Walter Reed Army Institute of Research (WRAIR)

WRAIR’S CRITICAL CONTRIBUTIONS TO BIOMEDICAL INNOVATIONS FOR INFECTIOUS DISEASE AND MILITARY PSYCHIATRY AND NEUROSCIENCE

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COMMANDER

Protect, Project, Sustain.
THE Premier Biomedical Research Team for the U.S. Department of Defense
Infectious diseases (ID) will continue to represent a threat to the Soldier and global citizen in both conflict and peacetime.

Brain health and behavioral resilience are long term legacy issues of the active Warfighter and veteran.
Welcome

WRAIR: A National Resource for Enduring Military Biomedical Needs

Center for Military Infectious Diseases Research

- Assets in the Continental US (CONUS) and Outside CONUS (OCONUS)
- Vaccine Development
- Drug Development
- Wound Infections
- Bench to Bedside Capacity (Clinical Trials, Bioproduction)

Center for Military Psychiatry and Neuroscience

- Psychological Resilience
- Sleep Management
- TBI, Neuroprotection and Neurorestoration
- Knowledge Products
WRAIR Organization Chart

HEADQUARTERS

Science Director

Center for Infectious Disease Research
- Military HIV Research Program (MHRP) (formerly Retrovirology)
- Military Malaria Research Program (MMRP) (formerly Malaria Vaccine Dev Experimental Therapeutics)
- Bacterial Diseases Branch
- Entomology Branch
- Preventive Medicine Branch
- Viral Diseases Branch

Shared Services
- Transitional Medicine Branch
- Veterinary Services Program (formerly Vet Med & Pathology)

Center for Military Psychiatry & Neuroscience Research
- Applied Neurobiology Branch
- Behavioral Biology Branch
- Closed-Head Brain Injury Branch
- Military Psychiatry Branch
- Research Transition Branch

Overseas Lab Operations
- AFRIMS - Thailand
- USAMRU - Europe
- USAMRU - Kenya

Business Plans & Programs

Research Support
- HQs Company
- Quality Activities Office
- Human Resources (Civilian) Branch
- Medical Audio, Visual, Library Branch
- Human Resources (Military) Branch
- Operations & Security Branch
- Human Subjects Protection Branch
- Resource Management Branch
- Information Management Branch
- Safety & Environment (Joint) Office
- Logistics Branch
- Science Education & Strategic Communications Office
Center for Infectious Disease Research

- Malaria
- HIV
- Dengue
- Leishmaniasis
- Bacterial and Diseases
- Arthropod Vector Control
CONUS and OCONUS Assets

Additional Research Sites

- Tanzania
- Uganda
- Cameroon
- Nigeria
- Mozambique
- Cambodia
- Vietnam
- Philippines
- Bangladesh
- Bhutan
- Nepal
- Mongolia

Unmatched International research capabilities and relationships
Center for Strategic International Studies (CSIS) provided Independent evaluation of DoD medical laboratories. Report released July 2011, finds that DoD labs:

- Protect deployed forces
- Fill a critical niche in developing vaccines and therapies
- Leverage partnerships with other U.S. government agencies
- Strengthen the scientific community in the host country and impact global health
WRAIR FY 14 Direct Allotments by Funding Source

Key  O&M: Operations and Management; GDF: Guidance to Develop the Force; RDT&E: Research, Development, Test and Evaluation; DHP: Defense Health Program

~53%
WRAIR FY 14 Reimbursables by Type and Collaborator

Key CRADA: Cooperative Research and Development Agreement; IAA: Interagency Agreement; Military Interoffice Purchase Request: MIPR

Total Fiscal Year 2014 Reimbursable Funding
$12,046,833

~47%

CRADA Non-Profit
$3,985,873
33%

CRADA Private Company
$3,623,992
30%

CRADA University
$783,028
7%

MIPR /IAA Navy
$3,273,224
27%

MIPR /IAA Other Government
$380,717
3%

Does not include
PEPFAR $65M
NIH/HIV $10M
OCONUS $8M
**U.S. Military Contributions to ID Research**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1990</td>
<td>Tuberculosis test, 1990</td>
</tr>
<tr>
<td>1991</td>
<td>HAV vaccine, 1991</td>
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<tr>
<td>1992</td>
<td>Adult RDS treatment, 1992</td>
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<tr>
<td>1995</td>
<td>Malaria drug, Malarone licensed, 2000</td>
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<tr>
<td>1995</td>
<td>Malaria, 1995 Phase I/II vaccine trials</td>
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<tr>
<td>1997</td>
<td>HIV/AIDS, 1997 Non B vaccine</td>
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<tr>
<td>1999</td>
<td>HIV/AIDS, 1997 Largest Phase III vaccine study</td>
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<tr>
<td>2000</td>
<td>Malaria, 2004 Vaccine/drug development and trial</td>
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<tr>
<td>2001</td>
<td>Ebola vaccine prototype, 2001</td>
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<tr>
<td>2003</td>
<td>HIV/AIDS, 2003 ID E. Africa variant</td>
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<tr>
<td>2004</td>
<td>JEV, 2009 Vaccine approval</td>
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<tr>
<td>2006</td>
<td>Malaria drug, 2007</td>
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<tr>
<td>2007</td>
<td>RV144 results announced</td>
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<tr>
<td>2009</td>
<td>Next Gen HIV Vaccine Consortium Formed 2013-</td>
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<tr>
<td>2010</td>
<td>Leishmaniasis, 2008-10 Phase III trial</td>
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<tr>
<td>2011</td>
<td>Malaria trial, 2010-11</td>
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<tr>
<td>2012</td>
<td>Dengue Phase 2 Trials 2012-13</td>
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<tr>
<td>2013</td>
<td>HIV/AIDS, 2009 RV144 results announced</td>
</tr>
<tr>
<td>2014</td>
<td>Next Gen HIV Vaccine Consortium Formed 2013-</td>
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WRAIR Operations in Africa

U. S. Army Medical Research Unit-Kenya (USAMRU-K), Nairobi, Kenya

- Conducts bench science, surveillance, and testing of infectious disease medical countermeasures and diagnostics
- Approx. 40-year partnership with the Kenyan Government
- 14 Active Duty U.S. Army personnel, 2 GS
- > 300 local employees
- Malaria, dengue, HIV, diarrheal diseases, vector control, disease surveillance (GEIS)
- Capabilities in Kenya, Nigeria, Tanzania, and Uganda
  - R&D effort and President’s Emergency Plan For AIDS Relief (PEPFAR) efforts
- Known as the Walter Reed Project (WRP)
Research and Diagnostic Centers

- Kondele Basic Science Research Lab
- Obama Children’s Hospital Research Wing
- Ward 8 in-patient research facility

Malaria Diagnostic Center
Military to Military Collaborations

- WRAIR works directly with foreign militaries to develop HIV care and treatment programs.
- Close ties with the Nigerian, Kenyan, and Tanzanian militaries.
  - Key element in AFRICOM medical engagement strategy
WRAIR Operations in Georgia

- WRAIR scientists have been working in the Georgia and the surrounding region for years in support of Defense Threat Reduction Agency (DTRA) programs.

- At the request of the Georgian Prime Minister, DoD is in the process of establishing a Medical Research Unit in Tbilisi Georgia.
  - Conduct surveillance, training, research, and response activities related to emerging infectious disease threats
  - Develop vaccines, therapeutics, and prevention products
Poised for the Pivot to Asia

The U.S. military has an ongoing obligation to the health of its Service Members to ensure that effective prevention and treatment measures are readily available.

- Deployment puts Service Members at increased risk to a diverse and broad range of disease threats
  - Unique strains of malaria, Dengue, HIV

- Effective infectious disease countermeasures minimize costs:
  - Treatment
  - Lost duty time
  - Medical logistical burden
  - Sunk training/deployment costs
WRAIR Operations in Southeast Asia

 Armed Forces Research Institute of the Medical Sciences (USAMC-AFRIMS)
 Bangkok, Thailand

- Conduct bench science, surveillance, and testing of ID medical countermeasures and diagnostics
- 28 Active Duty U.S. Army personnel
- 420+ local employees
- 50-year partnership with the Royal Thai Army conducting infectious disease research
  - Malaria, dengue, Japanese encephalitis, scrub typhus, HIV, diarrheal diseases, disease surveillance (GEIS)
- AAALAC-accredited animal facility with 600 nonhuman primates
- BSL-3 laboratory, CAP certified
Center For Military Psychiatry and Neuroscience

- Psychological Resilience
- Sleep Management
- TBI Neuroprotection and Neurorestoration
Center For Military Psychiatry and Neuroscience Contributions

1990
3 Patents for discovering anticonvulsant properties of dextromethorphan (1990-1994)

1995
Developed Army Suicide Event Report, 2000: Adopted DOD-wide in 2010

2000

2005
Eight Iterations of MHATs in Iraq and Afghanistan, 2003-2012

2010
TBI Biomarkers Identified, 2004

2015

Evidence of Sleep Banking Identified, 2009

Novel Animal Model of Penetrating Brain Injury Developed, 2006

Phase 2 Intrepid 2566 Drug Trial to Mitigate Brain Injury Initiated, 2010

Impact of Secondary Blast from IEDs Identified, 2010

“Battlemind” Training Developed, Validated and Implemented, 2007

Impacts of Secondary Blast from IEDs Identified, 2010
Military Psychiatry and Neuroscience

WRAIR researchers develop tools to:

diagnose, prevent, and mitigate the effects of psychological demands, continuous operations, and brain trauma on the health and well-being of our Service Members.
Military Psychiatry

**MISSION:** Improve psychological functioning
Reduce the impact of mental disorders
Enhance the resilience of Soldiers, Leaders, and Families
*Improve diagnoses, treatment and management across the continuum of TBI*

**PRODUCTS:** Comprehensive survey-based mental health assessments for Army and DoD. Responsible for staffing and implementing in-theater Mental Health Advisory Teams (MHATs)
Validated psychological resiliency programs
Brain Health, Neuroprotection & Neurorestoration

MISSION:
Reduce death and the chronic residual disability caused by brain injury. Focus on improved diagnostics and the discovery of novel therapeutic strategies, and study mechanisms for restoration of function during chronic states

PROGRESS:
Identifying molecular biomarkers of brain injury and treatment efficacy. Developing and evaluating novel neuroprotective and neurorestoratIve mechanisms and treatment modalities.
LATBI -- Proposed Solution for Tomorrow

Phase I: Reference Lab
- **Advantages**
  - Accuracy
  - Sensitivity
  - Precision
  - Throughput
  - FDA approval
  - Flexible platform
- **Disadvantages**
  - Size & weight
  - Need for sample preparation
  - Power and space requirements
  - Cost of instrument and assay
  - Separate and multiple reagent storage

Phase II: Point-of-care
- **Advantages**
  - Smaller size/weight
  - No sample prep
  - Lower cost
  - Assay speed
- **Disadvantages**
  - Potentially lower sensitivity, accuracy, and/or precision
  - No feasibility clinical data
  - Time to FDA clearance

Phase III: Handheld
- **Advantages**
  - Small size/weight
  - Assay speed
  - Low cost
  - Stable reagents
  - Finger-prick sample
- **Disadvantages**
  - Lower sensitivity, accuracy, and/or precision
  - Time to FDA clearance
  - CLIP/CLIA issues for approval

Fixed Facility

Combat Support Hospital

Point of Injury/Battalion Aid Station
U. S. Army Medical Research Unit Europe (USAMRU-E) Sembach, Germany

- The Army’s behavioral health (BH) research asset located with operational units
- Addresses emerging BH issues and develops information products while providing rapid response to senior leaders
- Expertise conducting studies with operational units and complex randomized trials in the field
- 30 year partnership with EUCOM

USAMRU-E Staff of 13
- 10 are scientific
Leveraging Capacity and Expertise to Serve the Soldier

- Prominent Infectious Disease and Military Behavioral Health and Neurosciences Research Groups
  - Only Malaria Drug Discovery/Development Program for the U.S.
  - Close Partnerships with the State Dept, NIAID and private industry

- Unmatched International capabilities and relationships
  - OCONUS Research Platforms – Europe, Asia, Africa
  - 6 CONUS and OCONUS CAP-Accredited Diagnostic Labs
  - Clinical Trials Centers on 3 Continents

- State-of-the-Art Facilities
  - Pilot Bioproduction Facility—a Strategic DoD Asset
  - AAALAC- Accredited Animal Facilities (US & Thailand)
  - CAP certified and BSL3 laboratories
Protecting the health and safety of our Service Members


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