Armed Services Biomedical Research Evaluation and Management COI

19 April 2017
Dr. George Ludwig, Ph.D., SES
Chair, Science & Technology Advisory Group (STAG)
• Since establishment in 1981, ASBREM has provided a durable senior leader forum for communication, assessment and resolution of biomedical R&D enterprise issues that extends beyond the scope of COIs and the Joint S&T Steering Committee:
  – Organizational policy and process improvement to facilitate DoD research strategy inclusive of intramural and extramural partners and focused on medical equities
  – Infrastructure management (people & facilities)
  – Coordination of technology transition planning across all program elements
  – Linkage to the practice of medicine

• Examples:
  – Creation of joint process for management of military infectious disease research
  – ASBREM led co-locations in BRAC91
  – ASBREM led 2008 GDF analysis of management structure and investment level

• ASBREM ensures appropriate engagement of medical stakeholders & subject matter experts that understand unique issues involved in DoD biomedical R&D and the larger federal and private sector biomedical R&D community
**Evolution of ASBREM Structure 1981-2013**

- **1981** – ASBREM Committee established as DoD response to Congressionally-mandated consolidation; original membership is Medical Materiel Flag Officers (2-star) from each Service, with 7 JTCGs.

- **1992** – DDR&E and ASD(HA) installed as Chair and Co-Chair of ASBREM Committee at Congressional direction.

- **1996 - 2007** – ASBREM Steering Group serves as Biomedical Reliance Panel (with rotating chairmanship) within Defense Reliance organization, developing and recommending Tri-Service research plans and objectives.

- **1998** – JTCG-1 (Military Dentistry) formally disestablished.

- **2005** – DATSD(NCB) and JTCGs 3 and 4 for Medical Biological and Chemical Defense effectively withdraw.

- **2007-2013** – Committee expanded through invited members to comprehensively represent DoD medical RDT&E; new JTCGs established for Medical Informatics, Simulation and Training (JTCG-1), and Clinical and Rehabilitative Medicine (JTCG-8).
# Overview of COI Portfolio

## Membership:

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<th>ASBREM COI Steering Leadership</th>
<th>Joint Technology Coordinating Groups</th>
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<td><strong>COI &amp; Senior Leader Advisory Group Chair</strong></td>
<td><strong>JTCG-1 Biomedical Informatics &amp; Health Information Systems and Technology</strong>&lt;br&gt;<strong>JTCG-2 Military Infectious Disease</strong>&lt;br&gt;<strong>JTCG-3 Military Operational Medicine</strong>&lt;br&gt;<strong>JTCG-4 Medical Radiological Defense</strong>&lt;br&gt;<strong>JTCG-5 Medical Chem Bio Defense</strong></td>
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<td><strong>Science &amp; Technology Advisory Group Chair</strong></td>
<td><strong>JTCG-6 Combat Casualty Care</strong>&lt;br&gt;<strong>JTCG-7 Medical Radiological Defense</strong>&lt;br&gt;<strong>JTCG-8 Clinical Medicine and Rehabilitation</strong>&lt;br&gt;<strong>JTCG-9 Medical Chem Bio Defense</strong></td>
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<td><strong>Advanced Development Advisory Group Chair</strong></td>
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Office of the Assistant of Defense for Research and Engineering  
OASD Nuclear, Chemical, and Biological Defense Programs  
Defense Threat Reduction Agency (DTRA)  
Joint Science and Technology Office for Chemical and Biological Defense (JTSO-CBD)  
Defense Advanced Research Projects Agency (DARPA)  
Principal Assistant for Research and Technology, USAMRMC  
Office of the Assistant Secretary of the Army for Acquisition, Logistics, and Technology  
US Navy Bureau of Medicine and Surgery  
Office of Naval Research  
Marine Corps  
US Special Operations Command  
Office of the Chairman Joint Chiefs of Staff  
Air Force Surgeon General  
Force Protection and Counter Weapons of Mass Destruction, J8  
Program Executive Officer, Chemical and Biological Defense  
USU Vice President for Research  
Defense Logistic Agency  

*Multi-agency and all Services Represented*
COI Activity In-Year

- **New areas of cross-Service collaboration**
  - Initiated development of a DoD Integrated Biomedical Research & Development Strategy

- **Major efforts**
  - Updated ASBREM charter in coordination
  - DHP Review & Analysis expanded to include ASBREM agencies, VA, NIH
    - Detailed overview of each Task Area led by the JPC/JTCG chair

- **Engagements with organizations, individuals, entities outside DoD**
    - Topics including infectious diseases, operational medicine, combat casualty care, medical chemical and biological defense, blast injury, advanced medical technology, battlefield trauma, protection system performance and injury patterns, medical information management system, modeling and simulation technologies for training, rehabilitative medicine
    - Additional data exchange agreements, project arrangements, CRADAs, MTAs, and personnel exchange assignments
JTCG Success Stories

- **JTCG 6: Junctional Hemorrhage Control Devices**
  - Stops severe blood loss from junctional vessel disruption
  - FDA cleared for axilla and inguinal hemorrhages as well as a pelvic binder
  - SOCOM and Army are fielding the SAM™ Junctional Tourniquet (SJT)
  - SJT with USAISR, as well as NAMRU-SA, tested the junctional tourniquet. USAMRMC Test Branch performed altitude testing. Down-select and fielding through HRCOE and USAMMA/USAMMDA

- **JTCG 8: Vascularized Composite Transplantation (VCA)**
  - Demonstration of hand/arm and face transplantation; Improves functional and aesthetic deficits
  - Technical challenge: Transfer of tissue between genetically different individuals of same species;
  - Armed Forces Institute of Regenerative Medicine (AFIRM), Army, Navy, Air Force, NIH, VA, and ASD(HA), DHP Biomedical Translation Initiative

SGT(R) Brendan Marrocco

STOP THE BLEEDING
JTCG Success Stories

- **JTCG 5: Micronutrient Supplement Programs**
  - A multivitamin iron program for female iron deficiency and a calcium/vitamin D-fortified snack bar (Performance Readiness Bar) for optimization of bone health & protection from stress fracture were implemented at all Army IET sites in FY17.
  - Studies of iron supplementation in female Air Force recruits reduced medical attrition 26%.
  - Studies on calcium and vitamin D supplementation / fortification in Army and Navy populations prevented up to 20% of stress fractures and increased bone health during basic training.

- **JTCG 2: Phage Therapy for MDR Acinetobacter baumannii**
  - NMRC’s Biological Defense Research Directorate (BDRD) and Infectious Diseases Directorate (IDD) developed libraries of naturally-occurring phages.
  - NMRC approached by Dr. Schooley, M.D at UCSD about an emergency case involving a seriously ill patient infected with MDR A. baumannii.
  - BDRD received the patient’s pathogen isolate under a sharing agreement; Used it to identify and prepare a phage cocktail tailored to the isolate.
  - Acting under FDA Emergency Use Authorization, Dr. Schooley administered the experimental cocktail and another phage preparation to his patient.
  - Within 60 hours of initiation of treatment, the patient began what has become a remarkable recovery.
Questions?