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Securing DOD Research Funding to Fight Infectious Disease Threats

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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)

Military Health System Mission

- The 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:
 - 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 *9.6M 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

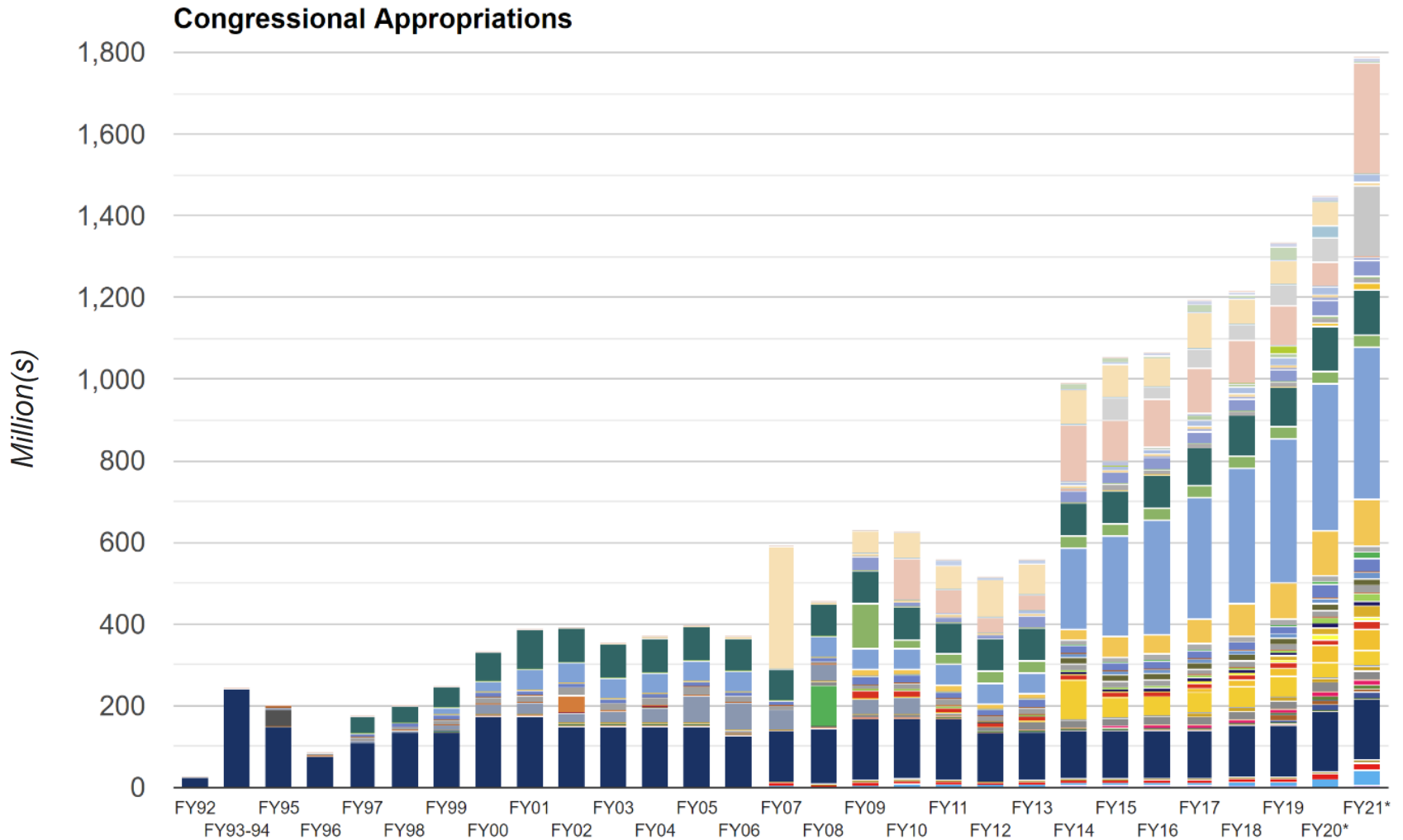
Congressionally Directed
Medical Research Program



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

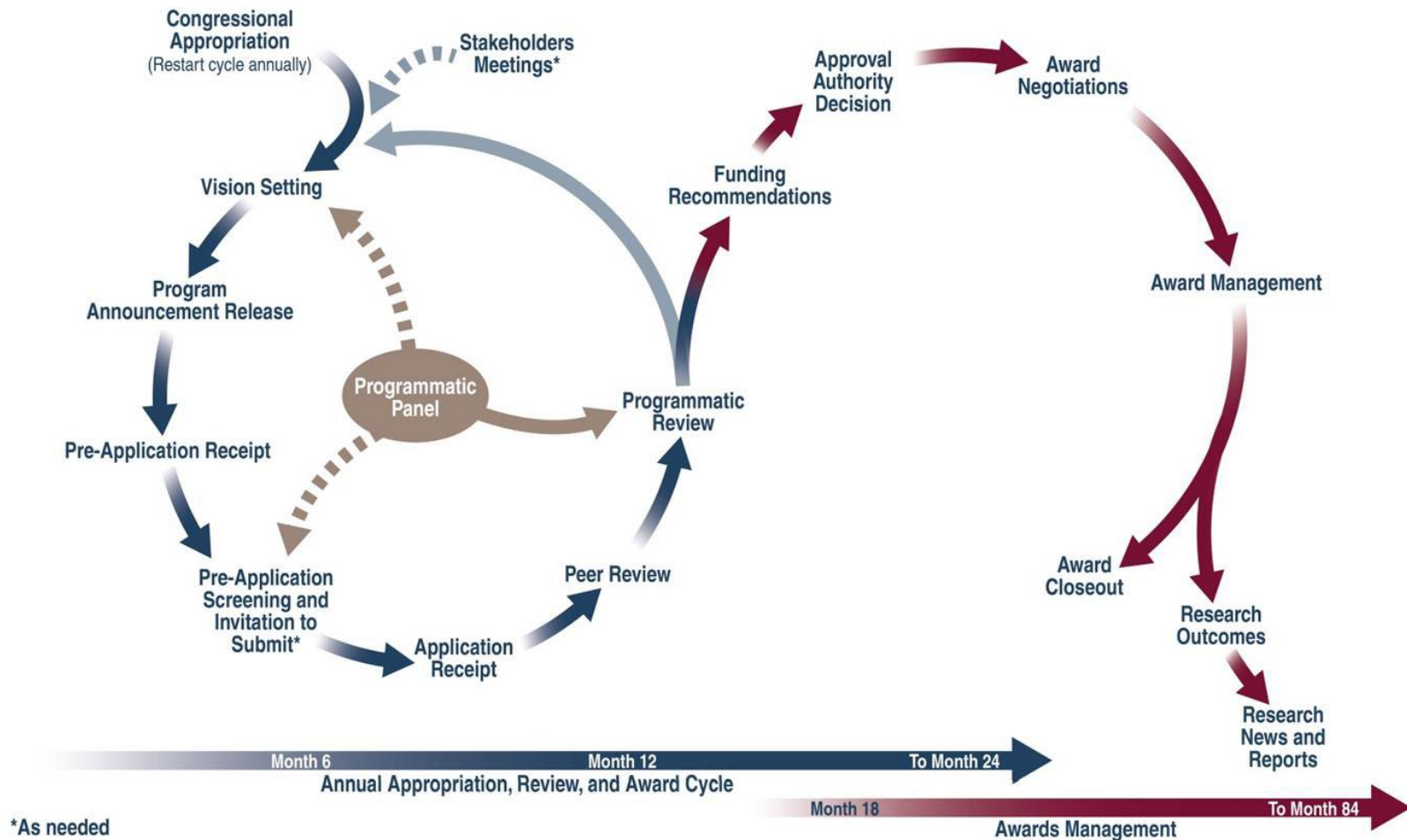


Program Name	\$M	Program Name	\$M
Peer Reviewed Medical Research	370	Rare Cancer Research	17.5
Psych Health and Traumatic Brain Injury	175	Peer Reviewed Parkinson's Research	16
Breast Cancer Research	150	Chronic Pain Management Research	15
Peer Reviewed Cancer Research	130	Pancreatic Cancer Research	15
Prostate Cancer Research	110	Alzheimer Research	15
Brain Injury & Disease Prevention	60	Autism Research	15
Kidney Cancer Research	50	Epilepsy Research	12
Ovarian Cancer Research	45	Reconstructive Transplant Research	12
Melanoma Research	40	Duchenne Muscular Dystrophy Research	10
Peer Reviewed ALS Research	40	Hearing Restoration Research	10
Spinal Cord Research	40	Lupus Research	10
Joint Warfighter Medical Research	40	Clinical Research	10
Peer Reviewed Orthopedic Research	30	Trauma Clinical Research	10
Toxic Exposures Research (New – GWI?)	30	Combat Readiness Medical Research	10
Multiple Sclerosis Research	20	Peer Reviewed Military Burn Research	10
Vision Research Program	20	Tuberous Sclerosis Complex Research	8
Lung Cancer Research	20	Bone Marrow Failure Disease Research	7.5
Orthotics and Prosthetics Outcomes Research	20	Tickborne Diseases Research	7
Peer Reviewed Neurofibromatosis Research	20	Alcohol and Substance Use Disorder Research	4

Forecast FY2022 CDMRP Programs - \$1.8B

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

Managing Expectations – Grant Funding Cycle



Topic	Topic	Topic	Topic
Arthritis	Fragile X	Musculoskeletal Disorders (Acute & Chronic Bone Conditions & Injuries) (New)	Pressure Ulcers
Cardiomyopathy	Friedreich's Ataxia (New)	Myalgic Encephalomyelitis/Chronic Fatigue Syndrome	Pulmonary Fibrosis
Congenital Heart Disease	Frontotemporal Degeneration	Myotonic Dystrophy	Respiratory Health
Diabetes	Guillain-Barre Syndrome (New)	Nephrotic Syndrome (New)	Rett Syndrome (New)
Dystonia	Hemorrhage Control	Non-Opioid Therapy for Pain Management	Rheumatoid Arthritis
Eating Disorders	Hepatitis B	Nutrition Optimization	Sleep Disorders and Restriction
Ehlers-Danlos Syndrome (New)	Hydrocephalus	Pancreatitis (New)	Suicide Prevention
Endometriosis	Hypercholesterolemia	Pathogen Inactivated Blood Products	Sustained Release Drug Delivery
Epidermolysis Bullosa	Hypertension	Peripheral Neuropathy	Trauma (New)
Familial Hypercholesterolemia	Inflammatory Bowel Diseases	Plant-based Vaccines	Vascular Malformations
Fibrous Dysplasia	Interstitial Cystitis (New)	Platelet-like Cell Production	Viral Diseases
Focal Segmental Glomerulosclerosis	Malaria	Polycystic Kidney Disease	Women's Heart Disease
Food Allergies	Mitochondrial Disease		

Forecast FY2022 **PRMRP** 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

2021 PRMRP Discovery Awards

Award	Topic	Compliant Applications Received	Awards Made	Total Funds
<u>Discovery Award</u>	Emerging Viral Diseases	50	10 (20%)	\$2,955K
	Hepatitis B	5	0 (0.0%)	\$0
	Myalgic Encephalomyelitis/Chronic Fatigue Syndrome	9	1 (11.1%)	\$325K
	Plant-Based Vaccines	2	0 (0.0%)	\$0
	Respiratory Health	41	8 (19.5%)	\$2,246K
	Sustained Release Drug Delivery	18	2 (11.1%)	\$619K
	Entire Program	482	71 (14.7%)	\$21,242K

2021 PRMRP Other Awards

Award	Topic	Compliant Applications Received	Awards Made	Total Funds
<ul style="list-style-type: none"> • <u>Clinical Trial (CTA)</u> • <u>Expansion (EA)</u> • <u>Focused Program (FPA)</u> • <u>Investigator-Initiated Research (IIRA)</u> • <u>Technology/Therapeutic Development (TTDA)</u> 	Emerging Viral Diseases	55	7 (12.7%)	\$13,003K
	Hepatitis B	4	2 (50%)	\$8,676K
	Myalgic Encephalomyelitis/Chronic Fatigue Syndrome	4	1 (25%)	\$2,517K
	Plant-Based Vaccines	1	0 (0.0%)	\$0
	Respiratory Health	46	10 (21.7%)	\$29,043K
	Sustained Release Drug Delivery	23	4 (17.4%)	\$9,422K
	Entire Program	609	98 (16.1%)	\$304,316K

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

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Investigator-Initiated Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH18PRMRPIIRA

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- Pre-Application Submission Deadline: 5:00 p.m. Eastern time (ET), June 12, 2018
- Invitation to Submit an Application: July 2018
- Application Submission Deadline: 11:59 p.m. ET, September 20, 2018
- End of Application Verification Period: 5:00 p.m. ET, September 24, 2018
- Peer Review: November 2018
- Programmatic Review: January 2019

This Program Announcement must be read in conjunction with the General Application Instructions, version 20180329. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

DoD FY18 Peer Reviewed Medical Investigator-Initiated Research Award

1

- 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

General Application Instructions
Version 20160210
Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs

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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.

DoD General Application Instructions 1

Two Tier Proposal Review Process – Full Proposals

Scientific Peer Review – Tier 1

- Evaluated on Scientific and Technical Merit
- Both Scientific and Consumer/Stakeholders
- Evaluated Independently
- Provided evaluation summary
- Statement outlining strengths and weaknesses
- Overall Score

Programmatic Review – Tier 2

- Evaluated on Programmatic Relevance
- Both Scientific and Consumer/Stakeholders
- Comparison to other Proposals
- Panel Makes Funding Recommendation
- Balances Peer Review Score and Program Relevance

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](#)
 - [USASPENDING.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

This generic Statement of Work document is intended to assist applicants with the format preferred by CDMRP. This particular SOW does not contain any specific scientific information and is intended to be easily modifiable for any project. Not all components will be applicable for every project; please consult your Program Announcement for specific award requirements.

**STATEMENT OF WORK – Month/Day/Year
PROPOSED START DATE Aug XX, 20XX**

Site 1: Research Institution Name
Address for Org #1
PI: XXXXXXXXX

Site 2: Research Institution Name
Address for Org #2
Partnering PI: YYYYYYYYYY

Specific Aim 1(specified in proposal)	Timeline	Site 1	Site 2
Major Task 1	Months		
Subtask 1	1-3	Dr. X	Dr. Y
Subtask 2	1-3	Dr. X	Dr. Y
Subtask 3	3	Dr. X	
Milestone(s) Achieved			
Local IRB/IACUC Approval	3		
Milestone Achieved: HRPO/ACURO Approval	6		
Major Task 2			
Subtask 1	1	Dr. Y (total # human subjects)	Dr. X
Subtask 2	1	Dr. Y	Dr. X (total # of animals)
Subtask 3	2-3	Dr. Y	Dr. X
Milestone(s) Achieved:	4		Dr. X
Specific Aim 2			
Major Task 3			
Subtask 1	1	Dr. X	Dr. Y
Subtask 2	5	Dr. X	Dr. Y
Milestone(s) Achieved:	9	Dr. X	Dr. Y

Peeps, Smoking and Alcohol

Insert ERMS/Log Number and Task Title Here

Insert Award Number Here

PI: Marsha Mallow, PhD
\$200,000

Org: Just Born Quality Confections

Award Amount:

Hypothesis

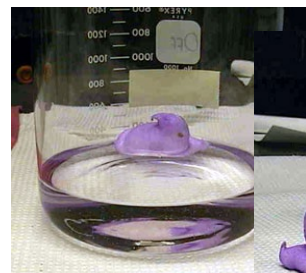
We hypothesize that exposure of Peeps to smoking and alcohol will have no effect on behavior, form, or flavor.

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

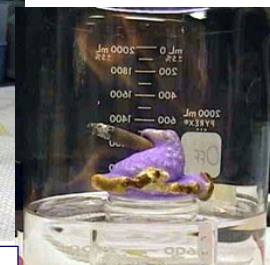
In our first aim, we will expose Peeps to 95% ethyl alcohol in a controlled environment. We will evaluate the Peeps for swimming ability and determine effect on flavor. In our second aim, we will expose Peeps to filtered cigarettes. Each Peep will be expected to consume one cigarette and will be evaluated 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.



Aim 1: Peeps and Alcohol



Aim 2: Peeps and Smoking



Aim 3: Peeps and Alcohol and Smoking

Timeline and Cost

Activities	CY	22	23	24	25
Peeps and Alcohol					
Peeps and Smoking					
Peeps and Alcohol and Smoking					
Final Report and Publication					
Estimated Budget (\$K)		\$50	\$50	\$50	\$50

Updated: 3 March 2022

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

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
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- [LinkedIn](#)