairs

Partnering Networks

- Military Hospitals
- Military Research and Development Commands
- Military Public Health Commands
- Non-DoD Partners

- Proposed
FY14 Expenses Distribution

73% • Protocols
11% • Central Support
8% • Site Infrastructure
6% • Research Support
2% • Research Education

FY14 Protocol Expenses by Research Area

31% • Human Immunodeficiency Virus
28% • Trauma Related Infections
15% • Acute Respiratory Infections
14% • Deployment and Travel Related Infections
7% • Skin and Soft Tissue Infections
4% • Sexually Transmitted Infections
1% • Emerging Infectious Diseases and Antimicrobial Resistance

FY14 Expenses by Sponsor

68% • National Institute of Allergy and Infectious Diseases
1% • International Network for Strategic Initiatives in Global HIV Trials, NIAID Division of AIDS
20% • US Navy Bureau of Medicine and Surgery
4% • Global Emerging Infections Surveillance and Response System
2% • Uniformed Services University of the Health Sciences
2% • Defense Medical Research and Development Program
1% • Military Infectious Diseases Research Program
1% • Military Vaccine Agency
1% • US Army Medical Materiel Development Activity