Securing DOD Research Funding to Fight Infectious Disease Threats

Elizabeth Barrows, Federal Funding Specialist

March 10, 2022 Webinar
Agenda

- Military Health System Research and Innovation
- DOD Collaboration and Funding Options
- Congressionally Directed Medical Research Program
- Brief Introduction to DOD Award Applications
- Key Points
- Contact Info
Military Health System Research and Innovation
(Health.mil/Military-Health-Topics/Research-and-Innovation)
The Military Health System (MHS) enables the National Defense Strategy by providing a Medically Ready Force, a Ready Medical Force, and improving the health of all those entrusted to its care. The complex and interrelated missions include:

- To ensure America’s 1.4 million active duty and 331,000 reserve-component personnel are healthy so they can complete their national security missions.
- To ensure that all active and reserve medical personnel in uniform are trained and ready to provide medical care in support of operational forces around the world.
- To provide a medical benefit commensurate with the service and sacrifice of more than 9.6 million active duty personnel, military retirees, and their families.

The Defense Primer is also a good reference about the MHS.
Medical Research and Development

- Research, Development, and Acquisition (RDA) enhances the related programs of the Army, Navy, Air Force, and Defense Advanced Research Projects Agency (DARPA)

- Vision
  - Advance collaborative, innovative medical research and development to improve military community health and save lives on and off the battlefield.

- Mission
  - Implement best practices to responsibly design, prioritize and integrate medical research, development and acquisition programs across the continuum of care. By fostering strategic partnerships and transitioning medical discoveries to deployable products, RDA will enhance the readiness and resilience of the military community.
Working with the Department of Defense

- Dual-hatted Stakeholder
  - Funds research and development
  - Purchases the resulting medical products
- Direct Military Relevance
- Organized Under Joint Program Committees
  - JPC-2: Military Infectious Diseases Research Program
  - JPC-5: Military Operational Medicine Research Program
  - JPC-6: Combat Casualty Care Research Program
  - JPC-7: Radiation Health Effects Research Program
JPC-2: Military Infectious Diseases
Research Program

• Mission
  • To plan, coordinate and oversee for the DOD requirements-driven medical solutions that PREVENT, PREDICT, and TREAT infectious diseases threats to the total force maximizing Warfighter readiness and performance.

• Research Program Focus
  • Emerging infectious diseases: Prevent; Treat; Predict
  • Combat wound infections/Sepsis: Prevent; Treat; Predict
  • Dengue fever: Prevent; Treat; Predict
  • Hantavirus: Prevent; Treat; Predict
  • Bacterial diarrheal disease: Prevent; Predict
  • HIV: Prevent; Predict
Joint Program Executive Office – Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)

- **Mission**
  - To Protect the Joint Force from weapons of mass destruction by generating affordable capabilities

- **Research Program Focus**
  - Countering Emerging Threats Rapid Acquisition and Investigation of Drugs for Repurposing (CET-RAIDR)
  - Biological Defense Innovation Program (BDIP)
  - Plague Monoclonal Antibodies (PLG MAB)
  - Antiviral Oral Therapeutics Program (AVO TX)
  - CBRN Support to Command & Control (CSC2)
  - Modernize the Mask
  - Hazard Mitigation
DOD Collaboration and Funding Options
Variations in Research & Development Opportunities

• **Size Range**
  - Small
    - Collaborative or paid work with DOD scientists such as military specific product testing
  - Large
    - Phase III Clinical Treatment Trials where Industry can receive $10M+

• **Project Length**
  - A few months (e.g., specific product testing in an animal model)
  - Discrete or ongoing/renewing
  - Decades of support (e.g., vaccine development and manufacture)

• **Product Acquisition**
  - Small compared to commercial market
  - Timelines can be irregular
  - In rare cases, can be primary market
Accessing Defense R&D Funding

- US Army Medical Research and Development Command
  - Partnering Website
- Submit your New Products and Ideas
- Respond to Requests for Information (RFI) or Requests for Quotation (RFQ) – Sam.gov Contract Opportunities
- Respond to a Program Announcement – Grants.gov
  - Opportunity Number: W81XWH*
- OTA’s – DOD-affiliated Membership Organizations
  - Medical Technology Enterprise Consortium - MTEC
  - Medical CBRN Defense Consortium - MCDC
Congressionally Directed Medical Research Program
CDMRP

- Congressional funding addition to the Defense Appropriations Bills
- Driven by advocacy organizations and Congressional member interests
- Doesn’t exist until that year’s Defense Appropriation Bill becomes law
- Congressionally Directed Medical Research Program - CDMRP
  - Peer Reviewed Medical Research Program – PRMRP
  - Combat Readiness – Medical Research Program – CRRP
  - Tick-Borne Disease Research Program - TBDRP
Congressionally Directed Medical Research Program
### Forecast FY2022 CDMRP Programs - $1.8B

- Values from FY22 Omnibus Spending Bill released 3/9/22
- Not official until signed into law

<table>
<thead>
<tr>
<th>Program Name</th>
<th>$M</th>
<th>Program Name</th>
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</thead>
<tbody>
<tr>
<td>Peer Reviewed Medical Research</td>
<td>370</td>
<td>Rare Cancer Research</td>
<td>17.5</td>
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<tr>
<td>Psych Health and Traumatic Brain Injury</td>
<td>175</td>
<td>Peer Reviewed Parkinson's Research</td>
<td>16</td>
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<td>Breast Cancer Research</td>
<td>150</td>
<td>Chronic Pain Management Research</td>
<td>15</td>
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<td>Peer Reviewed Cancer Research</td>
<td>130</td>
<td>Pancreatic Cancer Research</td>
<td>15</td>
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<td>Prostate Cancer Research</td>
<td>110</td>
<td>Alzheimer Research</td>
<td>15</td>
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<tr>
<td>Brain Injury &amp; Disease Prevention</td>
<td>60</td>
<td>Autism Research</td>
<td>15</td>
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<td>Kidney Cancer Research</td>
<td>50</td>
<td>Epilepsy Research</td>
<td>12</td>
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<tr>
<td>Ovarian Cancer Research</td>
<td>45</td>
<td>Reconstructive Transplant Research</td>
<td>12</td>
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<td>Melanoma Research</td>
<td>40</td>
<td>Duchenne Muscular Dystrophy Research</td>
<td>10</td>
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<tr>
<td>Peer Reviewed ALS Research</td>
<td>40</td>
<td>Hearing Restoration Research</td>
<td>10</td>
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<td>Spinal Cord Research</td>
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<td>Lupus Research</td>
<td>10</td>
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<td>Joint Warfighter Medical Research</td>
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<td>Clinical Research</td>
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<td>Peer Reviewed Orthopedic Research</td>
<td>30</td>
<td>Trauma Clinical Research</td>
<td>10</td>
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<tr>
<td>Toxic Exposures Research (New – GWI?)</td>
<td>30</td>
<td><strong>Combat Readiness Medical Research</strong></td>
<td>10</td>
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<td>Multiple Sclerosis Research</td>
<td>20</td>
<td>Peer Reviewed Military Burn Research</td>
<td>10</td>
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<tr>
<td>Vision Research Program</td>
<td>20</td>
<td>Tuberous Sclerosis Complex Research</td>
<td>8</td>
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<td>Lung Cancer Research</td>
<td>20</td>
<td>Bone Marrow Failure Disease Research</td>
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<td>Orthotics and Prosthetics Outcomes Research</td>
<td>20</td>
<td><strong>Tickborne Diseases Research</strong></td>
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<tr>
<td>Peer Reviewed Neurofibromatosis Research</td>
<td>20</td>
<td>Alcohol and Substance Use Disorder Research</td>
<td>4</td>
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Managing Expectations – Grant Funding Cycle

Congressional Appropriation (Restart cycle annually)

Vision Setting

Program Announcement Release

Pre-Application Receipt

Pre-Application Screening and Invitation to Submit*

Application Receipt

Peer Review

Programmatic Review

Funding Recommendations

Approval Authority Decision

Award Negotiations

Award Management

Award Closeout

Research Outcomes

Research News and Reports

*As needed

Annual Appropriation, Review, and Award Cycle

Month 6

Month 12

To Month 24

Month 18

To Month 84

Awards Management
### Forecast FY2022 PRM RP Topics

- Topics taken from FY22 Omnibus Spending Bill released 3/9/22
- Areas of Encouragement will be included in solicitations
2021 PRMRP Emerging Viral Disease

- Predictive outbreak modeling tools
- Rapid and testable prediction of protection
- Pre-symptomatic diagnostics
- Animal models of novel infections
- Predict response to vaccination or infection
- Risk assessment strategies for diseases and interventions
<table>
<thead>
<tr>
<th>Award</th>
<th>Topic</th>
<th>Compliant Applications Received</th>
<th>Awards Made</th>
<th>Total Funds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discovery Award</td>
<td>Emerging Viral Diseases</td>
<td>50</td>
<td>10 (20%)</td>
<td>$2,955K</td>
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<tr>
<td></td>
<td>Hepatitis B</td>
<td>5</td>
<td>0 (0.0%)</td>
<td>$0</td>
</tr>
<tr>
<td></td>
<td>Myalgic Encephalomyelitis/CFS</td>
<td>9</td>
<td>1 (11.1%)</td>
<td>$325K</td>
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<tr>
<td></td>
<td>Plant-Based Vaccines</td>
<td>2</td>
<td>0 (0.0%)</td>
<td>$0</td>
</tr>
<tr>
<td></td>
<td>Respiratory Health</td>
<td>41</td>
<td>8 (19.5%)</td>
<td>$2,246K</td>
</tr>
<tr>
<td></td>
<td>Sustained Release Drug Delivery</td>
<td>18</td>
<td>2 (11.1%)</td>
<td>$619K</td>
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<tr>
<td></td>
<td>Entire Program</td>
<td>482</td>
<td>71 (14.7%)</td>
<td>$21,242K</td>
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</tbody>
</table>
## 2021 PRMRP Other Awards

<table>
<thead>
<tr>
<th>Award</th>
<th>Topic</th>
<th>Compliant Applications Received</th>
<th>Awards Made</th>
<th>Total Funds</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Clinical Trial (CTA)</td>
<td>Emerging Viral Diseases</td>
<td>55</td>
<td>7 (12.7%)</td>
<td>$13,003K</td>
</tr>
<tr>
<td>• Expansion (EA)</td>
<td>Hepatitis B</td>
<td>4</td>
<td>2 (50%)</td>
<td>$8,676K</td>
</tr>
<tr>
<td>• Focused Program (FPA)</td>
<td>Myalgic Encephalomyelitis/Chronic Fatigue Syndrome</td>
<td>4</td>
<td>1 (25%)</td>
<td>$2,517K</td>
</tr>
<tr>
<td>• Investigator-Initiated Research (IIRA)</td>
<td>Plant-Based Vaccines</td>
<td>1</td>
<td>0 (0.0%)</td>
<td>$0</td>
</tr>
<tr>
<td>• Technology/Therapeutic Development (TTDA)</td>
<td>Respiratory Health</td>
<td>46</td>
<td>10 (21.7%)</td>
<td>$29,043K</td>
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<tr>
<td></td>
<td>Sustained Release Drug Delivery</td>
<td>23</td>
<td>4 (17.4%)</td>
<td>$9,422K</td>
</tr>
<tr>
<td></td>
<td>Entire Program</td>
<td>609</td>
<td>98 (16.1%)</td>
<td>$304,316K</td>
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</tbody>
</table>
Brief Introduction to DOD Award Applications
Organization Registrations

- **Sam.gov**
  - Free registration
  - Requires significant time to validate
  - Start early – start now!

- **Electronic Biomedical Research Application Portal (eBRAP)**
  - Free registration
  - Company and Principal Investigator
  - DOD Pre-applications submitted through eBRAP

- **Grants.gov**
  - Free registration
  - DOD Full Applications submitted through grants.gov
Application Documents

- Download ALL Award Documents
- Program Announcement
- General Application Instructions
- Templates and Supporting Documents
- Program Announcement
- Eligibility
- Specific dates
- Funding ceilings
- Focused topics of interest
- Supersedes the General Instructions
- CDMRP Webinar Series
Military Specific Application Components

- Pre-proposals
- Required
- Administrative or Juried
- Military Relevance
- Statement of Work
- Quad Chart

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**General Application Instructions**

**Version 2010.02.10**

**Department of Defense**

**Defense Health Programs**

**Congressionally Directed Medical Research Programs**

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<td>B. Content and Form of Pre-Application Submission</td>
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<td>C. Content and Form of Full Application Submission</td>
<td>8</td>
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<td>D. Applicant Verification of Grants.gov Submission in eBRAP</td>
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This General Application Instructions document is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the Program Announcement, is available for downloading from Grants.gov.
# Two Tier Proposal Review Process – Full Proposals

<table>
<thead>
<tr>
<th>Scientific Peer Review – Tier 1</th>
<th>Programmatic Review – Tier 2</th>
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</thead>
<tbody>
<tr>
<td>• Evaluated on Scientific and Technical Merit</td>
<td>• Evaluated on Programmatic Relevance</td>
</tr>
<tr>
<td>• Both Scientific and Consumer/Stakeholders</td>
<td>• Both Scientific and Consumer/Stakeholders</td>
</tr>
<tr>
<td>• Evaluated Independently</td>
<td>• Comparison to other Proposals</td>
</tr>
<tr>
<td>• Provided evaluation summary</td>
<td>• Panel Makes Funding Recommendation</td>
</tr>
<tr>
<td>• Statement outlining strengths and weaknesses</td>
<td>• Balances Peer Review Score and Program Relevance</td>
</tr>
<tr>
<td>• Overall Score</td>
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</tbody>
</table>
Military Relevance

- Understand the Target(s) of the Program
  - Read the announcement
  - Visit all related DOD sites
    - CDMRP Program Page
    - Specific DOD Program Page (MIDRP or JPEO-CBRND)
  - Familiarize yourself with decisionmakers
- Understand the Military Environment
- Understand the Competition
  - What has been funded previously?
    - CDMRP – Award Search Page
    - NIH – NIH RePorter
    - USA SPENDING.gov – ALL federal awards (contracts and grants)
  - Who are your commercial competitors?
  - How is the DOD currently solving the problem your product solves?
DOD Sponsored Conferences

- Military Health System Research Symposium
  - Tentative: August 8-11, 2022 in Orlando, FL
  - Cancelled in 2020 and 2021
  - Research abstracts were due February 16, 2022

- Special Operations Medical Association Scientific Assembly
  - May 2-6, 2022 in Raleigh, NC
  - Research abstracts due in mid-November

- 10th International DOD State of the Science Meeting on Blast Injury
  - Postponed – no date set
  - Organized for the DOD Blast Injury Research Coordinating Office
Statement of Work

- Align with Narrative
- Tasks, Subtasks, Milestones, Deliverables
- Fully Describes Proposed Project
- Inc. # and type of subjects or animals
- Include Regulatory Review
- 2-3 Months
- Include Milestones
- Realistic
Hypothesis
We hypothesize that exposure of Peeps to smoking and alcohol will have no effect on behavior, form, or flavor.

Study/Product Aim(s)
• Identify the effects of Alcohol on Peeps
• Identify the effects of Smoking on Peeps
• Identify the combined effects of Alcohol and Smoking on Peeps

Approach
In our first aim, we will expose Peeps to 95% ethyl alcohol in a controlled environment. We will evaluate the Peeps for swimming ability and determine effect on flavor. In our second aim, we will expose Peeps to filtered cigarettes. Each Peep will be expected to consume one cigarette and will be evaluated on behavior and flavor. In our final aim, we will determine if there is any synergistic effect when Peeps are exposed to both smoking and alcohol. Peeps will be evaluated based on form and flavor.

Timeline and Cost

<table>
<thead>
<tr>
<th>Activities</th>
<th>CY 22</th>
<th>CY 23</th>
<th>CY 24</th>
<th>CY 25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peeps and Alcohol</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Peeps and Smoking</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peeps and Alcohol and Smoking</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Final Report and Publication</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

| Estimated Budget ($K) | $50 | $50 | $50 | $50 |

Goals/Milestones (Example)

CY22 Goal – Complete Aim 1
☑ Peeps Tested with Alcohol

CY23 Goals – Complete Aim 2
☐ Peeps tested with Cigarettes

CY24 Goal – Complete Aim 3
☐ Peeps tested with Alcohol and Cigarettes

CY25 Goal – Final Report
☐ Complete Final Report and Publication Draft

Comments/Challenges/Issues/Concerns
• Seasonal supply of Peeps may pose a concern, but with the addition of multiple holiday shapes, we will ensure timely completion of the study within an appropriate model system
• No budget issues are anticipated

Budget Expenditure to Date
Projected Expenditure: $0
Actual Expenditure: $0

Updated: 3 March 2022
Key Points
Key Points

- **READ SOLICITATIONS CAREFULLY**
  - Read solicitation topic areas, focus areas, areas of encouragement for relevance to your research
  - Relevance to the identified Defense Research Program is important
  - Determine if your research is of interest to multiple Programs
  - Engage CDMRP Help Desk early if there are changes from pre-application
  - Pay attention to all attachments
  - Biostatisticians are on review panels
  - Review the Research Program web site for info on topics of interest, stakeholders’ meeting summaries, and the state of the science
  - Newspaper headlines do not always equal programmatic interest/funding availability
Key Points

- Don’t use inaccurate military jargon
- Allow enough time to get budgets and letters of collaboration/support – particularly from US federal collaborators
- Keep solicitation’s stated target population in mind
- Apply again if not funded
- Every application is considered a new application
- If funded - develop a strong relationship with your program manager/grants officer representative

- Know the solicitation’s target population which may include some or all below:
  - Military (active duty: 18-45 years old, generally healthy)
  - Service member dependents (spouses and children)
  - Veterans (any former member of the military at any age)
  - Retirees (completed a military career, 40+)
  - Civilian (all ages)
Questions?

- Elizabeth Barrows, MS
- Rare.lizard@gmail.com
- LinkedIn