Innovation Award

The IDCRP was awarded the 2013 Microsoft Life Sciences Innovation Award for the development, deployment, and use of a tablet-based mobile electronic data capture system. This offline-enabled, mobile, tablet-based electronic data capture (EDC) system called Mi-Forms, developed by the North Carolina-based Mi-Corporation, allows data collection globally without immediate internet connection, and has vastly streamlined data collection for an ongoing trial to treat traveler’s diarrhea.

Marketing Award

COL Kortepeter accepts from Mr. Crites, Art Director, Henry M. Jackson Foundation the 2011 Gold MARCOM statuette which was awarded for the IDCRP Annual Report. IDCRP also received a 2012 Gold MARCOM award for its website. MARCOM is an international creative marketing competition that receives approximately 6000 entries per year.

The Kaiser Family Foundation Report writes:

“Key DoD organizations involved in these [infectious diseases medical research and development] activities include:

- Military Infectious Diseases Research Program
- Walter Reed Army Institute of Research
- Naval Medical Research Center
- Infectious Disease Clinical Research Program (IDCRP) at Uniformed Services University for Health Sciences.”
Before the first interagency agreement was drafted between the National Institute of Allergy and Infectious Diseases (NIAID) and the Uniformed Services University (USU) that established the Infectious Disease Clinical Research Program (IDCRP), a planning framework was signed in 2005 that recognized the common objective of promoting the study of infectious diseases in the military. With the close of 2013, the IDCRP has completed its ninth year since that planning framework was written. During this time, we have been successful, not because of what we have accomplished by ourselves, but because of the accomplishments we have shared with numerous collaborators. We recognize the importance of partnering with multiple different organizations within and outside the military hospital commands, with military research commands, military medical surveillance organizations, academic organizations, industry, and, of course, the NIAID. We welcome the complementary skills and capabilities all these organizations bring toward realizing a common objective. A recent report by the Kaiser Family Foundation about the Department of Defense’s (DoD) Global Health infectious disease research listed the IDCRP as one of the key DoD organizations involved. This was a nice recognition of IDCRP’s successful clinical research efforts.

One of the more notable achievements of the past year was the launch of our traveler’s diarrhea treatment trial among volunteers in the US and United Kingdom (UK) military in Afghanistan, Djibouti, and Kenya in partnership with overseas laboratories in Cairo (NAMRU-3) and Nairobi/Kericho (USAMRU-K). We have also begun a partnership with the National Institutes of Health (NIH) (NIAID, National Institutes of Mental Health [NIMH], National Institute of Neurological Disorders and Stroke [NINDS]) to study neurocognitive disease in HIV-infected individuals. Moreover, we have completed our initial study report on hygiene measures at Fort Benning, Georgia to reduce the incidence of skin and soft tissue infections. This last study was a massive two year trial that enrolled over 30,000 trainees. We have also begun enrolling patients in our multidrug-resistant gonococcal (GC) surveillance study and are in the process of setting up a GC research repository at USU. You will find these and many other achievements discussed in the following pages.

At the beginning of 2013, we commenced a scientific strategy review to assess how we might continue to capitalize on our strengths going forward. In order to ensure we captured the needs of the military providers at the bedside, as well as other stakeholders, we conducted a survey and compared that input with our existing portfolio and a literature review. We plan to present our findings to the Steering Committee before we finalize the strategy. Once we receive approval, we intend to use this as our scientific roadmap for the next five years.

Despite the significant DoD budgetary and travel challenges this year, we remain focused on our mission. I am grateful for the strong support we continue to receive from organizations such as the Navy Bureau of Medicine and Surgery, the Armed Forces Health Surveillance Center, and the Military Infectious Disease Research Program, as well as the long-standing support from the NIAID, the USU, and the Henry M. Jackson Foundation for the Advancement of Military Medicine. I am thankful for the dedicated teams of individuals at the IDCRP headquarters and across the world who are focused on finding solutions to the infectious disease issues that affect our military beneficiaries.

I continue to appreciate the opportunity to serve as the leader of this great network of scientists, clinicians, site managers, clinical research coordinators, regulatory specialists, data managers, biostatisticians, laboratory technicians, and operations managers who are also working toward the common purpose of reducing the impact of infectious diseases on the military population. This work would not be possible without the dynamic support of our active duty infectious disease chiefs, our collaborators at the individual research sites, and the guidance of our Steering Committee.

Mark G. Kortepeter, MD, MPH
Colonel, US Army Medical Corps
Director
INTRODUCTION

TO THE IDCRP

The Infectious Disease Clinical Research Program (IDCRP) was formed in 2005 through an Interagency Agreement between the National Institute of Allergy and Infectious Diseases (NIAID) and the Uniformed Services University (USU). The NIAID, recognizing the untapped resource presented by the Department of Defense (DoD) population, provided critical support to expand the portfolio of the existing DoD TriService AIDS Clinical Consortium (TACC) network to encompass clinical research about other infectious diseases of military importance.

The IDCRP is a multi-center, translational research platform designed to broaden collaborations among Military Health System (MHS) and NIAID investigators as well as develop affiliations, when appropriate and relevant, with partners from other government agencies, academia, and industry. The program operates within the Department of Preventive Medicine and Biometrics at USU through partnership with the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF). The IDCRP draws on the unique strengths of both the MHS and NIAID, and the product development expertise of the US Army Medical Research and Materiel Command/Naval Medical Research Center (USAMRMC/NMRC). The MHS comprises a diverse worldwide group of hospitals and clinics serving as many as nine million DoD beneficiaries. The IDCRP is poised to leverage the robust clinical and pharmaco-economic data repositories archived by the MHS to answer key research questions. Through the IDCRP, DoD clinicians and investigators treating military beneficiaries have the ability to partner with experienced IDCRP, NIAID, and USAMRMC/NMRC investigators to take advantage of the robust data management and regulatory support from the program, as well as clinical trials monitoring support from NIAID. Consequently, research coordination for multi-center projects can be accomplished that is outside the scope of individual hospital research departments. IDCRP is not a funding agency but, instead, leverages and manages funding to conduct protocols addressing research gaps.

Research concepts considered by IDCRP are focused on clinical infectious disease questions of importance to the DoD. A concept is brought to one of the IDCRP science working groups where the idea is discussed and refined into an answerable research question from which a protocol and research plan are developed. Sites are selected within the MHS treatment facilities or other military units based on the required study population, and the protocol will then be executed by a collaboration of uniformed, civilian and contract investigator and staff.
Stakeholders
Governing Board

Steering Committee (7 members)

USU  MRMC  Infectious Disease Consultants to Surgeons General (USA, USN, USAF)  AFHSC  NIAID

Program Coordination Center

Program Director

Deputy Program Director
Science Director

Deputy Science Director

Co-Director, Research Operations - Data Coordination & Analysis
Co-Director, Research Operations - Research Development & Site Implementation

Chief, Data Coordination Center
Chief, Clinical Research Administration

Clinical Trials Site at Military Treatment Facilities

Active Duty ID Service Chief
Site Principal Investigator
Research Coordinators & Other Site Personnel

Site Manager
Additional Physician Investigators
IDCRP Science Directorate

The IDCRP research portfolio has continued to diversify and grow in size and impact across the seven Research Areas. This year brought an important restructuring of IDCRP Research Areas under a unified Science Directorate allowing for greater coordination and effectiveness in execution of research plans. Several initiatives have been started this year that focus on project management effectiveness, increased coordination with clinical sites, statistical support integration within research teams, and collaborative efforts with Data Coordination Center teams to advance more real-time electronic data capture systems across the clinical network.

Most notably, the Science Directorate has led a critical reappraisal of the IDCRP scientific strategy across all seven Research Areas utilizing standardized methodology to assess military clinical infectious disease (ID) challenges in need of directed high quality research. Evidence gaps were identified using a military ID community survey combined with a broad stakeholder outreach effort. Within each research portfolio, priority gaps were evaluated against existing aims to create a proposed five-year research plan. Throughout the process, there have been broad outreach and dialogue with military ID clinicians across all Services, IDCRP investigative teams, military public health/preventive medicine leaders involved in ID surveillance efforts, and scientists and leaders across the military ID research and development community. The Research Area-specific Scientific Strategic Plans will be presented for IDCRP Steering Committee review in early FY14 before comprehensive program-wide implementation.

The IDCRP strives to conduct high priority, high quality science to provide evidence-based improvements in clinical practice and DoD policies for preventing and treating infections affecting the United States military and military beneficiaries. Details of current activities and key accomplishments of the Research Areas are noted in the following pages.
The IDCRP has focused efforts on evaluation and development of new treatment strategies for combat-related trauma infectious complications. Infections in these complex wounds remain a major challenge requiring well-designed clinical research in the areas of prevention and management. Treatment strategies have been complicated by the emergence of multidrug-resistant bacterial organisms and aggressive new threats such as invasive molds. Furthermore, infections of the bone or on rehabilitative/restorative hardware may recur at a much later date.

These challenges are being evaluated through multiple protocols, most notably the Department of Defense-Department of Veterans Affairs (DoD-Va) Trauma Infectious Disease Outcomes Study (TIDOS), which is now entering its fifth year of recruitment and enrollment. TIDOS is a multi-site, prospective, observational cohort study, using predefined standardized methodology to evaluate the 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 specialties (e.g., medical, surgical) and across commands at Landstuhl Regional Medical Center, Water Reed National Military Medical Center, San Antonio Military Medical Center, US Army Institute for Surgical Research, Walter Reed Army Institute of Research, Naval Medical Research Center, St. Louis Veterans Affairs (VA) Medical Center, and the Uniformed Services University to address priority research issues affecting wounded personnel. TIDOS microbiology projects have expanded this past year to include analyses investigating bacterial antagonism in wounds, presence of antibiotic resistance genes and their associations with antibiotics, and production of biofilms.

The Infectious Disease-Orthopedic Surgery collaborative protocol investigating trauma-related osteomyelitis risk factors and management completed data collection for tibial and femur fractures this past year. Analysis and reporting of findings began in the fall of 2013. The IDCRP has also partnered with the US Army Medical Materiel Development Activity (USAMMDA) to examine the utility of a novel, broad-spectrum, aminoglycoside antibiotic, arbekacin, for the management of multidrug-resistant gram-negative bacterial infections.

Trauma Patient Admissions - TIDOS, (June 2009-September 2013)
Activities and Accomplishments

- Since the TIDOS project initiation in June 2009, clinical and microbiological data have been collected and analyzed from over 5000 injured personnel; over 1250 of these individuals are enrolled in the TIDOS long-term cohort that follows service members into the VA system.

- The TIDOS team has worked cooperatively with the US Army Institute of Surgical Research (USAISR) Joint Trauma System (JTS) to implement and activate the DoD Trauma Registry web-based infectious disease module.

- JTS clinical practice guidelines (CPG) for the identification and treatment of suspected invasive fungal infections (IFI) in war wounds were developed through TIDOS research. The research supporting the CPG will be published in the journal, *Surgical Infections*. A Defense Medical Research and Development Program grant will investigate molecular methods to improve IFI diagnosis.

- Three years of multidrug-resistant organism surveillance data collected from participating military treatment facilities were published in the Armed Forces Health Surveillance Center publication, *Medical Surveillance Monthly Report*.

- TIDOS project findings were presented at multiple scientific conferences including those of the Infectious Diseases Society of America, Surgical Infection Society, Society of Military Orthopedic Surgeons, Military Health System Research Symposium, and US and Canadian Academy of Pathology and produced six publications in peer-reviewed journals.

Acute Respiratory Infections

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 in both deployment and recruit training settings. The gathering of young adults living in close quarters adds to the heightened risk for infection. Novel pathogens, such as the Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and avian influenza strains, also pose significant risk to military populations. The Acute Respiratory Infection Consortium (ARIC), a multi-site, multi-disciplinary clinical research network for the study of ARI, is addressing numerous research objectives related to the diagnosis and etiology, epidemiology and immunology, as well as prevention and treatment of ARI among US military personnel and their beneficiaries.

HIGHLIGHTS

- Rhinovirus identified as a major cause of influenza-like illness among adults, with some requiring hospitalization.

- A new standardized symptom tool (FluPRO) has been developed with NIAID, and is undergoing validation.

- Novel treatments for severe influenza (hyperimmune plasma) are being evaluated.
At the core of the ARIC is the Natural History Study, an observational, longitudinal, cohort study of the epidemiology and clinical characteristics of influenza-like illness. The multi-site network also provides a foundation on which to conduct diagnostic and interventional trials for ARI.

Activities and Accomplishments

- After four seasons, over 1300 adults and children have enrolled in the ARIC Natural History Study.

- Collaborators at the Naval Medical Research Center Unit 6 (NAMRU-6) and the Walter Reed Army Institute of Research (WRAIR) are characterizing the genotype of human rhinovirus and influenza isolates from ARIC Natural History Study participants.

- A protocol supported by MILVAX investigating the effectiveness of self-administration of live-attenuated influenza vaccine completed enrollment in its second season.

- ARIC sites participate in a NIAID-sponsored, multi-site, randomized controlled trial for the treatment of severe influenza with hyperimmune plasma.

Deployment into developing countries poses the most common and well known infectious disease risk for military personnel. The IDCRP has focused on expanding clinical research to this critical area by establishing projects investigating clinical questions prior to deployment, during travel, and upon return to the US. The Travel Related Infectious Disease Risk Assessment, Outcomes, and Prevention (TravMil) network, based at DoD International Travel Clinics at the Naval Medical Center Portsmouth, the Naval Medical Center San Diego, and the Walter Reed National Military Medical Center, is at the core of this research. The project has enrolled over 1500 individual travelers, and is now expanding enrollment to include operational military groups outside the major medical centers.

The Treatment of Traveler’s Diarrhea (TREAT TD) study is a deployment research project directly focusing on field interventions through a randomized, double-blind, controlled trial to evaluate the efficacy of various single-dose regimens for the treatment of acute infectious diarrhea. This multi-site collaboration involving US and United Kingdom (UK) deployed forces brings together investigators from the Naval Medical Research Center; the Naval Medical Research Unit-3 (Cairo, Egypt); the US Army Medical Research Unit-Kenya (Nairobi, Kenya); the Department of Military Medicine; the Royal Centre for Defense Medicine; Birmingham, United Kingdom (UK), Naval Medical Center Portsmouth; and the USU. Findings from this study will be critical to the development of new DoD clinical guidelines for the diagnosis and management of traveler’s diarrhea among deployed military personnel.
Activities and Accomplishments

• TREAT TD site initiation and enrollment is underway at all three clinical sites -- Camp Lemonnier, US Naval Expeditionary Base, Djibouti; British Army Training Unit, Nanyuki, Kenya; and the UK Role 3 Joint Force Hospital, Camp Bastion, Afghanistan.

• The development stage for the TravMil molecular diagnostic self-collected stool card has been completed. The validation protocol has been approved and is underway with investigators at the Naval Medical Research Unit 6, Lima, Peru. It will be followed by full implementation within the TravMil project. The multiplex polymerase chain reaction (PCR) panel includes the most common diarrheal pathogens. The diagnostic strategy will provide the information on pathogen etiology required to advance the TravMil platform for future multisite interventional trials such as vaccine efficacy evaluation.

• Over 1500 persons have enrolled in the TravMil cohort. Twenty-six percent thus far have experienced traveler’s diarrhea, the most common infectious complication described.

Biodefense/Emerging Infectious Diseases

Much of the IDCRP’s scientific program, including work already covered in other areas of this report on respiratory illness, traumatic injury associated drug-resistant organisms, skin and soft tissue/methicillin-resistant Staphylococcus aureus (MRSA) infections, and gonococcal resistance, can be dually categorized as involving both bioterrorism agents and emerging infections research. Because clinical events related to prevention and treatment of potential agents of bioterrorism are rare in the continental US, IDCRP is hoping to build this portion of the portfolio through collaborations with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) in areas with endemic disease caused by such agents. Companion protocols for contingency treatment investigational new drugs will also support refinement of future outbreak responses.

HIGHLIGHTS

• In adult military, primary smallpox vaccinees, antibody titers appear to wane faster than in children based on historical data.

• A Phase II study of a NIAID DNA-based vaccine for Ebola/Marburg viruses was completed in Uganda.

Activities and Accomplishments

• IDCRP is partnering with the US Army Medical Research Institute of Infectious Diseases (USAMRIID) to assess antibody response differences between anthrax vaccinees and those with cutaneous disease in the Republic of Georgia.

• All study visits have been completed for the Ebola/Marburg phase II vaccine trial (IDCRP Ebola/Marburg Vaccines Study) conducted in Uganda in partnership with Makerere University in Kampala, Uganda (MUWRP); the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center (VRC); and the Walter Reed Army Institute of Research (WRAIR) Military HIV Research Program (MHRP). Immunologic analyses and reporting will be completed this year.
Skin and soft tissue infections (SSTI), often caused by methicillin-resistant Staphylococcus aureus (MRSA), lead to significant disease burden among military personnel, frequently adversely affecting operational requirements. Of particular concern is the effect of MRSA-associated SSTI in recruit training settings or close quarters such as shipboard. The IDCRP has emphasized research efforts focused on in-depth epidemiological investigation and interventional field research, testing personal hygiene-based strategies. The research team has continued to build collaborations centered at Fort Benning, Georgia. The team successfully completed a multi-component education and hygiene cluster-randomized trial (with over 30,000 recruits) investigating the effectiveness of chlorhexidine-based body wash against MRSA SSTI among military recruits. The intervention failed to prevent SSTI in this population known to be at high-risk for disease.

The results of the trial emphasize the need for additional research, including studies of disease transmission, host immunology, and microbial factors. Ultimately, knowledge gleaned from these studies will support ongoing translational research such as the development and evaluation of vaccines for MRSA.

Activities and Accomplishments

- The final report for the cluster-randomized trial evaluating strategies to prevent MRSA was completed and presented to collaborators at the Centers for Disease Control and Prevention and to command leadership at Fort Benning, Georgia.

- Enrollment in an observational study to characterize the clinical and molecular epidemiology and estimate the cost burden of MRSA SSTI among recruits is ongoing.

- Molecular characterization of clinical and colonizing S. aureus strains and identification of S. aureus virulence factors affecting recruits at Fort Benning continue and include description of factors of microbial ecology that may influence risk of disease.

- Collaborative partnerships between USU, NMRC, and NIH investigators have been established to lead several immunological studies investigating host susceptibility, as well as humoral and cellular immune responses following S. aureus infection and/or colonization.

HIGHLIGHTS

- In a trial involving over 30,000 recruits, topical chlorhexidine had limited effectiveness in preventing MRSA SSTI.

- Among recruits, cellulitis was the most common clinical diagnosis of SSTI. On average, SSTI cases were diagnosed 45 days after the start of a training cycle.
Since the beginning of the HIV epidemic in the early 1980s, over 10,000 active duty military service members have been diagnosed with HIV. Although the rate of new infections remains low, the continued high rate of non-HIV sexually transmitted infections among active duty troops provides evidence of the ongoing risk and persistence of the threat from this pathogen. The IDCRP HIV research program is focused on the health, longevity, and function of HIV infected active duty and other military beneficiaries as well as prevention of new HIV infections among active duty service members. The centerpiece of this research program is the longstanding US Military HIV Natural History Study (NHS) which has enrolled over 5500 HIV infected active duty and beneficiaries since 1986, collecting data and blood samples in a highly valued repository.

Due to mandatory routine HIV testing, the active duty force is a screened population. As a consequence, the majority of those who become infected are dated seroconverters, having a negative test preceding the positive test. This unique aspect of the military setting allows understanding of early events and the time course of HIV disease. Because our population is also healthy, racially diverse, and educated, with open access to healthcare and medications, we are able to conduct investigations without many confounders that plague other cohort studies, such as drug abuse, non-compliance, and lack of follow-up. Combined, these assets have resulted in hundreds of published manuscripts that have advanced the fields of HIV science and care.

Our research program is focused on current concerns for HIV infected military members, their care providers, and their commanders, including complications such as neurocognitive and kidney diseases, long term antiretroviral medication adherence, and therapy outcomes. Our goals are: understanding, predicting, and preventing adverse consequences of HIV infection; identifying why some with HIV are able naturally to control the infection and progress more slowly than most; evaluating the cost effectiveness of HIV treatment; distinguishing ongoing risk behaviors resulting in

HIGHLIGHTS

- DoD maintains the single largest [HIV] seroconverter population in the US, and contributed data to a report from UN Programme on HIV/AIDS.

- HIV associated neurocognitive disorders are lower in military subjects than in most other cohorts (19% vs 18-73%), but still represent one of the most serious consequences of HIV in this population.

- A new IDCRP/NIAID/Drexel University collaboration was established to study HIV neurocognitive disease, an emerging long-term morbidity from the chronic infection.
acquisition of new sexually transmitted infections; and preventing new HIV infections among active duty.

Activities and Accomplishments

- To update models of decline in CD4 cells, a component of the human immune system, the Joint United Nations Programme on HIV/AIDS (UNAIDS) requested, and we provided, data from our cohort, the largest single seroconverter population in the US. These models are used internationally for care guideline and research purposes.

- In FY2013, the IDCRP HIV program submitted 17 manuscripts, 12 of which have been published/accepted, and five of which are under review. Several more will be submitted before the end of the calendar year. Although travel restrictions limited submissions, 9 of 11 submitted abstracts were accepted and presented at national meetings.

- Among this year’s publications was a report demonstrating a significant proportion (19%) of those studied had evidence of neurocognitive impairment in spite of early HIV diagnosis and treatment. This report highlights the need for ongoing study, particularly of interventions to prevent and treat this serious complication.

- Investigators from the IDCRP entered into a new collaboration with scientists from four NIH Institutes and Drexel University to develop a cohort study of HIV associated neurocognitive impairment (HAND), submitting an NIH grant that was received with enthusiasm and highly scored. This study will provide key insights into the pathogenesis and detection of HAND as well as the foundation for future interventional trials.

- Upon the repeal of, ‘Don’t Ask, Don’t Tell,’ a protocol amendment to assess behavioral risk factors for HIV acquisition was submitted to and approved by the Institutional Review Board. Data collection will begin in late 2013; this information will provide new strategies for educating active duty personnel about prevention of HIV.

HIGHLIGHTS

- IDCRP, supported by the AFHSC/GEIS, is studying GC resistance because of rising β-lactam antibiotic resistance and changing treatment policy for gonorrhea nationwide.

- IDCRP has partnered with AFHSC/GEIS and USU to establish a GC resistance reference laboratory to monitor and better understand the emerging resistance mechanisms.

- IDCRP found 14.5% of male service members were positive for HPV (all serotypes combined) at service entry. Of those that were negative, 34.2% seroconverted ten years later, while still in the military, to one or more HPV serotypes, a higher rate than that of their civilian counterparts.

Given the age and socio-demographics of military personnel, Sexually Transmitted Infections (STIs) prevalence remains higher among military than civilian populations matched on age, race and geographic location. Research interest in STIs and their relevance to the military has grown recently, particularly in light of the emergence of multidrug-resistant Neisseria Gonorrhoeae (GC). The emergence of β-lactam resistance among GC has changed treatment paradigms and led the Centers for Disease Control and Prevention (CDC) to list
this as an urgent threat to the US population. The IDCRP, supported by the Armed Forces Health Surveillance Center (AFHSC) Global Emerging Infection Surveillance and Response System (GEIS), is a leader within the Department of Defense (DoD) in studying GC resistance among symptomatic active duty members at continental US sites. Clinical sites currently involved in IDCRP STI research include Fort Bragg (Fayetteville, NC), Fort Carson (Colorado Springs, CO), Fort Lewis (Tacoma, WA) and Fort Sam Houston (San Antonio, CO). An IDCRP study published in this year’s STI-focused issue of AFHSC’s Medical Surveillance Monthly Report (MSMR, Vol. 20, No. 2, February 2013) showed a high human papillomavirus (HPV) prevalence rate among active duty members at accession (14.5%) as well as a high incidence rate ten years later (34.2%) among those still in the military. This provides potential justification for HPV vaccination among men in the military.

Activities and Accomplishments

- Two Navy installations (Naval Medical Center Portsmouth and Naval Medical Center San Diego) have been funded as additional study sites, leveraging existing IDCRP infrastructure.

- In partnership with Dr. Ann Jerse, IDCRP has established a GEIS-funded, DoD GC resistance reference laboratory and GC isolate research repository at USU.

- Using existing GEIS funded GC resistance study initiatives, USU and laboratories outside the continental US are establishing agreements permitting confirmatory resistance testing and repository storage of GC isolates at the USU reference laboratory.

## Protocols

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<tr>
<th>IDCRP#</th>
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<td>MAMC, NMCP, NMCSD, SAMMC, WRNMMC</td>
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<td>IDCRP-059</td>
<td>Transmission of Seasonal Influenza in four Distinct Regions of Peru</td>
<td>Montgomery</td>
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<td>Anti-Influenza A H1N1 Immune Plasma for Treatment of Influenza A H1N1 2009</td>
<td>Danko</td>
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<td>IDCRP-063</td>
<td>Rifaximin</td>
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<td>IDCRP-064</td>
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<td>IDCRP-065</td>
<td>OCONUS Traveler’s Diarrhea</td>
<td>Riddle</td>
<td>BATUK-Kenya, Camp Bastion-Afghanistan, Camp Lemonnier-Djibouti</td>
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<td>IDCRP-066</td>
<td>Cost Burden of MRSA-SSTI</td>
<td>Morrison</td>
<td>APHC, Ft. Benning, NMCPHC, USU</td>
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<td>IDCRP-068</td>
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<td>IDCRP-070</td>
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<td>Burgess</td>
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<td>IDCRP-071</td>
<td>ABC susceptibility to Colistin</td>
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<td>IDCRP-072</td>
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<td>IDCRP-073</td>
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<td>USU</td>
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<td>SAMMC, WRNMMC</td>
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## Sub-Studies of Protocols

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<thead>
<tr>
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<th>IDCRP Sites</th>
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<td>IDCRP-000-03</td>
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<td>IDCRP-000-04</td>
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### Key

**Active**
Studies enrolling or working toward enrollment or in data collection.

**Fully Enrolled**
Studies no longer enrolling, in analysis and/or manuscript production.

**Closed**
Studies that are recently completed.
RESEARCH
FOCUS AREAS

CLINICAL
RESEARCH SITES

The Program Coordination Center
Walter Reed National Military Medical Center (WRNMMC)

The Walter Reed National Military Medical Center (WRNMMC) is a key clinical site for the IDCRP. The Infectious Disease Service Chief, CAPT Timothy Burgess, is actively involved in IDCRP activities both locally and internationally. Drs. Anuradha Ganesan and Amy Weintrob comprise WRNMMC’s IDCRP Research Principal Investigators (PI) group. Dr. Ganesan is interested in translational research which includes the study of novel therapeutics designed to modulate the chronic immune activation observed in HIV-infected persons and the use of molecular-based diagnostic methods to identify infectious diseases. Dr. Weintrob’s interests include examining the effects of genetic polymorphisms on HIV disease progression and the response to antiretroviral therapy and analyzing the properties of infection and colonization with multidrug-resistant bacteria in healthcare settings. In addition to her role as a PI at WRNMMC, Dr. Weintrob serves as the Deputy Director of the Trauma Infectious Disease Outcomes Study (TIDOS) project that looks at infection-associated clinical outcomes in hospitalized medical evacuees following traumatic injury.

There are a total of 19 WRNMMC IDCRP staff members who work collaboratively with active duty personnel to support protocols spanning a majority of the IDCRP's research agenda including trauma related infection, HIV and other sexually transmitted infections, and respiratory diseases.

The skills, talents, and education of the WRNMMC staff are diverse and wide ranging. The WRNMMC team encompasses Research Assistants, Administrative Support Personnel, Clinical Research Coordinators (CRCs), and Registered Nurse (RN) CRCs.

Naval Medical Center San Diego (NMCSD)

The Naval Medical Center San Diego (NMCSD) is a major military medical treatment facility that provides care to Department of Defense (DoD) beneficiaries and serves as a teaching hospital and research center. The NMCSD supports numerous military populations including the US Navy (USN) Special Forces Units; US Marine Corps (USMC) recruits; USN/USMC flight population; and Pacific Fleet, incorporating US Navy ships and submarines.

IDCRP research is conducted in the Infectious Disease/Travel Clinic at the NMCSD. Study participants are also recruited from local San Diego Branch Clinics and other departments within the NMCSD including the Military Health Center, the Deployment Health Center, the Pediatrics Department, and the Emergency Department.

The NMCSD Research group supports multiple studies in several IDCRP research areas including HIV, acute respiratory diseases, and deployment related infections. In late 2013, the NMCSD group will expand its investigation of sexually transmitted infections (STI) and participate in the IDCRP’s gonorrhea resistance (GC Resistance) study.

In addition to the IDCRP’s site director, Service Chief CDR Vince Barthel, and Fellowship Program Director CAPT Mary Bavaro, the research team at NMCSD comprises 10 IDCRP staff members, including a Site Manager, an Assistant Site Manager, an Administrative Assistant, and 7 CRCs. A new physician from the University of California, Los Angeles, Dr. Robert Deiss, joined the team in the Fall of 2013.
Brooke Army Medical Center (BAMC) is comprised of the San Antonio Military Medical Center (SAMMC), the Center for the Intrepid, the Fort Sam Houston Primary Care Clinic, the McWethy Troop Medical Clinic, the Taylor Burk Clinic at Camp Bullis, the Schertz Medical Home, and the Corpus Christi Occupational Health Clinic. SAMMC is the Department of Defense’s (DoD) largest inpatient medical facility, containing 425 beds, and the DoD’s only US Burn Center and Level I Trauma Center. The San Antonio Military Health System (SAMHS) also includes the Wilford Hall Ambulatory Surgical Center (WHASC), the DoD’s largest outpatient ambulatory surgery center; 19 primary care clinics; and over 100 specialty services.

The SAMMC Infectious Disease Service, led by COL Clinton Murray, has supported the HIV Natural History study for 23 years and continues to serve as one of two major US sites enrolling and following patients in the Trauma Infectious Disease Outcomes Study (TIDOS). This work has generated multiple laboratory studies in collaboration with the BAMC Department of Clinical Investigation. The proximity of SAMMC and the Institute of Surgical Research (ISR) provides the key link for collaboration on the TIDOS protocol.

The site also supports the Acute Respiratory Infection Consortium (ARIC) research, located primarily at the Fort Sam Houston Adolescent and Family Medicine clinics, and the IDCRP’s growing research network for studying Sexually Transmitted Infections (STI) including the Global Emerging Infections Surveillance and Response System (GEIS) funded, gonorrhea resistance (GC Resistance) protocol. A new site physician, Dr. Thomas O’Bryan recently joined the team from the Penn State University College of Medicine in Hershey, Pennsylvania.

The Naval Medical Center Portsmouth (NMCP), Virginia, is the oldest continuously running hospital in the Navy medical system. The NMCP has been actively participating and enrolling subjects in IDCRP protocols since 1998. In July, 2012, CDR Karl Kronmann, who previously served for 3 years as the Officer-in-Charge at Naval Medical Research Center Unit 3 (NAMRU-3) in Ghana, took over leadership of the site. CDR Kronmann’s research interests include vector-borne febrile infections and influenza. He currently serves as the Site Principal Investigator for the ARIC Natural History Study. Rounding out the IDCRP leadership at NMCP are Research Physician, Dr. Tahaniyat Lalani and Site Manager, Rezalina Tant. Dr. Lalani joined the IDCRP in 2008, after completing her residency and fellowship at Duke University Medical Center in Durham, North Carolina. Dr. Lalani is part of the clinical staff at NMCP and serves as the Principal Investigator for the Deployment and Travel Related Infectious Disease Risk Assessment, Outcomes, and Prevention Strategies among Department of Defense Beneficiaries (TravMil) Study. Dr. Lalani’s research interests include travel related infectious diseases, bacteremia and endocarditis. Rezalina Tant joined the IDCRP in 2007. She manages a team comprising CRCS, a Laboratory Research Assistant, and Administrative Support staff.

As the lead site for the TravMil Study, the NMCP team presented preliminary research results this past year at the American Society of Tropical Medicine and Hygiene Conference. The site is currently increasing enrollment among deployed active duty personnel and incorporating clinical trials and effectiveness studies in the TravMil portfolio. The NMCP also continues to enroll patients in several other IDCRP protocols including the ARIC Natural History Study, the Severity Symptom Grading Scale for Influenza Infection (FluPRO) Study, the Influenza A Plasma Treatment Trial, and the HIV Natural History Study.
The Madigan Army Medical Center (MAMC), in Fort Lewis, Washington, joined the IDCRP network in 2010, in the wake of the H1N1 influenza pandemic. Located on Joint Base Lewis-McChord, MAMC comprises a network of Army medical facilities located in Washington and California that serves more than 120,000 active duty service members, their families, and retirees. From its opening in 1944, as a temporary hospital for war wounded, Madigan has grown into a tertiary care medical center providing a wide array of medical services such as general medical and surgical care, patient-centered adult and pediatric primary care, 24-hour emergency room care, specialty clinic care, and behavioral health and wellness services. As the US Army’s second largest medical treatment facility, Madigan is one of only three designated Level II trauma centers in Army Medicine and one of four in the state of Washington. Madigan maintains approximately 240 beds for inpatient care and can expand to accommodate more than 300 inpatients. Outpatients account for nearly one million visits annually.

The IDCRP presence at the site was launched with the opening of the ARIC Natural History examining potential acute respiratory infection therapies. In 2013, a study estimating gonorrhea treatment resistance (GC Resistance) was added at the site. Principal Investigator, Dr. Mary Fairchok, supports the Program’s activities at MAMC along with the site’s Clinical Research Nurse, Cindy Baker, and the CRC, Debra Angell. In October 2013, Susan Chambers, RN, joined the group as Site Manager. Dr. Fairchok has been at MAMC since 1994, as an active duty Army physician until her retirement in 2007. She joined the IDCRP in 2010. She is Board Certified in General Pediatrics and in Pediatric Infectious Disease; her research interests include respiratory viruses, immunizations and staphylococcal disease.

Martin Army Community Hospital (BMACH), serving the combat forces at Fort Benning, Georgia, joined the IDCRP network in 2010. It is led by Site Principal Investigator MAJ Brian Lanier. Natasha Law serves as the Clinical Site Manager/Lead CRC. The research team consists of Arile Hadley, Keisha Kirby, Demond Lyles, and Adam Taylor. Fort Benning has served as the location for a large scale clinical trial assessing hygiene-based prevention measures for skin and soft tissue infections in military trainees. With the assistance of the Defense Medical Research and Development Program and USU, research activities also include epidemiology and immunology of skin and soft tissue infections and treatment effectiveness studies. BMACH provides an excellent platform for further deployment related research efforts.
Womack Army Medical Center (WAMC)

Womack Army Medical Center - Ft. Bragg proudly serves 160,000 beneficiaries, the largest regional population in the Army. It provides care not only to airborne forces, but also to Special Forces and command elements. Currently, it serves as a key site for surveillance of sexually transmitted infections (STI).

Evans Army Community Hospital

Evans Army Community Hospital - Ft. Carson serves a large troop population at Fort Carson, home of the 4th Infantry Division and Special Forces. IDCRP research efforts at this facility currently include STI surveillance.

Landstuhl Regional Medical Center (LRMC)

The Landstuhl Regional Medical Center (LRMC), in historic Landstuhl, Germany, is the initial entry point for many of the casualties from Iraq, Afghanistan, and Africa. It serves as the linchpin for the Trauma Infectious Disease Outcomes Study (TIDOS). Trauma patients who are medically evacuated from Afghanistan (Operation Enduring Freedom) receive treatment at LRMC prior to evacuation to the US for definitive care. The IDCRP personnel on-site, who begin tracking patient specimens and medical procedures, include research coordinators Jean Brooks, RN; Carmen Lopez, RN; and Amber Lane; and microbiology technician Yadira Guerad. The team, headed by Col Brad Lloyd and MAJ Kate Hinkle, routinely interacts with other healthcare personnel involved in the care of patients with combat-related traumatic injuries.
Camp Lemonnier Djibouti

The Treatment Facility at Camp Lemonnier serves as the hub for our diarrhea research with deployed service members. The camp, administered by the US Navy, is located in Djibouti and is the only fixed U.S. medical treatment facility in Africa.

Tripler Army Medical Center (TAMC)

Tripler Army Medical Center (TAMC), in Honolulu, Hawaii, serves as the medical center supporting Pacific operations. It has been involved in the HIV Natural History Study since the late 1990’s. The IDCRP research is supported by Natural History Study Site Principal Investigator, COL Tomas Ferguson. CRC Torri Fuller conducts on-site recruiting, enrolling, and participant follow up for the study in the Infectious Disease Clinic at TAMC. Because of its location, “at the tip of the spear,” in the Pacific region, the TAMC site holds significant potential for conducting other types of deployment-related research including studies of respiratory disease, travel-related illness, and sexually transmitted infections.

British Army Training Unit Kenya (BATUK)

The Program has successfully partnered with coalition medical facilities and their staff to answer solve infectious diseases problems of mutual interest. These notably include the UK Role 3 Joint Task Force Hospital, Camp Bastion, Afghanistan and the British Training Unit (BATUK) in Nanyuki, Kenya, which are participating in our traveler’s diarrhea studies.
Scientific Support

The success of multi-center research depends on both logistical and scientific support from the study coordination office. IDCRP research is sustained by a number of excellent critical support teams encompassing human resources, finance, program management, grant management, scientific review, and regulatory affairs. Also integral to the multi-center study are clinical operations, centralized data management, statistical analysis, and scientific writing. Although a few of these functions are provided by the Henry M. Jackson Foundation (HJF) Headquarters and the National Institute of Allergy and Infectious Diseases (NIAID), the IDCRP has utilized a blended model wherein most of these roles are embedded directly within the IDCRP itself. Most are located at the Program Coordination Center (PCC) in Rockville; some are allocated to our larger clinical trial sites. These critical support functions are often performed unobtrusively, but they provide the foundation that allows the research teams to focus on science.

Elements of Embedded Scientific Support at IDCRP

- finance and contracting
- regulatory affairs
- statistics
- grant management
- clinical operations
- scientific writing
- centralized data management
- scientific review

Data Coordination Center (DCC)

The Data Coordination Center (DCC) is the home of the IDCRP’s SAS and Oracle programmers, data system designers, data managers, and data entry staff. This group provides expertise to principal investigators for the conceptualization, design, collection, management, analysis, and publication of research study data.
For data acquisition and management, the DCC utilizes multiple systems that allow it to receive data in either paper or electronic formats. Our primary system is ClinPlus, a traditional desktop/laptop based electronic data capture (EDC) software; however, this past year we introduced mobile computing capabilities using Mi-Forms software products on tablets. This new system allows the DCC to extend its reach and enroll subjects who may seek treatment at places other than our fixed hospital sites, as well as conduct in-person surveys electronically. The DCC is also able to receive survey data via the Qualtrics online data platform web site and scanned standardized forms via Scantron, a hardcopy data capture device. For data post-acquisition processing and analysis, the DCC’s programmers can produce tables, listings, and figures; create analysis datasets; and analyze data for publication. The tools for completing this work include the SAS, Oracle, R, and SQL programs.

- Over 66,000 paper Case Report Forms (CRFs) were entered in 2013. This represents a downward trend for paper CRFs compared with either FY11 or FY12, and is a result of our successful planned transition to EDC.

- We successfully implemented mobile data acquisition capabilities utilizing Mi-Forms software on tablets at our sites outside the continental United States, and selected Mi-Forms as the standard software used for mobile data collection globally.

- The DCC has successfully attained access to the Medical Health System Data Repository. This will improve our ability to get clinical data from electronic medical records for research studies.

- A key focus of the DCC this year has been on improving study-level data processing, cleaning, creation of datasets, and preparation for analyses.

HIGHLIGHTS

- Successfully launched mobile electronic data collection capabilities utilizing tablets and Mi-Forms, winning an award from Microsoft for IT innovation.

- Expanded use of electronic data capture, which will replace paper CRFs in all future studies.
The IDCRP Regulatory Affairs team consists of staff located at the network’s Military Treatment Facilities and the IDCRP Program Coordination Center (PCC). Program personnel, led by the Head of Regulatory Affairs, perform essential duties including assisting in protocol development; conducting intensive evaluation of Institutional Review Board (IRB) submissions; consulting with investigators during IRB review processes; coordinating with IRB staff to address concerns; performing on-site quality assurance and auditing; tracking study milestones; and maintaining regulatory documents for the program.

The Regulatory Affairs Head, often in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID) Regulatory Compliance and Human Subject’s Protection Branch (RCHSPB), conducts a thorough review of all IDCRP studies to provide the USU Infectious Disease (ID) IRB with high quality submissions and reduces the need for issuance of post-review protocol stipulations. Provisions are made to review, for human subjects considerations, all research protocols and amendments, consent and Health Insurance Portability and Accountability Act (HIPAA) documents, recruiting material, and case report forms.

The RCHSPB personnel serve as monitors for prospective IDCRP protocols that involve greater than minimal risk for subjects. Monitoring ensures the protection of human subjects, validates the integrity of data collection and capture, and verifies compliance with applicable regulatory bodies.
The USU ID IRB

The USU Infectious Disease Institutional Review Board (ID IRB), established in 2008, via a Memorandum of Understanding, created a single review pathway for multi-center ID research and eliminated the need for multiple and repetitive scientific, ethical, and second level reviews at multiple medical treatment facilities.

The ID IRB is composed of representatives of military treatment and research facilities participating in the IDCRP network and members who provide representation and/or advocacy for particular subgroups. With these resources and the unique military perspective behind them, the ID IRB fulfills its duty to safeguard the rights and welfare of human subjects.

The Office of the Under Secretary of Defense for Personnel and Readiness USD(P&R)/Triservice Headquarters Panel (HQ Panel) provides administrative review of ID IRB determinations for research that is Food and Drug Administration (FDA) regulated, greater than minimal risk, or international in scope. Because it involves collaboration between service representatives and the USD(P&R), the HQ Panel eliminates the need for separate reviews by the USD(P&R) and each participating service.

Since its creation, the ID IRB has reviewed over 70 domestic and international research protocols.

All Protocols by IRB Review Type

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<th>Review Type</th>
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<td>Greater Than Minimal Risk</td>
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<tr>
<td>Minimal Risk</td>
<td>47%</td>
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<tr>
<td>Exempt</td>
<td>36%</td>
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Current Institutional Agreements for IRB Review

- Naval Hospital Jacksonville
- US Naval Medical Research Unit #6
- Naval Medical Research Center
- Naval Hospital Camp Lejeune
- Naval Health Research Center
- US Naval Medical Research Unit #3
- Naval Medical Center San Diego
- Naval Medical Center Portsmouth
- Walter Reed National Military Medical Center
- Womack Army Medical Center
- Tripler Army Medical Center
- US Army Institute of Surgical Research
- Wilford Hall Ambulatory Surgical Center
- Dwight D Eisenhower Army Medical Center
- Brooke Army Medical Center
- Landstuhl Regional Medical Center
- Western Regional Medical Command
- US Army Medical Research Institute of Infectious Disease
- Walter Reed Army Institute of Research
A core part of the IDCRP mission is to develop military medical officers, throughout their careers, to become leaders in clinical research. IDCRP promotion of professional development ranges from assisting in the education of medical students, to supporting research collaborations with residents and fellows in graduate medical education, to serving as research mentors for MPH and PhD candidates at USU and elsewhere. During FY 2013, these activities included teaching graduate level courses in clinical trials and biostatistics at USU. The education program relies upon the support of IDCRP’s professional staff at the PCC, with significant help from our National Institute of Allergy and Infectious Diseases (NIAID) partners, and research staff and active duty collaborators throughout the IDCRP network. In order to maximize the likelihood for success of trainee projects, the IDCRP has recently developed a new mentorship paradigm designed specifically for trainees with limited time to do research.

**New Graduate Medical Education (GME) Research Paradigm Highlights**

- The goal is to produce a paper and/or a national conference presentation within a short, focused period.

- The aim of the program is to develop skills in the areas of science concept formulation, team-based research, data analysis and interpretation, manuscript preparation, and oral and poster presentation.

- The paradigm includes a roadmap with specific deliverables and timelines accompanied by a portfolio of appropriate project ideas that leverage ongoing IDCRP studies.

- The paradigm is being reviewed by program leaders at the DoD’s major ID fellowship training sites.

**HIGHLIGHTS**

- IDCRP professional staff members have served as advisors or committee members for dozens of trainees.

- Trainee projects have led to nearly a dozen publications and an equal number of presentations at national conferences.
Fiscal Year 2013 has been a time of uncertainty for organizations that depend on federal funds to accomplish their mission. Fortunately, the IDCRP finds itself comparatively well positioned to weather these challenges, thanks in large measure to our sponsors. Multi-year funding received in FY2013 will sustain several major Program areas through FY2015. Support from the NIAID continues to provide core funding for IDCRP infrastructure, research activities, and new protocol development.

Over the last several years, the IDCRP has made a significant transition in its funding model. Prior to FY2009, the Program was funded only by the NIAID Interagency Agreement. Beginning in FY2009, the IDCRP made a concerted effort to diversify funding sources by engaging sponsors interested in supporting specific protocols or projects. In FY2009, the IDCRP received five funding awards in addition to the NIAID Interagency Agreement. In the four years that followed, through FY2013, the IDCRP has received 53 additional grants and contracts.

The largest IDCRP protocols, by budget, are now supported by multi-year funds. This includes the HIV Natural History Study, the Trauma Infectious Disease Outcomes Study (TIDOS), and the Acute Respiratory Infection Consortium (ARIC) Natural History Study. These long term commitments by our sponsors remain instrumental to the continuation and success of these projects and of the IDCRP as a whole.

Through this period of growth, the IDCRP has realized some efficiencies. Over the last five years, protocol spending has increased from 71% to 77% of Program resources, allowing more and larger projects using a smaller relative share of resources for administration.

Although it is difficult to predict future funding, the IDCRP has cultivated a diversified financial base on which to build a successful future. In the face of funding uncertainty for federally sponsored research, we continue to be flexible and to improve our financial and grants management processes to remain efficient and responsible stewards of the resources provided by our sponsors.
Figure 1 - Distribution of FY13 Expenses

Figure 1 demonstrates the percentage of IDCRP expenditures directly supporting protocol execution. In total, 77% of IDCRP funding is used to support scientific protocols and 23% is used to support Program infrastructure including 10% for central program administration, 5% for site administration, and 7% to support scientific infrastructure which encompasses the Data Coordination Center, Statistics group, and Program Repositories.

Table 3 - IDCRP Year-Over-Year Income (by year of receipt)

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<th>FY08</th>
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<td>DHHS</td>
<td>CDC</td>
<td>$1,991,000</td>
<td>$298,167</td>
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<td>$2,587,335</td>
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<td>DHHS</td>
<td>Total</td>
<td>$10,000,000</td>
<td>$11,991,000</td>
<td>$12,087,950</td>
<td>$14,116,141</td>
<td>$17,000,000</td>
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<tr>
<td>DoD</td>
<td>MILVAX</td>
<td>$440,703</td>
<td>$507,000</td>
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<td>DoD</td>
<td>AFHSC/GEIS</td>
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<td>$500,000</td>
<td>$387,000</td>
<td>$739,000</td>
<td>$651,266</td>
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<td>DoD</td>
<td>MIDRP</td>
<td>$410,000</td>
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<td>DoD</td>
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<td>$45,622</td>
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<td>DoD</td>
<td>DHP</td>
<td>$922,000</td>
<td>$1,009,000</td>
<td>$563,000</td>
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<tr>
<td>DoD</td>
<td>BUMED</td>
<td>$2,525,861</td>
<td>$3,329,140</td>
<td>$6,757,000</td>
<td>$6,444,000</td>
<td>$1,850,000</td>
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<td>DoD</td>
<td>USAMMDA</td>
<td>$97,235</td>
<td>$70,000</td>
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<td>DoD</td>
<td>Total</td>
<td>$10,000,000</td>
<td>$5,271,186</td>
<td>$3,874,762</td>
<td>$8,715,857</td>
<td>$9,435,000</td>
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<td>Annual IDCRP Income</td>
<td>$10,000,000</td>
<td>$17,262,186</td>
<td>$15,962,712</td>
<td>$22,831,998</td>
<td>$26,435,000</td>
<td>$13,490,266</td>
<td>$105,982,162</td>
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Table 3 illustrates the funding history of the IDCRP, by amount, sponsor, and fiscal year. It highlights the diversity of our sponsors and the growing success of the Program in attracting multi-year funding. This trend reached its peak in FY2012. What appears as a dramatic drop in income in FY2013 is, in fact, a reflection of sponsors’ willingness to provide up-front funding for protocols executed over two or three years. Since 2008, the IDCRP has averaged nearly $18 million per year in new funding.
Publications and Presentations


Staff Additional Publications Associated Work


Research Related Presentations

2013 Infectious Diseases Society of America Meeting, San Francisco, California


5. Lalani T, Tribble DR, et al. Neutralizing Activity of Antibodies Following Vaccination with Staphylococcus aureus Recombinant Alpha-Toxoid (rAT) and Recombinant Panton-Valentine Leukocidin Toxoid (rLukS-PV).


United States and Canadian Academy of Pathology 102nd Annual Meeting, Baltimore, Maryland

Downing K, Tribble DR, and Wells J. The Utility of Frozen Section in the Detection of Invasive Fungal Species in Combat-Related Injury.

Surgical Infection Society (SIS) 33rd Annual Meeting, Las Vegas, Nevada


Military Health System Research Symposium, Fort Lauderdale, Florida


Society of Military Orthopaedic Surgeons 55th Annual Meeting, Vail, Colorado


International Workshop on HIV Observational Databases 2013, Cavtat, Croatia

Macalino G. STI Joint Modeling.

American Society of Tropical Medicine and Hygiene 2013, Washington, DC

1. Lalani T, Maguire JD, Fraser J, Johnson MD, Ganesan A, Burgess T, Vancea A, Richesson D, Tribble D, TravMil Study Team. Traveler’s Diarrhea: Epidemiology, Treatment and Outcomes in a Large Prospective Cohort of Department of Defense Beneficiaries.


Department of Defense Resources, NIAID, S. aureus Vaccine Workshop

Overcoming Challenges in S. aureus Vaccine Development. IDCRP-055/-074 Presentation. June 2013.

20th Conference on Retroviruses and Opportunistic Infections, Atlanta, Georgia

1. Yue L, Okulicz J, Agan B, Hunter E, Marconi V. Epitope Escape and Virus Evolution in the HIV-1 Gag Gene from Controllers with Long-Term Non-Progression.

2. Okulicz J, Yue L. Epitope Escape and Virus Evolution in the HIV-1 gag Gene from Controllers with Long Term Non-Progression.

3. Macalino G, Ganesan A. The Increases in Syphilis Cases in the HIV Natural History Study (NHS), a Cohort of HIV-Infected US Department of Defense Beneficiaries is, in Part Attributable to Repeat Infections.

4. Agan B. The VACS Index Predicts Mortality in a Young, Healthy HIV Population Starting HAART.

5. Weintrob A. Whole Genome Sequencing of HIV-Infected African Americans with Rapid Disease Progression or Long Term Non-Progression.

Experimental Biology Meeting, Boston, Massachusetts


AMSSUS-The Society of Federal Health Professionals, Seattle, Washington


Investigator Additional Professional Activities

Committees/Peer Review Panels:

1. Medical Subject Matter Expert, US delegation to the Biomedical Advisory Committee, NATO
2. Consultant to the Army Surgeon for Biodefense

3. Member, Oversight Committee - Military Infectious Disease Research Program/JPC-2 IPT

4. Member, Scientific Board of Advisors - 2013 Biomedical Advanced Research and Development Authority (BARDA)

**Member, Steering Committee:**

1. Department of Defense Global Emerging Infection Surveillance (GEIS) Program Enteric Surveillance

2. Military Infectious Diseases Research Program (MIDRP) Program Area D (Prevention of Diarrheal Diseases)

3. Combat Casualty Care Research Program (CCCRP), Neurotrauma Drug Development Panel

4. Member, Integrated Product Team (IPT)/Product Working Group

5. Military Infectious Disease Research Program (MIDRP) Bacterial Diarrhea Vaccine

6. Military Infectious Disease Research Program (MIDRP) Next Generation Malaria Drug

7. Staphylococcal Vaccine Working Group

**Member, Data and Safety Monitoring Committee (SMC):**

1. Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID) Protocol, 09-0066, Phase 1 Study to Determine the Safety and Efficacy of an Oral ETEC Candidate Vaccine, Attenuated, Recombinant Double Mutant Heat-Labile Toxin (dmLT) from Enterotoxigenic Escherichia coli.

2. DMID Protocol, 12-0023, A Phase 1 Dose Escalating Study of Double Mutant Heat-Labile Toxin LTR192G/L211A (dmLT) from Enterotoxigenic Escherichia coli (ETEC) by Sublingual or Oral Immunization to Determine Safety and Immunogenicity of a Multi-dose Regimen in Adult Humans.

3. USAMMDA Protocol, S-11-23, A Phase I, Randomized, Placebo-Controlled, Observer-blind, Two-dose Primary Vaccination Study of WRAIR Tetravalent Devue Virus Purified Inactivated Vaccine (TDENV-PIV) in Healthy Adults in Puerto Rico.

4. USAMMDA Protocol, S-11-14, A Double-Blind, Randomized, Controlled, Dose Escalation Clinical Trial of an Antiplaque Chewing Gum — a Phase 1 Safety and Tolerability and Phase 2a Safety, Tolerability and Proof of Concept in a Gingivitis Population

5. Dr. Grace Macalino has been appointed Chair of the Steering Committee for the GEIS STI Pillar.

**Clinical Care:**

1. Attending physician, Infectious Diseases Consultation Service; Ward Attending, Internal Medicine Service, Walter Reed National Military Medical Center (WRNMMC)

2. Staff physician, International Travel Clinic, WRNMMC

**Teaching:**

**USU:**

1. Course Director - Epidemiology and Control of Infectious Diseases (PM0514), Malaria Epidemiology and Control (PM0569), Clinical Trial Design and Analysis (PM0996); Dept of Preventive Medicine and Biometrics

2. Lecturer – USU Introduction to Clinical Trials (PM0900), Models of Emerging Infectious Diseases (EID503), Principles and Practices of Tropical Medicine (PM0560), and Travel Medicine (PM0990).

3. Preceptor, MSIII Internal Medicine Clinical Rotation

4. Instructor, MS II Medical Threat Assessment Exercise (MCM 2011)

5. Mentor, Infectious Diseases Fellow research projects

6. USU DrPH thesis committee chair and member; PhD Dissertation Committee, Drexel University

**Other Courses:**

1. Course instructor, USAMRIID Medical Management of Biological Casualties; Navy Military Tropical Medicine Course; WRAIR Tropical Medicine Course; West Virginia University Tropical Medicine Certification Course

2. Invited Lecturer, Armed Forces Radiobiology Research Institute (AFRRI), Bethesda, MD: “Ebola Virus: Using Telemetry to Gain New Insights into a Deadly Disease”

**Reviewer, Peer Reviewed Journal:**

Vaccine, Clinical Infectious Diseases, Pediatric Infectious Disease Journal, Military Medicine, PLoS ONE, BMC Infectious Diseases, American Society of Tropical Medicine and Hygiene

**Other Service:**

1. IRB Member, Walter Reed Army Institute of Research

2. Prospective Medical Student Interviewer, USU

3. Member, USU Preventive Medicine & Biometrics Department Committee for Advancement, Promotion, and Tenure (CAPT)

4. SME Consultation, Touchpoint Analysis Problems (TAPS), MS II Deployment Exercise Simulation

5. Annual Program Review Committee, Clinical Group, American Society of Tropical Medicine and Hygiene
Who we are: The IDCRP is a tri-service Department of Defense clinical research program in infectious diseases facilitated by the Henry M. Jackson Foundation. We are staffed by military, government civilian, and foundation personnel.

What we are: The IDCRP was established as an ongoing collaboration between the National Institute of Allergy and Infectious Diseases (NIAID) and the Uniformed Services University (USU) to answer clinical questions on infectious disease threats that are relevant to the military and the NIAID.

Where we are: The Program Coordination Center is located at USU in Bethesda, Maryland.

IDCRP research personnel are at 10 military medical treatment facilities: WRNMMC (Maryland), NMCP (Virginia), NMCSD (California), SAMMC (Texas), MAMC (Washington), TAMC (Hawaii), WAMC (North Carolina), Martin ACH (Georgia), LRMC (Germany) and Camp Lemonnier (Djibouti). We collaborate with medical staff at Evans ACH (Colorado), Camp Bastion (Afghanistan), BATUK (Kenya) and 9 other military research institutions: NHRC, WRAIR, NMRC, USAMRIID, MUWRP, KEMRI, NAMRU-6, NAMRU-2, and USAISR.

Number of currently active protocols: 51 protocols

How to reach us: Infectious Disease Clinical Research Program
Department of Preventive Medicine and Biometrics
Uniformed Services University
4301 Jones Bridge Road, Building 28
Bethesda, MD 20814

Mailing address:
IDCRP
11300 Rockville Pike, Suite 600
Rockville, MD 20852

Email: idcrp@idcrp.org

Web site: www.idcrp.org

Mission: To conduct infectious disease clinical research of importance to the military through a unique, adaptive, and collaborative network to inform health policy and practice and disseminate findings in peer reviewed literature.

Vision: To substantially reduce the impact of infectious diseases in the military population through collaborative clinical research.
Headquartered within the Department of Preventive Medicine and Biometrics at the Uniformed Services University (USU) in Bethesda, MD, the Infectious Disease Clinical Research Program (IDCRP) manages a worldwide network of Department of Defense (DoD) clinical and research centers that have collaborated to investigate infectious disease challenges facing the military. With a presence at the largest DoD medical centers, the IDCRP conducts research at 18 military medical facilities and collaborates with 12 military research sites across the world. Working in tandem with active duty investigators at each of these sites, the IDCRP has over 100 employees. Participating centers are partners in the IDCRP's network Infectious Disease Institutional Review Board (IRB) at USU. With a central Scientific and IRB review process, the IDCRP is ideally positioned to conduct multi-center research protocols. At present, there are over 51 active protocols in the IDCRP's research portfolio.

Mission: To conduct infectious disease clinical research of importance to the military through a unique, adaptive, and collaborative network to inform health policy and practice and disseminate findings in peer reviewed literature

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