

## Symposium for Research Administrators

### University of Wisconsin-Madison October 25<sup>th</sup>, 2022

## Developing Quality Department of Defense (DoD) Proposals

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Biomedical Engineering, COE, UW-Madison



## Navigating DoD Biomedical Funding

Competition for NSF and NIH funding is increasing; DoD has WISE HEALTH numerous funding opportunities to complement NSF and NIH

Topics discussed today include:

Overview

Education Development

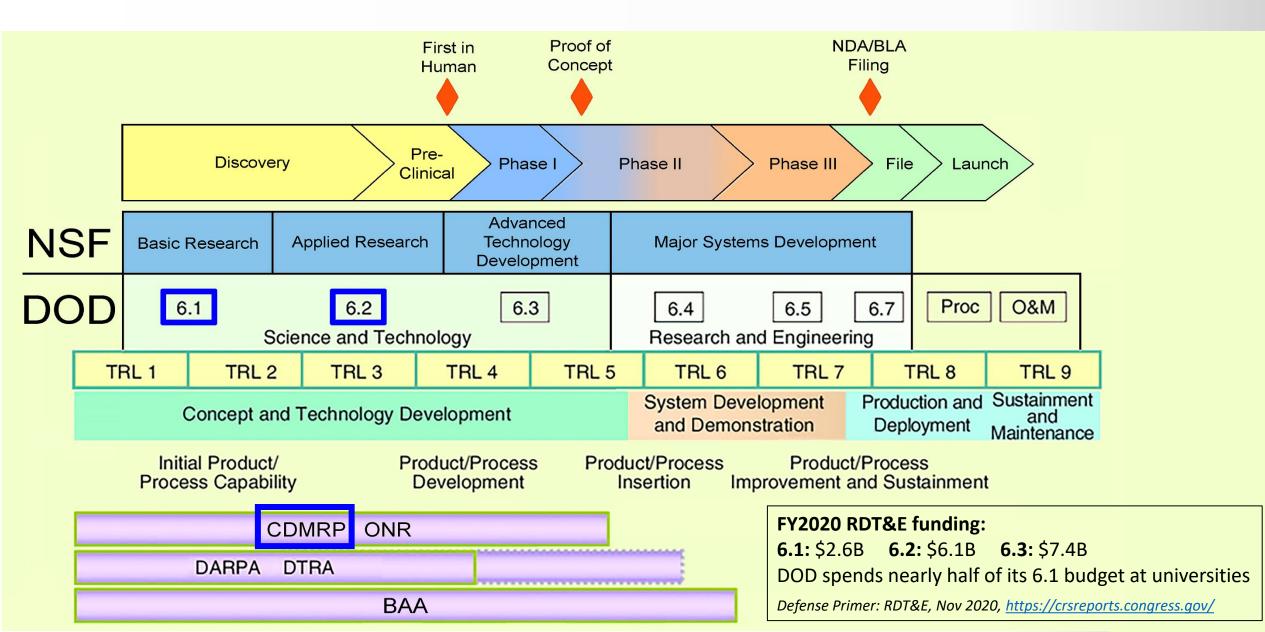
- DoD-focused grantsmanship
- DoD (CDMRP) application format(s) and content
  - The eBRAP system
  - Pre-applications
  - Verifications



## Overview



## Scope of DoD Biomedical Research Support





## DOD's Approach to Biomedical R&D

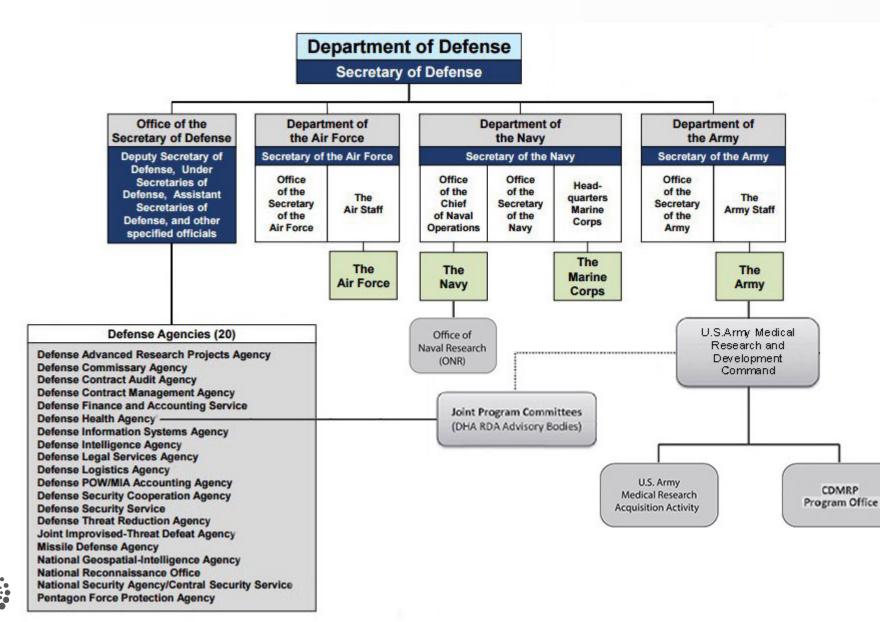
### A Primer on the Military Health System's Approach to Medical Research and Development

Todd E. Rasmussen, MD, Arthur L. Kellermann, MD, MPH, and Terry M. Rauch, PhD, MPH, MBA

### Abstract

The Military Health System (MHS) has a medical research program aimed at a wide range of health-, disease-, and injury-related topic areas that works with civilian academic institutions and the biomedical industry to accomplish its goals. There are many opportunities for civilian academic institutions and "requirements-driven" research. At the highest level, requirements are aligned with the National Security Strategy and National Defense Strategy, though requirements documents list specific areas in medicine with unmet needs. Military labs and the Uniformed Services University of the Health Sciences, which

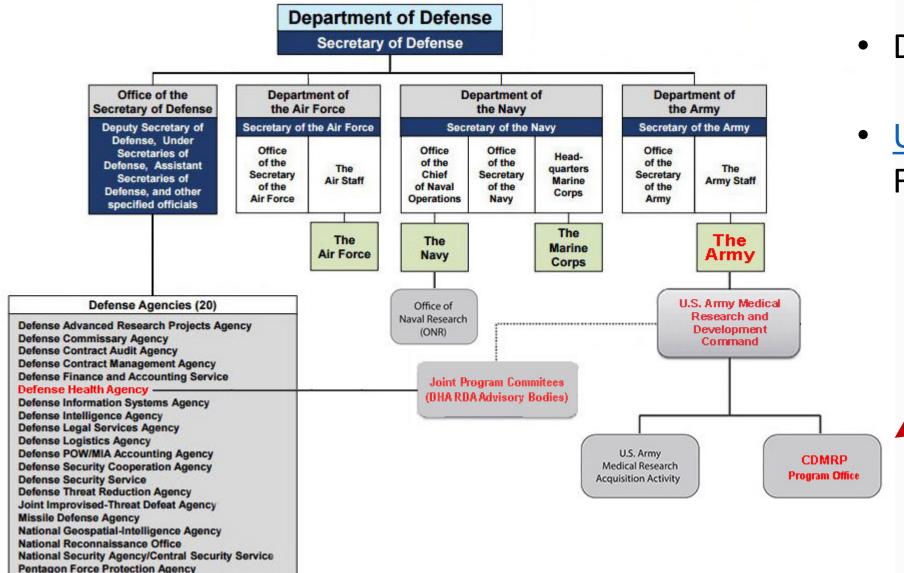
## The Complexity of DoD Biomedical Funding Support



- Mission-driven
- Topic-specific
- Numerous, independent funding streams

## Warfighter-focused vs. civilian applications

## The Complexity of DoD Biomedical Funding Support



- DHA (<u>R&D</u> is "J-9")
  - <u>JPC</u>
- <u>USAMRDC</u> (Army Futures Command)

<u>CDMRP</u>

## Congressionally Directed Medical Research Program (CDMRP)

- Topics are driven by Congressional member interests and advocacy organizations
- Congressional funding added to the Defense Appropriations Bill
  - Exists when the Defense Appropriation Bill becomes law
- Mechanisms support the spectrum from concept to clinical trial
- Numerous independent disease focus areas and several "umbrella" programs
  - Combat Readiness-Medical Research Program CRRP
  - Peer Reviewed Medical Research Program PRMRP
  - Defense Medical Research and Development Program DMRDP



## CDMRP Funding for FY22

- Alcohol and Substance Abuse Disorders
- Amyotrophic Lateral Sclerosis
- Autism
- Bone Marrow Failure
- Breast Cancer
- Chronic Pain Management
- Combat Readiness-Medical
- Duchenne Muscular Dystrophy
- Epilepsy
- Gulf War Illness
- Hearing Restoration
- Joint Warfighter Medical
- Kidney Cancer

- Lung Cancer
- Lupus
- Melanoma
- Military Burn
- Multiple Sclerosis
- Neurofibromatosis
- Neurotoxin Exposure Treatment Parkinson's
- Orthotics and Prosthetics Outcomes
- Ovarian Cancer
- Pancreatic Cancer
- Peer Reviewed Alzheimer's
- Peer Reviewed Cancer (20+)

- Peer Reviewed Medical (49+)
- Peer Reviewed Orthopaedic
- Prostate Cancer
- Rare Cancers
- Reconstructive Transplant Research
- Scleroderma
- Spinal Cord Injury
- Tick-Borne Disease
- Traumatic Brain Injury and Psychological Health
- Tuberous Sclerosis Complex
- Vision
- Defense Medical Research and Development



## Peer Reviewed Medical Research Program (PRMRP) Funding for FY22

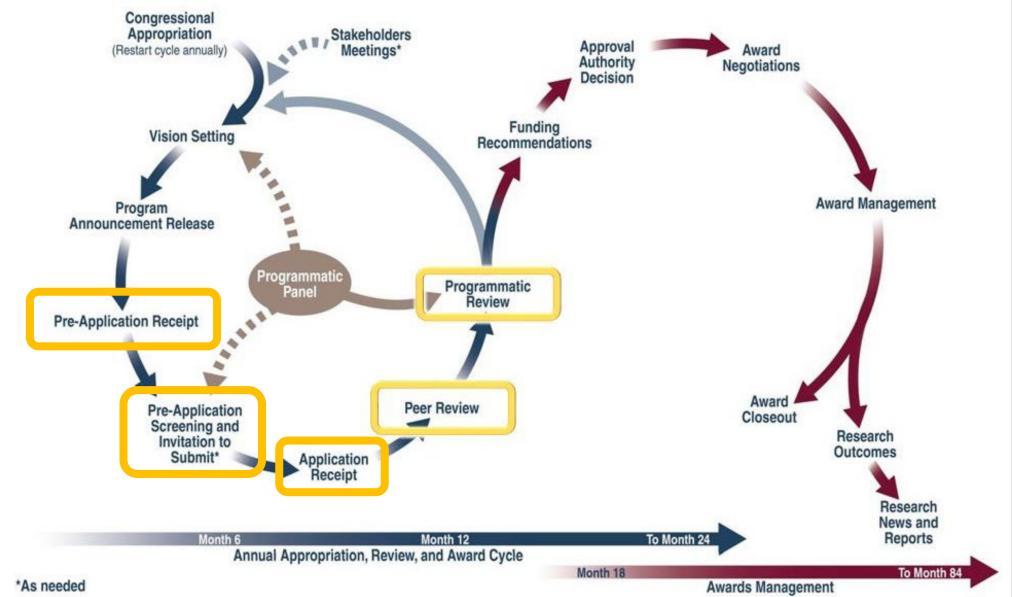
- Arthritis
- Cardiomyopathy
- Congenital Heart Disease
- Diabetes
- Dystonia
- Eating Disorders
- Ehlers-Danlos Syndrome
- Endometriosis
- Epidermolysis Bullosa
- Familial Hypercholesterolemia
- Fibrous Dysplasia
- Focal Segmental Glomerulosclerosis
- Food Allergies
- Fragile X
- Friedreich's Ataxia
- Frontotemporal Degeneration



- Guillain-Barré Syndrome
- Hemorrhage Control
- Hepatitis B
- Hydrocephalus
- Hypertension
- Inflammatory Bowel Diseases
- Interstitial Cystitis
- Malaria
- Mitochondrial Disease
- Musculoskeletal Disorders
- Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome
- Myotonic Dystrophy
- Nephrotic Syndrome
- Non-Opioid Therapy for Pain Management
- Nutrition Optimization
- Pancreatitis
- Pathogen-Inactivated Blood Products

- Peripheral Neuropathy
- Plant-Based Vaccines
- Platelet-Like Cell Production
- Polycystic Kidney Disease
- Pressure Ulcers
- Pulmonary Fibrosis
- Respiratory Health
- Rett Syndrome
- Rheumatoid Arthritis
- Sleep Disorders and Restriction
- Suicide Prevention
- Sustained Release Drug Delivery
- Trauma
- Vascular Malformations
- Viral Diseases
- Women's Heart Disease

### CDMRP's Application and Review Process



RED Research Education Development



DoD Provides Many Resources Online, as do DoD-Supportive Organizations



rs expressed in this presentation are those of the author not reflect the official policy or position of the Department my Department of Defense, or the U.S. government

https://www.youtube.com/watch?v=FUxznBwwXNY



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### Congressionally Directed Medical Research Programs

### FUNDING AND REVIEW PROCESS





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### https://www.youtube.com/watch?v=APRXLZO-HnE





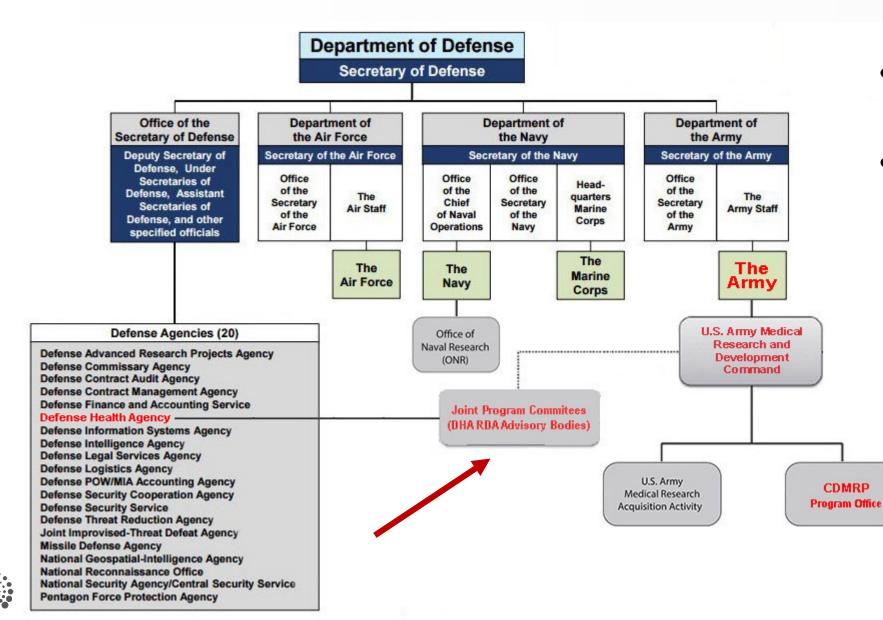
## **CDMRP** Webinar Series

### https://cdmrp.health.mil/pubs/Webinars/webinar\_series.aspx

- Funding Opportunities and Strategies for Success
- High Risk/High Gain Funding Opportunities
- Team Science Funding Opportunities
- Clinical Research and Clinical Trial Funding Opportunities
- Funding Opportunities for the Development of Technology and/or Resources
- Funding Opportunities for Early Career Investigators
- Consortium-Type Funding Opportunities



## The Complexity of DoD Biomedical Funding Support



- DHA (<u>R&D</u> is "J-9")
  - <u>JPC</u>
- USAMRDC (Army Futures Command)
  - <u>CDMRP</u>

## The Joint Program Committees (JPCs)

JPCs consist of medical and military technical experts

Recent streamlining has resulted in three active JPCs

Military Infectious Diseases Research Program (JPC-2)

• Wound Infection Prevention and Management; Antimicrobial Countermeasures

Military Operational Medicine Research Program (JPC-5)

• Injury Prevention and Reduction; Psychological Health and Resilience; Physiological Health; Environmental Health and Protection

Combat Casualty Care Research Program (JPC-6)

• Hemorrhage Control and Resuscitation; En Route Care; Forward Surgical and Intensive Critical Care; Neurotrauma and Traumatic Brain Injury; Traumatic Tissue Injury



## **DoD-Focused Grantsmanship**



(#)

## Successful DoD Funding is about Respect, Relationships, and Results

- Demonstrate respect through your communication with DoD
  - Speak their language
    - DoD jargon is no different than campus acronyms (RSP, OVCRGE, SMPH, COE, WARF)
  - Be responsive
    - Prompt communication signals you value their time
  - Tailor applications to address DoD's stated research problem
    - A PI should never just "repurpose" an NIH or NSF grant
- Develop relationships with key stakeholders and internal DoD champions
  - Develop a purposeful, genuine relationship-building effort
  - Be aware of opportunities and strategic, stage-appropriate engagement
  - Collaborate with DoD and VA
- Be results-oriented; DoD funds success
  - View DoD R&D support as a targeted investment within a larger portfolio
  - Emphasize commercialization and industry partnerships
  - Be aware of DoD proposal writing specifics
    - Funds are milestone-driven contracts, generally not open-ended research grants

## Any Questions about DoD-Specific Grantsmanship or DoD Funding Mechanisms?



## **CDMRP** Applications

Format(s), Content and Submission Process





## **CDMRP** Application Process

- DOD Pre-applications are submitted through the Electronic Biomedical Research Application Portal (<u>eBRAP</u>)
  - New Principal Investigators must register on the DoD's online system prior to submitting information for their first proposal at <u>https://ebrap.org/eBRAP/register/Register.htm</u>
    - (301) 682-5507 Monday to Friday (except Holidays) 8:00 a.m. 5:00 p.m. ET
    - <u>help@eBRAP.org</u>
  - Frequently Asked Questions
  - <u>Commonly Made Mistakes</u>
  - <u>eBRAP User Guide</u>
- DOD Full Applications are submitted through Grants.gov



### eBRAP Preview (Application Elements)

### **Funding Opportunities and Forms**

#### Vision Research Program (VRP)

#### Synopsis of VRP Award Mechanisms

#### General Application Instructions Version 702

Award Mechanism	Documents and Forms	Opens	Submission Deadline	Actions
Clinical Trial Award	FY22 VRP Clinical Trial Award Program Announcement	05-10- 2022	07-15-2022 - (Pre-application - Pre- Proposal) 11-09-2022 - (Application)	
Focused Translational Team Science Award	FY22 VRP Focused Translational Team Science Award Program Announcement	05-10- 2022	07-15-2022 - (Pre-application - Pre- Proposal) 11-09-2022 - (Application)	
Investigator-Initiated Research Award	FY22 VRP Investigator-Initiated Research Award Program Announcement	05-10- 2022	07-15-2022 - (Pre-application - Pre- Proposal) 11-09-2022 - (Application)	
Translational Research Award	FY22 VRP Translational Research Award Program Announcement	05-10- 2022	07-15-2022 - (Pre-application - Pre- Proposal) 11-09-2022 - (Application)	

Show All Current Funding Opportunities



## eBRAP Preview (Application Elements)

#### **Generic Forms for Application Submission**

	MS Office	PDF
Suggested CDMRP Biographical Sketch	<b>B</b>	n/a
Suggested Quad Chart Template		n/a
Pre-application Budget Summary Form	<b>1</b>	n/a
Suggested Collaborating DoD Military Facility Budget Format	🖻 or 🗐	n/a
Suggested DoD Military Budget Format	n/a	1
Common Blinding Mistakes and How to Avoid Them	<b>1</b>	
Suggested SOW Format	<b>1</b>	1
Suggested SOW Strategy Clinical Research	<b>1</b>	
Suggested SOW Strategy Generic Research	<b>1</b>	1
Public Health Service Inclusion Enrollment Report	n/a	



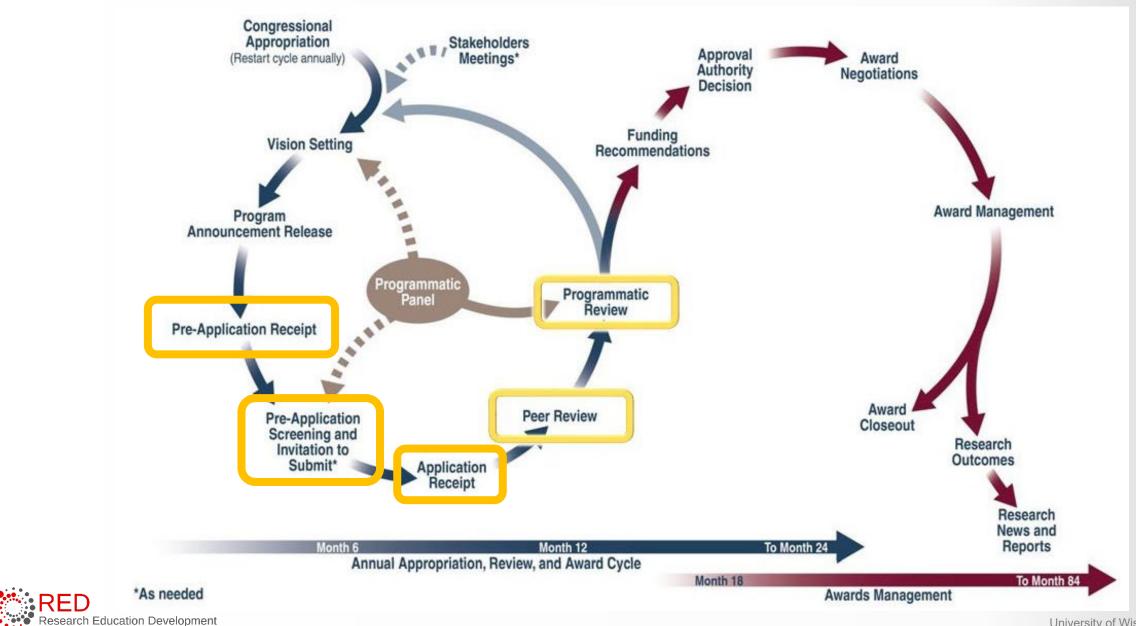
## eBRAP Preview (Post-award Support Elements)

Regulatory Document Forms		
	MS Office	PDF
Safety & Environmental Resources	n/a	n/a
Environmental Compliance Assurance	<b>1</b>	₩
eBRAP Regulatory File Drop-Off Instruction Guide	n/a	₽
Appendix for Animal Use in Research, Development, Testing, Evaluation, and Training	n/a	n/a
Guidance for Submission of Changes to Animal Care and Use Protocols	n/a	n/a
Adverse or Regulatory Events Requiring Reporting to ACURO	n/a	n/a
Office of Human Research Oversight Resources and Overview	n/a	n/a

#### **Progress Report Formats**

	MS Office	PDF
Award Expiration Transition Plan	n/a	₫.
Annual/Final Progress Report Format	E I	n/a
Semi-Annual Technical Progress Report template	<b>1</b>	n/a
Quarterly Progress Report Format	B	n/a
Suggested Quad Chart Template	<b>S</b>	n/a
Suggested Award Chart Template		n/a
Technical Reporting Requirements	n/a	n/a
Public Health Service Inclusion Enrollment Report	n/a	

### **CDMRP's Application and Review Process**



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# Application Documents (available through eBRAP)

### **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

#### I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

**Defense Health Program** 

**Congressionally Directed Medical Research Programs** 

Investigator-Initiated Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-22-VRP-IIRA

Assistance Listing 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), July 15, 2022
- Invitation to Submit an Application: September 2022
- Application Submission Deadline: 11:59 p.m. ET, November 9, 2022
- End of Application Verification Period: 5:00 p.m. ET, November 14, 2022
- Peer Review: January 2023
- Programmatic Review: March 2023



## Elements of a Pre-proposal

- Some form of pre-proposal or letter of intent is required
- Early discovery mechanisms may just have a letter of intent, which is administrative
- The majority of mechanisms require a pre-proposal, which is juried

Submitted through eBRAP

- Tab 1 Application Information
- Tab 2 Application Contacts
- Tab 3 Collaborators and Key Personnel
- Tab 4 Conflicts of Interest
- Tab 5 Pre-Application Files
  - Preproposal Narrative (two-page limit)
    - Research Idea/Rationale
    - Objective(s)/Hypothesis(es), Specific Aims, and Approaches
    - Impact:
    - Personnel
  - Pre-Application Supporting Documentation (uploaded as individual files)
    - References Cited (one-page limit)
    - List of Abbreviations, Acronyms, and Symbols
    - Key Personnel Biographical Sketches (*six-page limit per individual*)
- Tab 6 Submit Pre-Application



## **Full Application Submission Components**

SF4	24 Research & Rel	ated Application for Federal Assistance			
	Attachment 1	Project Narrative: Upload with file name "ProjectNarrative.pdf"			
	Attachment 2	Supporting Documentation: Upload with file name "Support.pdf"			
	Attachment 3	<i>Technical Abstract:</i> Upload with file name "TechAbs.pdf"			
	Attachment 4	Lay Abstract: Upload with file name "LayAbs.pdf"			
ts	Attachment 5	Statement of Work: Upload with file name "SOW.pdf"	Military specific		
Attachments	Attachment 6	Impact Statement: Upload with file name "Impact.pdf"	application		
	Attachment 7	Relevance to Military Health Statement: Upload with file name "Military.pdf"			
ttao	Attachment 8	Animal Research Plan: Upload with file name "AnimalPlan.pdf" if applicable	components		
At	Attachment 9	<i>Human Subjects/Samples Acquisition and Safety Procedures:</i> Upload with file name "HumProc.pdf" <i>if applicable</i>	highlighted		
	Attachment 10	<i>Representations:</i> Upload with file name "RequiredReps.pdf"			
	Attachment 11	Suggested Collaborating DOD Military Facility Budget Format: Upload with file name			
		"MFBudget.pdf" <i>if applicable</i>			
Research & Related Personal Data					
		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field			
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the			
Res	earch & Related	appropriate field			
Senior/Key Person Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to					
Profile (Expanded)		the appropriate field			
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key			
		person to the appropriate field			
Research & Related Budget, Attach Budget Justification (BudgetJustification.pdf) to the appropriate field					
Project/Performance Site Location(s) Form					
Research & Related Subaward Budget Attachment(s) Form, if applicable29					

Research Education Development

# Submission, Validation, and Application Verification

- The pre-application and application submission process should be started early to avoid missing deadlines.
  - There are no grace periods.
  - Failure to meet either of these deadlines will result in submission rejection.
- Full Application Confirmation Process
- *Submission:* Ideally submit 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission.



# Submission, Validation, and Application Verification

- Validation: eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.
- Verification: The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. Other application components may be changed until the end of the application verification period.

Application Submission Deadline: 11:59 p.m. ET, November 9, 2022

**End of Application Verification Period:** 5:00 p.m. ET, November 14, 2022

## Any Questions about CDMRP Application Format(s), Content and/or Submission Processes?

