

### SA Military Medical Industry Day

# SAN ANTONIO MILITARY MEDICAL RED (PART 2)



**VELOCITY\_TX** 

### AGENDA

Networking (11:30am - 12:00pm) Program (12:00pm - 1:00pm) Introduction to AIM 2024 Health R&D Summit Patti Geppert, PhD - SAMMI Director VelocityTX Naval Medical Research Unit- San Antonio Brief CDR Rachel Werner DDS, PhD - Acting Chief Science Director **Brooke Army Medical Center Brief** Joseph Maddry, MD- Chief, Department of Clinical Investigation **Department of Veteran's Affairs Brief** Alicia Swan, PhD-Director of Rehabilitation Research Q&A and Closing

Military Medical Industry Day

#### Full-Day Conference

- 335+ Attendees
- 50+ Companies

#### Three Pre-Event Symposiums

• 75+ Attendees

Focus on private-sector collaboration

# BEXARBIO

**Pitch Competition** 

#### 100+ Attendees

#### **48** Applicants

- 13 States
- 1 International

12 advanced to semi-final round

4 finalists selected to present at BexarBio

**San Antonio Military Health** 

and University Research Forum

#### Full-Day Research Forum:

300+ Attendees

#### Researchers from:

- Military
- Academia
- Nonprofit Research Institutes
- Industry



### LEVERAGING AIM: UNDERSTAND DOD MEDICAL REQUIREMENTS

- Attend podium and poster presentations by researchers
  - 12 one-hour podium sessions
  - 60+ research posters over two days
- Listen to panels on the vision for DoD medical product development and DHA portfolio managers
- Talk to researchers and end-users from Army, Air Force, Navy, BAMC and Veteran's Affairs at 10-minute one-on-one pitch sessions.
  - Sign-up for 10 minute time slots on day of meeting

### LEVERAGING AIM: ONE-ON-ONE SESSIONS TOPIC AREAS

- Blood and Shock Resuscitation
- Hemorrhage and Edema Control
- Battlefield Pain Management
- Traumatic Brain Injury Polytrauma Related
- Engineering/Automation Technology
  - Bioengineering
  - 3D printing
- Dental/Maxillofacial Injury and Surgery R&D

Combat Wound Care

- Infection/sepsis: diagnosis, treatment, prevention
- Burns: assessment and treatment
- Military Medical Simulation/Education/Training
- Rehabilitation
- Patient Safety
- Healthcare Operations

### LEVERAGING AIM: LEARN HOW TO COLLABORATE

- Learn how to:
  - collaborate with researchers for product development
  - sell to the DHA and VA
  - find end-users for your medical products
- Learn how to fund your research and product development
  - Grants and contracts
  - Congressional Special Interest
  - Consortium OTA's
  - SBIR/STTR
  - Angel Investors and Venture Capital
- See innovative dual-use medical technology
- Networking



#### **Register Today** Early bird pricing ends March 31!





### **UPCOMING PRE-MEETING WEBINARS**

#### MAY 20, 2024 Mechanisms for Collaboration, Technology Transfer, and Commercialization with the Military

Introduction to military technology transfer mechanisms that will be discussed in detail at the AIM 2024: Health R&D Summit



Scan to go to the AIM 2024 Pre-Event Webinar Webpage Registration open soon for future events



### PAST PRE-MEETING WEBINARS (RECORDINGS)

- Regulatory Strategy- Importance of FDA Interactions (2023)
- Licensing Technologies from the Military (2023)
- Mechanisms for Private Sector Collaborations with Military Teams (2023)
- Keys to Collaborating with the Military (2022)
- Military Medical Needs, Requirements and Funding (2022)
- Tales from the Field (2022)

https://www.velocitytx.org/support/sammi/

## OFFICE HOURS AT VELOCITYTX: US ARMY INSTITUTE FOR SURGICAL RESEARCH

Friday 11:00am – 1:00pm CT

Dual-Use Topic Areas of Interest include:

- Medical AI technologies
- Clinical decision support systems and advanced display technologies
- Advanced physiologic sensors and monitoring
- Medical robotics and automation
- Advanced medical imaging
- Organ support technologies
- Devices for critical care in the battlefield

Contact Patti Geppert for more information: patti@velocitytx.org



### Naval Medical Research Unit San Antonio Command Brief

Rachel L. Werner, DDS, MS, PhD CDR, DC, USN Acting Chief Science Director 22 April 2024

#### ★ READINESS THROUGH RESEARCH & DEVELOPMENT ★



### Mission

Conduct gap-driven combat casualty care, craniofacial, and directed energy research to improve survival, operational readiness, and safety of Department of Defense personnel engaged in routine and expeditionary operations.



United States Navy Photo(s)

#### ★ READINESS THROUGH RESEARCH & DEVELOPMENT



### **Facilities**

#### Battlefield Health and Trauma Research Institute

NAMRU-SA shares the BHT with the US Army Institute of Surgical Research and the US Air Force Dental Evaluation and Consulting Service

#### Tri-Service Research Laboratory

NAMRU-SA also shares joint facilities at TSRL with the US Air Force 711<sup>th</sup> Human Performance Wing







### **Scope of Research**

### NAMRU-SA scientists conduct basic, applied, and advanced technology research and development *From Bench to Bedside*



United States Navy Photo(s)



### **Naval Medical Research Enterprise**



#### ★ READINESS THROUGH RESEARCH & DEVELOPMENT

☆



### **Command Directorates & Departments**

#### **Science**

#### □ Combat Casualty Care and Operational Medicine

- Biomedical Systems Engineering and Evaluation
- Cellular and Immune Based Adjuncts For Casualty Care
- Expeditionary and Trauma Medicine

#### Directed Energy Health Effects

- Laser Health Effects
- Electromagnetic Health Effects
- Health Effects Modeling and Simulation

#### Craniofacial Health and Restorative Medicine

- Biomaterials
- Epidemiology
- Environmental Surveillance
- Maxillofacial Injury and Disease

#### Veterinary Sciences

Veterinary Research

#### Administrative Operations & Resource Management

#### Administrative Operations

- Administrative Operations
- High Reliability Operations

#### Resource Management

- Acquisitions & Procurement
- Materials Management

#### NAMRU-SA Staff

Military: 20, Civilian: 28, Contractor: 57 ORISE/Interns: 8

#### ★ READINESS THROUGH RESEARCH & DEVELOPMENT

★



#### **Combat Casualty Care and Operational Medicine**

- Biomedical Systems Engineering and Evaluation
  - Imaging systems to visualize the distribution of blood in dental pulp and assess pulp vitality
  - Use of machine learning algorithms to improve combat casualty care
  - Testing and improvement of various devices
    - Tourniquets
    - Endotracheal tubes
    - Field sterilizer
  - Polar medicine research







United States Navy Photo(s)



#### **Combat Casualty Care and Operational Medicine**

- Cellular and Immune Based Adjuncts for Casualty Care
  - Evaluation of the regenerative potential of stem cells and other biologics in combination with novel polymer scaffolds for critical size bone defects
  - Development of 2D and 3D cell-based platforms to rapidly screen for novel therapeutics in the treatment of shipboard casualties
  - Use of in vitro model of endotheliopathy to validate efficacy of newly-developed blood products for treatment of hemorrhagic shock





#### **Combat Casualty Care and Operational Medicine**

- Expeditionary and Trauma Medicine
  - DoD's only polytrauma hemorrhage model
  - Conduct investigation of multi-function resuscitation fluids and other blood analogues for use in prolonged care scenarios
  - Conduct investigation of maritime and shipboard hemorrhage control
    - REBOA and adjunct treatment strategies
    - Expand duration and indication of use for XSTAT





https://hbo2therapeutics.com/

#### ★ READINESS THROUGH RESEARCH & DEVELOPMENT



#### □ Directed Energy Health Effects

#### Medical Laser Health Effects

- Investigation of the health effects of laser injuries expected in the use of high-energy laser systems
- Development of the mechanistic understanding of laser injuries to develop diagnoses, treatment plans, and clinical practice guidelines for battlefield, en route, and prolonged care scenarios
- Investigation of triage efforts for laser injuries on the battlefield
- Development and testing of laser countermeasures
- Establish novel safety standards for DoD training and operational environments





United States Navy Photo(s)

#### ★ READINESS THROUGH RESEARCH & DEVELOPMENT 7



#### Directed Energy Health Effects

#### • Electromagnetic Field (EMF) Health Effects

- Investigation of the Health Effects of EMF, electrical current, and acoustic energy injuries
- Development of the mechanistic understanding of EMF injuries to develop diagnoses, treatment plans, and clinical practice guidelines for battlefield, en route, and prolonged care scenarios
- Investigation of triage efforts for EMF injuries on the battlefield
- Development and testing of EMF countermeasures
- Establish novel safety standards for DoD training and operational environments



https://science.nasa.gov/





United States Navy Photo(s)



#### Directed Energy Health Effects

- Medical Modeling and Simulation of Directed Energy Health Effects
  - Development of medical predictive models of DE injuries
  - Model and predict wound severity and treatment options for DE injuries



https://fda.gov

 $\bigstar$ 



#### □ Craniofacial Health and Restorative Medicine

- Biomaterials
  - Development of electrospun 3D collagen-based nanofibrous scaffolds for craniofacial surgery
  - Development of novel bioprinted microneedle hydrogel dressings for delivery of customizable therapeutics
  - Development and evaluation of self-healing composite dental restorative material with increased longevity to reduce dental emergencies occurring during deployments
  - Investigation of effects of extreme environments on the integrity of dental and pharmaceuticals as well as on the providers and procedures for administration







**Electrospun scaffolds** 





#### **Craniofacial Health and Restorative Medicine**

- Epidemiology
  - Investigation of medical evacuations related to dental emergencies and maxillofacial traumatic injuries
  - Investigation of dental emergencies and individual medical/dental readiness criteria for process improvement and improved clinical practice guidelines



The Burden of Dental Emergencies, Oral-Maxillofacial, and Cranio-Maxillofacial Injuries in US Military Personnel

Laura Lee\*; LT Noel Dickens, DC, USN\*; COL Timothy Mitchener, DC, USA†; Iram Qureshi\*; Sylvain Cardin\*; John Simecek\*



United States Navy Photo(s)



#### **Craniofacial Health and Restorative Medicine**

- Environmental Surveillance
  - NAMRU-SA is the Navy's designated agent for mercury abatement
  - Development and evaluation of Environmental Protection Agency (EPA)-compliant amalgam separation systems
  - Evaluation of dental line cleaners and treatments for heavy metals solubility via inductively coupled mass spectroscopy



 $\bigstar$ 



#### □ Craniofacial Health and Restorative Medicine

- Maxillofacial Injury and Disease
  - Development of novel therapeutics targeting fungal biofilms
  - Evaluation of nanoparticle-targeted laser therapy against antibiotic-resistant biofilm infections
  - Engineered phage technology for treatment and detection of craniofacial diseases, snakebite envenomation, and casualty care





#### □ Veterinary Sciences

- Support all Navy protocols
- Support Air Force protocols (59th Medical Wing and & 711th Air Force Human Performance Wing)
- Support the Army Nurse Anesthetist training program
- Casualty care protocol for working dogs





United States Navy Photo(s)



### **Medical Research Sponsors and Stakeholders**



☆



### **Naval Medical Research Unit San Antonio Collaborations**



★







### Brooke Army Medical Center Department of Clinical Investigation

Col Joseph Maddry, MD

Controlled by: CUI Category: LDC/DISTRO POC:



 The views expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of the Defense Health Agency, Department of Defense, nor the U.S. Government.

CUI





Improving Health and Building Readiness. Anytime, Anywhere — Always

### **Clinical Investigation**

An organized inquiry into and possible development of knowledge or products related to clinical health problems for any conditions of concern in providing healthcare to the beneficiaries of the MHS including active duty personnel, dependents, and retired personnel. Cls represent a special category of healthcare research. Cls are intended to improve quality of medical, dental, nursing and allied health science care provided to beneficiaries of DoD health services or support the graduate health sciences education (GHSE) programs, other allied health programs of the Military Services, and Uniformed Services University of the Health Sciences (USUHS).

CUI





### **CIP Branch Functions**



- Management Support alignment with DHA and GME requirements
- Policy Support related DoDI and DHA-PI
- Process Support standardization of CIP practices
- Resource Support scope and staffing
- Contracting Support local needs



Ę

Improving Health and Building Readiness. Anytime, Anywhere — Always

CUI



### **CIP Branch Sites**



CUI



Ę

Improving Health and Building Readiness. Anytime, Anywhere — Always



### **CIP Funding**

- Where does funding come from?
- DHP O&M funds
  - Funds civilian staff positions
  - Procurement funds to purchase equipment as applicable a process.

CUI

• Clinical Investigations may be conducted with grant funding from other federal agencies or non-federal sources as permissible







### **Department of Clinical Investigation (DCI)**

CUI

- A stand-alone hospital department
- Chief Army billet, 61 series (physician)
- Mission Statement: to promote, coordinate, support and oversee organized scientific inquiry in basic, translational, and clinical research at Brooke Army Medical Center (BAMC) and foster collaboration with other institutions in the Region. DCI facilitates and supports the entire process of research approval including research proposal preparation, submission, review, monitoring, funding and contract management of approved research, by providing program administration, education and consultation for all research activities at Brooke Army Medical Center and other Military Treatment Facilities and clinics covered under its Assurances











Improving Health and Building Readiness. Anytime, Anywhere — Always



### **BAMC DCI - Collaborations**

CUI



- The San Antonio Market has a robust life science/medical research community
- 1. Velocity Texas
- 2. BiomedSA
- 3. Southwest Research Institute
- 4. UT Health
- 5. Military sites:
  - 59th CIRS/WHASC
  - BAMC/CFI/USAISR
  - MEDCoE







### **BAMC DCI – Policy Responsibilities**

- Department of Clinical Investigation is the proponent of 4 hospital policies:
- 1. CIP Policy
- 2. Cadaver Use
- 3. Scientific Review
- 4. Reimbursement







#### CUI

### **Research Priorities – how do we execute them?**

- Support GHSE
  - Leadership attend MSEC, GMEC and other executive committees in the hospital.
  - Statistician rounds in all departments to provide advice.
  - Compiled rosters of clinical research coordinators for all hospital departments.

- Support Trauma mission
  - Re-prioritizing acquisition of broad-use equipment.
  - Moving away from highly specialized, highly technical, Al-driven modeling and bioinformatics contracts.



Improving Health and Building Readiness. Anytime, Anywhere — Always





### Thank you!

CUI



Improving Health and Building Readiness. Anytime, Anywhere — Always



# Research Partnerships with the Department of Veterans Affairs (in South Texas)

Alicia Swan, Ph.D. Director of Rehabilitation Research Assistant Chief, Human Research South Texas Veterans Health Care System (STVHCS) April 22, 2024







Veterans Health Administration



### **Disclaimers**

- This material is the result of work supported with resources and the use of facilities at the South Texas Healthcare System, Audie L. Murphy Medical Center, PM&R/Polytrauma Service.
- The contents or opinions presented do not represent the views of the U.S. Department of Veterans Affairs or any other Federal Agency of the United States Government.
- Authors have no conflicts of interest to report.



### **Strategic Research Priorities at the VA**

- Increase Veterans' access to high-quality clinical trials
- Increase the substantial real-world impact of VA research
- Put VA data to work for Veterans
- Actively promote diversity, equity, and inclusion within our sphere of influence

#### VA Research by the Numbers (For Fiscal 2023)



Active research sites nationwide 105



Published research articles authored or co-authored by VA investigators 11,107



Total congressional appropriation for VA medical and prosthetic research \$916M



Active funded research projects (including VA funding and other sources) 7,431



Active funded principal investigators 3,774

Total research budget (including other VA and non-VA sources, such as NIH) \$2.3B

5

Infographic by VA Research Communications, November 2023 Illustrations: © iStock/Olena Chernenka, Andrew\_rybalko, all\_is\_magic, sesame, Misha Shutkevych.



**VA Funding Opportunities** 



- Can I be an investigator on a study at the VA?
  - Yes, however...
    - VA employees have fewer barriers; non-employees effectively need to become volunteers who go through the administrative equivalent of being hired by the VA
    - In order to apply for VA funding as a PI, one must have a 5/8ths VA appointment (employment)

- I have a study and want to recruit Veterans. Can I do that at the VA?
  - Yes, however...
    - Know that recruitment-only protocols are rare
    - You can request to have a study flyer posted, but it must include a Non-VA disclaimer in a process overseen by the Office of Public Affairs
    - Well articulated partnerships with VA clinical/research partners tend to fare the best

\*\* \* \* \*

- I have science friends who want to work on VA project with me. Is that allowed?
  - Yes, however...
    - Be aware that the VA takes Privacy, Data Security, and Human Subjects protections very seriously (read: stricter rules, more administration)
    - Data sharing can require a legal agreement be executed between institutions

- My company wants to partner with the VA for Research. Can we do that?
  - Yes, however...
    - Be aware that the VA cannot directly participate. Instead, the nonprofit corporation (FAVHR) administrates extramural (i.e., non-VA) research funding
    - You'll still want to find a clinical/research partner at the VA, but we want you to find them, so just reach out
    - Plan/act early and often as administration can sometimes be more protracted than in other sectors

### (a)

### **Research Administration at our VA**

- Regulatory/Oversight
  - IRB (UTHSCSA\*)
  - IACUC (STVHCS)
  - R&D service (STVHCS)
- Institutional Partners
  - Non-profit corporation (FAVHR)
  - Affiliate University (UTHSCSA)







### Where do I start?

- Research & Development (R&D) Service
  - Chief: Amrita Kamat, PhD
  - Amrita.Kamat@va.gov
  - Human Research Director: Alicia Swan, PhD
  - Alicia.Swan@va.gov
- FAVHR
  - CEO: Michelle Trimble, MBA
  - Michelle.trimble@favhr.org

