

Toxic Exposures Research Program (TERP) Overview

HIGH-IMPACT RESEARCH

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CDMRP 
Department of Defense

Outline

- **Congressionally Directed Medical Research Programs (CDMRP) Overview**
- **Fiscal Year (FY) 2022 Toxic Exposures Research Program**
 - **Congressional Language**
 - **Coordination with the VA**
 - **Vision and Mission**
 - **Program Cycle**
 - **Anticipated Funding Mechanisms**
 - **TERP and Gulf War Illness**
- **TERP Webpage Overview**

CDMRP Overview



Vision and Mission

Vision

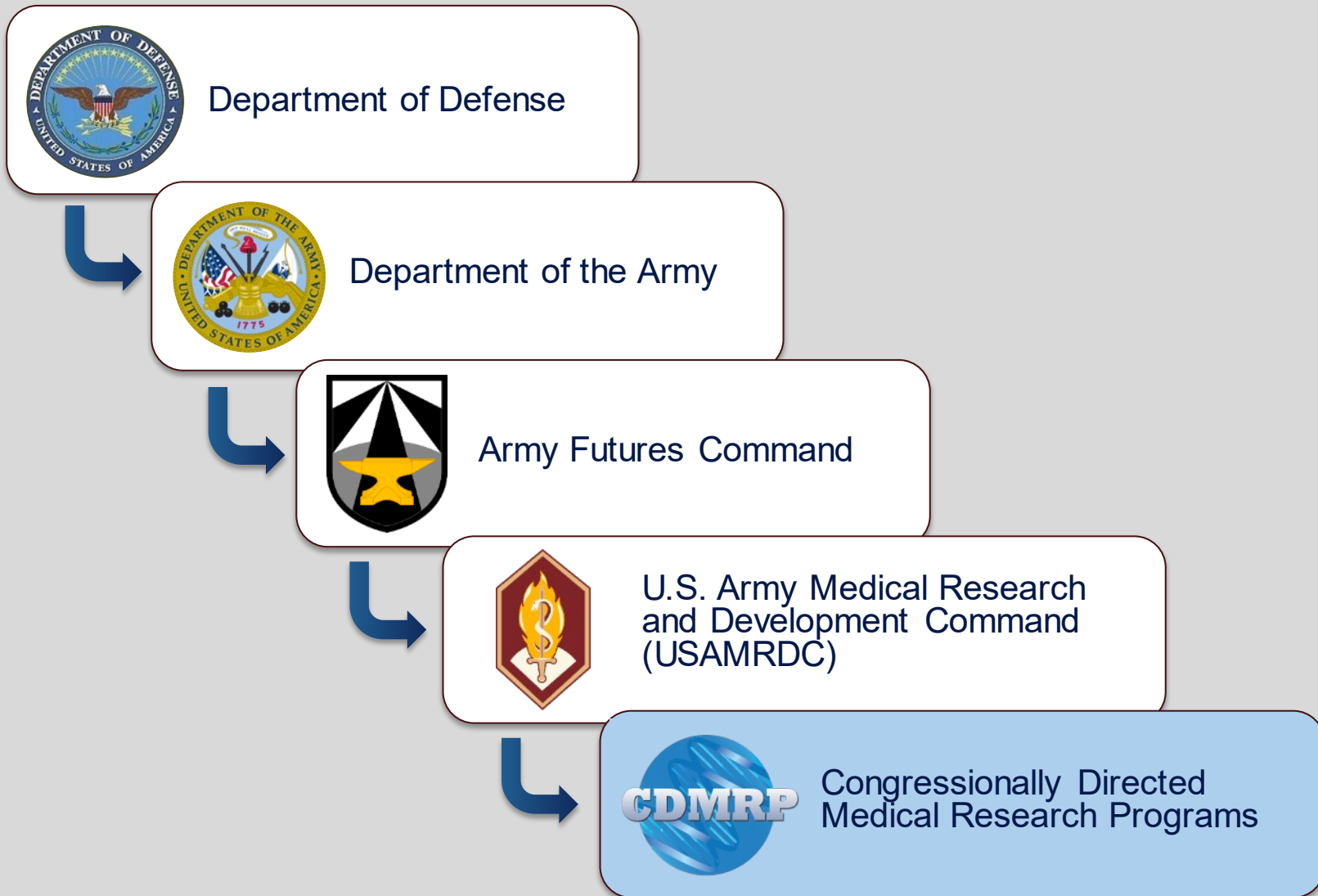
Transforming healthcare through innovative and impactful research



Mission

Responsibly manage collaborative research that discovers, develops, and delivers health care solutions for Service Members, Veterans and the American public

CDMRP - Organizational Structure



About CDMRP



Hallmarks



- ◆ Congress adds targeted research funds to the DOD budget
- ◆ Funds high-impact innovative research
- ◆ Avoids duplication with other funding agencies and targets unfunded/unmet gaps
- ◆ Funding opportunities publically announced and competed
- ◆ Follows the National Academy of Medicine-recommended model for application review
- ◆ Consumers participate throughout the process and are the “True North” and foundation of the programs
- ◆ Annually adapts each program’s vision and investment strategy allowing rapid response to changing needs
- ◆ Funding flexibility
 - ❖ Funds obligated up-front; limited out-year budget commitments
 - ❖ No continuation funding
 - ❖ No “pay line” – funding recommendations are based on portfolio composition, adherence to mechanism intent, relative impact, and technical merit
- ◆ Transparency and accountability to stakeholders
- ◆ Low management costs maximize research dollars

Goal of the Two-Tier Review Process

To develop funding recommendations that balance the most meritorious science across many disciplines and offer the highest promise to fulfill the programmatic goals set forth in the funding opportunity

Peer Review

- ◆ Criterion-based evaluation of full proposal
- ◆ Determination of “absolute” scientific merit
- ◆ **Outcome: Summary Statements**
 - ❖ No standing panels; reviewers are recruited based on expertise needed
 - ❖ No contact between applicants, reviewers, and program staff

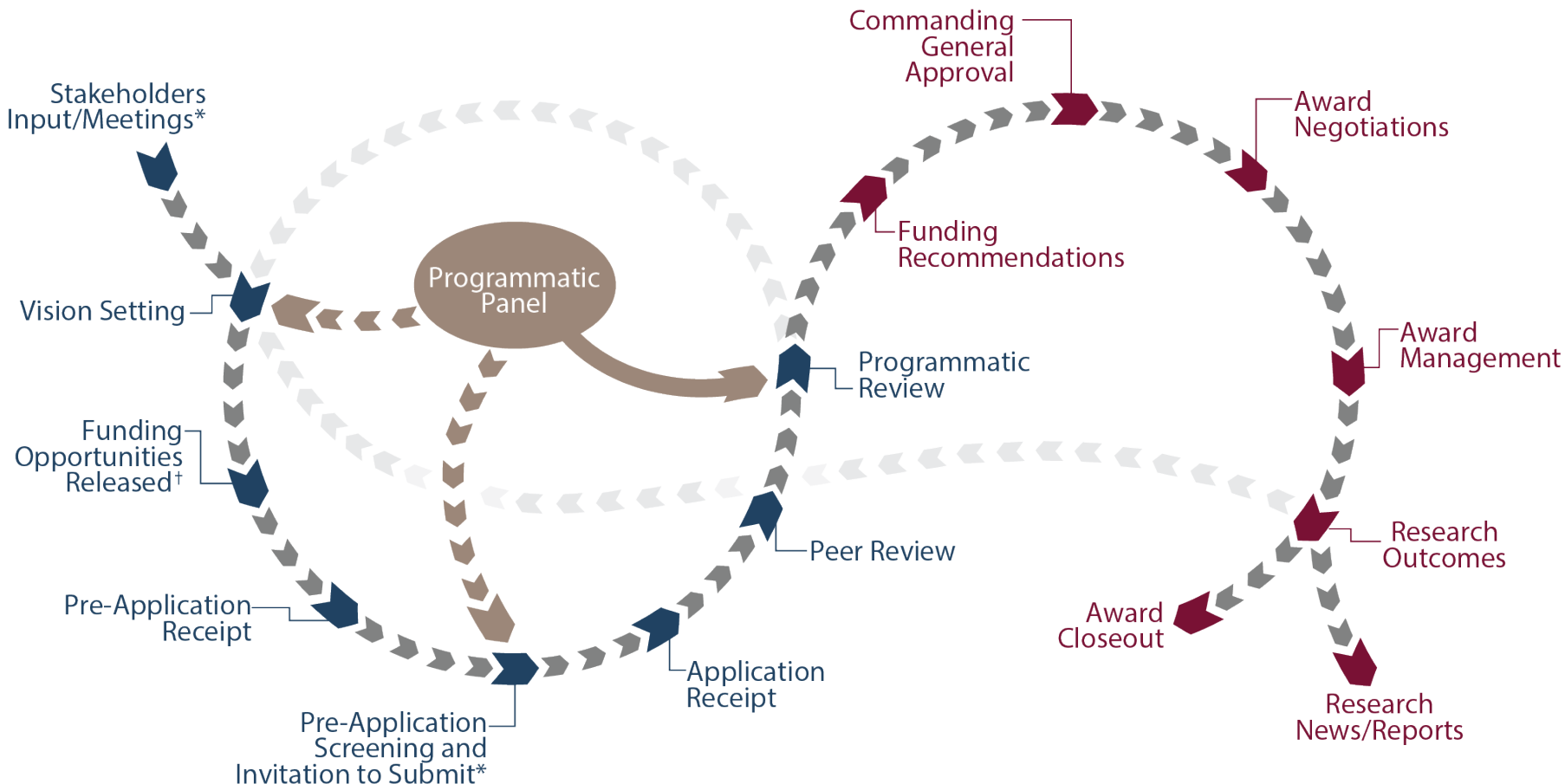
Partnership



Programmatic Review

- ◆ Comparison among proposals of high scientific merit
- ◆ Determination of adherence to intent, program relevance, and potential for impact
- ◆ **Outcome: Funding Recommendations**
 - ❖ No “pay line” (portfolio balance)
 - ❖ Funds obligated up-front; limited out-year budget commitments (but milestones imposed)
 - ❖ No continuation funding

CDMRP Program Cycle



Month 6

Month 12

To Month 24

Annual Appropriation, Review, and Award Cycle

Month 18

To Month 84

Awards Management

*As needed

†Pending Congressional appropriation

CDMRP FY22 Appropriations

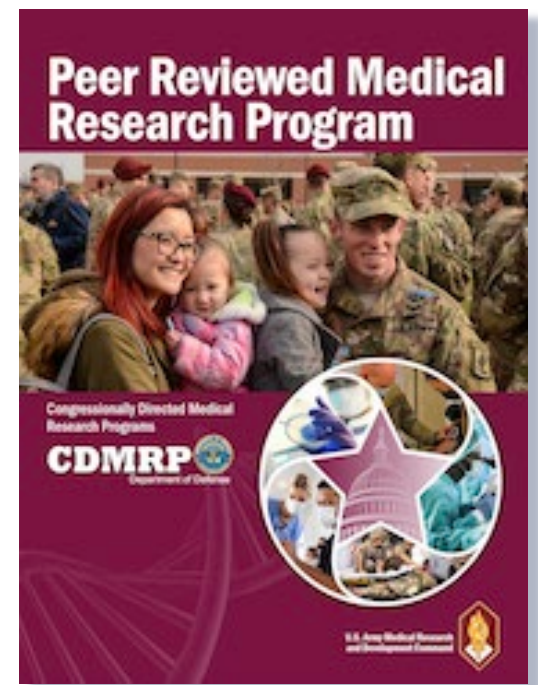
Research Program	FY22 \$M	Research Program	FY22 \$M
Alcohol and Substance Use Disorders	\$4.0	Orthotics and Prosthetics Outcomes	\$20.0
Amyotrophic Lateral Sclerosis	\$40.0	Ovarian Cancer	\$45.0
Autism	\$15.0	Pancreatic Cancer	\$15.0
Bone Marrow Failure	\$7.5	Parkinson's	\$16.0
Breast Cancer	\$150.0	Peer Reviewed Alzheimer's	\$15.0
Chronic Pain Management	\$15.0	Peer Reviewed Cancer (20 Topics)	\$130.0
Combat Readiness Medical	\$10.0	Peer Reviewed Medical (50 Topics)	\$370.0
Duchenne Muscular Dystrophy	\$10.0	Peer Reviewed Orthopaedic	\$30.0
Epilepsy	\$12.0	Prostate Cancer	\$110.0
Hearing Restoration	\$10.0	Rare Cancers	\$17.5
Joint Warfighter Medical	\$40.0	Reconstructive Transplant	\$12.0
Kidney Cancer	\$50.0	Spinal Cord Injury	\$40.0
Lung Cancer	\$20.0	Tick-Borne Disease	\$7.0
Lupus	\$10.0	Toxic Exposures	\$30.0
Melanoma	\$40.0	Traumatic Brain Injury and Psychological Health	\$175.0
Military Burn	\$10.0	Tuberous Sclerosis Complex	\$8.0
Multiple Sclerosis	\$20.0	Vision	\$20.0
Neurofibromatosis	\$20.0	TOTAL = \$1.54 B	

Consolidated Appropriations Act, 2022

“The agreement notes the number of known and unknown potentially harmful substances that servicemembers are exposed to as part of their military service. Research linked to exposures through various congressionally directed medical research programs, including the Peer-Reviewed **Neurotoxin Exposure Treatment Parkinson's Research Program**, started in 1997 with a focus on dopaminergic neurons that result in Parkinson's disease. Since 2006, the **Peer-Reviewed Gulf War Illness Research Program** has also received congressionally directed funding to study the health impacts caused by deployment of warfighters during the Persian Gulf War. The agreement remains committed to helping veterans affected by **Parkinson's disease, Gulf War illness, and others exposed to potentially toxic substances which result in multiple, diverse symptoms and health abnormalities.**”

Previous CDMRP Efforts Related to the TERP

1. **Gulf War Illness Research Program (GWIRP)** – Funded from FY06-FY21
2. **Neurotoxin Exposure Treatment Parkinson's Research Program (NETP)** – renamed in FY22 to the Parkinson's Research Program (PRP)
3. **Peer Reviewed Medical Research Program (PRMRP)** – Burn Pits and Metals Toxicology Topic Areas (not offered in FY22)



GWIRP

GWIRP

- Congressional Appropriations:
 - \$236M (FY06-FY21) supporting over 240 awards
 - No FY22 Congressional appropriation
- Supported research spanning the entire pipeline from early/mechanistic studies through Phase 2/3 clinical trials
 - Pathobiology
 - Treatments
 - Detection and Diagnosis (Biomarkers)
 - Research Resources
- Gulf War illness and its treatment is included in the FY22 TERP Congressional language.

TERP Congressional Language

“Transitioning related research to a new, broader program, including neurotoxin exposure treatment research, research on Gulf War illness, exposures to burn pits, and other service-related exposures to potentially toxic chemicals and materials will allow the research community to improve scientific understanding and pathobiology from exposure, more efficiently assess comorbidities, and speed the development of treatments, cures, and preventions.”

“The funds provided in this program are directed to be used to conduct research of clear scientific merit and direct relevance to **neurotoxin exposure; Gulf War illness and its treatment; airborne hazards and burn pits; as well as toxic military exposures in general, including prophylactic medications, pesticides, organophosphates, toxic industrial chemicals, materials, metals, and minerals.**”

“The inclusion of the toxic exposures research program shall not prohibit research in any other congressionally directed research program that may be associated with conditions or health abnormalities which may have been the result of toxic exposures.”

Key Points:

- \$30M appropriation
- Support for:
 - Neurotoxin exposure
 - Gulf War illness and its treatment
 - Airborne Hazards and burn pits
 - Other military service-related toxic exposures in general, including prophylactic medications, pesticides, organophosphates, toxic industrial chemicals, materials, metals and minerals
- “improve scientific understanding and pathobiology from exposure, more efficiently assess comorbidities, and speed the development of treatments, cures, and preventions.” = maximum benefit to Service Members, Veterans, and the American public
- Language also calls for coordination with the VA

What is the TERP?

The TERP is....

- A new, broader program
- Intended to have a maximum benefit to Service Members, Veterans and the American public
- Ultimately looking to support hypothesis-driven, meritorious, impactful scientific research that is, at times, high-risk but if successful, highly rewarding!
- Coordinating closely with other federal funding agencies and key stakeholders.

TERP/VA Coordination

- VA HOME and ORD contacts briefed on the TERP soon after its inception
- VA MERP Task Force Co-Director on TERP Programmatic Panel
- Program Manager for VA Gulf War Veterans Research Program and MERP Co-Director invited to Programmatic Review and Vision Setting meetings.
- VA investigator on TERP Programmatic Panel
- Presentation/attendance at RACGWVI meetings
- Congressional language encourages collaborations between researchers at military or veteran institutions and non-military research institutions to leverage the knowledge, infrastructure, and access to military and veteran populations*.
- Congressional language calls for the coordination with similar activities at the VA

* Funding opportunities will include full and final language.

TERP Vision and Mission

Vision

Minimize and mitigate the impact of military-relevant toxic exposures and improve the quality of life of those affected.

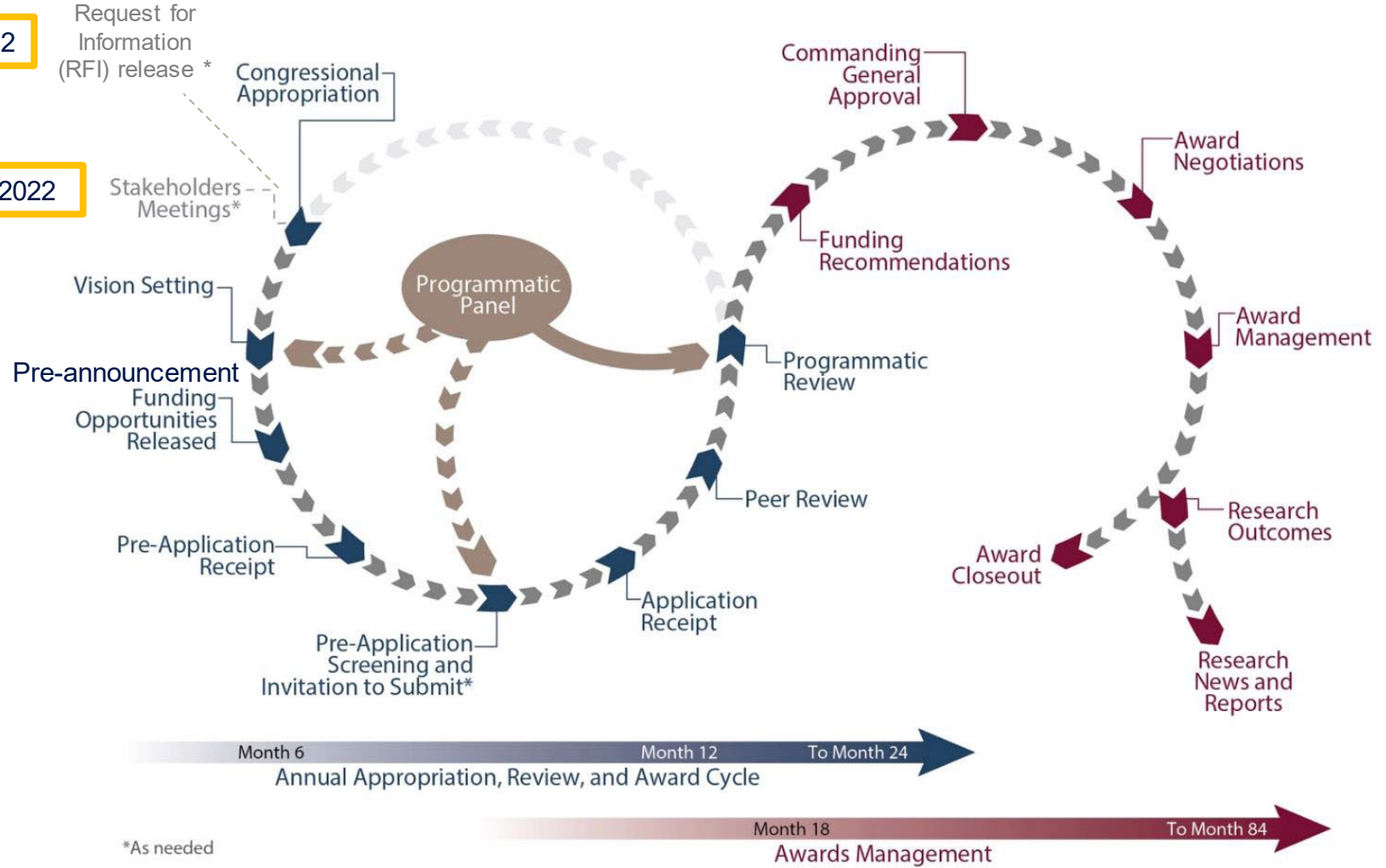
Mission

Support innovative and impactful research aimed at identifying and understanding the pathological mechanisms, outcomes and comorbidities associated with toxic exposures in order to facilitate the prevention, diagnosis and treatment of the invisible and visible diseases and symptoms that are associated with toxic effects impacting Service Members, Veterans and the American public.

TERP's FY22 Program Cycle

Apr -May 2022

15-16 Jun 2022



TERP FY22 Stakeholders Meeting

- Stakeholders Meeting Book, and Summary and Presentations can be found on the TERP website
- Presentations include an overview of the former GWIRP research portfolio
- Summary includes high level overview of discussions of each breakout group, aligned with the four Topic Areas provided in the TERP's Congressional language, including Gulf War illness and its treatment



U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
 CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
 TOXIC EXPOSURES RESEARCH PROGRAM (TERP)
FISCAL YEAR 2022 (FY22) STAKEHOLDERS MEETING
 VIRTUAL
 15-16 JUNE 2022

Summary of Stakeholders Meeting Outcomes and Identified Research Gaps

The following is a summary of the main topics discussed during the FY22 TERP Stakeholder Meeting. Please note that all comments are not captured in this summary report. This summary also does not reflect the opinions or views of the TERP, the CDMRP or the Department of Defense (DOD).

A virtual Stakeholders Meeting of the FY22 TERP was held 15-16 June 2022. Consumers impacted by toxic exposures, advocates, other federal funders, and academic, clinical, and military subject matter experts across various fields of toxic exposures came together to discuss broad perspectives on research and knowledge gaps and patient priorities across the Topic Areas provided in the TERP's FY22 Congressional language, which include:

- Neurotoxin exposure
- Gulf War illness (GWI) and its treatment
- Airborne hazards and burn pits
- Toxic military exposures in general, including prophylactic medications, pesticides, organophosphates, toxic industrial chemicals, materials, metals, and minerals

Specifically, the goals of the TERP Stakeholders Meeting were to: (1) identify knowledge gaps, targeted outcomes, and patient needs related to the four major Topic Areas that align with the TERP's FY22 Congressional language, (2) identify underfunded areas of military-related toxic exposure research and patient care, (3) discuss coordination with other agencies/organizations that fund toxic exposure research, and (4) discuss potential approaches the TERP may use to close some of the identified gaps.

Meeting participants were identified based on responses to the TERP Request for Information (RFI) (results can be found in the TERP Stakeholders Book), and invites were balanced across backgrounds and disciplines. Prior to the meeting, participants were placed into breakout groups based on the area of interest/expertise they identified in their RFI response. Participants were asked to respond to a single pre-meeting question posted on SurveyMonkey © so they could succinctly provide their top three research gaps related to the Topic Area of their assigned breakout groups. The breakout groups were consistent with the four major Topic Areas from the FY22 TERP Congressional language that established the TERP. The four breakout groups were:

- Neurotoxin Exposure
- GWI and Its Treatment
- Exposures to Airborne Hazards and Burn Pits

TERP's FY22 Program Cycle

Apr -May 2022

Request for Information (RFI) release *
Congressional Appropriation

15-16 Jun 2022

Stakeholders Meetings*

July 2022

Vision Setting

18 Aug 2022

Pre-announcement Funding Opportunities Released

Anticipate NLT 30 Sept 2022

Pre-Application Receipt

Pre-Application Screening and Invitation to Submit*

Programmatic Panel

Application Receipt

Peer Review

Commanding General Approval

Funding Recommendations

Programmatic Review

Award Negotiations

Award Management

Research Outcomes

Award Closeout

Research News and Reports



*As needed

FY22 TERP

Anticipated Funding Opportunities*

- The FY22 TERP Pre-announcement was released 18 Aug and can be found on the TERP website

\$500K**

Investigator-Initiated Research Award:

Supports studies that will make an important contribution toward research and/or patient care for a disease or condition related to toxic exposures.

\$800K**

for the single investigator award

\$1.6M**

for the partnership option

Translational Research Award:

Supports hypothesis-driven, high impact translational research that will accelerate the advancement of promising ideas.

\$1.5M**

for the single investigator award

\$2.5M**

for the partnership option

Clinical Trial Award:

Supports clinical trials for new products, pharmacologic agents, devices, clinical guidance, and/or emerging approaches and technologies.

*please refer to the FY22 TERP Pre-announcement for full details

** funding amounts refer to anticipated maximum direct cost limits

FY22 TERP – Program Goals*



Elucidate mechanisms of how toxic exposures result in adverse effects, including but not limited to toxicities, malignancies, neurologic and respiratory disorders, cardiac complications, sleep disorders, immune system dysfunction, gastrointestinal issues, etc. *(list is not all inclusive).*



Diagnose the effects of toxic exposures, understand the phenotypic/genotypic and clinical outcomes associated with short-term and long-term exposures and predict disease progression.



Predict and prevent toxic exposures by identifying strategies that can anticipate, identify, monitor and prevent Service Members and the American public from adverse effects of exposures to toxic substances.

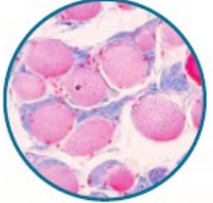


Develop therapeutics, treatments and strategies to minimize symptoms and disease progression associated with toxic exposures.

(Not in order of importance)

* Funding opportunities will include full and final language.

FY22 TERP – Topic Areas*



Neurotoxin Exposure



Gulf War Illness and Its Treatment



Airborne Hazards and Burn Pits



Other Military Service-Related Toxic Exposures in General
Including Prophylactic Medications, Pesticides, Organophosphates, Toxic Industrial Chemicals, Materials, Metals, and Minerals

Each Topic Area includes a number of Focus Areas and/or Areas of Encouragement.

* Funding opportunities will include full and final language.

FY22 TERP – Gulf War Illness

Focus Areas and Areas of Encouragement for the Gulf War Illness and Its Treatment Topic Area*

- 1. Rapidly advance effective treatments for ill Gulf War (GW) Veterans with an emphasis on those treatment regimens that can be repurposed and are readily and clinically available.**
 - Treatment studies proposing clinical and confirmatory studies using objective biomarkers to demonstrate efficacy are encouraged.
 - Treatments that address symptoms and aim to improve quality of life and/or are individualized for patients are encouraged.
 - Clinical trials with a clear description of transition plan and path forward with FDA compliance to advance treatments are encouraged.
- 2. Identify and validate objective biomarkers for the diagnosis and monitoring of GWI and its progression and/or for assessing treatment efficacy.**
- 3. Evaluate the pathological and molecular mechanisms associated with GWI.**
 - Mechanistic studies having clear implications for translational studies that are relevant to humans are encouraged.
 - Translational studies that have near term impacts on the ill GW Veteran populations are encouraged.
 - Mechanistic studies that consider the aging process and associated comorbidities are encouraged.
- 4. Evaluate non-pharmacologic treatments (e.g., therapies/programs/services) that will significantly benefit the quality of life for the GWI patient community.**
- 5. Other applications focused on GWI and its treatment will also be considered as long as they address a TERP Program Goal.**

* Funding opportunities will include full and final language.



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(including our pre-announcement)

News & Highlights

Defense Health Program
Department of Defense
Toxic Exposures Research
Program Anticipated
Funding Opportunities for
Fiscal Year 2022 (FY22)

More...

Vision

Minimize and mitigate the impact of military-relevant toxic exposures and improve the quality of life of those affected

Mission

Support innovative and impactful research aimed at identifying and understanding the pathological mechanisms, outcomes and comorbidities associated with toxic exposures in order to facilitate the prevention, diagnosis and treatment of the invisible and visible diseases and symptoms that are associated with toxic effects impacting Service Members, Veterans and the American public

Feedback

Click here to provide feedback/comments to the TERP

Stakeholder Book & Meeting Summary

Toxic Exposures



Vision - Minimize and mitigate the impact of military-relevant toxic exposures and improve the quality of life of those affected

There are a number of known and unknown potentially harmful substances that Service Members are exposed to during their military service. The CDMRP has previously received Congressional support for research aimed at providing healthcare solutions for some of the diseases/conditions linked to these exposures, including the Peer-Reviewed Gulf War Illness Research Program, the Peer Reviewed Medical Research Program Burn Pits and Metals Toxicology topic areas and the Peer-Reviewed Neurotoxin Exposure Treatment Parkinson's Research Program. Congress remains committed to helping Veterans affected by Parkinson's disease, Gulf War Illness, and others exposed to potentially toxic substances which result in multiple, diverse symptoms and health abnormalities. The Consolidated Appropriations Act, 2022 provides \$30 million for a peer-reviewed, Toxic Exposures Research Program (TERP). The TERP is a new, broad program that will allow the research community to improve scientific understanding and pathobiology of toxic exposures, efficiently assess comorbidities, and speed the development of treatments, cures, and preventions. In line with the Congressional language, appropriated funds will be used to conduct research of clear scientific merit and direct relevance to neurotoxin exposure, Gulf War Illness and its treatment, airborne hazards and burn pits, as well as military service-related toxic exposures in general, including prophylactic medications, pesticides, organophosphates, toxic industrial chemicals, materials, metals, and minerals. The TERP will coordinate with similar activities in the U.S. Department of Veterans Affairs and encourage collaborations between researchers at military or Veteran institutions and non-military research institutions to leverage the knowledge, infrastructure, and access to military and Veteran populations.

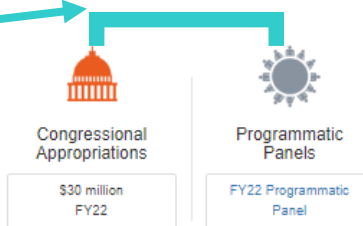


The CDMRP held a virtual Stakeholders meeting on 15-16 June 2022, where individuals with relevant expertise and experience came together to identify knowledge gaps, targeted outcomes, and patient needs in neurotoxin exposure, Gulf War Illness and its treatment, exposures to airborne hazards and burn pits, and other military service-related toxic exposures in general, including prophylactic medications, pesticides, organophosphates, and toxic chemicals, materials, metals, and minerals, that can advance the state of the science and improve patient care. The FY22 TERP Stakeholders Book and FY22 TERP Stakeholders Meeting Summary, including the presentation slides, are provided below:

- [FY22 TERP Stakeholders Book \(1.7 MB\)](#)
- [FY22 TERP Stakeholders Meeting Summary and Presentations \(22.5 MB\)](#)

The full text for the appropriation supporting the inception of the Toxic Exposures Research Program can be found on pages 150-151 of the Joint Explanatory Statement as Division C, Part 2 of H.R. 2471, the Consolidated Appropriations Act, 2022. (Retrieved from: https://docs.house.gov/billssthisweek/20220307/BILLS-117RCP35-JES-DIVISION-C_Part2.pdf).

Appropriation & FY22 Programmatic Panel



Further Information

Website

<http://cdmrp.army.mil/terp>

(effective ~19 Sept)

<http://cdmrp.health.mil/terp>

Twitter

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(twitter.com/CDMRP)

YouTube

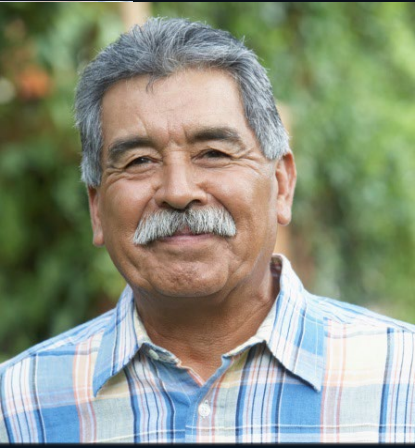
youtube.com/user/CDMRP

- ◆ Program information and publicity
- ◆ FY22 Funding Opportunity Announcements
- ◆ Feedback form

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Thank you

