

# CDMRP



Department of Defense



Department of Defense  
**Congressionally Directed Medical Research Programs**

## **Fiscal Year 2022**

## **Toxic Exposures Research Program**

## **Stakeholders Meeting**

*U.S. Army Medical Research and Development Command*



**The views and opinions of the authors may not reflect the official policies or positions of the Department of the Army, Department of Defense, or U.S. Government.**

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## Agenda

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

**MEETING AGENDA**

**Wednesday, 15 June 2022**

<i>9:30-10:00 a.m.</i>	Call into Meeting and Registration	All Participants
<i>10:00 a.m.</i>	Welcome and Introductions	Dr. Melissa (Missy) Tursiella
<i>10:10 a.m.</i>	Moment of Silence	Ms. Chelsey Simoni
<i>10:15 a.m.</i>	Meeting Overview and Objectives, Ground Rules for Discussion	Mr. Scott Wheeler
<i>10:20 a.m.</i>	Leidos Administrative Remarks	Ms. Alexandria Bakke
<i>10:25 a.m.</i>	Overview of CDMRP	COL Sarah Goldman
<i>10:40 a.m.</i>	Overview of TERP Congressional Language and Request for Information Results	Dr. Tursiella
<i>11:00 p.m.</i>	CDMRP Gulf War Illness Research Program Presentation	Mr. Brett Chaney
<i>11:20 p.m.</i>	CDMRP Peer Reviewed Medical Research Program Overview for Toxic Exposures Research	Dr. Kathryn Argue
<i>11:35 a.m.</i>	CDMRP Neurotoxin Exposure Treatment Parkinson's Research Presentation	Dr. Stephen Grate
<i>11:50 a.m.</i>	<i>Break</i>	All Participants
<i>12:00 p.m.</i>	Department of Veteran's Affairs (VA) Health Outcomes Military Exposures Presentation	Dr. William Culpepper
<i>12:15 p.m.</i>	VA Gulf War Research Program Presentation	Dr. Karen Block
<i>12:30 p.m.</i>	National Institute of Health National Institute of Neurological Disorders and Stroke	Dr. David Jett

	Office of Neural Exposome and Toxicology Presentation	
12:45 p.m.	Military Operational Medicine Research Program Performance in Extreme Environments Presentation	Dr. Wayne Matheny
1:00 p.m.	<i>Lunch</i>	All Participants
<b><i>Breakout Session</i></b>		
2:00 p.m.	Neurotoxin Exposure	Group Participants
	Gulf War Illness and Its Treatment	Group Participants
	Exposures to Airborne Hazards and Burn Pits	Group Participants
	Other Military Service-Related Toxic Exposures in General, Including Prophylactic Medications, Pesticides, Organophosphates, and Toxic Industrial Chemicals, Materials, Metals and Minerals	Group Participants
4:45 p.m.	Closing Remarks	Dr. Tursiella
5:00 p.m.	Meeting Adjournment	All Participants

## **Thursday, 16 June 2022**

9:30-10:00 a.m.	Call into Meeting and Registration	All Participants
10:00 a.m.	Welcome	Dr. Tursiella
10:05 a.m.	Housekeeping Remarks	Mr. Wheeler and Ms. Bakke
10:10 a.m.	Report Out from Neurotoxin Exposures Breakout Group	Breakout Leader
10:20 a.m.	Group Discussion on Neurotoxin Exposures	Mr. Wheeler
10:40 a.m.	Report Out from Gulf War Illness and Its Treatment Breakout Group	Breakout Leader
10:50 a.m.	Group Discussion on Gulf War Illness and Its Treatment	Mr. Wheeler
11:10 p.m.	Report Out from Exposures to Airborne Hazards and Burn Pit Breakout Group	Breakout Leader
11:20 p.m.	Group Discussion on Exposures to Airborne Hazards and Burn Pits	Mr. Wheeler
11:40 p.m.	Report Out from Other Military Service-Related Toxic Exposures Breakout Group	Breakout Leader
11:50 p.m.	Group Discussion on Other Military Service-Related Toxic Exposures	Mr. Wheeler
12:10 p.m.	<i>Lunch</i>	All Participants

### ***Breakout Session***

1:00 p.m.	Neurotoxin Exposure	Group Participants
	Gulf War Illness and Its Treatment	Group Participants
	Exposures to Airborne Hazards and Burn Pits	Group Participants
	Other Military Service-Related Toxic Exposures	Group Participants
2:30 p.m.	Group Discussion on Common Themes	Mr. Wheeler
3:00 p.m.	Overarching Themes and Outcomes from the Meeting and Closing Remarks	Dr. Tursiella
3:30 p.m.	Meeting Adjournment	All Participants

## Overview: CDMRP History

The Congressionally Directed Medical Research Programs (CDMRP) is a global funding organization within the Department of Defense (DOD) U.S. Army Futures Command and within the U.S. Army Medical Research and Development Command (USAMRDC). The CDMRP responsibly manages research that discovers, develops, and delivers health care solutions for Service Members, Veterans, and the American public. The CDMRP originated in fiscal year 1992 (FY92) when the U.S. Congress first appropriated funds to the DOD for breast cancer research.

Since its first appropriation in FY92, the CDMRP has grown to 35 programs in FY22. The CDMRP implements the investment of congressionally directed dollars provided annually to fund groundbreaking, high-impact, meritorious research that targets critical gaps in health care. The DOD does not request these funds; they are added to DOD's budget each year by the U.S. Congress, and specific research areas and guidance are defined by the congressional language. In addition, the CDMRP provides support as requested for the management of Defense Health Program core dollars directed at both intramural and extramural military medical research portfolio areas.

## Program Cycle

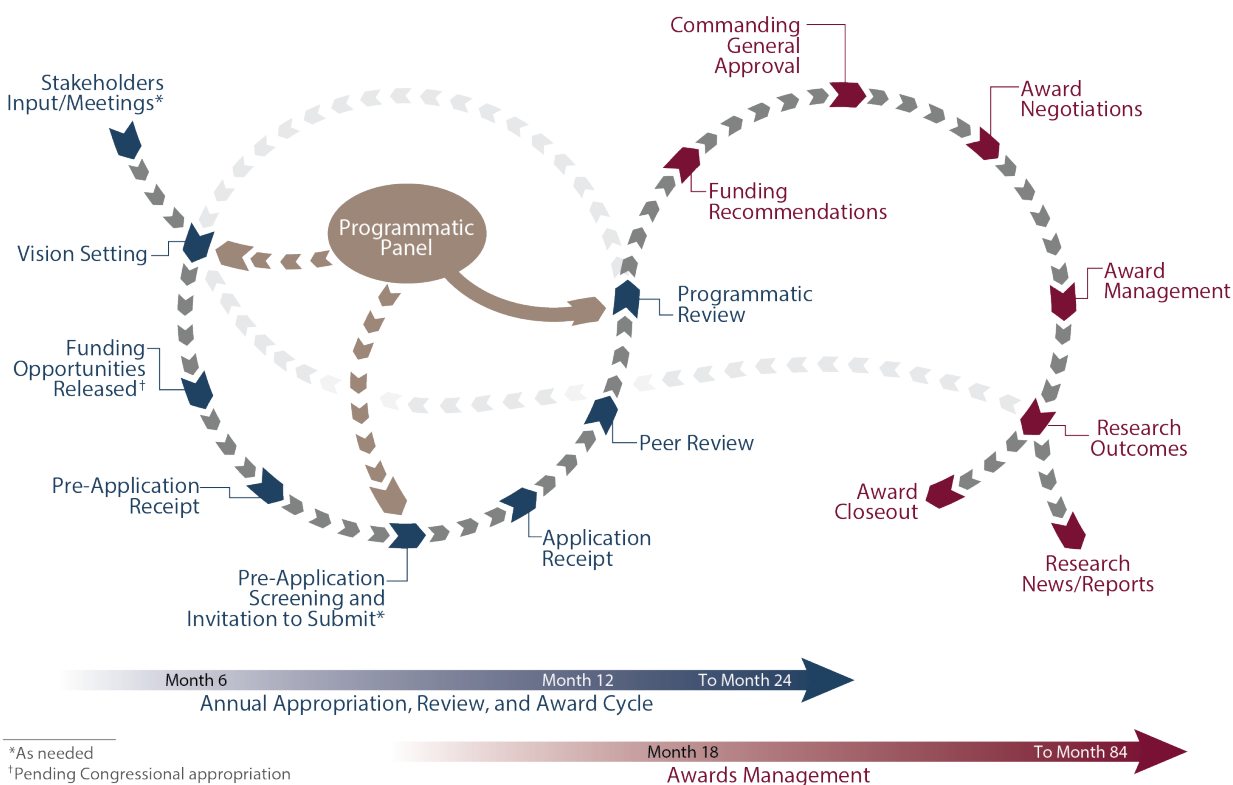
Upon receipt of annual Congressional appropriations, the CDMRP executes its program cycle process (Figure 1), which includes an inaugural Stakeholders Meeting (public meeting) for each new program in which key knowledge gaps are identified and information is collected for presentation to the Programmatic Panel at the program's Vision Setting Meeting. The annual Vision Setting Meeting includes the Programmatic Panel and CDMRP program staff and is where the program's mission and vision statements, focus areas, strategic plan, and yearly investment strategy and funding opportunities are established. After Vision Setting, the Programmatic Panel's investment strategy recommendations are translated into program announcements (PAs). Once the PAs are released and applications have been received, the CDMRP initiates its two-tier review process, which is described below.

To ensure that each program's research portfolio reflects both the most meritorious science and the most programmatically relevant research, the CDMRP developed a two-tier model based on recommendations from a 1993 Institute of Medicine (IOM) report.<sup>1</sup> The IOM (now the National Academy of Medicine) recommended a two-step review procedure for research applications that was composed of a scientific peer review and a separate programmatic review (Figure 1). The scientific peer review is conducted by an external panel that is recruited specifically for each peer review session. Peer review involves the expertise of scientists, clinicians, military members, and consumers (patient advocates). Each application is judged on its own scientific and technical merit with respect to the described criteria in the funding opportunity solicitation. The second tier of review is conducted by a Programmatic Panel and includes discussions by experts in the field. These

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<sup>1</sup>Institute of Medicine (US) Committee to Review the Department of Defense's Breast Cancer Research Program. A Review of the Department of Defense's Program for Breast Cancer Research. Washington (DC): National Academies Press (US); 1997. 1, Introduction. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK233671/>

experts, which include scientists, clinicians, consumers, and members of the military, assess the applications based on the scientific peer review ratings and summaries, a balanced portfolio, programmatic intent, and scientific merit. Scientifically sound applications that best meet the program's interests and goals are recommended for funding by the Programmatic Panel. Once approval is received for the funding recommendations, awards are made and assigned to the program team for full-cycle support of research and outcomes.



**Figure 1. CDMRP Annual Program Cycle.**

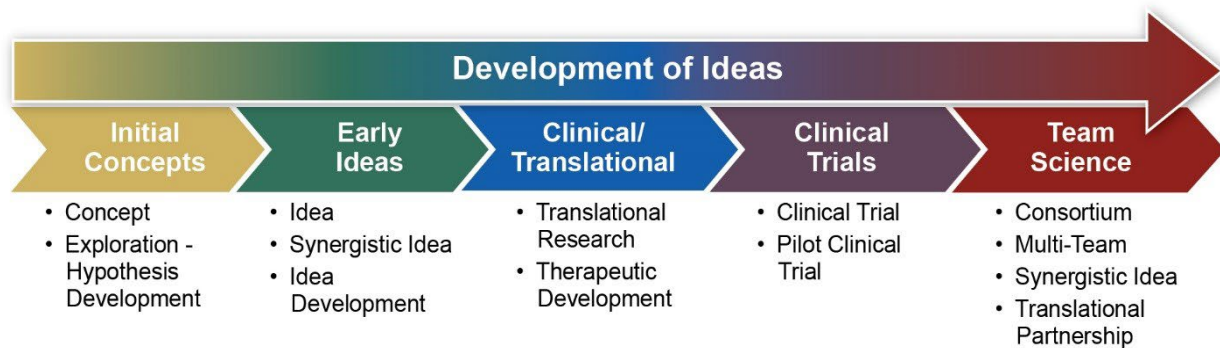
## Consumer Involvement

A unique hallmark of the CDMRP is the inclusion of consumers in its programmatic cycles. Consumers may be patients, survivors, family members, or caregivers of people living with a disease, injury, or condition funded by a CDMRP program. Consumer reviewers participate as full voting members in both peer review and programmatic review. Participation of consumers leads to an expanded perspective by both scientists and consumers. Consumers keep the needs of the consumer community at the forefront of scientific discussions and remind scientists of the human dimension of the disease/injury/condition. Consumer reviewers report greater understanding of the benefits and burdens imposed on patients participating in research studies. After participating in the review process, they return home with hope for a cure, better treatment, or an improved quality of life for those living with their illness, as well as greater understanding of the research that may be funded. This increases consumer awareness of the importance of research and strengthens the relationship between the scientific and consumer communities.



## CDMRP Spectrum of Research

The CDMRP funds research across a wide spectrum of development, from initial concepts through clinical trials. The CDMRP also allows Principal Investigators (PIs) to be awarded at many stages in their careers, from trainees through established, senior researchers, at a variety of institutions. The examples provided in Figure 2 are not prescriptive or exhaustive. Award mechanisms may be customized for a specific research program or created for a specific intent when necessary.



*Figure 2. Examples of CDMRP Funding Opportunities and Maturity of Research.*

## Statement of Problem: Toxic Exposures in the Military

More than 3.7 million U.S. Service Members have participated in operations in Iraq, Kuwait, Saudi Arabia, Bahrain, the Gulf of Aden, the Gulf of Oman, Oman, Qatar, the United Arab Emirates—a region known collectively as the Southwest Asia Theater of Military Operations—and Afghanistan since 1990.<sup>2</sup> Individuals who served in this region were likely to have been exposed to a number of toxic agents, including, but not limited to, oil-well fire smoke, emissions from open burn pits, dust and sand suspended in the air, pollution from local industries, and exhaust from diesel vehicles. Additionally, Service Members may be exposed to a number of known and unknown substances as part of other deployments and/or non-deployed military service. Collectively, these exposures to potentially toxic substances can result in diseases and conditions that adversely affect the readiness of our forces and the long-term health of our Veterans.

### Congressional Language Enacting the Toxic Exposures Research Program

While the CDMRP has historically funded toxic exposures research under its Gulf War Illness Research Program (GWIRP), Peer Reviewed Medical Research Program (PRMRP), and Neurotoxin Exposure Treatment Parkinson's (NETP) Program (discussed in subsequent sections), no single program has been charged with supporting research for the broader toxic exposure community.

In FY22, the Consolidated Appropriations Act, 2022, called for a Peer Reviewed Toxic Exposures Research Program (TERP) supported with a \$30 million (M) appropriation. The FY22 TERP will be managed by the CDMRP according to Congressional intent using a competitive selection and peer review process to support research relating to neurotoxin exposure, Gulf War illness (GWI) 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.

The full text for the appropriation supporting the inception of the TERP can be found below.<sup>3</sup>

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<sup>2</sup> National Research Council 2020. *Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations*. National Academies Press. Washington, DC. <https://doi.org/10.17226/25837>.

<sup>3</sup> 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](https://docs.house.gov/billsthisweek/20220307/BILLS-117RCP35-JES-DIVISION-C_Part2.pdf))

“The agreement notes the number of known and unknown potentially harmful substances that service members 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.

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. ***Therefore, the agreement recommends \$30,000,000 for a peer-reviewed toxic exposures research program. 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 agreement directs the Director of Congressionally Directed Medical Research Programs, to ensure that the program is conducted using competitive selection and peer-review for the identification of research with the highest technical merit and military benefit. Further, the agreement directs that this program be coordinated with similar activities in the Department of Veterans Affairs. Collaborations between researchers at military or veteran institutions and non-military research institutions are encouraged to leverage the knowledge, infrastructure, and access to military and veteran populations. 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.”

## Toxic Exposures Research at the CDMRP

### Gulf War Illness Research Program

DOD-funded GWI research began in 1994 with the establishment of a Gulf War Veterans' Illnesses Research Program (GWVIRP) to study the health effects of Service Members deployed in the 1990–1991 Persian Gulf War. From FY94 to FY05, the GWVIRP was managed by the U.S. Army Medical Research and Materiel Command's Military Operational Medicine Research Program (MOMRP). Research pertaining to GWI also was funded intermittently through the CDMRP's PRMRP, which supports selected military health-related research topics each fiscal year. The MOMRP shared management responsibility for the GWVIRP with the CDMRP in FY06 with separate \$5M appropriations.

Although the GWVIRP did not receive funding in FY07, a \$10M appropriation renewed the program in FY08, and the program was renamed the Gulf War Illness Research Program (GWIRP), to be managed fully by the CDMRP. Continued Veteran advocacy, together with program accomplishments, have resulted in more than \$236M in congressional appropriations through FY21. The GWIRP did not receive an FY22 appropriation; however, "Gulf War Illness and its Treatment" is indicated as a topic area under the new TERP.

The GWIRP portfolio includes over 200 research projects spanning investigations of basic pathobiology of GWI to clinical trials of pharmaceuticals and other therapies. Over the years, GWIRP-funded research has played a leading role in the fight against GWI by challenging scientists to explore new paradigms and emphasizing research that will accelerate the translation of promising ideas to application in the clinic. While fostering research across the GWI research landscape, the program has maintained a primary focus on treatments and biomarkers while prioritizing expansion, replication, and comparative studies that are critical for acceptance of new therapeutic protocols into general practice. GWIRP funding mechanisms have also promoted synergistic collaborations across disciplines, encouraged scientists outside of the GWI community to apply their expertise to questions in GWI, and integrated Gulf War Veterans and scientists in unique and meaningful research partnerships to improve program focus and impact.

### Peer Reviewed Medical Research Program

In FY99, Congress established the PRMRP to provide support for military health-related research of exceptional scientific merit toward the goal of improving the health and well-being of military Service Members, Veterans, and their family members. Throughout its 23-year history, Congress has appropriated \$3.45 billion to the program, which has supported more than 1,967 research awards in 224 unique topic areas representing various diseases and conditions, resulting in over 4,800 peer-reviewed publications and nearly 400 patent applications or patents granted. The FY22 congressional appropriation is \$370M to solicit research applications in 50 different topic areas. Since its inception, the PRMRP has supported topic areas related to toxic exposures, such as acute lung injury, burn pit exposure, metals toxicology, and respiratory health. Moving into FY22, the burn pit exposure and metals toxicology topic areas will not be offered under the PRMRP and are instead included in the congressional intent for the TERP, under the airborne hazards and

burn pits and other toxic military exposures in general, including prophylactic medications, pesticides, organophosphates, toxic industrial chemicals, materials, metals, and minerals research areas.

### **Peer Reviewed Neurotoxin Exposure Treatment Parkinson's Program**

The NETP was initiated in FY97 to provide support for research of exceptional scientific merit leading to an understanding of the cause, prevention, and treatment of Parkinson's disease (PD) in the context of neurotoxin exposure.

The vision of the NETP is to eliminate PD through neurotoxin exposure and treatment-related research in partnership with scientists and consumers. The NETP invests in scientific research to better understand and treat the neurodegenerative effects of PD associated with military deployment, environmental, and/or occupational exposures. Research into military service-related risk factors is critical for past, present, and future Service Members who may be affected PD. Appropriations for the NETP from FY97 through FY21 totaled \$484.8M. Parkinson's research will continue for FY22 under a new program name, the Parkinson's Research Program (PRP), and while the PRP may still support neurotoxin-associated PD research, the TERP congressional language includes "neurotoxin exposure" as a topic area.

### **Toxic Exposures Research at the Military Operational Medicine Research Program**

The mission of the Joint Program Committee -5 (JPC-5)/MOMRP is to develop effective biomedical countermeasures against operational stressors and to prevent physical and psychological injuries during training and operations in order to maximize the health, readiness and performance of Service Members and their families in support of the Army Human Performance Optimization and Enhancement, Human Dimension, Multi-Domain Battle, Army Big 6 Modernization Priorities and the DOD Total Force Fitness concepts. Its continuing mission is to protect the whole Service Member— head to toe, inside and out, across the operational spectrum.

The MOMRP provides planning, programming, and budgeting for biomedical research to deliver products and solutions to Service Members and families that address readiness, health, and performance throughout the deployment cycle and Service Member life cycle. Additionally, the MOMRP drives cutting-edge scientific research and delivers joint solutions to the battlefield and at home in a relevant, timely manner. MOMRP research is focused on four research portfolios: (1) Environmental Health and Protection, (2) Injury Prevention and Reduction, (3) Physiological Health and Performance, and (4) Psychological Health Post-Traumatic Stress Disorder and Resilience.

The Environmental Health and Protection portfolio is considered the most relevant to the intent of the TERP and includes studies focused on Service Member exposure to harsh conditions, extreme environments, and toxic industrial chemicals and materials. This portfolio emphasizes detecting, monitoring, and assessing the risk of toxic environmental exposure during both training and combat operations.

## Meeting Outcomes

### Purpose

The Stakeholders Meeting is an opportunity to engage stakeholders in an open-dialogue forum to identify knowledge and capability gaps, as well as underfunded areas that will help inform future the TERP research investment discussions.

### Stakeholder Participants

Representatives from toxic exposure-related non-profit organizations, academia, government institutions, industry, and the public are invited to share broad perspectives on which initiatives have the greatest potential to propel the science forward, break down potential barriers in research and patient outcomes, address key knowledge or scientific gaps, and identify potential approaches for the treatment of toxic exposures.

### Key Meeting Activities

- Presentations from key organizations highlighting the current state of research related to Service-related toxic exposures
- Focused breakout sessions to identify gaps in specific areas of Service-related toxic exposure research
- Identify and prioritize research areas of emphasis to close the gaps in specific areas of Service-related toxic exposure research
- Discussion of concurrent management strategies across federal agencies for Service-related toxic exposure research

### Outcomes

- Summary of relevant gaps, refinement of the state of the science in Service-related toxic exposures, identification of potential challenges, and strategic goals for success.
- Input from the Stakeholders meeting will be used by the TERP Programmatic Panel to recommend the overall TERP goals, priorities, focus areas, and investment strategy.
- The final outcomes of the Stakeholders meeting do not represent the final program strategy of the TERP.

## Guidelines for Stakeholders Meeting Discussion

- Identify knowledge gaps rather than solve problems
- Everyone participates; no one dominates
- Listen to understand
- Use “I” statements
- One speaker at a time
- Disagree without being disagreeable
- Share your unique perspective
- Stay open to new ways of doing things
- All ideas are valid
- Critique ideas, not people
- Respect each other’s thinking and value their contributions
- Treat everything you hear as an opportunity to learn and grow
- Staying on schedule is everyone’s responsibility; honor the time limits
- State your “headline” first, then provide the supporting information as necessary
- Be brief and meaningful when voicing your opinion
- Listen with care instead of “building your story”
- Stay engaged
- Seek common ground and understanding (not problems and conflict)
- Stay out of the weeds

## Tips for Teleconferences/Virtual Meetings

- Live notetakers takers will be participating in this meeting; please always introduce yourself prior to speaking
- Use mute when not speaking
- Raise your hand when you would like to say something
- Utilize chat for technical support

## Fiscal Year 2022 Toxic Exposures Research Program Request for Information

In response to the FY22 Congressional appropriation, the TERP released a Request for Information (RFI), as part of initial market research to establish a State of the Science ahead of the Stakeholders Meeting. The RFI was posted on SAM.gov from 28 April to 15 May 2022 and was disseminated via email and posted on the TERP website. Once SAM.gov was accessed, respondents were then directed to complete the RFI using a SurveyMonkey platform. The full text from the RFI, the questions from SurveyMonkey, and a summary of the results are provided below. A total of 265 responses were received.

### Toxic Exposures Research Program FY 2022 Request for Information

**Subject:** Toxic Exposures Research Program Fiscal Year 2022 Stakeholder Request for Information

THIS IS NOT A REQUEST FOR PROPOSALS (RFP) OR A REQUEST FOR QUOTATIONS (RFQ); IT IS STRICTLY A REQUEST FOR INFORMATION (RFI). NEITHER UNSOLICITED PROPOSALS NOR ANY OTHER KINDS OF OFFERS WILL BE CONSIDERED IN RESPONSE TO THIS RFI. NO CONTRACT WILL BE AWARDED PURSUANT TO THIS ANNOUNCEMENT.

**1.0 DISCLAIMER:** This RFI is issued solely for information and planning purposes and does not constitute a solicitation. Neither unsolicited proposals nor any other kind of offers will be considered in response to this RFI. Responses to this notice are not offers and will not be accepted by the Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI. The Government reserves the right to use any information submitted in public documents or websites. Responses to the RFI will not be returned. At this time, questions concerning the composition and requirements for a future RFP will not be entertained. The information which is being requested shall be entered into Survey Monkey; therefore, the Government is unable to protect proprietary/sensitive information. Interested parties shall not submit propriety and/or sensitive information through Survey Monkey.

**2.0 SUBJECT:** The Congressionally Directed Medical Research Programs (CDMRP) will hold a stakeholders meeting where individuals with relevant expertise and experience will be brought together to identify knowledge gaps, targeted outcomes, and product needs that can advance the state of the science and improve patient care. To expedite the process, the CDMRP is currently soliciting information on the identification of knowledge gaps, outcomes, and product needs in military service-related toxic exposures research.

**3.0 BACKGROUND:** A Peer Reviewed Toxic Exposures Research Program (TERP) for Fiscal Year 2022 (FY22) is included in the Consolidated Appropriations Act, 2022 at \$30 million (M). The FY22 TERP will be managed by the CDMRP according to Congressional intent to support research relating to 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.

The CDMRP will utilize its two-tier review process (<http://cdmrp.army.mil/about/2tierRevProcess>) to efficiently manage the TERP. The CDMRP will also hold a TERP Stakeholders meeting where individuals with relevant expertise and experience will be brought together to identify knowledge gaps, targeted outcomes, and product needs that can advance the state of the science and improve patient care. After the stakeholders meeting, a vision setting meeting will be held to recommend an investment strategy for the FY22 appropriation to answer some of the unmet medical needs, knowledge gaps, and consumer concerns.

#### **4.0 RESPONSE INSTRUCTIONS:**

Please provide responses to the RFI below. It is anticipated that your input will take 10-15 minutes.

**DISCLAIMER:** This RFI is issued solely for information and planning purposes and does not constitute a solicitation. Neither unsolicited proposals nor any other kind of offers will be considered in response to this RFI. Responses to this notice are not offers and will not be accepted by the Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI. The Government reserves the right to use any information submitted in public documents or websites. Responses to the RFI will not be returned. At this time, questions concerning the composition and requirements for a future RFP will not be entertained. The information which is being requested shall be entered into Survey Monkey; therefore, the Government is unable to protect proprietary/sensitive information. Interested parties shall not submit propriety and/or sensitive information through Survey Monkey.

**SUBJECT:** A Peer Reviewed Toxic Exposures Research Program for Fiscal Year 2022 (FY22) is included in the Consolidated Appropriations Act, 2022 at \$30 million (M). The FY22 TERP will be managed by the Congressionally Directed Medical Research Programs (CDMRP) according to Congressional intent to support research relating to 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.

The CDMRP will hold a virtual Stakeholders meeting on 15-16 June 2022, where individuals with relevant expertise and experience will be brought together to identify knowledge gaps, targeted outcomes, and product needs that can advance the state of the science and improve patient care. ***In order to expedite the process, the CDMRP is currently soliciting information on the identification of knowledge gaps, outcomes, products, 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.***

**BACKGROUND:** There are a number of known and unknown potentially harmful substances that Service members are exposed to as part of their military service. The Consolidated Appropriations Act of FY22 has called for CDMRP to create a new broad program that aims to “improve scientific understanding and pathobiology from exposure, more efficiently assess comorbidities, and speed the development of treatments, cures and preventions” for exposures to neurotoxins, burn pits and other airborne hazards, military service-related toxic exposures in general, including prophylactic medications, pesticides, organophosphates, toxic industrial chemicals, materials, metals, and minerals and for Gulf War illness and its treatment. 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/billsthisweek/20220307/BILLS-117RCP35-JES-DIVISION-C\\_Part2.pdf](https://docs.house.gov/billsthisweek/20220307/BILLS-117RCP35-JES-DIVISION-C_Part2.pdf) ).

Using this Congressional direction as a guide, please provide responses to the following RFI as they pertain to the topics listed below:

- Neurotoxin Exposure
- Gulf War Illness and Its Treatment
- Exposures to Airborne Hazards and Burn Pits
- Military Service-Related Exposures to Prophylactic Medications, Pesticides, Organophosphates, and Toxic Chemicals, Materials, Metals, and Minerals

For the purposes of responding to this RFI, please use the following research continuum definitions: “

Research Continuum	Definitions
Foundational Science	Elucidate basic research concepts, molecular mechanisms, and pathobiology of the effects of toxic exposure that could lead to new scientific discoveries, including development of biomarkers and treatments.
Epidemiology	Conduct population-level (including at-risk) descriptive studies of the patterns, causes, and effects of health and disease conditions with the overarching aim of identifying risk factors and targets for prevention.
Etiology	Understand the environmental causes of diseases/conditions associated with toxic exposure.
Prevention and Monitors	Develop preventive interventions and screening tools to assess and limit/prevent exposure.
Diagnosis and Treatment	Assessment of diseases, conditions, or other health abnormalities and comorbidities as a result of toxic exposures; biomarkers as a means to diagnose and/or measure progression or therapeutic efficacy; symptom amelioration at different stages of disease, and quantitative evaluations for treatment efficacy.
Survivorship and Quality of Life	Address length and durability of treatment, and long-term consequences of treatment rehabilitation.

**1. For each of the topics listed below, please indicate which of the following areas of the research continuum you believe are the most underfunded. Only one research area on the continuum can be selected per topic.**

	I am not experienced in this particular topic area (N/A)	Foundational Science	Epidemiology	Etiology	Prevention and Monitors	Diagnosis and Treatment	Survivorship and Quality of Life
Neurotoxin Exposure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Gulf War Illness and Its Treatment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Exposures to Airborne Hazards and Burn Pits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Military Service-Related Exposures to Prophylactic Medications, Pesticides, Organophosphates, and Toxic Chemicals, Materials, Metals, and Minerals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**2. For each topic area, please rank (1-6) the following areas of the research continuum based on which will have the most impact to the least impact. A score of 1 indicates that research area will have the MOST impact on the topic area while a score of 6 indicates that research area will have the LEAST impact.**

	I am not experienced in this particular topic area (N/A)	Foundational Science	Epidemiology	Etiology	Prevention and Monitors	Diagnosis and Treatment	Survivorship and Quality of Life
Neurotoxin Exposure	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Gulf War Illness and Its Treatment	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Exposures to Airborne Hazards and Burn Pits	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Military Service-Related Exposures to Prophylactic Medications, Pesticides, Organophosphates, and Toxic Chemicals, Materials, Metals, and Minerals	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**3. Based on the state of the science for each topic listed below, please select up to two types of studies that would be of the greatest benefit to that topic**

	I am not experienced in this particular topic area (N/A)	Initial Concept Studies	Early Ideas	Clinical/Translational	Clinical Trials	Team Science	Early Investigator/Career Development
Neurotoxin Exposure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Gulf War Illness and Its Treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exposures to Airborne Hazards and Burn Pits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Military Service-Related Exposures to Prophylactic Medications, Pesticides, Organophosphates, and Toxic Chemicals, Materials, Metals, and Minerals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**4. What obstacles are researchers and the patient/consumer community facing that could potentially be addressed by the TERP (100 character limit)?**

**5. How can the TERP respond to the current obstacles to facilitate progress (100 character limit)?**

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**6. Which of the following best describes your role in the toxic exposure research community? (Select all that apply)**

- ☐ Academia
- ☐ Clinician
- ☐ Foundation
- ☐ Governmental Program Administrator
- ☐ Industry
- ☐ Consumer/Patient/Caregiver/Advocate

Other (please specify)

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**7. From the list of topic areas below, please select the primary topic area that most closely aligns with your area of expertise/interest. A secondary topic area may also be selected, if applicable.**

	Neurotoxin Exposure	Gulf War Illness and Its Treatment	Exposures to Airborne Hazards and Burn Pits	Other Military Service-Related Toxic Exposures
Primary Topic Area	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Secondary Topic Area (if applicable)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**8. If you would like to be contacted regarding attendance at the upcoming FY22 TERP Stakeholders Meeting (virtual meeting for 15-16 June 2022), please provide your name, organization, email address, and phone number.**

*The TERP Stakeholders meeting attendee list will be balanced across disciplines, as appropriate, to facilitate discussion. The CDMRP may not be able to accommodate all interested respondents. However, the outcomes of the TERP Stakeholders meeting will be made publically available on the TERP webpage.*

Name	<input type="text"/>
Organization	<input type="text"/>
Email Address	<input type="text"/>
Phone Number	<input type="text"/>

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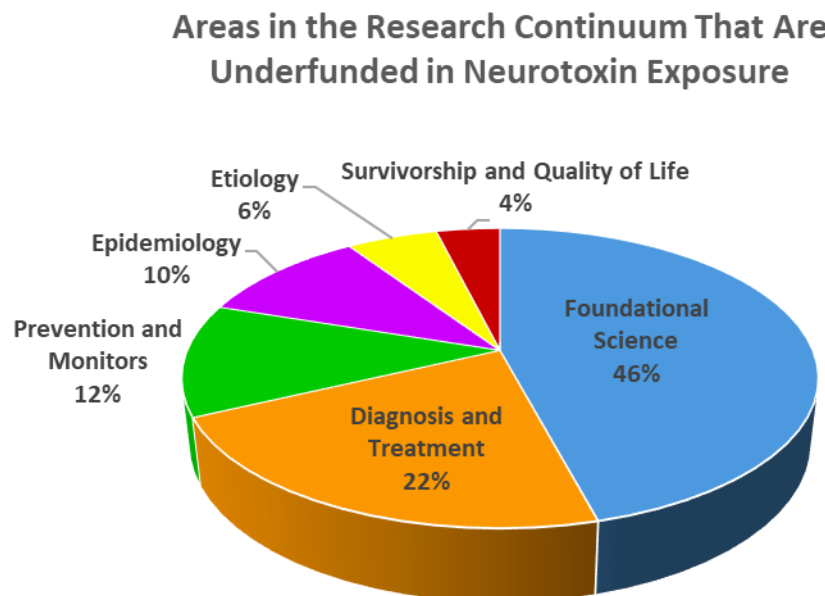
## Results and Analysis of Stakeholders' Request for Information

A total of 265 responses were received, tabulated, and categorized. The final results are provided below.

**Question 1: For each of the topics listed below, please indicate which of the following areas of the research continuum you believe are the most underfunded. Only one research area on the continuum can be selected per topic.**

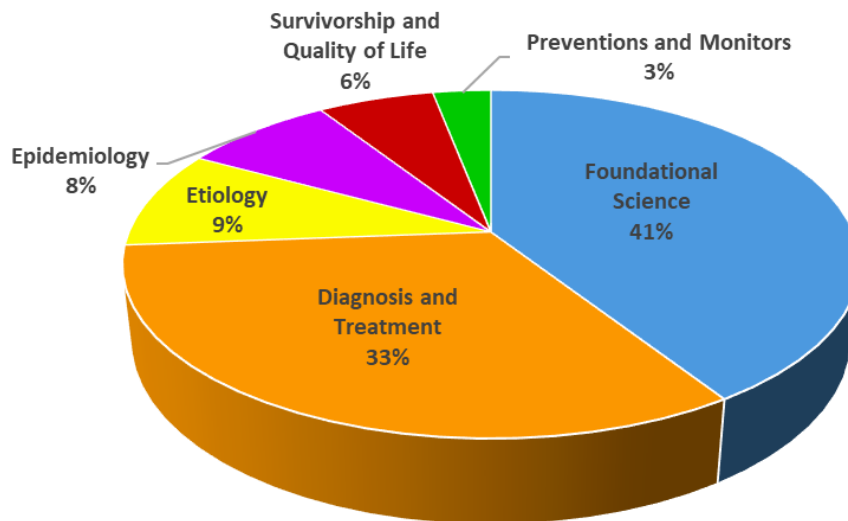
### Summary of analysis and data:

- For each topic area respondents were given the option to indicate that they were not experienced in this particular area and that precluded them from providing a response in that topic area.
- For all of the topic areas, foundational science and diagnosis and treatment were the top two areas of the research continuum that were identified as being underfunded.



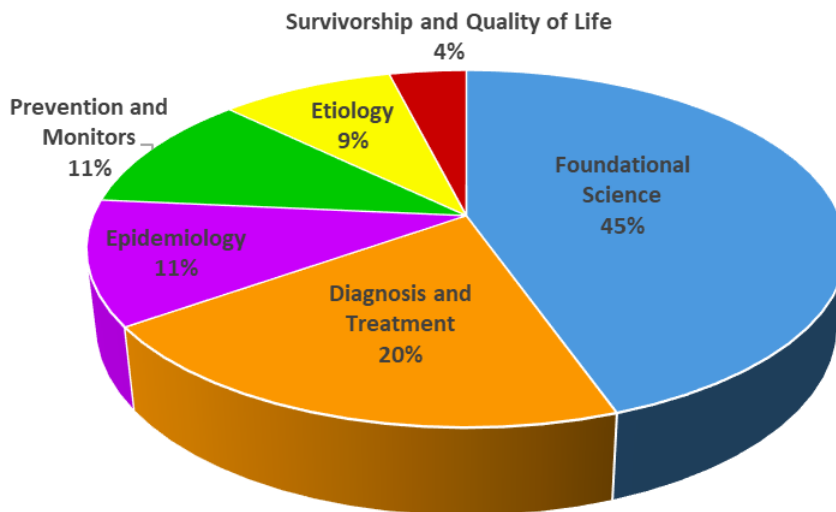
*Figure 3. Areas in the Research Continuum That Are Underfunded in the Neurotoxin Exposure Area. A total of 181 respondents provided answers for this question, and their responses are represented in the pie chart above; 84 respondents said they were not experienced in the field or left the question blank.*

### Areas in the Research Continuum That Are Underfunded in Gulf War Illness and Its Treatment



*Figure 4. Areas in the Research Continuum That Are Underfunded in the Gulf War Illness and Its Treatment Area. A total of 164 respondents answered this question, and their responses are represented in the pie chart above; 101 respondents said they were inexperienced in the field or left the question blank.*

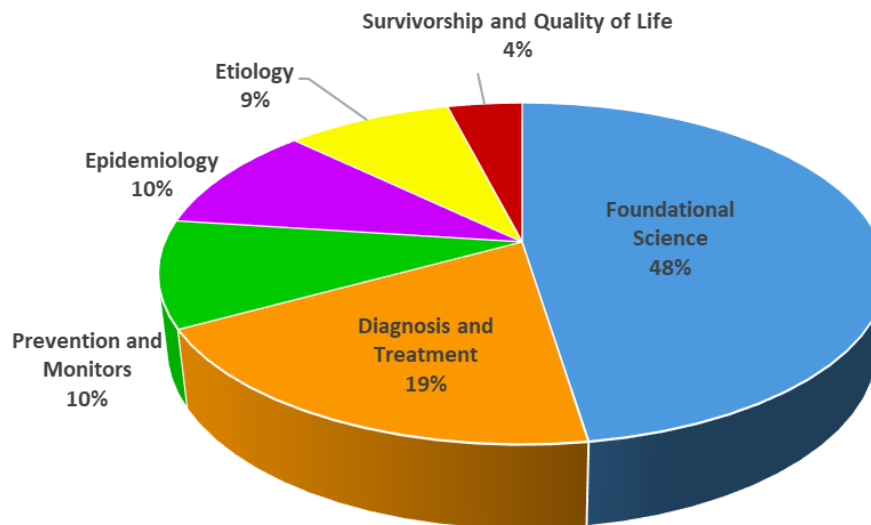
### Areas in the Research Continuum That Are Underfunded in Airborne Hazards and Burn Pits



*Figure 5. Areas in the Research Continuum That Are Underfunded in the Airborne Hazards and Burn Pits Area. A total of 204 respondents provided an answer to this question, and their responses are represented here; 61 said they were not experienced in the field or left the question blank.*



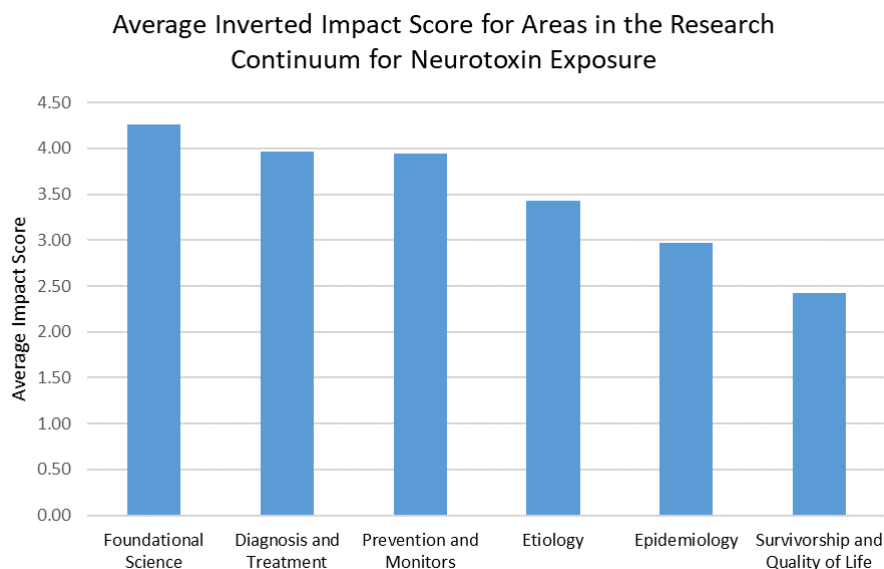
### Areas in the Research Continuum That Are Underfunded in Other Military Service-Related Exposures



*Figure 6. Areas in the Research Continuum That Are Underfunded in the Military Service-Related Exposures to Prophylactic Medications, Pesticides, Organophosphates, and Toxic Chemicals, Materials, Metals, and Minerals Area. A total of 227 respondents provided an answer to this question, and their responses are represented in the pie chart; 38 respondents left the question blank or said they were not experienced in the field.*

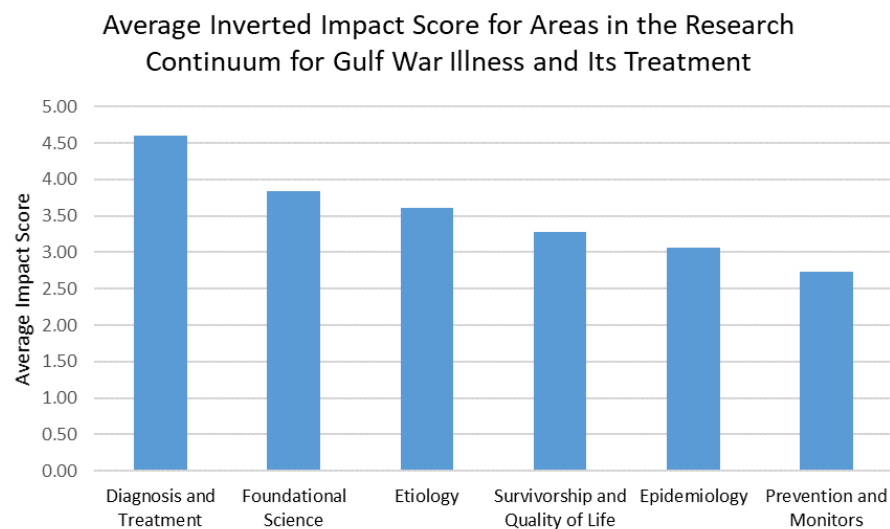
**Question 2:** For each topic area, please rank (1-6) the following areas of the research continuum based on which will have the most impact to the least impact. A score of 1 indicates that research area will have the MOST impact on the topic area while a score of 6 indicates that research area will have the LEAST impact.

**Summary of analyses and data:** The data were sorted into those who answered the question as intended by ranking the areas from 1 to 6 and those who did not rank the areas as instructed. The original question asked that the most impactful research area be scored with the number 1 and the least impactful area with the number 6. To simplify the analyses, the rankings were inverted such that those research areas that were ranked a 6 (least impactful) were plotted on the graphs as a 1, and a ranking of 2 was plotted on the graph as a 5. Responses that were completed as intended were averaged, and the inverted average rankings were displayed for all of the responses that appropriately ranked on a scale of 1 to 6. The average inverted impact scores for those responses that ranked as intended was found for each of the areas in the research continuum. These scores can be found in Figures 7 through 10 for each of the areas in the research continuum. Generally, foundational science and diagnosis and treatment ranked either first or second in terms of being most impactful for each of the four topic areas.



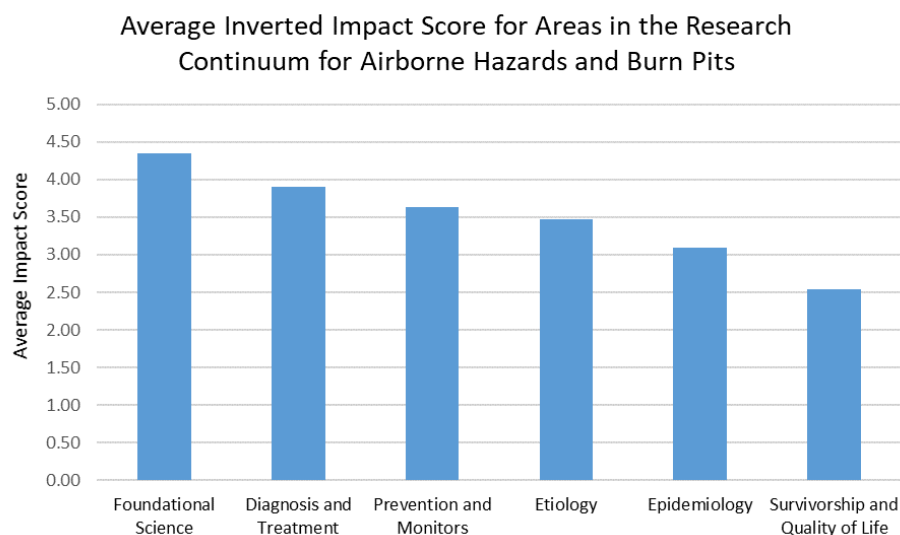
1st	Foundational Science
2nd	Diagnosis and Treatment
3rd	Prevention and Monitors
4th	Etiology
5th	Epidemiology
6th	Survivorship and Quality of Life

**Figure 7. The Average Impact Score for Areas of the Research Continuum for the Neurotoxin Exposure Area. A total of 111 respondents answered this question as intended, and their responses are shown in the figure above; 75 respondents said they were inexperienced in the field or left the question blank.**



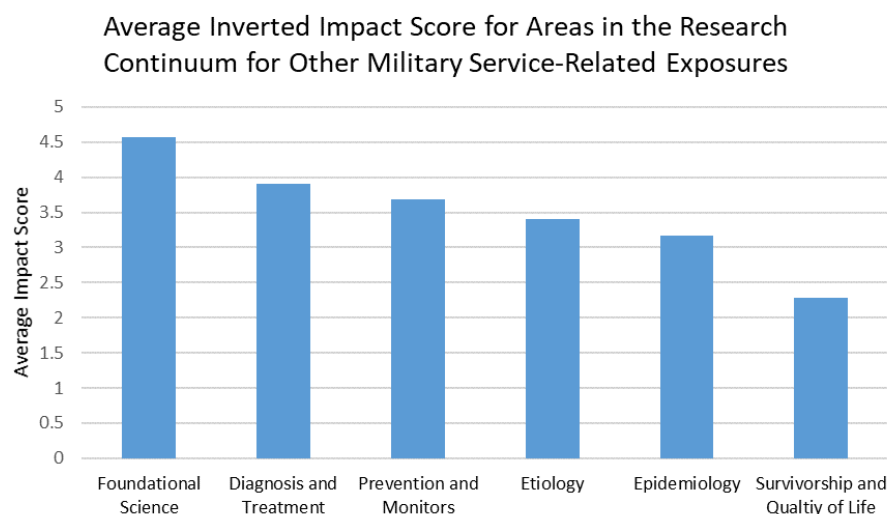
1st	Diagnosis and Treatment
2nd	Foundational Science
3rd	Etiology
4th	Survivorship and Quality of Life
5th	Epidemiology
6th	Prevention and Monitors

**Figure 8. The Average Impact Score for Areas of the Research Continuum for the Gulf War Illness and Its Treatment Area. A total of 98 respondents answered this question as intended, and their responses are reflected in the figure above; 101 respondents said they were inexperienced in the field or left the question blank.**



1st	Foundational Science
2nd	Diagnosis and Treatment
3rd	Prevention and Monitors
4th	Etiology
5th	Epidemiology
6th	Survivorship and Quality of Life

**Figure 9. Average Impact Score for Areas of the Research Continuum for the Airborne Hazards and Burn Pits Area.** A total of 114 respondents answered the question as intended, and their responses are reflected in the figure above; 63 said they were inexperienced in the field or left the question blank.



1st	Foundational Science
2nd	Diagnosis and Treatment
3rd	Prevention and Monitors
4th	Etiology
5th	Epidemiology
6th	Survivorship and Quality of Life

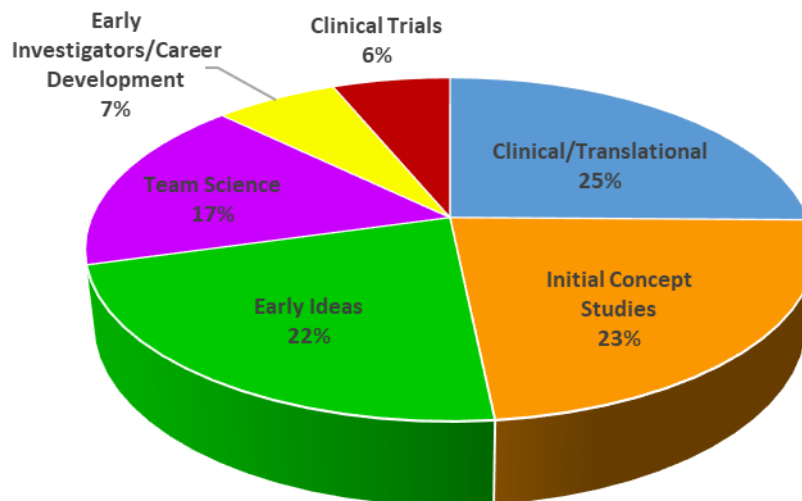
**Figure 10. Average Impact Score for Areas of the Research Continuum for the Military Service-Related Exposures to Prophylactic Medications, Pesticides, Organophosphates, and Toxic Chemicals, Materials, Metals, and Minerals Area.** A total of 135 respondents answered the question as intended, and their responses are reflected in the figure above; 41 respondents said they were inexperienced in the field or left the question blank.

**Question 3: Based on the state of the science for each topic listed below, please select up to two types of studies that would be of the greatest benefit to that topic.**

**Summary of Analysis and Data:**

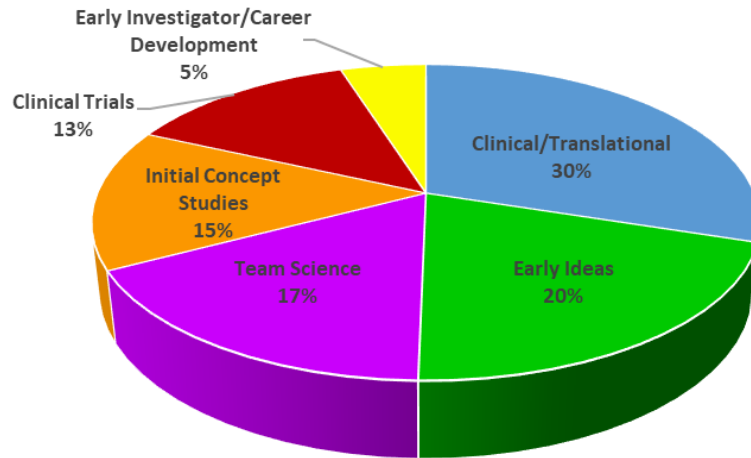
- For each topic area respondents were given the option to indicate that they were not experienced in this particular area.
- Overall, the top study type varied for each of the four topic areas, but early ideas, initial concept, clinical/translational and team science studies were consistently in the top four.

**Types of Studies That Would be Most Beneficial  
for Neurotoxin Exposure**



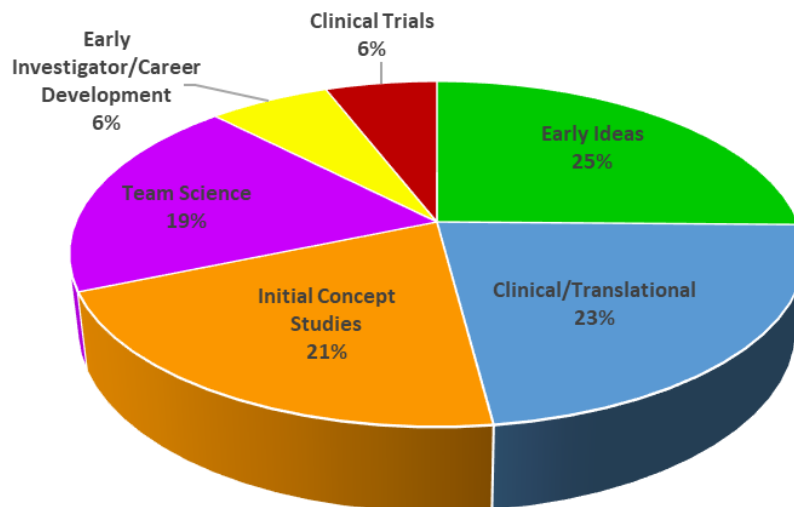
*Figure 11. Analysis of the Types of Studies That Would be Most Beneficial in the Neurotoxin Exposure Area. A total of 207 respondents answered the question, and their responses are reflected in the pie chart above; 58 said they were not experienced in the field or left the question blank.*

### Types of Studies That Would be Most Beneficial for Gulf War Illness and Its Treatment



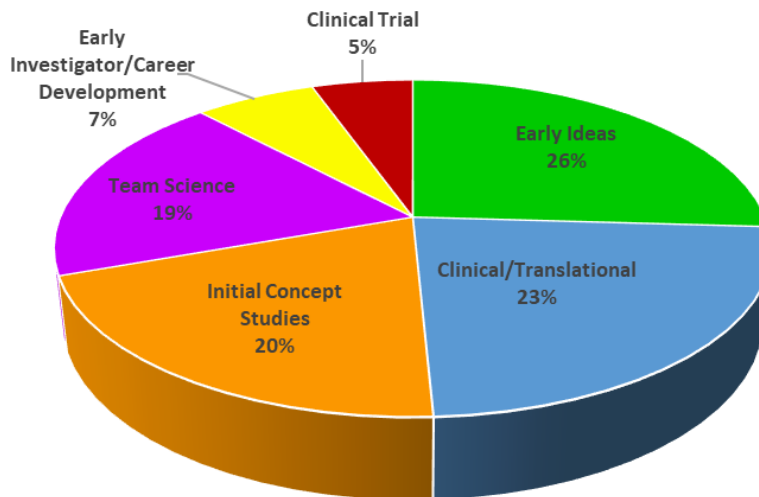
*Figure 12. Analysis of the Types of Studies That Would Be Most Beneficial in the Gulf War Illness and Its Treatment Area. A total of 187 respondents answered the question, and their responses are reflected in the pie chart above; 78 said they were not experienced in the field or left the question blank.*

### Types of Studies That Would be Beneficial for Airborne Hazards and Burn Pits



*Figure 13. Analysis of the Types of Studies That Would Be Most Beneficial in the Airborne Hazards and Burn Pits Area. A total of 222 respondents provided an answer to this question and their answers are reflected in the pie chart above; 43 said they were inexperienced in the field or left the question blank.*

### Types of Studies That Would be Most Beneficial for Military Service-Related Exposures



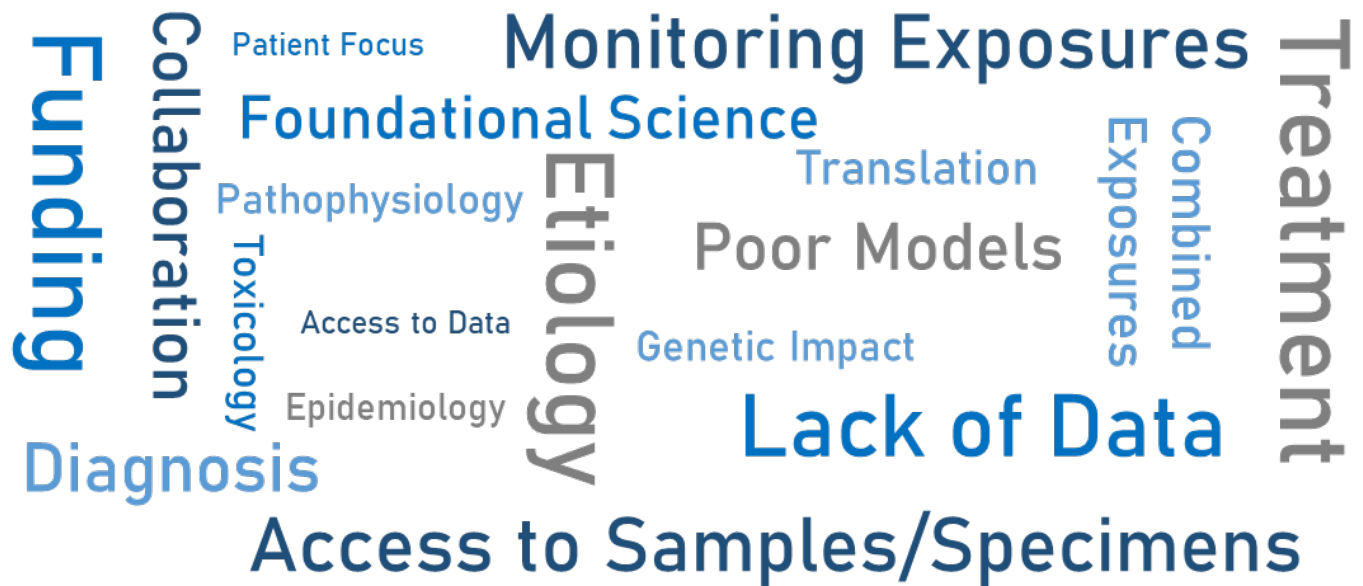
*Figure 14. Analysis of the Types of Studies That Will Be Most Beneficial in the Military Service-Related Exposures to Prophylactic Medications, Pesticides, Organophosphates, and Toxic Chemicals, Materials, Metals, and Minerals Area. A total of 245 respondents provided an answer to this question, and their responses are reflected above; 20 said they were not experienced in this topic area or left the question blank.*

### Question 4: What obstacles are researchers and the patient/consumer community facing that could potentially be addressed by the TERP?

#### Summary of Analysis and Data:

- Each respondent was given 100 characters to answer the question.
- The answers were grouped into overarching obstacles based on themes presented in the response.
- Each response could be counted in up to two of the overarching obstacles.
- All obstacles that had 5 or more responses were included in the word cloud in Figure 15.

# Poorly Defined Exposures



*Figure 15. Analysis of the overarching obstacles faced by researchers and the patient/consumer communities that can be addressed by the TERP. The size of the word corresponds to the number of responses that fell within that overarching obstacle.*

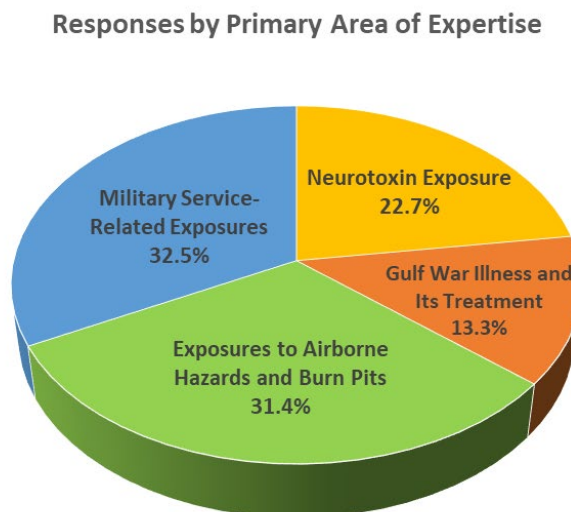
## **Question 5: How can the TERP respond to current obstacles to facilitate progress?**

### **Summary of Analysis and Data:**

- Each respondent was given 100 characters to answer the question.
- The answers were grouped into overarching solutions based on themes presented in the response.
- Each response could be counted in up to two of the overarching solutions.
- All solutions that had 4 or more responses were included in the word cloud in Figure 16.



*Figure 16. Analysis of the overarching solutions to obstacles faced by the research and patient/consumer communities that can be addressed by the TERP. The size of the word corresponds to the number of responses that fell within that overarching obstacle.*



*Figure 17. Analysis of the Primary Area of Expertise for the Respondent to the Request for Information.*



## Resources

- CDMRP: <https://cdmrp.army.mil/>
- Defense Health Agency Joint Program Committees: <https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Research-and-Engineering/Joint-Program-Committees>
- eBRAP: <https://ebrap.org/eBRAP/public/index.htm>
- Grants.gov: <https://www.grants.gov>
- Gulf War Illness Research Program (GWIRP): <https://cdmrp.army.mil/gwirp/default>
- Gulf War Veterans Research at the VA: <https://www.research.va.gov/topics/gulfwar.cfm>
- Health Outcomes Military Exposures (HOME): [Health Outcomes Military Exposures - Public Health \(va.gov\)](https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Research-and-Engineering/Joint-Program-Committees)
- Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan: <https://nap.nationalacademies.org/catalog/13209/long-term-health-consequences-of-exposure-to-burn-pits-in-iraq-and-afghanistan>
- Military Operational Medicine Research Program (MOMRP): <https://momrp.amedd.army.mil/>
- Neurotoxin Exposure Treatment Parkinson's Research Program (NETP): <https://cdmrp.army.mil/netp/default>
- Office of Research and Development: <https://www.research.va.gov/default.cfm>
- ONETOX: Neural Exposome and Toxicology Programs: <https://www.ninds.nih.gov/current-research/research-funded-ninds/translational-research/onetox-neural-exposome-and-toxicology-programs>
- Parkinson's Research Program (PRP): <https://cdmrp.army.mil/prp/default>
- Peer Reviewed Medical Research Program (PRMRP): <https://cdmrp.army.mil/prmrp/default>
- Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations: <https://www.nationalacademies.org/our-work/respiratory-health-effects-of-airborne-hazards-exposures-in-the-southwest-asia-theater-of-military-operations>
- U.S. Army Medical Materiel Agency (USAMMA): <https://www.amlc.army.mil/USAMMA/>

- U.S. Army Medical Materiel Development Activity (USAMMDA):  
<https://www.usammda.army.mil/>
- U.S. Army Medical Research Acquisition Activity (USAMRAA):  
<https://www.usamraa.army.mil/Pages/Main01.aspx>
- U.S. Army Medical Research and Development Command (USAMRDC):  
<https://mrdc.amedd.army.mil/>
- Department of Veteran's Affairs ([VA](#)) [Office of Research & Development \(va.gov\)](#)

## List of Abbreviations

CDMRP	Congressionally Directed Medical Research Programs
DOD	Department of Defense
FY	Fiscal Year
GWI	Gulf War Illness
GWIRP	Gulf War Illness Research Program
GWVIRP	Gulf War Veterans' Illnesses Research Program
IOM	Institute of Medicine
JPC	Joint Program Committees
M	Million
NETP	Neurotoxin Exposure Treatment Parkinson's
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
PA	Program Announcement
PD	Parkinson's disease
PI	Principal Investigator
PRP	Parkinson's Research Program
PRMRP	Peer Reviewed Medical Research Program
PTSD	Post-Traumatic Stress Disorder
RFI	Request for Information
TERP	Toxic Exposures Research Program
USAMRDC	U.S. Army Medical Research and Development Command
VA	U.S. Department of Veterans Affairs