IDCRP

Uniformed Services University

INFECTIOUS DISEASE CLINICAL RESEARCH PROGRAM

2024

ANNUAL REPORT

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Report prepared by
Leigh Carson, Senior Technical Writer/ Editor

LETTER FROM IDCRP LEADERSHIP

As a U.S. military medical school research center, it is our privilege to strive toward eliminating the impact of infectious diseases (ID) amongst the great individuals and organizations within the Department of Defense (DoD). Our objectives are to maximize relevant research, train future ID researchers, and uphold rigorous research stewardship. Our successes derive from the dedicated professionalism of our team members and enduring collaborations with clinical sites, laboratory partners, academia, and stakeholders.

During the past year, we bid "Fair Winds and Following Seas" to our exceptional Deputy Director, CDR Mark Simons, whose professionalism, expertise, and leadership were foundational to many impactful IDCRP contributions spanning the COVID-19 pandemic. We are delighted to welcome another outstanding Navy microbiologist, LCDR Sarah Jenkins, whose attributes, experience, and reputation suggest that she will be up to the challenge of filling CDR Simons' enormous figurative shoes.

In 2024, the Program hosted our 2nd week-long Science Symposium, which was highly successful and attended by ~300 participants including IDCRP personnel, active-duty investigators, collaborators, and stakeholders. MG (ret) Paul Friedrichs, Director of the White House Office of Pandemic Preparedness and Response Policy (OPPR), provided invaluable reflections as he delivered the inaugural Dr. Edmund Tramont Lecture in recognition of Dr. Tramont's lifetime of leadership in the fight against military ID. New to the 2024 symposium was the inclusion of discussion panels designed to focus IDCRP research to impact policy and practice. Topics included reducing sexually-transmitted infections (STIs) among active-duty service members through improved understanding of prevention and care, wartime readiness to lessen the battlefield infection burden, Dengue virus prevention approaches in deployed forces, and clinical trial next steps to mitigate acute respiratory infections (ARI) in active-duty service members.

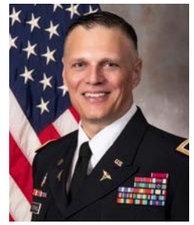
Each research area made substantial contributions to military medicine with 25 manuscripts published or accepted for publication. For example, investigators with expertise in wound infections are working with the University of Colorado and the Walter Reed Army Institute of Research on a study of infections and outcomes among adult civilian battlefield trauma victims in Ukraine. Enrollment in the clinical trial examining the effectiveness of the Bexsero® vaccine in reducing gonorrhea risk was completed and follow-up will occur in 2025; findings will inform guidance recommendations. New initiatives will result in a consensus-driven, evidence-based guideline on indications and interpretation of a travelers' diarrhea diagnostic platform and address gaps in norovirus mitigation in military settings. Findings from the clinical trial on the effectiveness of influenza vaccine formulations may help guide policy decisions regarding optimal vaccine formulations for use in the DoD.

During 2024, IDCRP leadership provided briefings to MG Friedrichs at OPPR and the Assistant Secretary of Defense for Health Affairs, and findings from ARI studies were utilized by the U.S. Food and Drug Administration Vaccines and Related Biological Products Advisory Committee to support vaccine decision making. Findings from the ARI EPICC protocol were also cited in a report to the Congressional Defense Committees and STI clinical trial findings were included in a Department of Health and Human Services guideline. Furthermore, IDCRP leadership continues to be involved with the USU School of Medicine Military Infectious Disease Innovation and Combat Casualty Care hubs. Regarding the IDCRP education mission, 58 trainees participated in IDCRP research projects in 2024 and COL O'Connell also presented at the International Conference of Military Medical Schools on maximizing value in military medical research collaborations.

As we look ahead, the program will leverage existing capabilities as we adjust to changing landscapes. We see opportunities to enhance preparation related to future pandemics and armed conflicts and have identified capability gaps driving impacts of "Military Congregate Setting Infections" in barracks and Navy vessels. Finally, we continue to refine research endpoint expression to influence relevant military outcomes.

Support from USU leadership and the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., as well as our Operational and Executive Steering Committees, remain critical elements for our success. The Program has also received funding and has cooperative partnerships with the Defense Health Program, U.S. Army Medical Materiel Development Activity, Military Infectious Diseases Research Program, Navy Bureau of Medicine and Surgery, and the Armed Forces Health Surveillance Division and Immunization Healthcare Division of the Defense Health Agency.

We thank our clinical research and support staff, and our active-duty and civilian investigator partners for their long-standing commitment to achieving the IDCRP's mission and recognize the service members and beneficiaries who participate in our studies. It is an honor to work alongside this excellent team.



Robert O'Connell, MD
Colonel, Medical Corps, U.S. Army
Director, IDCRP

Sarah A. Jenkins, PhD
Lieutenant Commander, Medical Service Corps, U.S. Navy
Deputy Director, IDCRP

David R. Tribble, MD, DrPH
Science Director, IDCRP

Core values: Compassion and Caring, Ethics and Integrity, Excellence in Scholarship, Innovation, and Selfless Service

Success Is Defined By: 1) Informing military health policy and practice through translation of research findings; 2) Publications and presentations within impactful and relevant peer-reviewed journals/forums; 3) Capability to respond to emergent infection threats and/or high-priority research initiatives; and 4) Key stakeholder satisfaction, including fostering the education of U.S. Armed Forces clinical infectious disease researchers

ABOUT IDCRP

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), Department of Preventive Medicine and Biostatistics, and the National Institute of Allergy and Infectious Diseases (NIAID) and through a cooperative agreement with The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF). The Program's work is executed through a unique, adaptive and collaborative, international clinical research network. This network directly benefits 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 the 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.

PROGRAM ORGANIZATION

Executive Steering Committee

Vice President for Research, USU (Chair)
Dean, School of Medicine, USU
Director, Division of Clinical Research (DCR), NIAID / National Institutes of Health
Director, Research and Development for Health Readiness Policy and Oversight, Defense Health Agency (DHA)
Director, Research & Engineering Directorate, DHA

Operational Steering Committee

Surgeons General Infectious Disease Consultants—Army, Navy, Air Force
Director, Global Emerging Infections Surveillance, Armed Forces Health Surveillance Division
Director, DHA Military Infectious Diseases
Chief, Collaborative Clinical Research Branch, DCR, NIAID
Chair, Department of Preventive Medicine and Biostatistics, USU
Veterans Affairs Representative (non-voting)
HJF Director of USU Operations (non-voting)

Program Coordination Center

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

NIAID Liaison
Chair, Scientific Review Board

Deputy Program Director
Director, Center Operations
- Chief, Data Operations
- Head, Regulatory Affairs and Quality Management
- Head, Clinical Research Management
- Head, Site Operations
- Head, Finance and Program Management
- Head, Repository and Laboratory Operations

Partner Organizations

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

VISION

To eliminate the impact of infectious diseases in the military population through collaborative clinical research.

MISSION

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

IDCRP RESEARCH AREAS

- **Acute Respiratory Infections (ARI)**— Strategic aims focus on high-priority respiratory pathogens with regard to enhancing detection in military populations, characterizing epidemiology and acute-to-chronic outcomes, predicting risk of severe outcomes and complications, and improving treatment and prevention strategies to reduce morbidity, mortality, and operational readiness loss.

- **Deployment and Travel-Related Infections**—Strategic aims focus on the evaluation of risk and operational impact of deployment and travel-related infectious threats for military personnel, effectiveness of current mitigation strategies, evaluation of knowledge of infectious disease threats and prevention methods, assessment of diagnostic test platforms and patient-reported outcomes, evaluation of novel preventive and treatment strategies for travelers' diarrhea, and assessment of the impact of emerging infectious diseases on U.S. military readiness.

- **Human Immunodeficiency Virus (HIV) and Sexually-Transmitted Infections (STI)**— Strategic aims focus on characterizing the epidemiology and chronic clinical outcomes of priority STIs in U.S. military personnel and beneficiaries, developing and evaluating mitigation strategies related to STI clinical outcomes, supporting development of biomedical countermeasures against STIs in military populations, evaluating care practices and costs related to priority STIs to identify gaps, and assessing novel treatment and prevention strategies for STIs (including HIV) in military populations to inform military policy and practice.

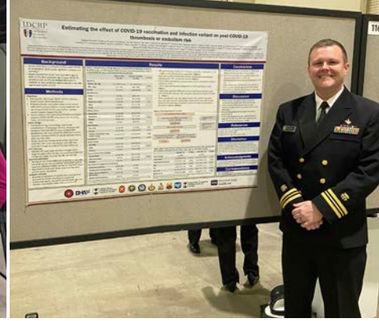
- **Wound Infections**—Strategic aims focus on addressing knowledge gaps in infection prevention, clinical management, microbiologic factors, and treatment outcomes in battlefield trauma infections and community-acquired skin and soft-tissue infections, particularly *Staphylococcus aureus*-related, to inform effective treatment strategies and preventive countermeasures, as well as the evaluation of Military Health System antibiotic stewardship programs to support process improvements.

Each area's 2024 accomplishments are presented in the following pages, along with information and projections for 2025.

ACUTE RESPIRATORY INFECTIONS (ARI)

The ARI Research Area Day of the 2024 IDCRP Science Symposium

CDR Mark Simons and Kat Schmidt of the ARI IDCRP team and Dr. Richard Agans and Monica Christian of U.S. Air Force School of Aerospace Medicine at the 2024 ASM Microbe meeting



LCDR Andrew O'Carroll at the 2024 AMSUS Meeting

Rates of acute respiratory infections (ARIs) and associated outbreaks among military personnel and their beneficiaries can result in substantial morbidity, as well as decreased operational readiness from reduced job performance and lost training days.

Simon Pollett, MBBS, IDCRP Associate Science Director and ARI Research Area Director

Rhonda Colombo, MD, MHS, ARI Research Area Deputy Director

The overarching aim of the ARI Research Area is to improve the detection, prediction, treatment, and prevention of high-priority respiratory pathogens (e.g., SARS-CoV-2, influenza, and adenovirus), as well as emerging respiratory threats, to maintain Force Health Protection.

Led by Dr. Rhonda Colombo, the Epidemiology and Prevention of ARIs at the U.S. Naval Academy (ARIA) study characterizes the epidemiology of respiratory viruses causing medically-attended ARIs in this training environment using enhanced virologic testing of residual clinical swabs combined with clinical data. During 2024, analyses examined risk factors associated with training time lost due to ARIs (e.g., infecting pathogens and coinfections), and explored ARI incidence and characteristics during specific training periods (e.g., Plebe Summer). Analysis is underway to provide clinical context to wastewater surveillance sequencing efforts being conducted at the U.S. Naval Academy by collaborators. In addition, comprehensive analyses of influenza cases examined whether partial influenza vaccine mismatch contributed to an influenza outbreak. Advanced machine learning approaches to more precisely define ARI symptom patterns are underway.

To inform recommendations for influenza vaccinations within the Military Health System (MHS), the open-label, randomized Pragmatic Assessment of Influenza Vaccine Effectiveness in the DoD (PAIVED) clinical trial evaluated the relative effectiveness of three licensed inactivated influenza vaccine formulations (i.e., egg-based, cell-culture-based, and recombinant) across four influenza seasons. Led by CAPT (retired) Timothy Burgess, data collected through PAIVED are being used to characterize influenza-like-illness in MHS beneficiaries with a focus on patient-reported outcomes, including risk factors for severe symptoms (e.g., smoking and obesity). In-depth comparison of influenza-like-illness experiences in healthcare workers versus non-healthcare workers was completed. Serum from participants in the PAIVED immunogenicity substudy were used to compare neuraminidase inhibiting antibody responses elicited by egg and cell-derived influenza vaccines.

Led by Dr. Simon Pollett, the Epidemiology, Immunology and Clinical Characteristics of Emerging Infectious Diseases with Pandemic Potential (EPICC) study is an observational cohort study of SARS-CoV-2 infections in active-duty service members and MHS beneficiaries. During 2024, an online survey was implemented with questions related to perceptions about MHS beneficiaries seeking ARI diagnostic testing and healthcare. Assessment of the contribution of SARS-CoV-2 T-cell specificity to acute severe COVID-19 was completed, and findings may support next-generation COVID-19 vaccines with increased T-cell specificity. Characterization of Long COVID has been a major focus with analyses on the impact of SARS-CoV-2 on sleep, herpes-zoster risk, and ocular health. In collaboration with the Department of Veterans Affairs (VA), risk factors for Long COVID are being compared in a DoD/VA cross-cohort analysis. Predictors of acute COVID-19 severity (e.g., type 2 diabetes), and proteomic, autoimmune, and transcriptomic markers of acute SARS-CoV-2 myocarditis were assessed. Findings from EPICC also contributed to an international study validating use of lung ultrasound for COVID-19 prognostication.

The Prospective Assessment of SARS-CoV-2 Seroconversion (PASS) study is using multiplex respiratory serology platforms to estimate rates susceptible individuals become infected over time during pandemic and post-pandemic periods for multiple respiratory viruses, including influenza and respiratory syncytial virus (RSV). PASS is also analyzing symptom pattern changes per COVID-19 infections and vaccinations and assessing immunogenicity with B-cell repertoire findings potentially identifying new pan-SARS-CoV-2 therapeutic monoclonal antibodies.

The Military COVID-19 Registry Analysis Project (M-RAP), led by Dr. David Tribble, refined evidence-based surveillance for COVID-19 diagnoses among active-duty personnel using electronic medical records, creating a framework that can be applied to other respiratory pathogens. COVID-19 incidence rates over a 30-month period have been compared to regional incidence trends, demonstrating how MHS data can augment national surveillance. Current analyses are examining specific post-COVID-19 neurological complications and the impact of the pandemic on healthcare utilization. A new protocol activated in 2024 is the ARI Repository Protocol, which is compiling specimens and clinical cohort data across multiple IDCRP ARI-related protocols. The repository will enable future respiratory virus pandemic research response (e.g., rapid diagnostic design).

For 2025, a new observational pandemic contingency protocol is being developed that can be tailored to various new ARI pandemics once activated. A follow-on study to the PASS protocol, with a broader pathogen focus to identify infection-resilient hosts, is also planned. A new EPICC follow-up questionnaire will examine the impact of COVID-19 on military travel, association between repeat infections and Long COVID risk, and participant perceptions on receiving MHS care for Long COVID. The EPICC study will collect existing fitness test data from active-duty participants to identify predictors of fitness loss after SARS-CoV-2 infection. Long COVID-19 biomarker analyses will continue to examine associations with clinical outcomes, with possible utility for Long COVID risk prediction and therapeutic development.

MILITARY IMPACT

Findings from EPICC, PASS, and M-RAP continue to offer insights into the detection, prediction, treatment, prevention, and functional illness outcomes of COVID-19, as well as other ARIs. Epidemiologic and surveillance findings from ARIA, including phenotypic and phylogeny data for an influenza A/H3N2 outbreak at the U.S. Naval Academy in 2024, were shared with leadership at the Naval Health Clinic Annapolis and the Armed Forces Health Surveillance Division (AFHSD). A report to the Congressional Defense Committees on Long COVID cited findings from EPICC. Moreover, data from ARIA on influenza strains were provided to the U.S. Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) to support decision making. Immunological findings from EPICC and PASS were also provided to the FDA VRBPAC to support vaccine booster decision-making and immunologic findings from EPICC were used to validate animal models to support future COVID-19 vaccine selection methodology. Findings from PAIVED may help guide policy decisions regarding ideal vaccine formulations for use in the DoD to support Force Health Protection.

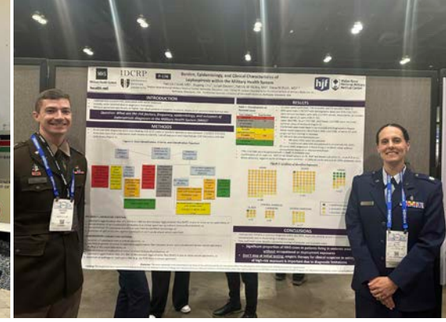
HIGHLIGHTS/KEY FINDINGS

- **Findings from EPICC related to Long COVID phenotypes, cardiorespiratory health, pulmonary function, and cognitive assessment were cited in the 2023 U.S. DoD Report to the Congressional Defense Committees on *The Effects of Long COVID on the Readiness and Retention of Servicemembers*.**
- **Assessment of self-collected nasal swabs previously used for SARS-CoV-2 rapid antigen testing through ARIA identified various genotypes of SARS-CoV-2, adenovirus, influenza, and RSV; these findings provide evidence that use of multiplex molecular sequencing and genotyping of respiratory pathogens from residual swabs have utility to support surveillance efforts at MHS training and clinical sites.**
- **Three symptom-based clusters related to post-COVID-19 conditions were identified and elevation of early post-infection biomarkers were associated with fatigue/difficulty thinking and sensory symptoms.**

DEPLOYMENT AND TRAVEL-RELATED INFECTIONS

The Deployment and Travel-Related Infections Research Area Day of the 2024 IDCRP Science Symposium

Treat TD 2.0 clinical trial investigative team members at Nyati Barracks Medical Center, Kenya



LT Patrick Graf with his mentor, Lt Col Dana Blyth, at the 2024 IDSA IDWeek

U.S. military personnel deployed overseas in support of combat operations, humanitarian service, and training exercises, as well as military recruits at training facilities within the United States, are at risk of developing infectious diseases. Along with posing a threat to the health of service members and recruits, these infections also impact operational readiness and Force Health Protection.

Tahaniyat Lalani, MBBS, MHS, Deployment and Travel-Related Infections Research Area Director

Enhancing infectious disease preparedness of U.S. Armed Services prior to and during deployment for prevalent and re-emerging infectious disease threats (e.g., bacterial diarrhea, norovirus, and arboviruses) classified as priorities of the Military Health System (MHS) remains the core mission of the Deployment and Travel-Related Infections Research Area.

As acute diarrheal disease is common among deployed service members and has a considerable impact on operational readiness, a major focus of the research area is on clinical trials assessing interventions to mitigate travelers' diarrhea (TD) and inform clinical practice guidelines (CPGs) for use in the deployed setting. Led by Dr. David Tribble, two clinical trials are underway, both in collaboration with the United Kingdom Ministry of Defence. As a continuation of the Trial Evaluating Ambulatory Therapy of TD (TrEAT TD) clinical trial, which demonstrated that a single high dose (1,650 mg) of rifaximin was effective for treating acute watery diarrhea, the TrEAT TD 2.0 clinical trial is assessing the efficacy of rifaximin at a lower dose (550 mg) for treating moderate/severe acute watery diarrhea compared to azithromycin (both with adjunct loperamide). The P2 clinical trial is a randomized placebo-controlled trial to assess the effectiveness of enterotoxigenic *Escherichia coli* passive immunoprophylaxis (Travelan®) for maintaining gut health of personnel during short travel or deployments (e.g., 10-20 days). Presently, enrollment is 50% completed for TrEAT TD 2.0 and 90% for P2. As enrollment for both clinical trials have been slower than expected due to cancellation of deployments or planned exercises and low TD rates in deployers, the enrollment periods have been extended. To bolster enrollment in TrEAT TD 2.0, expanding enrollment to include military exercises in the Indo-Pacific Command and Africa Command regions is being discussed.

Multiple surveillance studies are underway at overseas locations to examine the risk of emerging or re-emerging infectious disease threats and to further the understanding of how these infectious diseases affect the health of service members and operational readiness. Developed in collaboration with Preventive Medicine investigators of the III Marine Expeditionary Force, the Deployment Infection Threat Assessment and Outcomes Survey among U.S. Marines (MARSID) study is examining survey responses provided by U.S. Marines returning from military exercises in the Indo-Pacific Command region to estimate the incidence, trends, and operational impact of infectious diseases. During 2024, syndromic surveillance of U.S. Marines participating in an annual exercise with the Armed Forces of the Philippines (i.e., Balikatan Exercise) was completed. In addition, a new protocol, the Enhanced Infectious Disease Surveillance for U.S. Military Operations (MilOpsID) study, received USU Institutional Review Board approval and military exercises in different Combatant Command regions are being targeted for surveillance in 2025. The Leptospirosis in Jungle Warfare Training Environments (Leptospirosis JWT) study, which is being conducted to examine the military impact of leptospirosis in personnel undergoing jungle warfare training, enrolled >350 participants during the past year at training sites in Okinawa (Japan) and Hawaii. In collaboration with the Naval Medical Research Command, Hawaii Department of Health, and U.S. Army Public Health Command-Pacific, Camp Zama (Japan), paired sera and environmental samples are being assessed to identify pathogenic *Leptospira* species. Leptospirosis in high-risk deployed service members is also being examined through the Deployment and Travel-Related Infectious Disease Risk Assessment, Outcomes, and Prevention Strategies among DoD Beneficiaries (TravMil) study.

For the coming year, two new initiatives will address important gaps in Force Health Protection and inform consensus-driven, evidence-based CPGs. The first will address the lack of guidance related to use of culture-independent diagnostic platforms for TD by conducting a systematic review of assay performance characteristics, focusing primarily on the BioFire® Gastrointestinal Panel Assay, with the findings being used to design a prospective case-control study for use in operational settings. The second initiative will address the lack of effective norovirus countermeasures by conducting a landscape review to develop a technical report identifying gaps and prioritizing potential countermeasures for review by a panel of subject-matter experts and DoD stakeholders. Enrollment and follow-up in the TrEAT TD 2.0 and P2 clinical trials will also be completed. For the MARSID study, as survey response rates during the Balikatan Exercise was low, investigators are working to improve awareness of MARSID and MilOpsID for future exercises.

MILITARY IMPACT

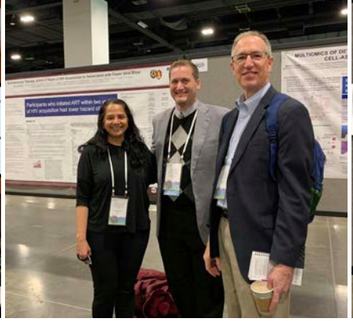
Identifying effective interventions to mitigate TD and develop evidence-based CPGs are priority goals of the research area. If TrEAT TD 2.0 determines that a lower dose of rifaximin is effective at treating TD, those findings will inform an update of the DoD CPG for the management of acute watery diarrhea in the deployed setting. Likewise, if Travelan® is found to be effective at maintaining gut health of deployed personnel, these findings may also be used to support development of a DoD CPG for prevention of TD. Leptospirosis findings through the TravMil and Leptospirosis JWT studies will inform guidelines regarding chemoprophylaxis against leptospirosis in high-risk groups. Findings from MARSID are supporting infectious disease threat assessment reports for dissemination to unit leadership and Combatant Commands. Drs. Lalani and Tribble continue to serve on the Global Emerging Infection Surveillance (GEIS) Enterics Steering Committee, offering feedback on the GEIS Enterics Roadmap and proposals. Assessment of provider-knowledge and prescription practice patterns for pre-travel/deployment healthcare also continue to be a focus for the research area. Lastly, translational research efforts are evaluating culture-independent diagnostics for diarrheal pathogen detection and assessing the influence of travel, antibiotic use, and diarrheal disease on the gut microbiome and resistome.

HIGHLIGHTS/KEY FINDINGS

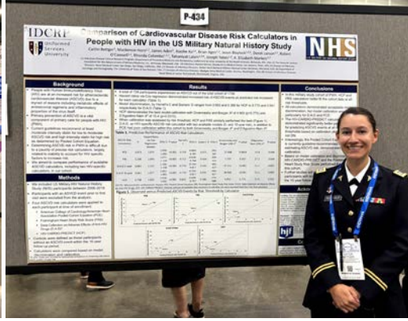
- **Using fecal samples collected through the TrEAT TD and Prevent TD clinical trials, the impact of antibiotics used for TD prophylaxis or treatment on the gut microbiome was examined. Overall, there was no significant worsening of gut microbiome diversity or increase in the carriage of antibiotic resistance genes, underscoring that these antibiotics can be effectively used with low risk of impact on the microbiome and resistome.**
- **Assessment of a Shiga toxin-producing *Escherichia coli* (STEC) outbreak at a U.S. Marine Corps Recruit Depot found that STEC infections in young adults who recover from acute illness were not associated with a higher likelihood of post-infectious sequelae.**
- **Between 2014 and 2018, 195 Chikungunya cases were identified in MHS beneficiaries and 32% had a rheumatic diagnosis after infection; however, no independent predictors of rheumatoid complications could be identified.**

HUMAN IMMUNODEFICIENCY VIRUS (HIV) AND SEXUALLY-TRANSMITTED INFECTIONS (STI)

The HIV/STI Research Area Day of the 2024 IDCRP Science Symposium



From left, Dr. Anuradha Ganesan, Dr. Trevor Crowell, and Dr. Brian Agan at the 2024 CROI Conference



MAJ Caitlin Bettger presenting at the 2024 IDSA IDWeek

Early diagnosis and rapid viral suppression have been accomplished for active-duty service members (ADSM) with HIV within the Military Health System (MHS). Nevertheless, the development of non-AIDS complications (e.g., neurocognitive impairment) remains a challenge. As rates of sexually-transmitted infections (STIs) are high among ADSMs, further assessment of effective countermeasures are needed.

Brian Agan, MD, Deputy Science Director and HIV/STI Research Area Director

With the goal to eliminate the occurrence and prevent adverse effects of STIs among ADSMs and MHS beneficiaries, the HIV/STI Research Area conducts research to characterize high-priority STIs, support development of STI biomedical countermeasures, assess care practice patterns and utilization, and evaluate STI prevention and treatment strategies to inform military policy.

In support of identifying effective STI countermeasures, a Phase II randomized, placebo-controlled, observer-blinded clinical trial of the group B Meningococcal (Bexerso®) Vaccine for Gonococcal Infection (MAGI Trial) is evaluating the effectiveness of the Bexsero® vaccine as a potential prevention strategy against *Neisseria gonorrhoeae* (gonococcus, GC) in high-risk populations. Led in the DoD by COL Eric Garges, this trial, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) Division of Microbiology and Infectious Diseases, is a collaboration including the University of Alabama at Birmingham and GlaxoSmithKline plc, and findings will help to inform clinical practice in the MHS. During 2024, enrollment was completed at Walter Reed National Military Medical Center, two sites in Thailand associated with the U.S. Military HIV Research Program, and the civilian academic sites, and one-year follow-up is targeted for completion in 2025. Collaborative efforts with multiple USU departments to support the pre-clinical evaluation of a combined GC/*Chlamydia trachomatis* (CT) vaccine also continued.

Led by Dr. Brian Agan, with longstanding support from the NIAID Division of Clinical Research, the U.S. Military HIV Natural History Study (NHS) has collected clinical data and blood specimens from >6,500 HIV+ ADSMs and MHS beneficiaries. During 2024, following on from the assessment of cardiovascular disease genetics in collaboration with the University of California San Francisco (UCSF) and Emory University, the association of acquired DNA mutations with risk of cardiovascular disease was assessed (UCSF and Vanderbilt University collaboration). Specimens from HIV NHS are also being used to examine the HIV reservoir. As part of a collaboration with the NIAID Vaccine Research Center, as well as the U.S. Military HIV Research Program, the initial screening of broadly neutralizing antibody responses among HIV NHS participants was completed with comprehensive characterization planned for 2025. Specimens and data were also shared with collaborators at the University of Minnesota (UMN) to validate results of their losartan clinical trial.

Through collaboration with the Department of Veterans Affairs (VA) Veterans Aging Cohort Study, a new study to evaluate quality and costs of DoD and VA HIV healthcare was funded and has been initiated. Furthermore, a new DoD-VA overlap cohort protocol (HIV-PROLONG) has been developed and is undergoing regulatory review. The goal of the retrospective HIV-PROLONG study is to further characterize HIV-associated comorbidities, long-term treatment outcomes, immune responses, co-infections, STIs, healthcare utilization, and quality of healthcare to support HIV cure.

With recent judicial rulings and interim guidance opening a pathway for individuals with well-controlled HIV to potentially join the military, understanding the impact of HIV-associated neurocognitive disorders (HAND) is a priority. Through the ALLHANDS study, led by Dr. Agan, the functional consequences of HAND among people with HIV (PWH), including ADSMs, in high-demand military settings are being assessed. Presently, HAND biotypes are being examined in collaboration with the National Institute of Neurological Disorders and Stroke, National Institute of Mental Health, and five other institutes through the National Institutes of Health.

During 2024, revisions to the GC Resistance Study to expand surveillance efforts and clinical outcome evaluations to include CT and *Mycoplasma genitalium* was approved. Led by CDR Mark Simons, the revised protocol also includes assessment of antimicrobial resistance (AMR) and the impact of high-priority STIs on operational readiness and patient-reported outcomes. Moreover, the USU GC Reference Laboratory and Repository, led by Dr Ann Jerse (USU) and coordinated by the IDCRP (funded by DoD Global Emerging Infections Surveillance [GEIS] program), continued to examine AMR among surveillance GC isolates received from overseas military sites (e.g., Kenya and Republic of Georgia) and identified resistance levels that warrant ongoing monitoring.

For 2025, a new study will assess the reactogenicity of the recombinant zoster vaccine (RZV, Shingrix®) among PWH <50 years of age. Funded by the Defense Health Agency (DHA) Immunization Healthcare Division, the findings will identify potential vaccine safety concerns and support DoD clinical practice in response to recommendations by the Advisory Committee on Immunization Practices. A new study in collaboration with UMN is also being developed to use HIV NHS specimens to study deficiencies in the hepatitis B vaccine response among PWH.

MILITARY IMPACT

Initiatives through the HIV/STI Research Area remain responsive to clinical HIV and STI-related research priorities of the DHA, including GEIS, the Tri-Service Infectious Diseases Working Group, and DHA Military Infectious Diseases. With the Virginia judicial decision that individuals with well-treated HIV should be allowed to join the military, information was provided to the Office of the Assistant Secretary of Defense for Health Affairs to inform a re-evaluation of DoD HIV policies. Findings from the MAGI clinical trial of the Bexsero® vaccine to reduce GC risk, as well as the forthcoming evaluation of the RZV vaccine, may also be used to inform military practice. Findings from HIV NHS have addressed DHA research priorities related to ADSM HIV care, treatment, and outcomes, and ALLHANDS findings on the impact and predictors of HAND among ADSMs with HIV may inform military policy. Surveillance and AMR findings from the GC Resistance Study and the GC Repository continue to be provided to GEIS to inform operational planning and COL Garges serves on the GEIS AMR Working Group.

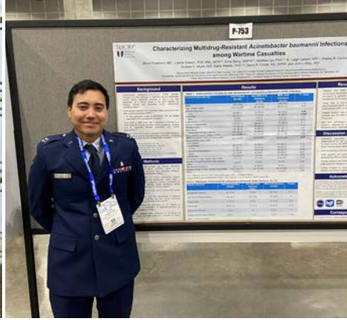
HIGHLIGHTS/KEY FINDINGS

- **The 2024 update to the Department of Health and Human Services *Guidelines for Use of Antiretroviral Agents in Adults and Adolescents with HIV* cited Dr. Anuradha Ganesan's IDCRP study (*J Infect Dis. 2011; 203: 756-64*) to support the new recommendations for statin therapy among PWH.**
- **In an ALLHANDS longitudinal study of PWH and matched controls, the progression of gray matter atrophy was significantly higher among PWH, suggesting that ongoing neurological damage may occur even in those with virologically-controlled HIV.**
- **Among 2,528 participants in the HIV NHS followed for a median of 11 years, 17% had documented serious non-AIDs events, which were associated with occurrence of low-level viremia (LLV); LLV was also associated with virologic failure compared to virologic suppression.**

WOUND INFECTIONS

The Wound Infections Research Area Day of the 2024 IDCRP Science Symposium

Dr. David Tribble and LCDR Sara Robinson with Dr. David Blake at the 2024 Annual Surgical Infection Society meeting



Capt Stone Frankford presenting at the 2024 IDSA IDWeek

Infections complicating battlefield trauma, particularly those with multidrug-resistant (MDR) and novel pathogens, adversely impact the health and recovery of wounded warriors. Community-associated skin and soft-tissue infections (SSTIs) also impose a high burden on the health of military personnel living in close quarters (e.g., recruits), as well as affecting frontline readiness through lost duty and/or training days.

Katrin Mende, PhD, Wound Infections Research Area Director

The overarching aim of the Wound Infections Research Area is to mitigate the infection burden among military personnel by supporting improvements in evidence-based clinical practice guidelines (CPGs) and identifying effective prevention and treatment strategies for battlefield-related wound infections and community-associated SSTIs.

Through the Trauma Infectious Disease Outcomes Study (TIDOS), led by Dr. David Tribble, recently completed analyses examined outcomes with penetrating and closed cranial injuries and burns, as well as evaluated the performance of a real-time commercial Mucorales assay to support trauma-related fungal infection diagnosis. A TIDOS follow-up cohort collected infection-related data after the initial hospitalization, and in collaboration with Dr. Jay McDonald of the Veterans Affairs St. Louis Health Care System, characterization of long-term impacts of battlefield trauma and trauma-related infections is underway, to include opioid use and post-traumatic stress disorder. Led by Dr. Katrin Mende, and in collaboration with multiple DoD laboratories, wound microbiology has been assessed through the TIDOS MDR and Other Virulent Organisms (MDR/VO) Trauma Infections Initiative. Current analyses are assessing the epidemiology and resistance characteristics of wound infections with *Acinetobacter baumannii* and *Staphylococcus aureus*.

Other TIDOS initiatives are focused on supporting the refinement and development of evidence-based CPGs and wartime preparedness. In collaboration with the University of Minnesota (UMN) and University of Michigan Medicine, data from military and civilian trauma patients are being utilized to assess outcomes with different post-trauma prophylactic strategies and examine the effectiveness of antimicrobial treatment of extremity wound infections. Findings from these analyses, with a systematic review conducted by the UMN Evidence-Based Practice Center, will provide an evidence base for use by a consensus panel to refine existing and develop new Joint Trauma System (JTS) CPGs for the prevention and treatment of battlefield-related wound infections.

In collaboration with the U.S. Army Institute of Surgical Research (USAISR) and U.S. Army's Telemedicine and Advanced Technology Research Center (TATRC), machine learning algorithms are being developed to support a clinical decision support tool to aid infection risk stratification of combat casualties in the prehospital setting, particularly with prolonged field care, and offer diagnostic support with enhanced precision following hospital admission. A Wartime Infection, Control and Prevention Knowledge, Attitudes, and Practices (KAP) Survey is being developed to identify areas where additional training and education of frontline providers may be needed regarding the management of infectious diseases during deployment. Through another initiative, technical recommendations and scientific/regulatory frameworks are being developed to inform a next-generation JTS DoD Trauma Registry Infectious Disease (ID) Module and Wartime Specimen and Isolate Repositories. 'On-the-shelf' clinical trial protocols for activation during future conflicts to examine the effectiveness of battlefield wound infection prevention and management strategies and products are being developed in collaboration with the George Washington University Biostatistics Center. Discussions are underway with the JTS and other stakeholders regarding potential research questions and interventions for assessment with the protocols.

Community-associated SSTIs, generally *S. aureus*, have been examined in congregate military populations through multiple IDCRP protocols and pooling the data and specimens from those protocols into the new SSTI Repository Protocol is nearing completion. Analysis of data in the repository, combined with a systematic review, will identify evidence gaps related to the prevention of community-associated SSTIs and inform potential prevention strategies and/or products for future prospective evaluation. During 2024, analyses were completed for the DoD Antimicrobial Stewardship Program (ASP) Study, which is the first IDCRP protocol to conduct an enterprise-wide framework analysis of the structure and outcomes of DoD ASPs within the Military Health System (MHS) in relation to the Centers for Disease Control and Prevention (CDC) Core Elements and compare the findings against national hospital results.

For 2025, collaborative initiatives designed to address gaps in combat casualty care will remain priorities. Building on the foundation of TIDOS, and in collaboration with the JTS, a new Military Trauma Infections – Southwest Asia Conflicts Cohort protocol is being developed to expand data collection for the full period of the wars in Iraq and Afghanistan and to include recent conflicts (2001-2023), which will allow examination of outcomes with different polytraumatic injury patterns, operational theaters, wound microbiology, and time periods (e.g., practice pattern changes). Comparative analyses of combat casualty data in collaboration with the United Kingdom Ministry of Defence and data collection through the Wartime Infection, Control and Prevention KAP Survey are also expected to occur in the coming year.

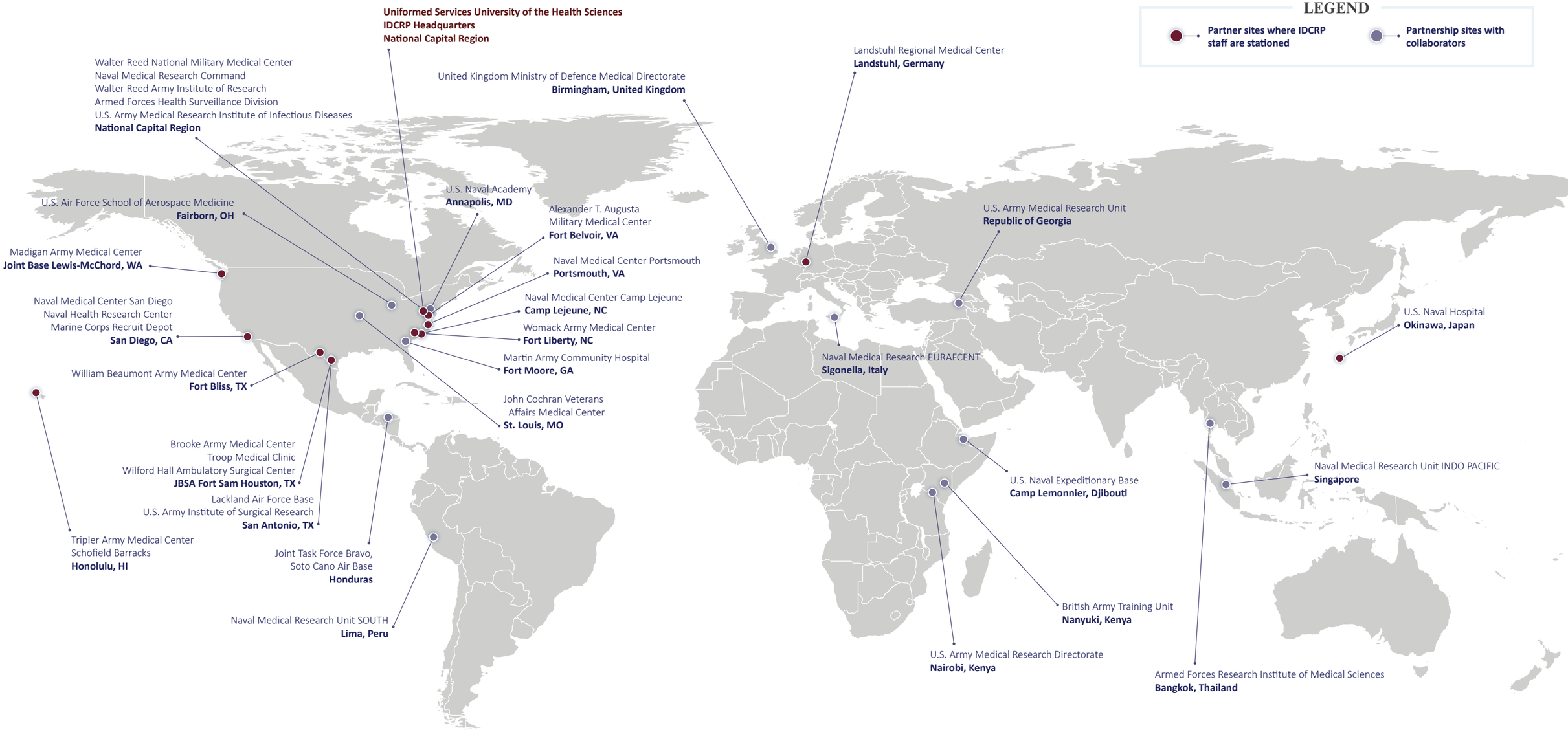
MILITARY IMPACT

Initiatives of the Wound Infections Research Area remain aligned with priorities of the Defense Health Agency (DHA) Military Infectious Diseases, JTS, and the MHS by addressing gaps in combat casualty care to support wartime preparedness and informing the development of a research infrastructure for future conflicts. The Wartime Infection, Control and Prevention KAP Survey will evaluate the familiarity of frontline providers with combat casualty care and infectious disease guidelines. The TIDOS team is also providing support for prospective, observational studies of Ukraine war-related wound infections conducted by the University of Colorado and in collaboration with the Walter Reed Army Institute of Research, Multidrug-Resistant Organism Repository and Surveillance Network (WRAIR MRSN). Through the DoD ASP Study, recommendations for areas where ASPs could be improved in military hospitals as compared to national standards were included in a technical report submitted to the DHA Antimicrobial Stewardship Committee. Findings from the Antibiotic-Resistant Bloodstream Infection (BSI) Study on BSI trends, resistance patterns, and mortality over a decade in MHS beneficiaries will help inform patient care.

HIGHLIGHTS/KEY FINDINGS

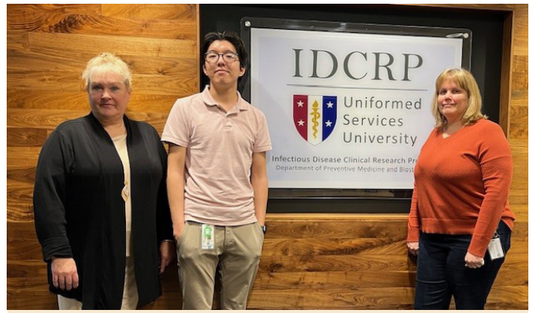
- **Assessment of SF-8 health survey responses from TIDOS cohort enrollees identified longitudinal downward trends in mental health during the 1st two years after the initial hospitalization, which were associated with having a traumatic brain injury, developing infections after the initial hospitalization, and time since hospitalization.**
- **Through the Antibiotic-Resistant BSI Study, mortality did not increase among MHS beneficiaries with BSIs over a 10-year period and mortality was often associated with advanced age and comorbidities, rather than having BSIs with highly resistant organisms.**
- **In an enterprise-wide evaluation of DoD hospital ASPs, there were similarities between DoD and national hospital adherence levels to CDC Core Elements with DoD hospitals slightly below national averages with regard to education, action, and tracking, but above national averages for leadership and reporting. A technical report with recommendations for areas of improvement was provided to the DHA Antimicrobial Stewardship Committee.**

IDCRP PARTNER NETWORK

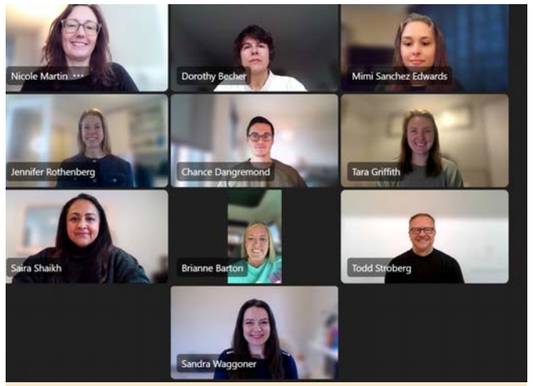


TEAM MEMBERS

Jim Min (left), Research Program Analyst, and Dr. John Powers (right), Chair of the Scientific Review Board



From left, Cindee Sheeler, Alex Park and Renee Bowers of the Research Support Group



The Clinical Research Management team

From left, Victoria Klimczak, Sheilah Rowe, Laurentine Sop, Leslie Tyler, and Alison Trump of the Program Management team

From left, Mark Fritschlanski, Clarke Ferrara, Roshila Mohammed, Elisa Chapo, and Dr. Lev Nevo of the Quality Management and Regulatory Affairs teams

The Data Coordination Center team

Team members at Naval Medical Center Portsmouth. From top left, Rezalina Tant, Susan Banks, LCDR Christie Joya, LCDR Michael Boatwright, and LCDR Varea Costello. From bottom left, Michele Cerroni, Denise Fitzpatrick, and Delaney Sisk

Team members at Landstuhl Regional Medical Center. From left, Col (ret) Joshua Hawley-Molloy, MAJ Andrew Wyatt, CPT (P) Madeline Fleit, and Sarah Murray

Team members at Okinawa. From left, LTJG Madalynn Hlatki, LT Natalie Spritzer, Anna Hernandez, Asia Cato, LCDR Vlad Stanila, and LCDR Alfred Smith

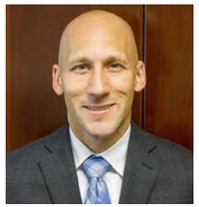
Team members at Tripler Army Medical Center. From left, Sophia Tran, Philipp Juern, Nathanial Copeland, Summer Willis, Emily Breech, and Sara Vivensi

Team members at Brooke Army Medical Center. From left, Lt Col David Lindholm, Veronica Wimberly, Dillon Nall, Terry Sjoberg, BarBea Clakley, Terry Merritt, Scott Merritt, Dr. Katrin Mende, and Maj Joseph Yabes

Team members at Madigan Army Medical Center. From left, Michelle Martin, Janine Bowman, Briana Jones, Sue Chambers, Christina Schofield, Cynthia Baker, and LTC Luke Mease

CENTER OPERATIONS

A robust, well-organized, and cohesive operational foundation is critical to maintain the ongoing success of the IDCRP clinical research portfolio.



Matthew Pearl, MS
Director, Center Operations

Sheilah Rowe
Head, Finance and Program Management

Todd Stroberg, RN, BSN
Head, Clinical Research Management

Center Operations is comprised of the core, logistical components critical to the oversight of a vast clinical research portfolio. Led by Mr. Matthew Pearl (Director, Center Operations), the goal of Center Operations is to ensure the efficient development and execution of high-quality clinical research through improved communication, standardization, and cooperation across the Program.

Program Management

During 2024, under the leadership of Ms. Sheilah Rowe, the Program Management team oversaw 32 funding awards in support of 48 protocols. A major effort over the past year was to further streamline and improve the efficiency of protocol development by increasing the participation of program managers during the earliest stages to inform appropriate funding strategies before protocols are submitted for review. Following receipt of awards, program managers maintained awareness of the financial health of the studies, providing status updates to the research teams to ensure the budget was considered during decision-making processes for the protocols. This greater integration of program managers with the research teams strengthened relationships and communication throughout the Program. In the upcoming year, goals of the Program Management team are to continue to improve efficiency, reduce redundancy, and enhance communication with the research teams regarding budget lifecycles as analyses progress.

Clinical Research Management

Led by Mr. Todd Stroberg, the Clinical Research Management team developed an IDCRP Protocol Handbook during the prior year to provide a comprehensive framework for the development and execution of clinical research protocols. During 2024, a Protocol Handbook Review Guideline was developed and all IDCRP personnel completed training on the handbook. The Clinical Research Management team also conducted six Protocol Operation Readiness Reviews, which are reviews prior to activation of protocols that examine operational procedures, regulatory documents, data quality management plans, and laboratory procedures. Clinical Research Managers (CRMs) participated in a new Protocol Projects Management course to enhance their understanding and capabilities needed to oversee clinical research protocols and completed training in use of Smartsheet software toolkits intended to standardize project management and metrics tracking. For 2025, lessons learned over the past year, as well as feedback from subject-matter experts, will inform development of a revised IDCRP Protocol Handbook and a Working Group will be formed to develop standardized protocol project management tools for use by CRMs.

Site Operations

Led by Ms. Susan Chambers, the Site Operations team executed and provided regulatory compliance for 19 active protocols, with 6 sites activating new studies in 2024. In response to the strategy of the Defense Health Agency (DHA) for standardization within the Military Health System (MHS), the site teams critically assessed, adapted, and modernized protocol-driven approaches related to participant engagement, data collection, and longitudinal cohort sustainment. As part of a Program-wide initiative to increase standardization across sites, site-based standard operating procedures (SOP) were assessed, programmatic procedures for SOPs were adapted, and a SOP adaptable template was established. In addition, site resourcing and utilization tools were developed to inform future protocol planning. For 2025, goals include to further optimize operational efficiencies, resource utilization, and readiness strategies to enhance operational support of protocol execution and engagement of key research populations.

Quality Management and Regulatory Affairs

During 2024, the Quality Management and Regulatory Affairs teams, led by Mr. Mark Fritschlanski, developed and implemented clinical monitoring plans and improved audit readiness approaches and procedures. The Quality Management team was also expanded to include dedicated Quality Assurance Specialists and the team assessed protocols in the IDCRP clinical research portfolio using risk-based monitoring approaches, which allows for the approach to be adjusted as the study evolves. To improve standardization across the Program, an online Quality Control and Quality Assurance platform was developed to allow team members real-time access to findings and be able to adjust studies in response to any identified risks. The Regulatory Affairs team supported investigative teams and CRMs during the past year by reviewing and providing regulatory consultations for 126 protocols and protocol-related materials prior to submission to the USU Institutional Review Board. For 2025, plans include further integrating Quality Management and Data Operations to improve quality assurance and strengthening core regulatory support at the sites in the Partner Network.

Repository and Laboratory Operations

During the past year, the Repository and Laboratory Operations team, led by Mr. Scott Merritt, continued development of the Specimen Tracking System (STS), which is a digital framework for managing specimens and associated data across study sites to reduce redundancies, enhance visibility across the Partner Network, and identify specimen/data issues in real-time. As part of the STS development, automated processes were initiated to include barcode label printing, shipping manifest generation, and shipment status notifications. Another effort over the past year was the initiation of transitioning specimen processing from the Military HIV Research Program Specimen Processing Laboratory to the IDCRP San Antonio Repository located at Brooke Army Medical Center. Once completed, this transition will significantly reduce biorepository costs for the Program. For the coming year, the team will continue to further advance the STS with the goal of integrating it with electronic data capture systems (e.g., REDCap) and specimen inventory software (e.g., Freezerworks).

Data Operations

Led by Mr. Edward Parmelee, the Data Coordination Center (DCC) provided support services for 32 IDCRP protocols in 2024, including the creation or modification of data collection projects, provision of analysis data and reports, and the acquisition of data from the MHS Data Repository. Also during the past year, a new Senior Data Operations Manager was hired to oversee the day-to-day operations of the DCC and three team members were trained in Inetsoft, which is a business intelligence processing software. Working with the Repository and Laboratory Operations team, functionality of the STS began to be integrated into the REDCap data collection system to improve automated processes at the sites. Data export and import processes related to REDCap were also improved. For the coming year, goals include standardization of data project management processes using the model set by the Clinical Research Management team, revision or creation of SOPs to improve data processing, and improvements of task management efforts through further use of automation.

Susan Chambers,
RN, BSN, CCRC
Head, Site Operations

Mark Fritschlanski
Head, Regulatory Affairs and Quality Management

Scott Merritt
Head, Repository and Laboratory Operations

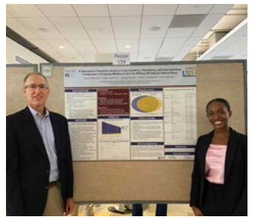
Edward Parmelee, MSc
Chief, Data Coordination Center

EDUCATION / MENTORSHIP

Advancing the education of the next generation of clinical infectious disease (ID) researchers in the U.S. Armed Services is a priority of the IDCRP.

Dr. Stephanie Richard (far left) with other USU personnel engaging with trainees at the 2024 USU Education Fair

Michael Celone receiving his PhD from USU



Dr. Brian Agan (left, mentor) with Taylor Mathis (right, MPH student, University of Pittsburgh) at the 2024 USU Summer Scholars Program symposium

As part of the IDCRP's education mission, opportunities are offered to residents, ID fellows, and medical/graduate students in the U.S. Armed Services at USU and military clinical sites within the IDCRP Partner Network to participate in ongoing IDCRP research studies, as well as to conduct research projects under the mentorship of IDCRP investigators. Sites within the IDCRP Partner Network include Brooke Army Medical Center, Madigan Army Medical Center, Naval Medical Center San Diego, Tripler Army Medical Center, and Walter Reed National Military Medical Center (WRNMMC). Trainees from the National Institute of Health (NIH), University of Maryland, Emory University, University of California San Diego, Georgetown University, University of Pittsburgh, and NOVA Southeastern University also contribute to IDCRP research projects. Participation in mentored research studies provides the trainee with practical, hands-on experience, which improves their understanding of the basic elements necessary to complete research studies (i.e., study design, data collection and analysis, and reporting of findings). The clinical ID research capstone curriculum for USU medical students, continuing GME activities at WRNMMC, and the Defense Health Agency-ID Working Group Subcommittee annual meeting are also supported by the IDCRP.

During 2024, 56 residents (across multiple specialties, including Internal Medicine, Preventive Medicine, Surgical, and Neurosurgical), medical/graduate students, ID Fellows, MPH students, and 2 post-doctoral trainees either began or completed their IDCRP-mentored research projects. One USU graduate student successfully defended her dissertation and received her doctorate in Public Health using data from the Wound Infections Research Area DoD Antimicrobial Stewardship Programs protocol. Data from the Acute Respiratory Infections Research Area EPICC, PAIVED, and PASS studies are also being used to support two post-doctoral projects, five PhD dissertations, and four MPH projects, while data from the HIV/Sexually-Transmitted Infections Research Area HIV Natural History Study and ALLHANDS protocols were utilized to support two PhD dissertations and one MPH project.

Seventeen oral and poster presentations involving trainees were presented at local and national conferences during the past year. Furthermore, eight manuscripts co-authored by trainees were published or accepted for publication and another six manuscripts were submitted for journal consideration. Trainees who participated in IDCRP-mentored research projects also received award recognition in 2024 (**see IDCRP Awards and Honors, page 20**).

The success of the IDCRP's education mission is dependent on effective engagement of trainees. As such, IDCRP investigators attend public health student practicum and project fairs, meet with medical students and ID Fellows to discuss research opportunities, and update medical training program Directors about available and upcoming IDCRP-mentored research opportunities. To further spark interest in clinical research, medical school graduates, USU faculty, and ID consultants are encouraged to talk with trainees about how clinical research has shaped the trajectories of their careers.

Overall, the IDCRP continues to be successful in achieving the goals of the Program's education mission to ensure high-quality clinical ID research in the Military Health System through fostering the growth of active-duty researchers.

SELECTED IDCRP TRAINEE EDUCATION PUBLICATIONS AND PRESENTATIONS

PUBLICATIONS

Topal S, Richard P, Young J, Ganesan A, Gleeson T, Blaylock J, Okulicz JF, Chu X, Agan B. Mandated Checkups, Knowledge of Own Health Status, and Chronic Care Utilization: The Effect of HIV Medical Evaluation Mandates on Healthcare Quality and Expenditure in a US-Single Payer System. *Health Economics*. 2024; 33(1): 59-81.

Ellis GC, Shaikh F, Carson ML, Sercy E, Stewart L, Andrews JM, Campbell WR, Mende K, Yabes JM, Tribble DR, Bialek R, Wickes BL, Ganesan A. A Semi-nested PCR Method for the Diagnosis of Invasive Fungal Infections in Combat Injured. *Open Forum Infectious Diseases*. 2024; 11(6): ofae078.

Walker PF, Bozzay JD, Schechtman DW, Shaikh F, Stewart L, Carson ML, Tribble DR, Rodriguez CJ, Bradley MJ. Non-Therapeutic Laparotomies in Military Trauma (2009-2014). *Surgical Endoscopy*. 2024; 38(10): 5778-5784.

Geringer MR, Stewart L, Shaikh F, Carson ML, Lu D, Cancio LC, Gurney JM, Tribble DR, Kiley JL. Epidemiology and Timing of Infectious Complications from Battlefield-Related Burn Injuries. *Burns*. 2024; 50(9): 107200.

Celone M, Beeman S, Han BA, Potter AM, Pecor DB, Okech B, Pollett S. Understanding Transmission Risk and Predicting Environmental Suitability for Mayaro Virus in Central and South America. *PLoS Neglected Tropical Diseases*. 2024; 18(1): e0011859.

Andronescu LR, Richard SA, Scher AI, Lindholm DA, Mende K, Ganesan A, Huprikar N, Lalani T, Smith A, Mody RM, Jones MU, Bazan SE, Colombo RE, Colombo CJ, Ewers E, Larson DT, Maves RC, Berjohn CM, Maldonado CJ, English C, Sanchez Edwards M, Rozman JS, Rusiecki J, Byrne C, Simons MP, Tribble D, Burgess TH, Pollett SD, Agan BK. SARS-CoV-2 Infection Is Associated with Self-Reported Post-Acute Neuropsychological Symptoms. *PLoS One*. 2024; 19(4): e0298481.

Chien A, Wu T, Lau CY, Pandya D, Wiebold Am, Agan B, Snow J, Smith B, Nath A, Nair G, NIH-DoD NeuroHIV Consortium. White and Gray Matter Changes Are Associated with Neurocognitive Decline in HIV Infection. *Annals of Neurology*. 2024; 95(5): 941-950.

PRESENTATIONS

2024 Military Health System Research Symposium, 26-29 August 2024, Kissimmee, FL.

Mayes C, Berjohn CM, Byrne C, Colombo RE, Ewers EC, Flanagan R, Fries AC, Ganesan A, Huprikar N, Jones MU, Lalani T, Larson DT, Lindholm DA, Mende K, Mody RM, Maldonado CJ, Maves RC, Rusiecki J, Saunders D, Schofield C, Smith AG, O'Connell RJ, Simons MP, Tribble DR, Agan BK, Burgess TH, Richard SA. Does SARS-CoV-2 Infection or Vaccination Impact Menstrual Health? Results from a Longitudinal Cohort Study among Military Health System Beneficiaries.

Connor TL, Goguet E, Haines-Hull H, Segard A, Laing E, Jones MU, Saunders D, Darcy ES, Olsen C, Kobi P, Kosh L, O'Connell RJ, Pollett S, Mitre E. Subclinical SARS-CoV-2 Infections and Endemic Human Coronavirus Immunity Shape SARS-CoV-2 Saliva Antibody Responses.

Wang W, **Bushan G**, Paz S, Stauft CB, Subramanian R, Goguet E, Lusvarghi S, Cong Y, Holbrook MR, Burgess T, Epsi N, Fries A, Agan B, Richard S, Mitre E, Wang T, Pollett S, Katzelnick L, Weiss CD. Antigenic Characterization of SARS-CoV-2 Variants Using Hamster and Human Sera and Antibody Landscapes of Humans with Diverse Vaccination and Infection Histories.

2024 IDSA ID Week, 16-19 October 2024, Los Angeles, CA

Frankford S, Stewart L, Sercy E, Igo M, Carson ML, Campbell WR, Wyatt AC, Mende K, Tribble DR, Kiley JL. Characterizing Multidrug-Resistant *Acinetobacter baumannii* Infections among Wartime Casualties.

Despain J, Mende K, Stewart L, Igo M, Seibert-Parzyszek I, Carson ML, Campbell WR, Wyatt AC, Tribble DR, Kiley JL. Characterization of the Inoculum Effect in Battlefield Trauma Patients with Methicillin-Susceptible *Staphylococcus aureus* Infections.

Mayes C, Berjohn CM, Byrne C, Colombo RE, Ewers EC, Flanagan R, Fries AC, Ganesan A, Huprikar N, Jones MU, Lalani T, Larson DT, Lindholm DA, Mende K, Mody RM, Maldonado CJ, Maves RC, Rusiecki J, Saunders D, Schofield C, Smith AG, O'Connell RJ, Simons MP, Tribble DR, Agan BK, Burgess TH, Richard SA. Does SARS-CoV-2 Infection or Vaccination Impact Menstrual Health? Results from a Longitudinal Cohort Study among Military Health System Beneficiaries.

Jones RD, Smidt K, Schofield C, Ganesan A, Campbell W, Hrncir D, Lalani T, Warkentien T, Mende K, Markelz AE, Berjohn C, Housel L, Modi J, Saperstein A, Williams A, McClenathan B, Collins L, Spooner C, Seshadri S, Maves RC, Utz G, O'Connell R, Simons M, Pollett S, Coles CL, Colombo RE, Burgess TH, Richard SA. Incidence and Severity of Influenza-like Illness in Cigarette Users: A Prospective Study.

Kautz M, Larson D, Sanders T, Hsieh H-C, McAnany J, Khodr ZG, Castaneda SF, Maves RC, Lalani T. A Case Control Study of Post Infectious Sequelae Following a Shiga Toxin-Producing *E. coli* (STEC) Outbreak at the U.S. Marine Corps Recruit Depot.

Lu Z, Parsons E, Richard SA, Alba C, Sukumar G, Rosenberger J, Zhang X, Burgess T, Agan B, Dalgard C, Pollett S, Malloy A. Patterns of T Cell Receptor Usage Reveal Associations with COVID-19 Severity.

Bettger C, Horn M, Aden J, Xu X, Agan B, Blaylock J, Larson D, O'Connell R, Colombo R, Lalani T, Yabes J, Markelz AE. Comparison of Cardiovascular Disease Risk Calculators in People Living with HIV in the US Military Natural History Study.

Endreson ML, Hsieh H-C, Joya C, Colombo RE, Schofield C, Lalani T, Larson D, Yabes J, O'Connell R, Blaylock J, Agan B, Ganesan A. Factors Associated with Liver Fibrosis Development in HIV-Monoinfected Patients within the Modern ART Era.

Graf PJ, Chu X, Davies J, Hickey PW, Blyth DM. Burden, Epidemiology, and Clinical Characteristics of Leptospirosis within the Active Duty Population of the Military Health System.

IDCRP AWARDS AND HONORS

During the past year, IDCRP investigators and trainees were recognized by various institutions. We congratulate CDR Mark Simons who was awarded the Defense Meritorious Service Medal for his service with the IDCRP. COL Robert O'Connell received a USU School of Medicine Dean's Impact Award for exceeding expectations as the Director of IDCRP and in leading the intra-departmental School of Medicine Military Infectious Disease hub, as well as being deployed to Honduras and Djibouti in support of the TrEAT TD 2.0 clinical trial. CAPT (retired) Timothy Burgess (PAIVED Principal Investigator) also received a USU Dean's Impact Award for going beyond expectations during his time serving as the Acting Chair of the USU Preventive Medicine and Biostatistics Department.

Dr. Simon Pollett received the James J. Leonard Award for Excellence in Clinical or Translational Research for his EPICC article on understanding hybrid immunity with regard to SARS-CoV-2. Dr. Rhonda Colombo received the COL William Crosby Superiority in Research Award, which honors those who demonstrate excellence in the design, performance, and publication of peer-reviewed research. LTC Milissa Jones (EPICC Associate Investigator) was selected as one of the 40 under 40 leaders in minority health for 2024 and also received a USU School of Medicine Dean's Impact Award. Lt Col David Lindholm (EPICC Associate Investigator) received the 2024 Lt. Gen Paul K. Carlton Jr. Graduate Medical Education Faculty Award in recognition for his work as the Associate Dean for Regional Education at USU and as co-lead of the San Antonio Uniformed Services Health Education Consortium Faculty Development subcommittee.

We congratulate MAJ S. Michael Goertzen for being awarded 3rd place in the Commander's Research Award for Clinical (Fellow) competitions for his work on the Acute Respiratory Infections Research Area COVID-19 Chronic Impairment with Pulmonary Symptoms (ChIPS) Study. LT Patrick Graf also was recognized for his work on the epidemiology of leptospirosis through the Deployment and Travel-Related Infections Research Area.

Name	Award/Honor	Awarding Organization
Academic or General Award / Honor / Recognition		
CDR Mark Simons	Defense Meritorious Service Medal	U.S. Department of Defense
Dr. Rhonda Colombo	COL William Crosby Superiority in Research Award	Tri-Service American College of Physicians
COL Robert O'Connell	School of Medicine Dean's Impact Award	USU
CAPT (retired) Timothy Burgess	School of Medicine Dean's Impact Award	USU
LTC Milissa Jones	School of Medicine Dean's Impact Award	USU
LTC Milissa Jones	Selected as '40 Under 40 Leader in Minority Health for 2024'	National Minority Quality Forum
Lt Col David Lindholm	Lt. Gen. Paul K. Carlton Jr. Graduate Medical Education Faculty Award	San Antonio Uniformed Services Health Education Consortium
Research-Related Award for IDCRP-Related Research Study		
Dr. Simon Pollett	2024 James J. Leonard Award for Excellence in Clinical or Translational Research	USU
MAJ S. Michael Goertzen	Commander's Research Award for Clinical (Fellow) 3rd place	San Antonio Uniformed Services Health Education Consortium
LT Patrick Graf	1st Place in Research Podium Competition	Tri-Service American College of Physicians

CDR Simons receiving his award from Dr. James Mancuso

Dr. Colombo being presented her award by CPT Ryan Duff at Madigan Army Medical Center

MAJ Goertzen being presented with his research award

IDCRP COLLABORATORS & PARTNERS

Department Of Defense Sites

U.S. Military Hospitals and Clinics

Alexander T. Augusta Military Medical Center, Ft Belvoir, VA
Brooke Army Medical Center, JBSA Ft Sam Houston, TX
Joint Task Force Bravo, Soto Cano Air Base, Honduras
Landstuhl Regional Medical Center, Germany
Madigan Army Medical Center, Joint Base Lewis-McChord, WA
Martin Army Community Hospital, Ft Moore, GA
Naval Medical Center Camp Lejeune, Jacksonville, NC
Naval Medical Center Portsmouth, VA
Naval Medical Center San Diego, CA
Schofield Barracks Health Clinic, Oahu, HI
Tripler Army Medical Center, Oahu, HI
Troop Medical Clinic, JBSA Ft Sam Houston, TX
U.S. Air Force School of Aerospace Medicine (USAFSAM)
U.S. Naval Academy, Annapolis, MD
U.S. Naval Expeditionary Base, Camp Lemonnier, Djibouti
U.S. Naval Hospital Okinawa, Japan
Walter Reed National Military Medical Center, Bethesda, MD
Wilford Hall Ambulatory Surgical Center, JBSA Ft Sam Houston, TX
William Beaumont Army Medical Center, Ft Bliss, TX
Womack Army Medical Center, Ft Liberty, NC

U.S. Military Research Commands

Naval Medical Research Command (NMRC)
- Biological Defense Research Directorate
- Operationally Relevant Infections Department
- Diagnostics and Surveillance Department

NMRC—Subordinate Commands
- Naval Health Research Center, San Diego, CA
- Naval Medical Research Unit INDO PACIFIC, Singapore
- Naval Medical Research Unit EURAFCENT, Sigonella, Italy
- Naval Medical Research Unit SOUTH, Lima, Peru

U.S. Army Institute of Surgical Research
U.S. Army Medical Research Institute of Infectious Diseases
U.S. Army Telemedicine & Advanced Technology Research Center
Walter Reed Army Institute of Research
- Emerging Infectious Diseases Branch
- Military HIV Research Program
- Multidrug Resistant Organism Repository and Surveillance Network
- Specimen Processing Laboratory
- Wound Infections
- Viral Diseases Branch
- Global Research Network
  - Armed Forces Research Institute of Medical Sciences, Bangkok, Thailand
  - U.S. Army Medical Research Directorate-Georgia, Tbilisi, Georgia
  - U.S. Army Medical Research Directorate-Africa, Nairobi, Kenya
  - U.S. Army Medical Research Directorate-West, WA, USA
- U.S. Army Medical Materiel Development Activity

Other U.S. Military Commands/Programs

Defense Health Agency (DHA)
- Armed Forces Health Surveillance Division (AFHSD)
  - Global Emerging Infection Surveillance (GEIS) Program
- Immunization Healthcare Division (IHD)

Bureau of Medicine and Surgery, Department of Navy (BUMED)
Congressionally Directed Medical Research Program (CDMRP)
Defense Advanced Research Projects Agency (DARPA)
Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense
DHA Military Infectious Diseases (DHA MID)
Navy and Marine Corps Force Health Protection Command (NMCFHPC)
San Antonio Uniformed Services Health Education Consortium (SAUSHEC)

United States Government Health Agencies

Biomedical Advanced Research and Development Authority
Centers for Disease Control and Prevention
Food and Drug Administration
Lawrence Livermore National Laboratory
National Institutes of Health
- National Cancer Institute
- National Institute of Allergy and Infectious Diseases
  - Division of AIDS
  - Division of Clinical Research
  - NIAID Flu Networks
  - Division of Microbiology and Infectious Diseases
  - Vaccine Research Center
- National Institute of Mental Health
- National Institute of Neurological Disorders and Stroke
- National Institute of Health Clinical Center

U.S. Department of Veterans Affairs
- Atlanta Veterans Affairs Medical Center
- James J. Peters VA Medical Center, Bronx, NY
- St. Louis Veterans Affairs Medical Center
- Veterans Aging Cohort Study
- Veterans Affairs Connecticut Healthcare System
- Veterans Affairs Puget Sound Health Care
- Veterans Affairs Sierra Nevada HealthCare System

Foreign Health Agencies and Organizations

International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b)
National Institute for Public Health and the Environment (RIVM), The Netherlands
Royal Thai Army Clinical Research Center
SEARCH Research Foundation and Innovation (IHRI) clinic
United Kingdom Ministry of Defence
- Royal Centre for Defence Medicine, Birmingham, UK
- British Army Training Unit, Nanyuki, Kenya
- Defence Medical Directorate, Birmingham, UK
- Defence Statistics (Health) MOD Abbey Wood

Academia

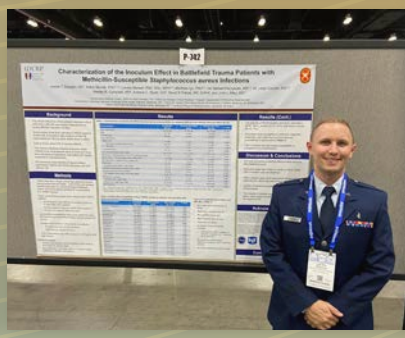
Broad Institute
Children's Hospital of Philadelphia
Cornell University
Emory University
George Washington University
Harvard T. H. Chan School of Public Health
Icahn School of Medicine at Mount Sinai
Johns Hopkins Applied Physics Laboratory
Johns Hopkins School of Medicine
Johns Hopkins Bloomberg School of Public Health
Michigan State University
San Diego State University
University of California-San Diego
University of California-San Francisco
University of Colorado
University of Georgia
University of Glasgow, Scotland
University of Maryland
University of Michigan Medicine
University of Minnesota
University of Nevada, Reno
University of Pennsylvania
University of Pittsburgh
University of Texas Health Science Center at San Antonio
University of Texas-San Antonio
University of Toledo College of Medicine and Life Sciences
University of Vermont
University of Virginia
University of Washington
Vanderbilt University
Washington University in St. Louis
Yale University

Research Organizations and Industry Partners

AstraZeneca plc
Antigen Discovery, Inc.
C2Sense, Inc.
GlaxoSmithKline plc
Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.
- Austere Environments Consortium for Enhanced Sepsis Outcomes (ACESO)

Integrated Biotherapeutics, Inc.
Janssen Pharmaceuticals, Inc.
Leidos Biomedical Research, Inc.





National Institute of Allergy and Infectious Diseases

IDCRP
Uniformed Services University

hjf

Infectious Disease Clinical Research Program

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

idcrp.usuhs.edu