The Congressionally Directed Medical Research Programs

CUTTING EDGE RESEARCH

The Role of Funders in Diversifying Clinical Trials and Clinical Research

Overcoming Barriers to Diversifying Clinical Trials
National Academy of Sciences Workshop

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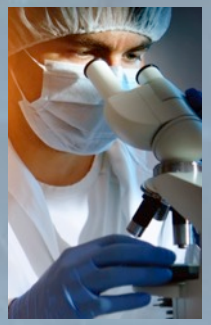


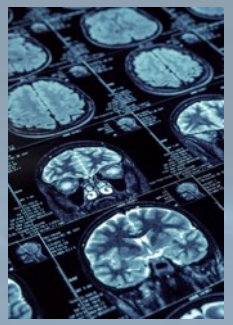
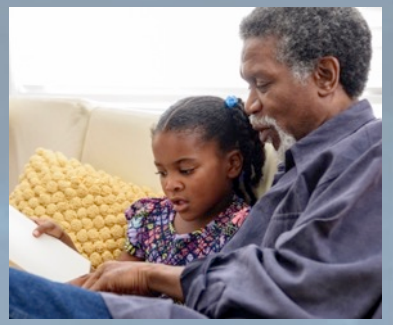

The views expressed in this presentation are those of the author and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government

CDMRP
Department of Defense

WHO is the CDMRP?

Department of Defense

Department of the Army

Army Futures Command

U.S. Army Medical Research and Development Command (USAMRDC)

CDMRP Congressionally Directed Medical Research Programs

CUTTING EDGE RESEARCH

FY21 CDMRP Funding

CDMRP Department of Defense

Program	$M	Program	$M
Alcohol and Substance Abuse Disorder	$4.0	Neurofibromatosis	$20.0
Amyotrophic Lateral Sclerosis	$40.0	Neurotoxin Exposure Treatment Parkinson's	$16.0
Autism	$15.0	Orthotics and Prosthetics Outcomes	$15.0
Bone Marrow Failure	$7.5	Ovarian Cancer	$35.0
Breast Cancer	$150.0	Pancreatic Cancer	$15.0
Chronic Pain	$15.0	Peer Reviewed Alzheimer's	$15.0
Combat Readiness	$10.0	Peer Reviewed Cancer (20 Topics)	$115.0
Duchenne Muscular Dystrophy	$10.0	Peer Reviewed Medical (42 Topics)	$370.0
Epilepsy	$12.0	Peer Reviewed Orthopaedic	$30.0
Gulf War Illness	$22.0	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	Scleroderma	$5.0
Lung Cancer	$20.0	Spinal Cord Injury	$40.0
Lupus	$10.0	Tick-Borne Disease	$7.0
Melanoma	$30.0	Traumatic Brain Injury and Psychological Health Research	$175.0
Military Burn	$10.0	Tuberous Sclerosis Complex	$8.0
Multiple Sclerosis	$20.0	Vision	$20.0
			Total $1.5B

CDMRP Policy on the Inclusion of Women and Minorities in Clinical Research

- It is the policy of CDMRP that women and individuals from minority groups be included in all CDMRP-funded clinical research studies, unless there is a clear, justifiable rationale that it is inappropriate with respect to the health of the subjects or the purpose of the research.
- Effective 1 October 2020 with incremental implementation ongoing
  - New requirements included in applicable FY21 funding opportunity announcements
    - Note: CDMRP funding opportunity announcements have included language encouraging inclusion of women and minorities in clinical trials since 2009
- Applies to all studies involving clinical research, not just clinical trials
  - Includes interventional clinical trials, observational clinical studies, and studies involving identifiable human biospecimens or datasets
- Requirements
  - Applicants required to include a strategy for inclusion of women and minorities appropriate to the objectives of the study, anticipated Inclusion Enrollment Report (IER) form(s) describing the composition of the proposed study population, and a rationale for the selection of subjects
    - Strategy for inclusion and proposed distribution of enrollment reviewed by peer reviewers
  - Funded PIs conducting clinical research required to submit updated IER form(s) with each annual and final technical report, describing actual enrollment data and any challenges encountered
    - CDMRP staff monitor and track inclusion when reviewing technical reports
  - Additional requirements for Phase III clinical trials
    - Applicants required to describe planned analyses of group differences in proposals
    - Funded PIs required to report results of these analyses to https://www.clinicaltrials.gov/
- Developed in coordination with the NIH. Collaboration with the NIH ongoing for conversion of the IER form to a common form for shared use
- Next steps
  - Collation of data across programs to enable analysis of policy efficacy and impact