

Active & Upcoming Opportunities

Upcoming Solicitations	RPI	White Paper	Full Proposal	Estimated Release Date
Combating Antibiotic-Resistant Bacteria	X			Active
Prototype Acceleration Award			X	Late March
Extracorporeal Life Support Device			X	Late March
Permanent Vascular Repair			X	Late March
Cellular Therapies for the Treatment of Hemorrhagic Shock			X	Early April
Broad Topic Request for Project Information	X			Early April
Operational Architecture			X	Early April
Regenerative Medicine Manufacturing		X		Late Spring
Systems Biology Approach to Infectious Disease		X		TBD

RPI - Combating Antibiotic Resistant Bacteria

- Indiscriminant use and lack of compliance have led to bacterial mutations that have caused drug resistance, resulting in a significant decrease in the number of available drugs effective to treat both rare and common bacterial infections.
- **Critical needs:**
 1. **Disease surveillance** to detect and control antibiotic-resistance
 2. Improved, affordable **diagnostics** that rapidly detect and/or characterize antibiotic-resistant bacteria
 3. Development of novel antibiotic **drugs or other non-traditional therapeutics** for the treatment of infections caused by antibiotic-resistant bacteria
 4. Development of novel **vaccines** to prevent the spread of resistant bacteria
 5. Advancement of **innovative therapeutic approaches** to combat or circumvent antibiotic-resistance
- Use of the “Project Information Template” is required (2-page limit)
- Responses due April 30

RPP - Prototype Acceleration Award

- Advance novel prototype technologies into the next major stage of development/milestone dependent upon their current maturity
- Examples – late animal testing and regulatory filing, manufacturing, next clinical trial, etc.
- Prior demonstration of proof-of-concept in a large animal model (if applicable) is required and an industrial partner should be engaged
- Funding may range from \$150-300k, POP is 12 months
- **Wound Care/Anti-infectives to include point of injury wound care**
 - Novel platforms for the delivery of wound care anti-infectives (integrated into bandages)
 - Novel anti-infectives with the ability to prevent the development of infections post injury
 - Novel anti-infectives that reduce inflammation and pain sensation
 - Therapies to fight antimicrobial resistance
 - Novel treatments for skin/wound infection
- **Regenerative Medicine**
 - Biologic therapies for muscle regeneration
 - Novel platforms for regenerative medicine applications to include bone regeneration, bone grafting, and rebuilding tissues or skin after injury (e.g., burn injury)

RPP – Extracorporeal Life Support Device (ECLS)

- Clinical need:
 - Injuries of current wars have led to alarming rates of respiratory and renal failure
 - Need to develop a single ‘bridge’ ECLS device that can be used in patients with both acute kidney injury and acute respiratory distress syndrome
 - Device must be able to fully support CO₂ removal while replacing the function of the kidneys through a standard dialysis catheter
- 12 device specifications outlined in the RPP
 - Battery power, life, lightweight, low logistical footprint, flow rates, dialysis catheters
- Program Structure:
 - Phase I: Development concept paper (proposal) that describes prototype design, timeline for prototype development, anticipated regulatory pathway, potential commercialization approach (10 pg limit)
 - Phase II: Submission of detailed engineering design ‘schematics’ (\$50k)
 - Phase III: Prototype Construction (\$170k)

RPP - Permanent Vascular Repair

- Develop products that can serve as permanent arterial and/or venous grafts for reconstruction/repair of traumatic injuries and demonstrate significant advancement toward regulatory approval for a vascular reconstruction indication
- Proposed products should be near FDA approval to initiate feasibility clinical trials (minimum of TRL 5)
- Initial funding may range from \$350-650k, POP is 12 months with option years
- Initial proposed efforts must include FDA engagement on clinical and manufacturing, with follow-on efforts to be determined based on feedback received (e.g., clinical trials in trauma patients or related surrogate populations)

RPP – Cellular Therapies for the Treatment of Hemorrhagic Shock

- Cell therapies that can be used to treat the inflammatory complications that arise after traumatic injury - **NOT** those that can be used to achieve hemostasis.
- Intent is to support a Phase II clinical study to evaluate the safety and efficacy of cellular therapy in the treatment of hemorrhagic shock in severely injured patients.
- Products being brought forth must be ready to enter the clinical stage within a short window and have all of the regulatory requirements for IND prepared for submission as a minimum.
- **Goals:**
 1. Produce clinical grade prototype cellular therapy agent in sufficient quantity to conduct a clinical assessment in a trauma patient population.
 2. Develop a clinical study to assess mechanistic and outcome based patient responses to administration of cellular therapies.
 3. Document sufficient patient population (number, severity, availability in the acute post injury phase, and ability to conduct exemption from informed consent) to ensure assessment of prototype cellular therapy is conducted in a timely manner.
 4. Consider capacity for future assessment of cellular therapies from a variety of sources (e.g., industry, academic labs, and international partners) in a well described clinical population as a reimbursable service

RPI – Broad Topic Request for Project Information

- Influence the Government’s FY18 decisions for funding and selection of project focus areas, Project Information Template is required (2 page limit)
- **Infectious Disease** – vaccines, anti-parasitic drugs, deployable field clinical diagnostics (human and vector), prophylactics and novel therapeutics
 - CARB; Systems biology that support the use of a single therapy for multiple clinical applications
- **Combat Casualty Care** – medical interventions used on the battlefield
 - TBI; Technologies that provide prolonged care on the battlefield (diagnostics, stabilization of extremities, hemostatics, wound dressings); Telehealth technologies (monitoring tools, prototypes for JIT training for bystander trauma resuscitation)
- **Clinical and Rehabilitative Medicine** – innovation in definitive and rehabilitative care to reset wounded Service members in terms of duty, performance, and quality of life
 - Regenerative medicine manufacturing; Vision restoration; Hearing; spinal cord injury; 3D bioprinting; Decell/recell; Artificial organ replacement; Systemic peripherally acting analgesics for severe acute pain; Assess neuromusculoskeletal injuries

RPI – Broad Topic Request for Project Information

- **Military Operational Medicine** - develop effective countermeasures against stressors and to maximize health, performance, and fitness
 - Wearable sensors; Hearing preservation; PTSD; Methods to detect or assess risk of injury; Nutrition-based interventions to promote recovery; Evidence-based tools that address behavioral health issues
- **Medical Simulation and Information Sciences** - use of technology for medical training and for the provision, management, and support of health services in the military
 - Health IT/Informatics (medical device interoperability, EHR, Precision medicine that uses genetic profiling or proteomics to identify improved clinical approaches), Medical Simulation and Modeling (Open source integrated virtual models for education and training, Program architecture, Holographic technologies for medical training, Medical synthetic training prototypes)
- **Advanced Medical Technologies** - develop initiatives and products that will increase medical mobility while ensuring access to essential medical expertise and support regardless of the operating environment
- **Advanced Medical Regulatory and Manufacturing Technologies** - develop initiatives and manufacturing-related products to support above areas to decrease the risk and time of product development advancing through the FDA regulatory process

RPP - Operational Architecture

- Joint Evacuation and Transport Simulation (JETS) program Operational Architecture Requirements
- Develop a systems of systems (SoS) approach that takes current simulation and training methods into an integrated approach for individual, squad, and unit training for specific clinical skills and operations.
- The system will provide training of GPM/JPM tasks (e.g., medic, corpsman, flight medic, Aeromedical nurse, Patient Control Cell member, etc.) flowing simulated patient(s) through the chain of evacuation from Role 1 to Role 4, and the ability to engage in training events with other Government agencies and Coalition Partners.
- The JETS SoS will take many access methods (e.g., computer, smart phone, hard-stand training centers, tablet, etc.). Training Centers are inter-connected with Point of Demand (POD) training, within a medical Synthetic Training Environment (mSTE) that is connected through a DoD training portal.

RPP - Operational Architecture

- **Goal** – An architecture that allows for asynchronous interface of several simulated tasks from multiple locations off several devices into a synthetic system.
- **Base Effort** – Develop prototype knowledge products that provide the System Architecture views for the Joint Evacuation and Transport Simulation (JETS) Capabilities Development Document (CDD) - AV-1; AV-2; OV-1; OV-2; OV-4; OV-5A; CV-2; CV-3; CV-6; SV-1; SV-2; SV-3; SV-7; SV-8.
- **Option 1** – Identification of current systems and development of integrated operational, system, and capability views into a functional operational architectural context.
- **Option 2** – Deliverables include a prototype Capabilities Production Document (CPD) for JETS Increment 1.
- **Option 3** - Provide improvement to current capabilities to incorporate more interchange, interaction, and access modalities.
- **Option 4** - Increase through plug ins the advent of new applications or technologies that enhance the overall breadth and depth of training.

RPP - Regenerative Medicine Manufacturing

- Goals (2016)

1. Development of universal, defined culture media for regenerative medicine
2. Bioreactors to enable efficient and cost-effective cell and tissue expansion for regenerative medicine products
3. Cell, tissue, and product preservation for regenerative and personalized medicine
4. Large scale manufacturing of regenerative medicine products
5. Dynamic and innovative quality assurance for regenerative medicine manufacturing

- Later stage projects, industrial partner engaged, cost share

RPP - Systems Biology Approach to Infectious Disease

Recently completed state of the science analysis:

- Mechanisms of Host Response to Infection
- Mechanisms of Pathogen Invasiveness and Immune response
- Development of Drug Resistance and Persisters
- Computational Analysis

RPP - Systems Biology Approach to Infectious Disease

- **Conduct technical reviews and analyses of the State of Science recommendations** with the purpose of identifying likely candidate bacteria to research and validate, and to potentially translate the recommendations
- **Create portfolio of activities** necessary to identify mechanisms of resistance which as a whole constitute the likely lion's share of resistance characteristics in bacteria, and focus on the underlying characteristics that elicit and sustain these mechanisms with a goal of identifying potential nullifying or counteracting strategies. This activity will require an expert panel to review and develop recommendations for a comprehensive set of mechanisms.
- **Goal** is to design an integrated research and prototype development portfolio of resistance mechanism discovery, integrated validation, and potential translation

Other Potential 2017 Funding Priority Areas

- PTSD Therapeutic drug
- Optic nerve/retinal repair for vision
- Hearing preservation and restoration
- Precision medicine through unlocking the power of genomics
- Physiological modeling/algorithms that can enable simulation training devices