At the close of FY2016, the Infectious Disease Clinical Research Program (IDCRP) completed our first decade of providing innovative leadership in clinical infectious disease research designed to inform and improve the care of the Warfighter. IDCRP remains the proven model for multicenter clinical research in the Military Health System (MHS). The Program’s sustained success is a product of the robust partnership between the Uniformed Services University of the Health Sciences, our Department of Defense (DoD) colleagues in the MHS and biomedical Research and Development commands, and the National Institute of Allergy and Infectious Diseases.

This year has seen continued evolution and productivity across our seven program research areas, yielding 68 presentations and 30 publications, and the generation of high-quality evidence and recommendations for senior leaders. Many more research area successes are outlined in the report that follows.

I wish to recognize USU’s leadership; our Operational and Executive Steering Committees; our long-standing partnership with NIAID; and The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF), which provides overall program implementation support. I also thank our DoD funding partners in the Defense Health Program, the Military Infectious Diseases Research Program, the Navy Bureau of Medicine and Surgery, and the Armed Forces Health Surveillance Branch of the Defense Health Agency for providing general guidance.

It is my very great privilege to return to IDCRP this year and assume the role of Director. I thank COL (ret) Scott Miller for his exceptional stewardship of the Program as Deputy and then Director, and Dr. David Tribble and Dr. Brian Agan for their interim leadership. As Acting Program Director for a substantial portion of 2015, Dr. Tribble capably navigated the Program, ensuring mission accomplishment and setting a course for the future. Dr. Agan ably supported Dr. Tribble, assuming many of the Science Director duties.

In September, we welcomed Major Charlotte Lanteri as Deputy Program Director, completing our Program leadership. Currently, IDCRP is well poised for continued success in the next decade and beyond.

Finally, our accomplishments are achieved through the hard work and collaboration of military and civilian investigators, a dedicated team of research professionals across the network, the research and administrative assistance staff at each Program site, and most importantly, the military service members and beneficiaries who volunteer to participate as research subjects. I offer many thanks to all of them.

Timothy H. Burgess, MD, MPH
Captain, Medical Corps, US Navy
Director, IDCRP

Charlotte Lanteri, Ph.D.
Major, U.S. Army
Deputy Director, IDCRP
EIDAR Director
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 program’s work is executed through a unique, adaptive and collaborative, international clinical research network. This network directly affects 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. Study outcomes have far-reaching implications for public health and disease prevention beyond military communities.

**IDCRP RESEARCH AREAS**

- **Acute Respiratory Infections**—The research area is addressing objectives related to the diagnosis, etiology, epidemiology, immunology, prevention, and treatment of acute respiratory infections among US military personnel and their beneficiaries.
- **Deployment and Travel Related Infections**—The IDCRP focuses efforts on describing the epidemiology of deployment and travel-related infections, evaluating pre-travel health care, and developing novel methodologies for identifying pathogens associated with febrile disease.
- **Emerging Infectious Diseases and Antimicrobial Resistance**—This area’s overall goal is to identify optimal preventive and therapeutic interventions and diagnostics resulting in the most effective response to and management of emerging infectious diseases.
- **Human Immunodeficiency Virus Infections**—The area’s strategic aims include mitigating specific complications of the virus among military HIV-infected patients; identifying, treating, and preventing HIV-associated neurocognitive disorders; developing and employing predictive models to optimize individual management of HIV; and improving therapeutic outcomes with the ultimate goal of functional cure of infection.
- **Skin and Soft Tissue Infections**—The overarching goal of the research area is to identify effective strategies for the prevention and control of the infections, a major cause of morbidity among congregate military personnel in deployment and training settings.
- **Sexually Transmitted Infections**—This research area seeks to improve the diagnosis, treatment, and prevention of sexually transmitted infections among active-duty members and their beneficiaries.
- **Trauma-Related Infections**—This area works to address knowledge gaps in infection prevention, clinical management, and treatment outcomes in battlefield trauma to inform DoD Joint Trauma System clinical practice.

Each area’s FY2016 accomplishments are presented in the following pages, along with information and projections for FY2017.

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

**MISSION**
To conduct multicenter infectious diseases clinical research, focusing on high-impact cohort and interventional trials, to inform and improve care of the Warfighter.

**PROGRAM ORGANIZATION**

**Executive Steering Committee**

- **Dean, School of Medicine, Uniformed Services University of the Health Sciences (USU), Chair**
- **Chief, Division of Clinical Research (DCR), National Institute of Allergy and Infectious Diseases (NIAID)**
- **Director, Research, Development and Acquisition, Defense Health Agency (DHA)**

**Operational Steering Committee**

- **Surgeon General’s Infectious Disease Consultants—Army, Navy, Air Force**
- **Director, Armed Forces Health Surveillance Branch**
- **Director, Military Infectious Diseases Research Program, MRMC**
- **Chief, Collaborative Clinical Research Branch, DCR, NIAID**
- **Chair, Department of Preventive Medicine and Biometrics, USU**
- **Veteran’s Administration Representative (non-voting)**
- **HIV Representative (non-voting)**

**Program Coordination Center**

- **Program Director**
- **Science Directorate**
- **Director**
- **Deputy Science Director**
- **Research Area Directors**

**Data Coordination Center**

- **Chief DCC**
- **Data configuration, management, and programming staff**

**Partner Organizations**

- Military Hospitals
- Military Research and Development Commands
- Military Public Health Commands
- Non-DoD Partners
Acute respiratory infections (ARIs) are an important research priority for the military as seasonal influenza and other outbreaks of ARIs have been of great significance to the US military for over a century and continue to pose a major threat to the health and operational readiness of military forces in all military settings.

Known respiratory pathogens (i.e., seasonal influenza and adenovirus) and novel pathogens, such as avian influenza viruses, pose significant risk to military populations. In FY2016, the ARI Research Area investigative team continued work on the Acute Respiratory Infection Consortium (ARIC) and its sub-studies to describe the etiology, epidemiology, and burden of ILI among active-duty personnel and mitigate the threat to operational readiness. The next phase of IDCRP’s ARI research builds on current investigations, focusing on reducing the ARI burden among military personnel and mitigating the threat to operational readiness.

The ARI Research Area is launching several new research initiatives in FY2017 to address these challenges, including:

- a study of ARI threats among congregated military trainees at Ft. Benning, Georgia
- an influenza breath test aimed at identifying a volatile organic compound signature indicative of influenza infection
- a study on influenza vaccine effectiveness
- an anonymous survey to describe the socio-demographics/lifestyle characteristics, burden of ILI, health-seeking behaviors, and hygiene practices among military trainees.

The ILI surveillance study for active-duty personnel and beneficiaries with severe ARI will continue to gather data on the diagnosis, etiology, epidemiology, and effective prevention and treatment of respiratory infections. Since 2009, the ARIC NHS has enrolled 1,631 cases of influenza-like illness (ILI) and severe acute respiratory infections (SARI).

The ILI surveillance study for active-duty personnel (ILIAD) examines the causes of excess respiratory morbidity in a congregated active-duty population with high influenza vaccination coverage at Ft. Sam Houston (FSSH), Texas. It is designed to estimate the syndromic and pathogen-specific incidence rates and to describe epidemiology of ILI and respiratory pathogens among active-duty personnel undergoing advanced training at FSSH. This study is in partnership with the Global Emerging Infections Surveillance (GEIS) section at the Armed Forces Health Surveillance Branch (AFHSB).

Data collected for this prospective surveillance study, at the McWethy Troop Medical Clinic, will be used to describe the incidence of infections, epidemiology, and burden of respiratory pathogens including influenza, adenovirus, and other emerging ILI pathogens in a congregated military population. Ongoing ILI surveillance activities at this site will provide critical data for monitoring and countering the threats posed by respiratory pathogens in high-risk military populations. An FY2017 study, Address Threats of Acute Respiratory Infections (ATARI), is a prospective, observational cohort study among Basic Combat Training trainees that describes the transmission dynamics, etiology, epidemiology, and burden of ILI viruses, including influenza and adenovirus, with an emphasis on other pathogens that may replace them as the leading causes of ILI in congregated military populations and recruits. This study will be the most comprehensive ARI military cohort to date and findings will aim to inform future ILI prevention and control strategies among trainees.

Another major ARIC NHS-linked study, Epidemiology, Immunology, Clinical Characteristics of Emerging Infectious Diseases (EpiCC-IID), will enroll DoD personnel and beneficiaries with severe ARI due to known and novel pathogens that have major outbreak or pandemic potential (e.g., influenza A/HN1, A/HN8, MERS-Cov). Enhanced data collection on clinical, laboratory, and immunologic characteristics of disease and impact of treatment on disease course will assist further study of the pathogens and allow a readiness platform to be activated in the event of a pandemic.

Military Impact

Although the number of acute respiratory infections in the military has declined over the past decade, figures show that ARIs remain a major cause of morbidity in active-duty personnel and a continued threat to operational readiness. ARIs are a leading cause of outpatient illnesses and are responsible for up to 33% of infectious disease hospitalizations in US active-duty military personnel per year. Respiratory infections account for an estimated half-million clinical encounters and approximately 115,000 lost duty or training days annually.

Without the ability to distinguish the etiology and natural history of these pathogens through timely surveillance, the impact of clinical management strategies on ILI recovery would remain largely undefined. Military personnel living in close quarters add to the heightened risk for infection. The ARIC NHS and its sub-studies described the etiology, clinical characteristics, and immunology of ILI among DoD beneficiaries from 2009 to the present. These studies also contribute to the knowledge of mandatory influenza vaccinations, effective treatment options to limit lost duty days, and identification of risk factors for ILI/SARI to limit their overall impact on military personnel.

HIGHLIGHTS

- Collaborated with other inter-disciplinary research areas and with external partners at NIAID and MHS.
- Collaborated extensively with DoD laboratories to investigate whole genome sequencing of viral isolates and evaluation of cytokine responses.
- FluPRO validation results were submitted to the Food and Drug Administration (FDA) as a novel severity symptom grading scale for influenza infection for use as a standardized symptom measurement scale tool in clinical studies, such as in the ARIC NHS and other ILI trials.
- Developed next-generation sequencing methods to determine ILI/SARI causes using biospecimens from the ARIC NHS, which is expanding with a grant from the USU Collaborative Health Initiative Research Program.
- Completed the FluPRO Phase 1 study investigating the safety of anti-influenza immune plasma as a novel therapeutic approach for the treatment of severe influenza.
Deployment and travel are the sources of several of the most common and well-known infectious disease threats among military personnel, as military combat, humanitarian assistance, and other activities in developing countries expose deployed troops to infectious diseases that can significantly affect operations.

Within the past several years, the DoD has encountered serious deployment-related infectious disease threats such as chikungunya and Zika viruses in South and Central America and Florida, and the Ebola epidemic that led to a large-scale deployment of troops into West Africa to provide assistance to medical staff.

In FY2016, the Deployment and Travel Related Research Area focused on:

- executing clinical trials related to the treatment and prevention of travelers’ diarrhea
- validating a stool collection method and diagnostic assay for field studies in travelers’ diarrhea
- executing observational studies and clinical trials in the group deployment setting

The core study of the research area, Deployment and Travel Related Infectious Disease Risk Assessment, Outcomes, and Prevention Strategies among Department of Defense Beneficiaries (TravMil), is a cohort study to describe the epidemiology of deployment and travel-related infectious disease, and the effectiveness of prevention and treatment strategies. Specifically, the study estimates the incidence and associated risk factors for travelers’ diarrhea, vector-borne febrile illnesses, andILI, based on clinical information, serological testing, and polymerase chain reaction (PCR) assays performed on specimens obtained prior to, during, and post-deployment/travel. Using post-travel surveys, it also estimates the utilization, compliance, side effects, and effectiveness of selected risk-reduction and self-treatment strategies. This study has thus far enrolled travelers taking more than 3,300 international trips.

Most notably this past year, the Trial Evaluating Treatment of Ambulatory Travelers’ Diarrhea (TrEAT TD) study, conducted at sites in Afghanistan, Djibouti, Honduras, Kenya, and Thailand through a collaboration between the US and United Kingdom militaries, was completed. The study supported use of single-dose antibiotic regimens in conjunction with loperamide for treatment of acute watery diarrhea. Study results were presented at a DoD clinical practice guideline development workshop sponsored by IDCRP and the Navy Medical Research Center. The recommendations will provide senior DoD leadership evidence to inform updated practice guidance.

Several follow-on analyses related to molecular detection of enteropathogens, acquisition of multi-drug resistant enterobacteriaceae, and the impact of treatment on microbiome and host-pathogen interaction are now underway.

The Prevent TD study is a randomized, double-blind, placebo-controlled study that examines the efficacy of once or twice daily treatment with Rifaximin, a semi-synthetic antibiotic, compared to placebo for prevention of travelers’ diarrhea. The study, which began enrollment in FY2016, aims to collect data on the efficacy of Rifaximin in prevention in regions with differing epidemiology of travelers’ diarrhea.

During FY2017, the Deployment and Travel Related Infectious Diseases Research Area will engage in an FDA-regulated clinical trial related to the prevention of travelers’ diarrhea. The trial will evaluate the efficacy of a probiotic taken daily for the prevention of travelers’ diarrhea. Several improvements to the deployment/travel infrastructure and processes are being made to allow for efficient execution of the clinical trial, including the addition of an external specialized data management team to ensure that data collection and reporting are compliant with FDA guidelines.

Another FY2017 project is a Knowledge, Attitudes, Practice, and Outcomes Study (KAPOS). The study will use existing medical record data to quantify the burden and distribution of deployment and travel-associated disease across DoD beneficiaries and identify patient and provider knowledge, attitudes, and practice inputs that affect the burden of disease and may be suitable for intervention.

**HIGHLIGHTS**

- DoD recommendations developed through a co-sponsored Deployment-related Diarrhea Treatment CPG Workshop
- Added two new sites to the TravMil network, making a total of eight DoD International Travel Clinics and pre-deployment clinics
- Achieved a high level of enrollment and follow-up in the TravMil study
- Collaborated with the University of Virginia on the development of a TaqMan Array Card PCR assay, which shows higher overall detection rates of enteropathogens associated with travelers’ diarrhea and virulence factors over other standard microbiological methods
- Developed the capacity to create diagnostic tools for pathogen identification that may be used across DoD laboratories

**MILITARY IMPACT**

The Deployment Travel Research Area’s focus on travel- and deployment-related infectious disease surveillance is generating an evidence base to refine deployment clinical practice guidelines. The use and evaluation of multiple treatment methodologies offer the Warfighter and other DoD beneficiaries multiple options to alleviate symptoms of acute infectious diarrhea and other illnesses and to enable them to return to normal duties quickly. Additionally, the preventive applications of this research assist in planning for future deployment or other travel.
Emerging infectious diseases, such as multidrug-resistant bacterial infections, Ebola, Zika, and countless other life-threatening pathogens, are persistent global health threats that can also cause considerable morbidity and mortality for the US military in disease-endemic areas.

A major focus of the Emerging Infectious Diseases and Antimicrobial Resistance (EIDAR) Research Area is to conduct clinical research investigating the etiology, epidemiology, clinical presentations, and outcomes associated with an array of emerging infectious diseases identified as major threats to the health of US military forces.

The EIDAR Research Area is well poised, via leveraging of a robust global network of IDCRP clinical teams at military treatment facilities, to employ a rapid response for reporting detection and clinical characterization of emerging and re-emerging pathogens threatening global US military operations.

In FY2016, the EIDAR Research Area had many accomplishments leading to the development of strategies for improving preparedness capabilities for early detection at the source of disease emergence.

Based on IDCRP’s involvement in an NIAID-sponsored multisite randomized control trial investigating ZMapp™ as a novel monoclonal antibody therapy for Ebola virus disease, the EIDAR team conducted a non-research study on the impact of Ebola screening on the MHS that led to the development of a concise questionnaire for military use in tracking similar future outbreaks. The Ebola contingency study, Epidemiology, Immunology and Clinical Characteristics of Emerging Infectious Diseases with Pandemic Potential (EpICC), is focused on understanding all aspects of emerging diseases that arise with no warning and are likely to affect the military population. The study was amended in 2016 to improve the collection of basic epidemiological data from affected military beneficiaries and was expanded to several other sites.

The Anthrax Immunologic Analysis study completed testing. Results from this study identified core Bacillus anthracis proteins that can be used to develop new and improved diagnostic assays.

Another FY2016 study will develop a database of all chikungunya cases diagnosed among military personnel and it will evaluate the impact of short- and long-term disability associated with the disease.

Regarding antimicrobial resistance, the EIDAR investigators are actively engaged in research to identify and promote best clinical practices for antimicrobial stewardship to prevent further multidrug resistance emergence. The team is collaborating with the Trauma Infectious Disease Outcome Study (TIDOS) and the Combat Wound Infection Multidrug-Resistant and other Virulent Organisms (MDRV/O) Initiative to investigate the trauma wound microbiology of MDRV/O infections across DoD laboratories. This initiative includes a sub-study that is evaluating antifungal resistance patterns in molds.

Two new protocols are in development for 2017, including studies on Borrelia tick-borne disease and Coccidioides fungal infection. The EIDAR research area is growing through the establishment of new strategic partnerships with DoD and external partners, with the goal of expanding IDCRP’s global reach in executing operational research to address emerging infectious disease threats worldwide immediately.

A new retrospective study is currently undergoing scientific review and will evaluate the relationship between phenotypic in vitro bacterial resistance and patient comorbidities on outcomes in drug-resistant bloodstream infections. This effort is the Capstone Project for a USU medical student.

Finally, in early 2017, IDCRP and EIDAR will be undertaking a new project in conjunction with the Combating Antibiotic Resistant Bacteria (CARR) initiative to develop new evidence for implementing antimicrobial stewardship in the MHS.

**HIGHLIGHTS**

- Established strategic collaborative partnerships with the Military Infectious Disease Research Program, US Army Medical Research Institute of Infectious Diseases, DHA, AFHSB GEIS Section, Centers for Disease Control and Prevention (CDC), DoD diagnostic laboratories, WHO International Severe Acute Respiratory Infection Consortium
- Collaborated extensively with Acute Respiratory Infections and Trauma-Related Infections research areas to address emerging antimicrobial resistance threats
- Launched new studies investigating emerging threats to deployed military and global populations, including Ebola and chikungunya

**MILITARY IMPACT**

Infectious diseases have been a significant source of morbidity and mortality among military forces for centuries. Rapid deployment of large numbers of military personnel into disease endemic areas heightens their risk of exposure to and infection with potentially life-threatening microbial infections. Moreover, service members returning to the US post-deployment potentially could transmit these infections to other military personnel, their families and friends, as well as the public.

The EIDAR research area is working to enhance current diagnostics, treatment, and preventive measures for emerging infectious diseases that pose the greatest threat to military readiness. The team also is addressing key microbiological questions for use in developing improved clinical practices to prevent the emergence and transmission of difficult-to-manage, multidrug-resistant bacterial and fungal infections in US military service members afflicted with trauma and combat wounds.
HUMAN IMMUNODEFICIENCY VIRUS (HIV) RESEARCH AREA

With approximately 350 new DoD HIV infections diagnosed annually and over 10,000 active-duty military service members having been diagnosed cumulatively, HIV remains an important research priority in the U.S. military and IDCRP.

Although many gaps in understanding HIV in the military system have been addressed, recognition and understanding of non-AIDS outcomes and other issues associated with long-term HIV infection and treatment continue to develop and highlight research needs. The IDCRP HIV Research Area focuses on ensuring the long-term health and function of infected service members and beneficiaries as well as primary HIV and secondary sexually transmitted infection (STI) prevention efforts.

The largest and most productive study in the HIV Research Area is the U.S. Military HIV Natural History Study (NHS), which celebrated its 30th anniversary in 2015. Since its inception, the NHS has enrolled over 6,000 individuals and it provides a large collection of data and specimens to study HIV among active-duty military service members and their beneficiaries. The military cohort of racially diverse, healthy, and young individuals is representative of a large portion of those in the US with HIV, but is unique among general HIV study populations, in part due to routine screening for HIV resulting in early HIV diagnosis and management.

Of note in 2016, was an NHS sub-study showing D-dimer to pre-HIV baseline levels for approximately 60% of subjects. Those who had residual elevation of this biomarker were significantly more likely to develop subsequent non-AIDS diagnoses, confirming a broadly held hypothesis. The current focus of the NHS is studying the long-term outcomes of people with HIV, including neurological health, establishing a foundation for HIV-related prevention, and optimizing HIV treatment by building toward options beyond antiretrovirals, such as a functional cure.

Two studies of resistant S. aureus bacterial colonization and infection among HIV-positive individuals were completed in 2016. The first of these was a study of Methicillin-resistant Staphylococcus aureus (MRSA) colonization among HIV-positive individuals with a trial of topical antibacterials to prevent skin and soft tissue infections. Although the intervention was not effective, the study has resulted in several published reports advancing this area of study.

The second study, published in PLoS Medicine, investigated the immunology of MRSA colonization and infection among HIV-positive persons in collaboration with field-leading experts. Two additional studies completed enrollment and follow-up: a study of Rifaximin, a novel antibiotic that might decrease systemic inflammation among HIV-positive persons through its effects on gut bacteria, and the Observational Study of Immune Reconstitution Inflammatory Syndrome in HIV (IRIS), a collaborative investigation with NAID and the US Military HIV Research Program (MHRP) to understand this potentially severe complication of HIV treatment.

After early unblinding and publication of the primary study results last year, the Strategic Timing of Anti-Retroviral Therapy (START) trial extended follow-up through the end of 2017 to maximize the future potential analyses.

The HIV Associated Neurocognitive Disorders (ALLHANDS) study successfully enrolled over half of its HIV-positive cohort and began enrollment of the HIV-negative controls. Planned analyses in the coming year will involve collaboration with NIH partners and include examination of cerebrospinal fluid (CSF) biomarkers, MRI data, and sensitivity of various neurocognitive tests in the diagnosis of HIV-Associated Neurocognitive Disorders.

In FY2017, initial analyses from the HIV Virtual Cohort protocol will extend NHS research on non-AIDS, in part by providing an HIV-negative control group to help understand which non-AIDS diagnoses are most important in the military setting. An amendment to the NIH CDA Zeta study, one of the earliest gene therapy trials in HIV, will allow collection of additional specimens to investigate long-term (11- to 15-year) outcomes. The ALLHANDS DoD protocol will complete most of its enrollment, and ongoing preliminary analyses will be presented to the NIH in March.

During FY2017, investigators also anticipate the development of several new studies and analyses in the pipeline. A planned addition to the NHS includes a participant satisfaction survey, which will help understanding of study retention and the willingness of subjects to participate in future interventional and reservoir studies. A social networks survey, to set the stage for interventional prevention trials, also is planned as is a sub-analysis, in partnership with the National Institute for Neurological Disorders and Stroke, to test CSF specimens for biomarkers associated with HIV-associated neurocognitive disorder (HAND) and HIV-associated dementia (HAD).

Other analyses to help inform and advance the HIV cure agenda include analyzing integrated HIV DNA longitudinally among early-treated NHS subjects with long-term HIV viral suppression (>10 years) to evaluate the effects of timing of treatment initiation on the level of HIV DNA integration. The HIV Research Area continues to explore the possibility of a therapeutic HIV vaccine or other cure intervention trial in conjunction with MHRP.

MILITARY IMPACT

The current HIV research portfolio is built with military impact as a central goal. By maintaining and continuing existing studies, investigators support the military by evaluating clinical care and serious outcomes among people with HIV.

The ALLHANDS study ultimately may have policy implications regarding the functions of active-duty HIV-positive military members. Work with HIV and STIs continues to inform policy to improve diagnosis and treatment of STIs, while work with the risk behavior and social networks surveys will progress toward improved understanding of HIV transmission risk and help target HIV prevention efforts within the military.

HIGHLIGHTS

- Celebrated the 30th anniversary of the U.S. Military HIV Natural History Study
- Determined that approximately 60% of successfully treated HIV-positive subjects continue to have elevated biomarkers compared to pre-HIV and those with elevated biomarkers were significantly more likely to develop complications
- Featured by the New England Journal of Medicine Journal Watch for the NHS manuscript "D-Dimer Levels before HIV Seroconversion Remain Elevated Even after Viral Suppression and Are Associated with an Increased Risk of Non-AIDS Events"
- Presented 18 posters and oral presentations at scientific and professional conferences and published or submitted over 20 manuscripts to scientific journals
In August 2016, the investigative team was awarded funding to conduct a phase 2 trial of an S. aureus vaccine candidate (NDV-3A, NovaDigm Therapeutics, Inc.) at Fort Benning. The trial will evaluate the safety, immunogenicity, and effectiveness of NDV-3A against nasal acquisition of S. aureus in the high-risk Infantry training population.

Trial preparations are under way and trial enrollment is expected to begin in fall/winter of 2017. Conducting a field-based trial for an S. aureus vaccine candidate in a high-risk population of military trainees will advance the body of knowledge regarding vaccine-based prevention measures and strengthen the site’s capacity for conduct of future interventional trials.

**MILITARY IMPACT**

SSTIs impose a significant operational, health care, and economic burden to the military. Research contributions from the SSTI Research Area have affected the military by:

- generating epidemiologic, clinical, immunologic, microbiologic, and genomic data of overall and S. aureus-associated SSTI
- enumerating the epidemiologic and economic burden of SSTI among military training populations
- establishing a clinical research platform on which interventional trials for SSTI can be supported.

Outbreaks of skin and soft tissue infections (SSTI) in military populations interrupt training cycles, compromise operational readiness, and impose a significant health care burden.

To date, hygiene-based SSTI prevention strategies have had limited effectiveness and an effective vaccine for S. aureus, the predominant cause of SSTI, remains elusive. Current research efforts in this area aim to describe the clinical characteristics and natural history of SSTIs in military populations and to address knowledge gaps in the infections.

Active efforts include the SSTI Cohort Study, an observational cohort study of S. aureus colonization and SSTI among high-risk US Army Infantry trainees at Fort Benning, Georgia. Four discrete training companies were recruited and followed throughout the 14-week training cycle. Trainees were routinely sampled to identify S. aureus colonization status, and incident cases of SSTI were prospectively identified.

Given the uniqueness of the study population and setting, this data will yield unique insights into the transmission dynamics of S. aureus in a military training environment. Over 600 trainees have been enrolled and have completed follow-up procedures, and >11,000 colonization swabs have been collected.

In FY2016, the team also initiated a study of S. aureus colonization and SSTI in the submariner population at King’s Bay, Georgia. Several laboratory-based efforts with collaborators at the Department of Wound Infections at the Naval Medical Research Center (NMRC), Department of Microbiology and Immunology at USU, and the NMRC Biological Defense and Research Directorate are evaluating the immunology, microbiome, and genomic epidemiology of SSTI in this population.

In September 2016, the team submitted grants in partnership with New York University and Harvard University to expand on current efforts in immunology and genomic epidemiology.

**HIGHLIGHTS**

- Awarded funding from the US Army Medical Material Development Activity’s Military Infectious Diseases Research Program for a Phase 2 trial of an S. aureus vaccine candidate
- Submitted grants in partnership with New York University and Harvard University to expand on current efforts in immunology and genomic epidemiology
- Used whole genome sequencing to describe the genomic epidemiology of USA300 associated with clusters of SSTI among Infantry trainees
- Successful execution of first comprehensive SSTI cohort study within a congregate military trainee population

**SKIN and SOFT TISSUE INFECTIONS RESEARCH AREA**

Outbreaks of skin and soft tissue infections (SSTI) in military populations interrupt training cycles, compromise operational readiness, and impose a significant health care burden.
Research interest in sexually transmitted infections (STIs) and their relevance to the military has grown with the development of antibiotic resistant gonorrhea.

The CDC recently identified Neisseria gonorrhoeae (GC) as one of the top three urgent drug resistant health threats in the U.S. Consistently, STI rates are higher among military populations compared to their civilian counterparts, and specific STIs, including Chlamydia trachomatis and Human Papilloma Virus, are on the rise among military personnel.

Noteworthy for the STI Research Area this year is the shift of funding for the GC Resistance Study and Repository to sustainment funding, with a work plan outlined for the next three years. The plan includes an expanded role for the IDCRP to work with USU and GEIS to support a Lab and Data Coordinating Center across other OCONUS GC resistance study efforts.

The study collects gonococcal isolates and clinical and risk behavior data at four military training facilities across the U.S to identify gonococcal resistance among U.S. military personnel.

For FY2017, GEIS funding was granted for CT molecular typing, using novel molecular techniques that could allow for identifying CT transmission networks, leading to targeted prevention efforts and potential advancements in vaccine development. The funds will allow conduct of this work within the HIV NHS population and high-risk HIV seronegative beneficiaries (patients on HIV pre-exposure prophylaxis [PrEP]).

Investigators are also working closely with the Defense Advanced Research Projects Agency to become one of their clinical sites to test a mobile point-of-care diagnostics platform being developed to allow for STI testing in field military settings. Additional plans for FY2017 include exploring expansion of the network to include other STIs and additional clinical sites (Fort Hood, Lackland Air Force Base, and Camp Lejeune).

The research team will continue to maintain a comprehensive technical watch of new STI vaccines and diagnostic platforms that may be of particular interest to the DoD, with the long-term goal of planning prevention studies incorporating behavioral interventions and STI vaccines.

**MILITARY IMPACT**

The STI Research Area has developed an STI clinical research network at many military sites with the assistance of the GEIS division at the AFHSB and NIAID.

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**MILITARY IMPACT**

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**HIGHLIGHTS**

- Enhanced knowledge of GC resistance, a significantly growing threat
- Expanded collection of GC isolates by broadening GC resistance inclusion criteria, as well as working directly with clinical microbiology laboratories
- Expanded GC resistance clinical study population to patients seeking HIV PrEP
- Completed susceptibility and basic genetic testing on the GC isolates received to date in collaboration with the USU Microbiology and Immunology Department
- Presented 12 posters at scientific and professional conferences and symposiums
TRAUMA-RELATED INFECTIONS RESEARCH AREA

Infectious complications of battlefield wounds are associated with high rates of morbidity and resultant disability.

During the past year, investigations have focused on priority MHS issues, such as multidrug-resistant bacteria and difficult-to-treat organisms, as well as infections associated with extremity wounds, the predominant injury pattern among wounded warriors. As part of the analysis of extremity wound infections, wound microbiology is also being thoroughly examined. In addition, analyses assessing health care economics and effectiveness of various antibiotic regimens are in progress or being developed.

The centerpiece protocol of this research area is the Trauma Infectious Disease Outcomes Study (TIDOS) led by Dr. David Tribble. The protocol collected infection-related information, such as medical management and clinical outcomes, on military personnel injured during deployment between 2009 and 2014. Enrollment in the TIDOS cohort closed in January 2015 and follow-up data collection continues through the DoD. In addition, infection-related data capture from the centralized Veterans Affairs Healthcare System are ongoing, through collaboration with colleagues at the St. Louis Veterans Affairs Medical Center.

Over the past year, investigators have refined the methodology for characterizing extremity wound infections, allowing for improved analysis and a better understanding of the burden of infections among combat casualties with poly trauma. The analysis of extremity wound infections over a three-year period was completed and data were presented at multiple conferences, including the Military Health System Research Symposium, the Infectious Disease Society of America’s IDWeek, and the DoD Blast Injury Research Program International State-of-the-Science meeting. Examination of extremity wound infections over the 5-year TIDOS study period is under way.

Another protocol is the Trauma-Associated Case-Control Osteomyelitis study. Osteomyelitis is a serious infection associated with open fractures that often results in multiple surgeries, prolonged hospitalization, and extended use of antibiotics.

During 2016, investigators completed osteomyelitis analyses related to open fractures of three anatomic regions: tibia, femur, and long bones of the arm. An objective of the analyses was the determination of risk factors for development of the disease, along with assessment of osteomyelitis recurrence after the initial disease resolution. Again, through collaboration with the St. Louis Veterans Affairs Medical Center, additional follow-up data from patients with osteomyelitis were collected from the VA system and will be analyzed in the upcoming year.

Multiple analyses were also either initiated or completed this past year under the TIDOS MDVNO initiative led by Dr. Katrin Mende. This collaborative effort across several DoD laboratories seeks to maximize understanding of complex wounds through use of the TIDOS microbiological repository. One of the completed analyses focused on Enterococcus spp., which is frequently isolated from polymicrobial wound cultures.

Another research protocol involves invasive fungal wound infections (IFIs), which emerged during the war in Afghanistan as a complication of blast trauma with high morbidity and mortality. Using data and specimens gathered through TIDOS, the IFI Molecular Diagnostics study, led by Dr. Anuradha Ganesan, is evaluating the use of PCR-based methods to aid in identifying molds in patients at risk of developing IFIs, which may result in improved treatment and outcomes. The study has fostered collaborations with several partners, including the DoD Joint Pathology Center.

MILITARY IMPACT

The research area’s aims and objectives remain high priorities for military medicine and continue to have significant clinical relevance during inter-war periods for improved understanding of ongoing issues among wounded personnel, and to enhance efforts with evidence-based approaches for the next conflict. Overall, the strengths and opportunities of the various studies in the Trauma-Related Infections Research Area provide a robust platform for the near future.

HIGHLIGHTS

- Determined that 23% of combat casualties with extremity wounds developed an infection with higher rates among patients with traumatic amputations (41% of patients with amputations and no other wounds developed an infection)
- Determined that 28% of patients with open tibial fractures and osteomyelitis had an osteomyelitis recurrence after resolution of initial infection
- Collaborated with the United Kingdom Ministry of Defence to compare country-level differences in infection prevention and management
- TIDOS investigators co-authored revisions of two Joint Trauma System Clinical Practice Guidelines related to prevention and treatment of IFIs and prevention of combat trauma infections
- TIDOS work was highlighted at the DoD Blast Injury Research Program’s International State-of-the-Science Meeting on Minimizing the Impact of Wound Infections Following Blast-related Injuries
THE IDCRP STAFF

The backbone of any organization is its staff. The IDCRP staff comprises dedicated, highly skilled, well-educated individuals with a career-based commitment to issues related to identifying, studying, and influencing the clinical study and treatment of infectious diseases.

In FY2016, IDCRP employed approximately 130 research and administrative-support personnel who assisted the program and accommodated a complicated workload servicing seven broad areas of infectious-disease research.

As a research-centric organization, at least 55% of the IDCRP workforce is composed of professionals interfacing directly with patients and subjects at military treatment facilities. Approximately 31% of all personnel are clinical research coordinators and related research staff members, the most common type of staff within the program.

Areas of expertise range across health, scientific, and medical concentrations and specialties. More than half of the staff members possess two or more degrees and all have a wealth of experience in multiple areas of the infectious disease spectrum.

The IDCRP staff also is quite diverse racially, ethnically, and culturally, representing many countries of origin as well as multiple areas of the US. Part of staff diversity also includes individual status as an HIF employee, federal government employee, USU employee, consultant, or active-duty military.

In terms of work locations, IDCRP staff work in offices, laboratories, medical facilities, military bases, and military field settings throughout the US and in several other countries. All staff members manage, conduct, assist, or support clinical research protocols and basic research operations. The many types of staff positions are outlined in the figure below.

DATA COORDINATION CENTER

The Data Coordination Center (DCC) of IDCRP supports all research areas in achieving the goals of their Scientific Strategic Plans by providing high-quality data management services.

The DCC team, led by Ed Parmelee, consists of data system designers, data managers, data entry staff, and SAS and Oracle programmers. The group provides expertise to principal investigators for the conceptualization, design, collection, management and cleaning, analysis, and publication of research study data. The center’s resources are used in all IDCRP studies for which the program is the primary data collector or data repository.

The DCC’s strategic focus is on ensuring high-quality data collection, management, processing, and access, as well as improving the efficiency and efficacy of processes and ensuring appropriate staffing needs. The center uses multiple systems to receive data in either paper or electronic format, including traditional desktop/laptop-based electronic data capture (EDC), tablet-based EDC, web-based survey tools, and form scanning. Use of these myriad systems allows the IDCRP to enroll and collect data from subjects at medical treatment and other facilities around the world.

The center is currently working on 26 studies across all IDCRP research areas, almost all of which involve development of new or modifications to existing data collection instruments and/or methodologies. The DCC Strategic Plan focuses on maintaining high personnel capabilities, modifying or replacing ineffective systems and procedures, and establishing expectations for standardization of DCC practices and methodologies to achieve the goal of excellent data collection, management, processing, and availability.

During FY2016, one of the main accomplishments was the external validation of the offline-capable, mobile-based data acquisition system, Mi-Forms, as being compliant with 21CFR11 (Code of Federal Regulations) and the subsequent creation of related internal policies and procedures in preparation for upcoming trials in FY2017.

In FY2107, the DCC goals are to prepare IDCRP further for the execution of FDA-compliant Investigational New Drug intervention trials, expand the data querying process improvements to all IDCRP DCC studies, use the new standardized data dictionary, and investigate the replacement of a current data collection system with a new one. The DCC expects to begin work on at least three new studies in FY2017.

HIGHLIGHTS

- Expanded use of the MHS Medical Database Repository as a primary or supplemental data source for IDCRP studies
- Improved overall efficiency of query processing, including replacing disparate query tracking tools with an Oracle database-based system
- Implemented the framework and user interface for a comprehensive data dictionary to serve as a repository of study-specific information and as a reference for the future creation of data capture systems
RESEARCH SUPPORT
and OPERATIONS

The IDCRP Research Support and Operations (RS&O) team is composed of a four-person Program Management and Finance team (PM/F) and the Research Support Group (RSG).

During FY2016, the team successfully implemented a root-to-stem reorganization of program operations, a new program management plan, and solidified efforts to reach current and out-year resource goals and overhaul financial management mechanisms. Through work by the RS&O Chief and IDCRP leadership, the program’s first comprehensive organization chart was developed, comprehensive audits were completed, and new financially informative reports were developed, including a multi-year financial forecast to predict broad future trends in program finances. The introduction of a new financial reporting system streamlined report production and saved a substantial amount of proposed development costs.

IDCRP study stakeholders to manage resources at the protocol level where actual site research takes place. Each protocol will be assigned its own unique task and sub-task number, which will ensure that site managers, investigators, and program managers can keep track of their studies on an ad hoc basis. In FY2017 one focus for RS&O will be development of an improved working relationship with individual Military Training Facility Command’s Clinical Investigation Departments to streamline expenses, create a better leadership framework at research sites, and promote current and future infectious disease research. In addition, the team looks to continue upgrading financial reporting and implementing robust HR, financial, training, education, and other policies that will strengthen the program in the future. Further changes and improvements within the RS&O department will ensure that IDCRP continues to shoulder current research successfully, and rise to future infectious disease research challenges.

The Clinical Research Management group handles the day-to-day protocol management activities for all seven research areas from the IDCRP’s Program Coordination Center (PCC). The group provides guidance and coordination to principal investigators, staff at military treatment facilities, and labs on the development, preparation, and conduct of research studies. In FY 2016, the Clinical Research Management group developed standardized recruitment language as well as a screening and enrollment log that is being used across all research areas for new studies. In addition, the new position of chief of clinical research management was created and filled by Daniel Rosenberg, PMP, MS, MA. Rosenberg and the clinical research managers are working toward standardizing the management of IDCRP protocols based on the concept of audit- and FDA inspection-readiness for the PCC and military treatment facilities.

The IDCRP SRB follows three review pathways: • Standard review • Low resource review • Chair review. This keeps the process flow as efficient as possible. The SRB chair determines the level of review required for each protocol and amendment, taking into consideration any specific pathway request from the Principal Investigators or the Senior Science Group. The SRB review process requires for each new research concepts are reviewed and recommendations to move forward to protocol development are made by the Concept Scoring Panel, Senior Science Group, and Operational Steering Committee of IDCRP.

The purpose of conducting this review is to ensure the scientific validity of each protocol, including that the research questions, hypotheses, aims, objectives, and methods are meaningful and feasible. This formative review is intended to improve the quality of protocol scientific content prior to IRB submission. SRB review is conducted for all new protocol submissions, including prospective and retrospective studies involving participants enrolled in existing protocols.

The Scientific Review Board (SRB) for IDCRP, chaired by NIAID liaison Dr. John Powers, is structured to execute independent and timely scientific reviews of clinical research projects and biomedical studies prior to USU Infectious Disease Institutional Review Board (IRB) submission. The scientific review process occurs after new research concepts are reviewed and recommendations to move forward to protocol development are made by the Concept Scoring Panel, Senior Science Group, and Operational Steering Committee of IDCRP.

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The IDCRP Regulatory Affairs team, led by John Morais at the Program Coordination Center and staff at the network of military treatment facilities, assists investigators and the program in the development and review of new research and assurance of compliance in ongoing research.

The team also serves as liaisons to USU, NIAID, and other regulatory entities critical to the successful execution of IDCRP research. Regulatory Affairs personnel assist in protocol development and regulatory pre-review of planned IRB submissions, consult with investigators and IRB staff to address concerns, conduct on-site quality assurance and auditing, track study milestones, and maintain regulatory documents for the program. Site regulatory staff members ensure local implementation requirements are met and that they are communicated to the local regulatory office.

During FY2016, 42 active nonexempt studies and 13 active exempt studies were conducted within IDCRP. A total of 62 protocol amendments and 40 continuing reviews were submitted to the IRB. To streamline the process further, the Regulatory Affairs team is developing and/or updating standard operating procedures (SOPs).

The new web-based Electronic Institutional Review Board (eIRB) system was launched in April 2016 under the proprietary name iRIS. It replaces IRBNet. iRIS supports DoD medical research submission and review across the MHS and partner agencies. The system assists researchers at the investigator and institution level with submission, management, and regulatory oversight of research protocols, supporting documents, and scholarly publications. The application is intuitive, guiding users through templates with smart forms and embedded logic throughout the submission process. The goal of iRIS is to eliminate redundancies and differences across the MHS and DoD and to harmonize the research process enterprise-wide.

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The IDCRP education mission uses three strategies to accomplish this goal:

- mentored research
- didactic learning
- research engagement.

The program provides mentored research opportunities on its projects to medical and public health students, medical residents, and fellows in the armed forces. IDCRP also assists in the development of a clinical research capstone curriculum in infectious diseases for medical students. In the past year, more than 20 trainees conducted research with IDCRP mentors resulting in 12 oral and poster presentations at national infectious diseases conferences, and 4 published papers in scientific journals.

The education program also supports the Armed Forces Infectious Disease Society (AFIDS) and continuing medical education activities at Walter Reed National Military Medical Center (WRNMMC). In addition, IDCRP develop and launched a new course teaching infectious disease fellows about the fundamentals of conducting clinical research that is taught by IDCRP investigators at WRNMMC.

Another education goal is to make these lectures available to other military medical trainees online. Raising awareness about infectious disease clinical research in the armed services is critical to the success of IDCRP’s education mission.

The mission is accomplished by IDCRP investigators attending student practicum and project fairs, meeting with infectious disease fellows and medical residents, providing information on opportunities to conduct mentored research with the program to medical training directors, and meeting with trainees to discuss the role of research in infectious disease practice.
HIV Research Area Trainee Publications


STI Research Area Trainee Publications


Dr. Brian Agan presenting training opportunities for students at USU

Trauma Research Area Trainee Publications


During FY2016, several members of the IDCRP Senior Research Staff received awards or honors from industry associations and conference competitions. Some of the Program trainees also won important association or USU awards or placed in research-based competitions.

These accomplishments are outlined below. The entire IDCRP leadership and staff congratulate the outstanding investigators and trainees who have shown noteworthy ambition and excellence in work production.

Senior Research Staff Awards and Honors

Dr. Yun receiving the Military Medicine Article of the Year Award

Navy Commander Namii Gutierrez accepting TEAT TD award for Captain Riddle and the TEAT TD team

Best General Poster Research Presentation Award

Dr. Brian Agan presenting travel medicine course as part of USU’s Master of Public Health program

AWARDS and HONORS

<table>
<thead>
<tr>
<th>Name</th>
<th>Award/Honor</th>
<th>Awarding Organization</th>
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<tbody>
<tr>
<td>Lead Author, Lt Col Heather C. Yun, MD, USAF, MC</td>
<td>2016 Military Medicine Article of the Year Award Healthcare-Associated Pneumonia Among United States Combat Casualties, 2009-2010 (TIDOS project)</td>
<td>AMSUS</td>
</tr>
<tr>
<td>Senior Author, COL Clinton K. Murray, MD, FACP, FIDSA</td>
<td>2015 MHSRS Outstanding Research Accomplishment, Team/Intramural</td>
<td>MHS Research Symposium</td>
</tr>
<tr>
<td>Lead Author, John H. Powers, MD, NIAID Lusison to IDCRP and multiple IDCRP staff contributing authors</td>
<td>Best General Poster Research Presentation “Evaluation of the Performance Properties of InFLuenza Patient-Reported Outcome (FLU-PRO) Instrument”</td>
<td>International Society for Pharmacoeconomics and Outcomes Research</td>
</tr>
</tbody>
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TRAINEE EDUCATION PUBLICATIONS
AWARDS and HONORS
(Continued)

Name | Award/Honor | Awarding Organization
--- | --- | ---
Kathryn J. Bello, DO | 2nd place, Commander’s Research Award for Resident Basic Science Work | USU
LT Christina M. Jamros, DO | Navy Resident Research Award | American College of Physicians
Capt David Lindholm, MD | 1st place, AFIDS Fellow Competition | AFIDS
Capt David Lindholm, MD | 2nd place, Fellows’ Commanders Research Award at graduation | USU
Capt David Lindholm, MD | 3rd place Commander’s Award for Fellow Research | San Antonio Uniformed Services Health Education Consortium
MAJ Aaron Farmer, MD | 1st place Commander’s Award for Fellow Research | San Antonio Uniformed Services Health Education Consortium
MAJ Aaron Farmer, MD | 3rd place Poster competition | Texas Infectious Disease Society
Capt David Lindholm, MD | Abstract highlighted at Young Investigator Plenary Presentation as one of top 12 abstracts | MHS Research Symposium
CPT Matthew Perkins, MD | 2nd place, AFIDS Fellow Competition | AFIDS

IDCRP COLLABORATORS and PARTNERS

Department Of Defense Sites
- U.S. Military Hospital and Clinics
- Brooke Army Medical Center, San Antonio, TX
- Marine Corps Base Camp Lejeune, Jacksonville, NC
- Camp Bastion, Afghanistan
- Landstuhl Regional Medical Center, Germany
- Madigan Army Medical Center, Joint Base Lewis McChord, WA
- Martin Army Community Hospital, Ft. Benning, GA
- Naval Medical Center Portsmouth, VA
- Naval Medical Center San Diego, CA
- San Antonio Military Health System, TX
- Soto Cano Air Base, Honduras
- Truop Army Medical Center
- Troup Medical Clinic, Fort Sam Houston, TX
- U.S. Naval Expeditionary Base, Camp Lemoine, Djibouti
- Walter Reed National Military Medical Center, Bethesda, MD
- William Beaumont Army Medical Center, El Paso, TX
- Womack Army Medical Center, Ft Bragg, NC
- U.S. Military Research Commands
- Naval Medical Research Center (NIMRC)
- NIMRC—Subordinate Commands
  - Biological Defense and Research Directorate
  - Naval Health Research Center, San Diego, CA
  - Naval Medical Research Unit No. 6, Lima, Peru
  - Naval Medical Research Center-Asia, Singapore
  - Naval Medical Research Unit No. 3, Cairo, Egypt
- Naval Submarine Medical Research Laboratory
- U.S. Army Institute of Surgical Research
- U.S. Army Medical Research Institute of Infectious Diseases
- Walter Reed Army Institute of Research
- U.S. Army HIV Research Program
- Multidrug Resistant Network
- Specimen Processing Lab
- HIV Infections

Other U.S. Military Commands/Programs
- Armed Forces Health Surveillance Branch (AFHSB), Global Emerging Infections Surveillance (GEIS) section
- Bureau of Medicine and Surgery, Department of Navy (BUMED)
- Congressionl Defense Medical Research Program (CDMRP)
- Defense Advanced Research Projects Agency (DARPA)
- Defense Health Agency (DHA), Immunization Healthcare Branch, Military Vaccine Programs
- DoD Global Emerging Infections Surveillance (GEIS) Program
- Navy Marine Corps Public Health Center (NMCP)
- Military Infectious Disease Research Program (MIDRP)
- San Antonio Uniformed Services Health Education Consortium

United States Government Health Agencies
- Centers for Disease Control and Prevention
- Food and Drug Administration
- National Institutes of Health
  - National Institute of Allergy and Infectious Disease
  - Division of AIDS
  - Division of Clinical Research
  - NIAID Flu Networks
  - Vaccine Research Center
  - National Institute of Mental Health
  - National Institute for Neurological Disease and Stroke
  - National Institute of Health Clinical Center

Foreign Health Agencies and Organizations
- British Army Training Unit, Nanyuki, Kenya
- Defence Medical Directorate, Rheinfelden, UK
- Defence Statistics (Health) MOD Abbey Wood
- Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran, Mexico City
- Instituto Nacional de Enfermedades Respiratorias Ismael Cosio Villegas, Mexico City
- Royal Centre for Defence Medicine, Birmingham, UK
- The Kirby Institute, Australia
- The Red Cross AIDS Research Centre
- United Kingdom Ministry of Defence
- World Health Organization (WHO), International Severe Acute Respiratory Infection Consortium

Public and Private Hospitals and Clinics
- Children’s National Medical Center, Washington, DC
- Hospital General Dr. Manuel Gea González, Mexico City, Mexico
- Hospital General de Aguascalientes Jaramillo Mejia, Buenos Aires, Argentina
- Department of Military Medicine, Royal Centre for Defence Medicine, Birmingham, UK

Academics
- Bryant and Stratton College
- Columbia University
- Drexel University
- Emory University
- Harvard University School of Public Health
- Johns Hopkins University, Bloomberg School of Public Health
- New York University
- University of California-Los Angeles
- University of California-San Diego
- University of California, Los Angeles College of Medicine, London, UK
- University of Copenhagen, Denmark
- University of Maryland-Baltimore
- University of Minnesota
- University of Nebraska
- University of North Carolina
- University of Pittsburgh
- University of Texas Health Science Center at San Antonio
- University of Texas Medical Branch
- University of Texas-San Antonio
- University of Toledo College of Medicine and Life Sciences
- University of Vermont
- University of Virginia
- University of Washington
- University of Western Australia
- University of Wuerzburg Medical Center, Germany
- Vanderbilt University
- Yale University

Research Organizations and Industry Partners
- Cherokee Nation Technology Solutions
- Diatheva Laboratories, LLC
- Henry M. Jackson Foundation for the Advancement of Military Medicine
- Leidos Biomedical Research, Inc.
- NovaDigm Inc.
- Scripps Research Institute
- Westat, Inc.
Infectious Disease Clinical Research Program

Uniformed Services University of the Health Sciences
Department of Preventive Medicine & Biostatistics

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