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Outline

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

WHO
Started by Congress in 1992, CDMRP manages focused biomedical research.

WHAT
Funds innovative and impactful biomedical research.

WHY
Accelerating research to advance cures, improvements, and breakthroughs.

WHERE
Research conducted in institutions around the world.

HOW
Two-tier review process involving scientists, clinicians, and consumers.

Transforming healthcare for service members, their families, and the American public.

https://cdmrp.health.mil
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

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

Video and additional information available at: https://cdmrp.health.mil/about/2tierRevProcess
## CDMRP FY22 Appropriations

<table>
<thead>
<tr>
<th>Research Program</th>
<th>FY22 $M</th>
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<tbody>
<tr>
<td>Alcohol and Substance Use Disorders</td>
<td>$4.0</td>
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<tr>
<td>Amyotrophic Lateral Sclerosis</td>
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<tr>
<td>Autism</td>
<td>$15.0</td>
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<tr>
<td>Bone Marrow Failure</td>
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<tr>
<td>Breast Cancer</td>
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<td>Chronic Pain Management</td>
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<td>Combat Readiness Medical</td>
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<tr>
<td>Duchenne Muscular Dystrophy</td>
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<tr>
<td>Epilepsy</td>
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<tr>
<td>Hearing Restoration</td>
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<tr>
<td>Joint Warfighter Medical</td>
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<td>Kidney Cancer</td>
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<tr>
<td>Lung Cancer</td>
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<td>Lupus</td>
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<td>Melanoma</td>
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<td>Military Burn</td>
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<td>Multiple Sclerosis</td>
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<td>Neurofibromatosis</td>
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<tr>
<td>Orthotics and Prosthetics Outcomes</td>
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<td>Ovarian Cancer</td>
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<td>Pancreatic Cancer</td>
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<td>Parkinson’s</td>
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<td>Peer Reviewed Alzheimer’s</td>
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<td>Peer Reviewed Cancer (20 Topics)</td>
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<tr>
<td>Peer Reviewed Medical (50 Topics)</td>
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<td>Peer Reviewed Orthopaedic</td>
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<td>Prostate Cancer</td>
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<td>Rare Cancers</td>
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<td>Reconstructive Transplant</td>
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<td>Spinal Cord Injury</td>
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<td>Tick-Borne Disease</td>
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<td>Toxic Exposures</td>
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<td>Traumatic Brain Injury and Psychological Health</td>
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<td>Tuberous Sclerosis Complex</td>
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<tr>
<td>Vision</td>
<td>$20.0</td>
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**TOTAL = $1.54 B**
“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

- **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.
“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

The full text for the appropriation supporting the inception of the TERP 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/billsthisweek/20220307/BILLS-117RCP35-JES-DIVISION-C_Part2.pdf).
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.
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

- **Request for Information (RFI) release**: Apr - May 2022
- **Pre-announcement**: 15-16 Jun 2022
- Programmatic Panel:
  - Vision Setting
  - Pre-application Receipt
  - Pre-application Screening and Invitation to Submit
  - Application Receipt
  - Peer Review
  - Programmatic Review
  - Funding Recommendations
  - Commanding General Approval
  - Award Negotiations
  - Award Management
  - Research Outcomes
  - Research News and Reports
  - Award Closeout

Annual Appropriation, Review, and Award Cycle

*As needed
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
TERP’s FY22 Program Cycle

Request for Information (RFI) release *
Apr - May 2022

15-16 Jun 2022

Congressional Appropriation

Stakeholders Meetings*

Vision Setting

Programmatic Panel

18 Aug 2022

Pre-announcement

July 2022

Anticipate NLT 30 Sept 2022

Funding Opportunities Released

Pre-Application Receipt

Pre-Application Screening and Invitation to Submit*

Application Receipt

Peer Review

Programmatic Review

Funding Recommendations

Commanding General Approval

Award Negotiations

Award Management

Research Outcomes

Research News and Reports

Award Closeout

Annual Appropriation, Review, and Award Cycle

*As needed
**FY22 TERP**

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

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**Translational Research Award:**
Supports hypothesis-driven, high impact translational research that will accelerate the advancement of promising ideas.

**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.

**Clinical Trial Award:**
- $1.5M** for the single investigator award
- $2.5M** for the partnership option
- Supports clinical trials for new products, pharmacologic agents, devices, clinical guidance, and/or emerging approaches and technologies.

**$1.6M**
for the partnership option

**$800K**
for the single investigator award

**$500K**

*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*

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

* Funding opportunities will include full and final language.
Focus Areas and Areas of Encouragement for the Gulf War Illness and Its Treatment

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.
Further Information

**Website**
http://cdmrp.army.mil/terp

(effective ~19 Sept)
http://cdmrp.health.mil/terp

♦ Program information and publicity
♦ FY22 Funding Opportunity Announcements
♦ Feedback form

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(twitter.com/CDMRP)

**YouTube**
youtube.com/user/CDMRP

Subscribe to News Releases, including Funding Opportunities
https://ebrap.org/eBRAP/programSubscription/Subscribe.htm

♦ TERP news
♦ Funding Opportunity Announcements
Thank you