

The DoD Should be the Home for Federally-Funded Trauma Research

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Disclaimer

The views expressed in this presentation are those of the presenter and do not reflect official positions of the Army, Air Force or the Department of Defense

Because of

- **Function**
- **Scope**
- **Mission Focus**
- **Expediency – the dye is cast**

Established Execution Function

- **Able to apply or execute large federal appropriation using identified funding opportunity announcements that are structured, competitive and accountable (e.g. Program Announcements, Requests for Proposals and the Broad Agency Announcement)**
- **The active program management of the investment by the DoD takes steps to avoid redundancy, create leverage among different awardees (military labs and civilian) and minimize and gaps in topics covered**

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Defense Medical Research and Development Program

2016

Joint Program Committee 6/

Combat Casualty Care Research Program

Prolonged Field Care Research Award

Established Execution Function

- While these competitive processes (funding cut lines of 5-15%) can be viewed as slow, intentionally separated from investigator applicants and sometimes “unfair”, they’re ultimately transparent and have high fidelity of function



Funding Research ■ Changing Practice ■ Creating Awareness

For Immediate Release

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NTI Is Awarded \$4.6M Contract for Repository and Military-Relevant Research

San Antonio, TX – October 7, 2015 – The National Trauma Institute, based in San Antonio, today announced the award of a \$4.6 million Department of Defense Extramural Medical Research grant to develop a National Trauma Research Repository (NTRR) and fund three promising studies with both military and civilian trauma care implications, whose results will be the first to populate the repository.

- **Example of DoD award to National Trauma Institute**

Scope & Meaning of Trauma Research

- DoD has for the 1st time broadly defined areas of trauma research within a federal program (i.e. domains of topics along the range of care – point of injury, en-route and facility-based)

DoD Trauma Research Program

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graph TD; A[DoD Trauma Research Program] --> B[Neuro-trauma]; A --> C[En-route Care]; A --> D[Forward Surgical Intensive Care]; A --> E[Hemorrhage & Resuscitation];
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**Neuro-
trauma**

**En-route
Care**

**Forward Surgical
Intensive Care**

**Hemorrhage &
Resuscitation**

- Within each “bin” are specific lines or topics of research spanning basic to applied to clinical (i.e. a functional framework for the \$)

Scope & Meaning of Trauma Research


TABLE 2. Lines of Research and Development Established From the More Clinical Definition of PFC Shown in Table 1

- 1. Research to enable performance of acute lifesaving interventions**
 - Hemorrhage control (extremity, junctional, torso, head and cervical)
 - Establish, confirm, secure, and maintain an endotracheal airway
 - Vascular and/or osseous access to enable all forms of resuscitation
 - Relief of tension physiology in the thorax
 - Acute pain management and methods of transition to prolonged sedation
- 2. Research to enable diagnostic/detection and physiologic monitoring**
 - Monitoring of hemodynamics and recording of hemodynamic trends
 - Detection of hydration and intravascular volume status and physiologic reserve
 - Detection of fracture and compartment syndrome (extremity, pelvis, cranial)
 - Chest imaging (i.e., tube placement and detection of effusion or collapse)
 - Detection of intracranial and or intraperitoneal fluid (i.e., blood)
- 3. Oxygen carrying capacity circulating volume**
 - Blood and blood components (available, stable, reduced logistical footprint)
 - Oxygen carrying blood substitutes
 - Crystalloid or colloid fluids
- 4. Damage-control interventions**
 - Debride and dress soft tissue injury including thermal
 - Extremity fasciotomy and or amputation and dressing
 - Extremity stabilization and reperfusion techniques (vascular shunt)
 - Procedural sepsis control (abdominal, thoracic)
 - Debride, decompress, and manage intracranial injury
- 5. Automation, tele-enabling, and data exchange**
 - Automated, including closed loop, ventilation and oxygenation
 - Total intravenous anesthesia, including closed loop
 - Recording of care scenarios (data capture and performance improvement)
 - Information delivery to enable care scenarios
 - Information from care scenarios to enable teleconsultation and diagnostics
- 6. Early organ support and replacement**
 - Neuroprotection and stabilization (optimization of cerebral perfusion pressure)
 - Passive filtration (electrolytes and other)
 - Extracorporeal membrane oxygenation
 - Renal and or hepatic replacement therapy
- 7. En route care (land, sea, and air)**
 - Physiologic impact of prolonged transport of critically injured patient
 - Level of damage-control and resuscitative capability for varied scenarios
 - Smart disposition of scaled en route care capability/automated and unmanned
- 8. Smart and targeted resupply of PFC scenarios**
 - Elements of PFC most critical and feasible for targeted resupply
 - Temporal course of care scenarios in which resupply is most valuable
 - Methods of resupply to sustain scenarios of PFC

J Trauma & Acute Care Surg
2015;79(4):Supplement1:S61-S63

Mission Focus – Delivering Solutions

MATURITY OF LIFE CYCLE RESEARCH	PROGRAM ELEMENT	IMPLICATION FOR MEDICAL RESEARCH
Science and Technology	6.1	Research on fundamental principles—including cellular and molecular biology and medical genetics—aimed at understanding the cellular, molecular, and physiologic mechanism underpinning human health and injury
	6.2	Applied or preclinical research—including animal models—preparing the ground for clinical research with patients
	6.3	Translational research focusing on iterative loops between basic and clinical research domains to accelerate (make more efficient and relevant) knowledge or materiel translation; includes applied and clinical methodology
Advanced Development	6.4	Single or multi-center clinical research— including pragmatic, observational, and comparative effectiveness studies—that deliver knowledge products for translation or prepare materiel products for regulatory phase
	6.5	Pivotal efficacy study for Investigational New Drug (IND), Individual Device Exemption (IDE), or Product License Application (PLA) and/or associated manufacturing and regulatory costs to achieve approval for a device, drug, biologic, or technology



- **DoD *requirements-driven* approach is designed to deliver solutions for care domains (i.e. life-cycle R&D to deliver knowledge & material products)**
- **Structure has intentional processes that helps avoid “research for research” sake and “valley of death” pitfalls of investigator initiated effort**

Mission Focus – Delivering Solutions

- DoD mission focus on efficiency promoted and demonstrated value in prospective, observational or comparative effectiveness clinical research
 -as opposed to traditional, higher risk (costly), and more regulatorily encumbered randomized, controlled trials



LITES Network



**TBI
Endpoints
Development**

Expediency – It's Just the Way it is

- DoD approach to trauma research is established & recognized

Military trauma research: Answering the call

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J Trauma & Acute Care Surg 2014;77(3)Suppl2:S55-S56

Top Priorities in Combat Casualty Care

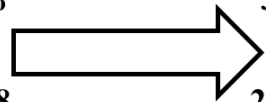
Gap in Care

Gap Resolved

9%



2008



39%



2014

- GAO prompted assessment of DoD research program demonstrates progress towards gap resolution

Expediency – There is No Going Back



**Caesar crossing the
Rubicon in 49 B.C.**

“Alea iacta est”