

Rehabilitation Clinical Trials: Innovations, Designs, and Tribulations

**Funding Agency Resources** 

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#### NIH/NICHD National Center for Medical Rehabilitation Research (NCMRR)

Joe Bonner, PhD – Health Scientist Administrator and Program Officer

#### **NIH National Center for Advancing Translational Sciences (NCATS)**

Christopher Hartshorn, PhD – Chief, Digital & Mobile Technologies Section

#### **Veterans Affairs Rehabilitation Research & Development (VA RR&D)**

Timothy Brindle, PhD - Scientific Program Manager

#### National Institute on Disability, Independent Living and Rehabilitation Research (NIDILRR)

Radha Holavanahalli, PhD – Rehabilitation Program Specialist

#### **Craig H. Neilsen Foundation**

Jacob Shreckengost, PhD – Program Officer Spinal Cord Injury Research on the Translational Spectrum (SCIRTS)

#### **Congressionally Directed Medical Research Programs (CDMRP)**

Patricia Henry, PhD – Program Manager

#### **National Science Foundation**

Grace Hwang, PhD – Program Director Disability and Rehabilitation Engineering (DARE) Program

## Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

#### **Research Grant Mechanisms (R Series)**

https://www.nichd.nih.gov/grants-contracts

#### **Research Project Grants (R01)**

- Investigator-initiated applications; focus on specific set of aims
- Budget: no boundaries, but typically \$250,000 (modular, direct costs) annually
- Duration: may request up to 5 years of funding; renewable
   Clinical trial not allowed: <u>PA-20-185</u>; Basic experimental studies with humans (BESH) required: <u>PA-20-183</u>; Clinical trial required: <u>PA-20-183</u>

#### **Small Research Grants (R03)**

- Pilot studies (feasibility); development of new methodology or technology
- Not renewable; not to be used to supplement funded projects
- Budget: up to \$50,000 per year (direct costs) for 2 years
- Parent R03 Clinical Trial Not Allowed: PA-20-200

#### Academic Research Enhancement Award (AREA) and Research Enhancement Award (REAP) Grants (R15)

- Only schools that have not been major recipients of NIH funds are eligible
- Potential for undergraduate research experience is important
- Budget: aggregate budget up to \$300,000 (direct costs) for up to 3 years; renewable AREA: Clinical trial not allowed: PAR-21-155; Clinical trial required: PAR-21-154
   REAP: Clinical trial not allowed: PAR-22-060; Clinical trial required: PAR-21-357

#### **NICHD Exploratory/Developmental Grants Program (R21)**

- Exploratory, high-risk/high-impact studies
- Budget: up to \$275,000 total direct costs distributed over 2 years
- Clinical trial not allowed: <u>PA-20-195</u>; Basic experimental studies with humans (BESH) required: <u>PA-20-196</u>; Clinical trial required: <u>PA-20-194</u>

#### Small Business Technology Transfer (STTR) Grants (R41/R42)

#### Small Business Innovation Research (SBIR) Grants (R43/R44)

- Innovative research that has potential for commercialization
- STTR: Academic/business collaboration; phase I: \$150,000 (1 year)/II: \$1,000,000 (2 years)
   Clinical trial not allowed: PA-22-178; Clinical trial required: PA-22-179
- SBIR: Primarily at business site; phase I: \$150,000 (6 months)/II: \$1,000,000 (2 years)
   Clinical trial not allowed: PA-22-176; Clinical trial required: PA-22-177

#### **Conference and Scientific Meeting Grants (R13 and U13)**

 Support conferences and workshops; Prior approval from program staff required Clinical trial not allowed: <u>PA-21-151</u>

#### **NICHD Research Education Programs (R25)**

- Innovative and interactive short-term educational courses for researchers
- Focused on high priority research areas for NICHD; Clinical trial optional: PAR-20-250

#### **Training & Career-Development Mechanisms**

https://www.nichd.nih.gov/grants-contracts/training-careers/extramural

#### **Individual Fellowships (F Series)**

https://researchtraining.nih.gov/programs/fellowships

- F30: Predoctoral Fellowship for Students at Institutions without NIH-Funded Institutional Predoctoral Dual-Degree Training Programs Parent F30: PA-21-050
- **F30:** Predoctoral Fellowship for Students at Institutions with NIH-Funded Institutional Predoctoral Dual-Degree Training Programs Parent F30: **PA-21-049**
- F31: Predoctoral Fellowship Parent F31: PA-21-051
- F31: Predoctoral Fellowship to Promote Diversity in Health-related Research: PA-21-052
- F32: Postdoctoral Fellowship Parent F32: PA-21-048

#### **Individual Career Development (K Series)**

https://researchtraining.nih.gov/programs/career-development

#### **K01: Mentored Research Scientist Development**

- Clinically trained individuals in targeted areas with advanced degree (e.g., PhD)
- 3 to 5 years of mentored training
- NICHD targets K01s in: medical rehabilitation; child abuse & neglect; population research Clinical Trial Not Allowed: <u>PA-20-190</u>; BESH Required: <u>PA-20-191</u>; Clinical Trial Required: <u>PA-20-176</u>

#### **K08: Mentored Clinical Scientist**

- Clinically trained (e.g., MD, DVM, DDS), seeking training in basic research
- 3 to 5 years of mentored support at 75-percent effort Clinical Trial Not Allowed: PA-20-203; BESH Required: PA-20-201; Clinical Trial Required: PA-20-202

#### **K23: Mentored Patient-Oriented Research Career Development**

- Clinically trained (e.g., MD), seeking training in patient-oriented clinical research
- 3 to 5 years of mentored support at 75-percent effort

Clinical Trial Not Allowed: PA-20-205; BESH Required: PA-20-204; Clinical Trial Required: PA-20-206

#### **K25: Mentored Quantitative Research Career Development**

- Quantitative or engineering background, entering into biomedical research
- 3 to 5 years of mentored support at 75-percent effort Clinical Trial Not Allowed: <u>PA-20-199</u>; BESH Required: <u>PA-20-198</u>; Clinical Trial Required: <u>PA-20-197</u>

#### K99/R00: Pathway to Independence Award

- No more than 4 years post-doctoral experience at time of application
- 1 to 2 years of mentored support (<\$100k/yr.), then three years faculty support (<\$249k/yr.)</li>
- NICHD Administrative review for transition from K99 to R00 phase
   Clinical Trial Not Allowed: PA-20-188; BESH Required: PA-20-189; Clinical Trial Required: PA-20-187
- Postdoctoral Career Transition Award to Promote Diversity (K99/R00)
   Clinical Trial Not Allowed: PA-21-271, BESH Required: PA-21-273, Clinical Trial Required: PA-21-272

#### **Institutional Training Grants (T32)**

https://researchtraining.nih.gov/programs/training-grants

To support Predoctoral and/or Postdoctoral Fellows: PA-20-142

#### Research Supplements to Promote Diversity in Health-related Research

- Individuals at any career level from under-represented racial and/or ethnic groups, disadvantaged backgrounds, having a disability, or re-entering research after family obligation are eligible. Must be US citizen/green card-national
- May not exceed duration of currently funded NICHD grant Clinical Trial Not Allowed: <u>PA-21-071</u>

## NCATS Information and Resources for 2022 MR3 Network Scientific Retreat

NCATS Website: <a href="https://ncats.nih.gov/">https://ncats.nih.gov/</a>

Open Funding Opportunities: <a href="https://ncats.nih.gov/funding/open">https://ncats.nih.gov/funding/open</a>

#### Rare Diseases Research Network (RDCRN) https://rarediseasesnetwork.org/

The Rare Diseases Clinical Research Network (or RDCRN) that advances research in rare diseases.

- NCATS coordinates a consortium of 10 NIH Institutes and Centers supporting clinical studies on
   >200 rare diseases
- A more-than-one-disease-at-a- time approach, the RDCRN studies at least 3 rare disease therapeutic areas together
- Patient advocacy groups are an integral part of the research team

#### Tissue Chips for Drug Screening <a href="https://ncats.nih.gov/tissuechip">https://ncats.nih.gov/tissuechip</a>

The Tissue Chip for Drug Screening program aims to develop bioengineered devices to improve the process of predicting whether drugs will be safe or toxic in humans.

Tissue Chip Funding Information: <a href="https://ncats.nih.gov/tissuechip/funding">https://ncats.nih.gov/tissuechip/funding</a>

#### Clinical and Translational Science Awards (CTSA) Program <a href="https://ncats.nih.gov/ctsa">https://ncats.nih.gov/ctsa</a>

The CTSA Program is designed to develop innovative solutions that will improve the efficiency, quality and impact of the process for turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public.

- CTSA Program Funding Information: <a href="https://ncats.nih.gov/ctsa/funding">https://ncats.nih.gov/ctsa/funding</a>
- CTSA Trial Innovation Network (TIN) https://trialinnovationnetwork.org/
  - The CTSA Trial Innovation Network addresses roadblocks in clinical trials and accelerates the translational of novel interventions into life-saving therapies.
  - The Trial Innovation Network offers study investigators of multi-site trials the ability to request an initial consultation or specific resources for a trial, whether funded or in the planning stages.
  - o TIN Liaison Team Member: <a href="https://trialinnovationnetwork.org/liaison-teams/?key-element=1601">https://trialinnovationnetwork.org/liaison-teams/?key-element=1601</a>
- National COVID Cohort Collaborative (N3C) https://ncats.nih.gov/n3c
  - The National COVID Cohort Collaborative (N3C) maintains one of the largest collections of clinical data related to COVID-19 symptoms and patient outcomes in the United States. With stewardship from NCATS, more than 75 institutions worked together to build this extensive database. Having access to a large, centralized data resource allows research teams to study COVID-19 and identify potential treatments as the pandemic evolves. Learn the facts about the N3C by downloading and sharing the N3C fact sheet (PDF 382KB).
  - o Researcher Essentials: <a href="https://covid.cd2h.org/for-researchers">https://covid.cd2h.org/for-researchers</a>

- Gain Access to the Enclave:
  - Complete the <u>Enclave Registration Checklist</u> to expedite your N3C Data Enclave account creation.
  - Follow the <u>Enclave Registration Instructions</u> to request and access your enclave account

#### NIH HEAL Initiative <a href="https://heal.nih.gov/">https://heal.nih.gov/</a>

The Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®, is an aggressive, transagency effort to speed scientific solutions to stem the national opioid public health crisis. Almost every NIH Institute and Center is accelerating research to address this public health emergency from all angles.

Resources of the Trial Innovation Network are here to support these HEAL projects. CTSA Hubs and their Liaison Teams will assist investigators applying for TIN resources to support their grant application, using our regular portal submission process.

- HEAL Initiative: Interdisciplinary Team Science to Uncover the Mechanisms of Pain Relief by Medical Devices (RM1 Clinical Trial Optional) (RFA-NS-23-003)
- Other HEAL funding opportunities: https://heal.nih.gov/funding





### Office of Research & Development (ORD) Rehabilitation Research & Development Service (RR&D)

#### **VA Research Information on the Web**

#### **VA ORD Supported Research**

Search on NIH RePORTER website: report.nih.gov/index.aspx

Search on Clinical Trials website: <u>clinicaltrials.gov</u>

VA ORD Main Site: www.research.va.gov

Career Development Program: <a href="www.research.va.gov/funding/cdp.cfm">www.research.va.gov/funding/cdp.cfm</a>
 Centers: <a href="www.research.va.gov/programs">www.research.va.gov/programs</a>

Research Videos: <u>www.research.va.gov/news/videos.cfm</u>

#### **Grant Writing Seminars:**

Training in Grantsmanship for Rehabilitation Research (TIGRR) <a href="http://tigrr.bme.unc.edu/">http://tigrr.bme.unc.edu/</a>

NIA Butler-Williams Scholars Program (formerly Summer Institute on Aging Research) –
 Applications accepted in March for attendance in July

US Bone & Joint Initiative (USBJI) Young Investigator Initiative <a href="http://www.usbji.org/programs/yii">http://www.usbji.org/programs/yii</a>

#### **Additional ORD Information**

- Handbooks: select under General ORD Policies
   <a href="http://www.research.va.gov/resources/policies/">http://www.research.va.gov/resources/policies/</a>
- Rehabilitation Research and Development <a href="http://www.rehab.research.va.gov/">http://www.rehab.research.va.gov/</a>
- Health Services Research and Development <a href="http://www.hsrd.research.va.gov/">http://www.hsrd.research.va.gov/</a>
- Biomedical Laboratory Research and Development http://www.research.va.gov/services/blrd/default.cfm
- Clinical Science Research and Development <a href="http://www.research.va.gov/services/csrd/default.cfm">http://www.research.va.gov/services/csrd/default.cfm</a>





## Office of Research & Development (ORD) Rehabilitation Research & Development Service (RR&D)

#### **RR&D Scientific Program Managers**



Timothy J. Brindle, PhD Musculoskeletal Health timothy.brindle@va.gov



Anthony Pacifico, PhD Brain Health & Injury anthony.pacifico@va.gov



Shirley Groer, PhD

Career Development, Career Scientist, Centers & REAPs
shirley.groer@va.gov



Lina Kubli, PhD Sensory Systems & Communication Disorders lina.kubli@va.gov



Audrey Kusiak, PhD SCI/Pain & Regeneration audrey.kusiak@va.gov



Brian Schulz, PhD
Rehabilitation Engineering &
Prosthetics/Orthotics
brian.schulz@va.gov

Vacant
Behavioral Health & Social Reintegration
rrdreviews@va.gov



Carole Sztalryd-Woodle, PhD Chronic Medical Conditions & Aging carole.woodle@va.gov





## Office of Research & Development (ORD) Rehabilitation Research & Development Service (RR&D)

#### **RR&D Research Award Types**

All applications undergo scientific peer review

- Center Awards
  - 5 years, \$1.26M/year
- Research Enhancement Award Program (REAP)
  - o 5 years, \$440K/year
- Merit Awards
  - \$1.2M total budget cap for 4 years
- Small Projects in Rehabilitation Research (SPIRE)
  - 1-2 years, \$115K/year

#### Intended for:

- o High Risk/High Impact research; for preliminary data & feasibility
- Small projects that can be completed in a two-year period, no powered studies
- o Preference given to Early Career Stage Investigators
- New scientific areas of focus for established investigators
- o Editorial-style review; 3 independent reviews in written form only
- Scoring limited to three designations: Highly Meritorious, Meritorious, or Not Meritorious

#### • Research Career Scientists

- o 5 7 years, salary support
- Career Development Awards (CDA) mentored research opportunities

#### All awards

- US citizen
- VA at time of award but not required at time of application
- VA primary mentor
- o Support includes awardee salary (except MD, shared with clinical care), protected research time
- o Review criteria emphasize candidate's qualifications, as well as mentorship, career development,
- o and research plans

#### CDA – 1

- Must apply within 2 years of training
- Award up to 2 years, provides full salary support, \$20K/year operational funds

#### CDA – 2

- Must apply within 5 years of training
- Award up to 5-years, full salary support, \$75K/year operational funds
- Minority Serving Institution (MSI) (previously Historically Black Colleges & University (HBCU))
  - Features of CDA-2
  - Additional mentor(s) from MSI/HBCU





## Office of Research & Development (ORD) Rehabilitation Research & Development Service (RR&D)

#### **CDA Submission Deadlines and Contacts**

Letter of Intent (LOI) Submission				
SERVICE	DEADLINE per Cycle	Email ADDRESS	CONTACT	
Biomedical Laboratory R&D	May 1 Nov1	vhacadereview@va.gov	Questions about the program should be send to the Career Development mailbox.	
Clinical Science R&D	May 1 Nov 1	vhacadereview@va.gov	Questions about the program should be send to the Career Development mailbox.	
Health Services R&D	April 15 Oct 15	robert.small@va.gov	Robert Small, BA (202) 443-5743	
Rehabilitation R&D	May 1 Nov 1	rrdreviews@va.gov	Shirley Groer, PhD (202) 443-5767	
MSI-CDA (HBCU & other)	Follows Service LOI Deadlines	BLRD/CSRD: <u>vhacadereview@va.gov</u> HSRD: <u>Robert.Small@va.gov</u> RRD: <u>rrdreviews@va.gov</u>	Contact the appropriate Service representative above regarding submissions	

#### **CDA Award Types: Eligibility and Conditions**

	CDA-1 (CS/BL* & RR&D)	CDA-2	MSI
Clinician salary	9 calendar months plus 1/8 <sup>th</sup> from VAMC	6-9 calendar months plus 1/8 <sup>th</sup> from VAMC	6-9 calendar months plus 1/8 <sup>th</sup> from VAMC
Non-clinician salary	7.5-12 calendar months	7.5-12 calendar months	7.5-12 calendar months
Project funds	\$20K/yr to extend work of mentor	\$75K/yr for independent Work	As per service-specific RFA
Award duration	Up to 2 years	3-5 years	Up to 2 years (BL/CS)* 3-5 years (RR&D)
Eligibility	Max of 2 years beyond completion of training	Max of 5 years beyond completion of training	Same as 1 or 2 plus mentors at both HBCU and VA

<sup>\*</sup>BL & CSR&D have targeted CDA-1 RFAs for VA psychiatrists, US military veteran scientists, suicide prevention, & MSI

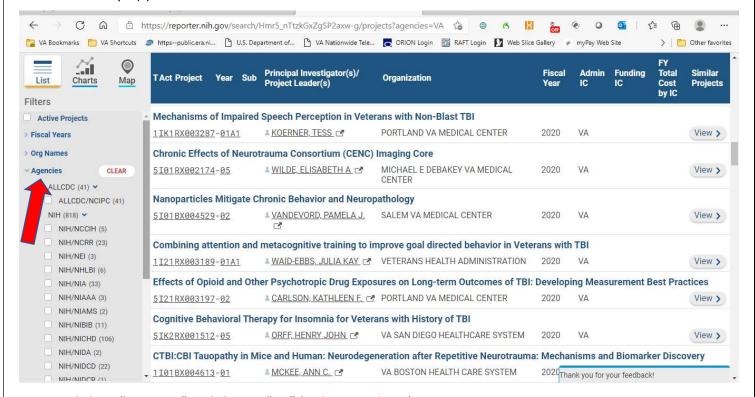




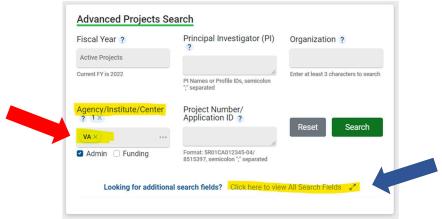
### INTERESTED TO LEARN ABOUT VA RESEARCH? GET STARTED!

#### Does VA fund research in my scientific area of interest and at what facilities?

- Search NIH RePORTER tool and use guidance as indicated below
  - User's guide manual and video: <a href="https://obsr.od.nih.gov/research-support/nihreporter/">https://obsr.od.nih.gov/research-support/nihreporter/</a>
  - NIH RePORTER query form: <a href="https://reporter.nih.gov/">https://reporter.nih.gov/</a>
  - o Enter topic(s) of interest in the Quick Search box. Then from the results:



- Click on "Agencies" and choose "VA" (red arrow-above)
- Or begin query for VA funded research and for VA Investigators:
  - o NIH RePORTER query form: <a href="https://reporter.nih.gov/">https://reporter.nih.gov/</a>
  - Scroll down to Advanced Projects Search
  - Search by Agency/Institute/Center: Select Veterans Affairs (VA) (red arrow below)









- The guery will generate a list of all active VA funded projects.
  - Click on the project title hypertext in the search results to get more information on each project.
  - Note the panel on the left for categories of information on the project.
- To search only for rehab funded VA projects, click on the option to "view All Search Fields" (blue arrow above). Under Project Number in the screen below, enter RX in the third box. See highlight.
  - RX for Rehabilitation R&D
  - BX for Biomedical Laboratory R&D
  - CX for Clinical Science R&D
  - HX for Health Services R&D

# Project Details Agency/Institute/Center ? 1 × VA × Admin Funding AND OR Project Number/ Application ID ? Format: 5R01CA012345-04/ 8515397, semicolon ',' separated OR

1 R01 CA 811099

### Who can I contact to learn more about VA research mission and priorities in my scientific area of interest?

- Contact the Office of Research and Development Scientific Program Managers:
  - o Rehabilitation R&D: https://www.rehab.research.va.gov/staff/science1.html
  - Biomedical Laboratory R&D and Clinical Science R&D: https://www.research.va.gov/services/shared\_docs/contacts.cfm
  - Health Services R&D: https://www.hsrd.research.va.gov/about/portfolio.cfm

#### Does VA support researchers early in their career?

• Yes, go to https://www.research.va.gov/funding/cdp.cfm

#### How do I find a VA mentor?

• Search the NIH RePORTER tool https://reporter.nih.gov/ for VA investigators working in your area of interest.

#### How do I learn more about starting research at a VA near me?

• Contact Associate Chiefs of Staff for R&D: https://www.research.va.gov/about/national\_directory.cfm

## Medical Rehabilitation Research Resource (MR3) Network Scientific Retreat on Rehabilitation Clinical Trials

### **Funding Agency Q&A Session**

Radha Holavanahalli, PhD.

National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)

Administration for Community Living, HHS

September 29, 2022

### NIDILRR's Mission

To generate new knowledge and to promote its effective use:



To improve the abilities of individuals with disabilities to perform activities of their choice in the community



To expand <u>society</u>'s capacity to provide full opportunities and accommodations for its citizens with disabilities

## What We Sponsor (Annual Budget of \$116 M)

Research & Development

 Interventions and products to improve long-term outcomes and community living

Capacity Building  Training young investigators and retraining clinicians to pursue research careers

Knowledge Translation  Promoting the use of R&D findings and products by people with disabilities, their families, and other stakeholders

## Core Principles

Social Model of Disability

Outcomes = (Person x Environment)

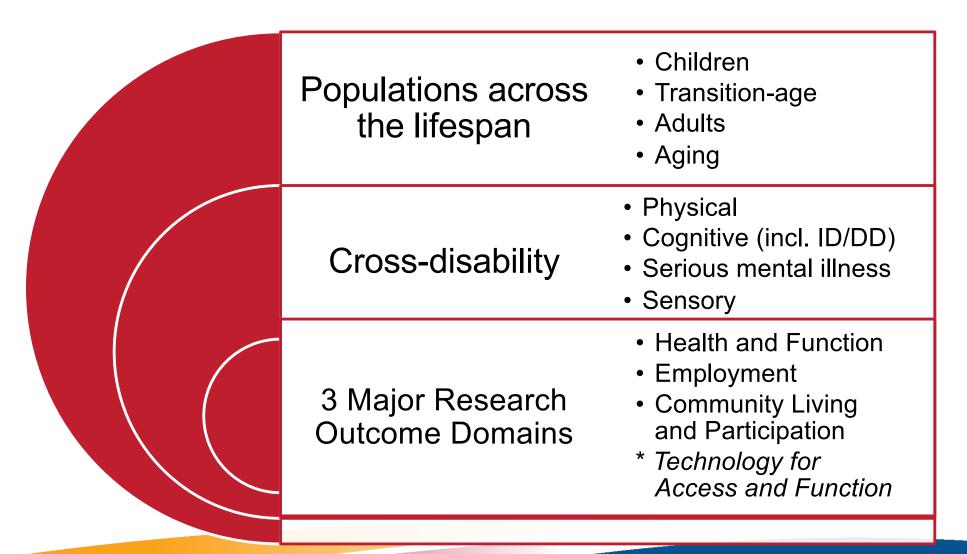
Rigor and Relevance

 NIDILRR optimizes the rigor of the R&D we sponsor, AND the relevance of the R&D to the lives of people with disabilities

Building the Evidence Base

 The ultimate aim of all NIDILRR R&D is evidencebased interventions and products to better serve and support people with disabilities in the community

## Breadth of Responsibility



## Applications: Rigor – Relevance Balance

#### Rigor

- Wide range of methods can be judged rigorous if appropriate for the study objectives and if consistent with the state of the science for a specific topic
- Largest percentage of peer review points available (40-50%)

#### Relevance

- Funding Opportunity Announcements require applicants to explain how proposed new knowledge and products will result in positive outcomes among people with disabilities.
- Peer review criteria (up to 20% of points)
- Grant requirements including grantee engagement with people with disabilities and other stakeholders

## Stages of Research

#### Research applicants

- must define the stage or stages of research that they propose to conduct
- Any rigorous quantitative, qualitative, or mixed-methods research can be appropriate, depending on the hypothesis or research question
- NIDILRR does not have an absolute preference for one methodological approach or research stage
- If research can be categorized under more than one stage including research that progresses from one stage to another, those stages must be clearly specified
- The stages are: exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation

## Types of Grant Awards

- Mary Switzer Research Fellowships
- Field-Initiated Projects (Research and Development) (FIP)
- Advanced Rehabilitation Research Training (ARRT)
- Small Business Innovation Research Grants (SBIR)
- Rehabilitation Research and Training Centers (RRTC)
- Rehabilitation Engineering Research Centers (RERC)
- Disability and Rehabilitation Research Projects (DRRP)
- SCI, TBI and Burn Injury Model System Centers (SCIMS, TBIMS,BMS)
- ADA National Network
- Knowledge Translation Centers

## Field-Initiated Project (FIP)

- Wide range of disability and rehabilitation topics and methods proposed by applicants
- Awards may be for research or development projects addressing one or multiple outcome domains
- Approximately 200 applications/year (NIDILRR's largest competition)
- Approximately 18 awards per year
- Up to \$200,000 per year
- Three-year awards

## Disability and Rehabilitation Research Projects (DRRP)

- NIDILRR's most flexible funding mechanism
  - Field-initiated or agency-driven
  - Various combinations of research, development, and related activities
- \$300,000–\$995,000 per year
- Up to five years
- 38 active awards
- Used to sponsor specific, large NIDILRR programs (Model Systems, ADA TA Centers)

## Model System Centers

- Comprised of:
  - Traumatic Brain Injury (16 Centers + National Data and Statistical Center)
  - Spinal Cord Injury (14 Centers + National Data and Statistical Center)
  - Burn Injury (4 Centers + National Data and Statistical Center)
  - Model Systems Knowledge Translation Center (MSKTC)
- In each Program, Centers:
  - Conduct site-specific research studies
  - Conduct Model Systems collaborative research studies
  - Contribute longitudinal data to a collective database
    - Data collected at regular intervals from the time of injury until death
    - The SCI, TBI and Burn Injury National Databases are the <u>oldest</u> and <u>largest</u> longitudinal databases in existence for the respective injury groups
    - Analyses of the databases generate knowledge re: long-term outcomes (in health, function, and community living and participation) and changes in outcomes over time as people age with the injury
  - Collaborate with the MSKTC to translate research findings for stakeholders
- Five-year awards; \$361,000 \$483,500 per center per year

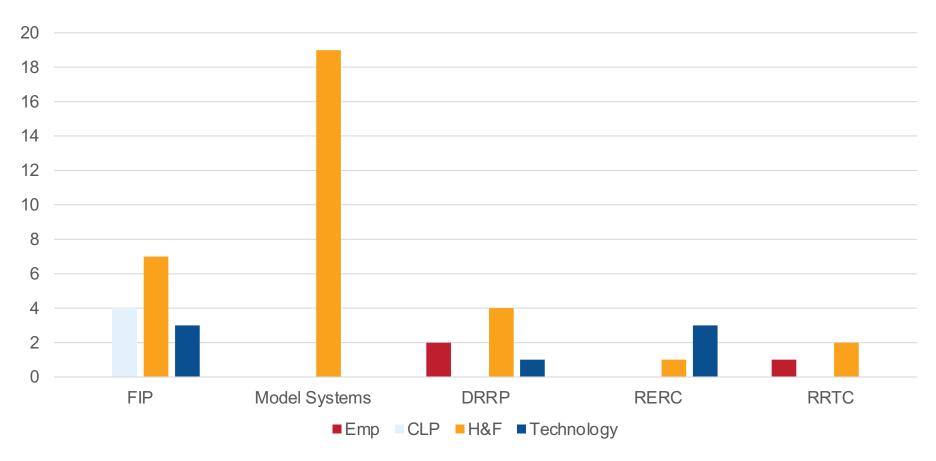
## Rehabilitation Research and Training Centers (RRTCs)

- RRTCs conduct multiple research projects at various stages
- RRTCs serve as "National Resource Centers" on specific topics
- Required to engage in research, as well as training, dissemination, and technical assistance
- NIDILRR may specify the general target population or outcome domain, or a specific topic that must be addressed
- Multiple RRTC competitions each year
- \$850,000 per year, on average
- Five-year awards

## Rehabilitation Engineering Research Centers (RERCs)

- RERCs engage in Research and Development, as well as Training, Technical Assistance, and Dissemination.
- RERC research activities generate New Knowledge in the form of peer-reviewed publications, seminars, & workshops
- RERC development activities generate New Products in the form of tools, models, methods, devices, applications, & standards
  - Product Development and Adoption is facilitated by a Technology Transfer Plan developed by the grantee; working with the KT4TT (a KT center).
- RERC Training Activities (e.g. coursework, internships) build Rehabilitation Engineering Capacity.
- Multiple RERC competitions each year. NIDILRR may specify the general rehabilitation engineering area to be addressed, or a specific topic that must be addressed
- Awards 21 active; 5-year duration; \$925,000 per year (average).

## Clinical Trials: Project Type By Funding Priority



#### • FIP:

- a randomized controlled trial to test the effectiveness of a financial literacy intervention called Building Financial Wellness (BFW) delivered to adults with serious mental illness (Community Living and Participation)
- examine the efficacy of an existing intervention, the Reinventing Yourself after SCI, which has been proven effective among individuals with spinal cord injury (SCI), for use in multiple sclerosis (MS). The Reinvention intervention is aimed at improving self-efficacy, psychological well-being, and quality of life via cognitive behavioral therapy and positive psychology techniques (Health and Function)
- evaluate the extent to which a novel treatment (T-WRITE) improves written language function and the use of text messaging for people with aphasia, who often have difficulty with writing and may struggle to use electronic communication that connects people to one another (Technology for Access and Function)

#### DRRP:

- the use of customized employment (CE) as an intervention to assist individuals with intellectual disabilities (ID) and/or autism spectrum disorder (ASD) to achieve integrated employment outcomes (Employment)
- a multisite, randomized, double-blind, placebo controlled trial of venlafaxine XR (Effexor XR) in 168 adults with spinal cord injury (SCI) and major depressive disorder (MDD) who are 18 to 65 years old and one or more years post injury.
   The purpose of the study is to examine the efficacy and tolerability of venlafaxine XR as a treatment for MDD (Health and Function)
- Community Access Through Remote Eyesight (CARE) Study a randomized clinical trial evaluating the efficacy of novel mobile application (app) technologies (including Seeing AI, Aira, and SuperVision+) to improve quality of life in older adults with low vision by expanding community access and providing assistance with activities of daily living (Technology for Access and Function)

### Model System Centers:

- a randomized controlled trial of Virtual-Environment Home Rehabilitation addresses the feasibility and practicality of a self-directed, technology-driven home rehabilitation program and analyzes whether technology-driven homebased rehabilitation improves functional outcomes for individuals with burns in a real-world setting
- a longitudinal randomized clinical trial to identify whether a home-based intervention that was demonstrated to be effective at reducing chronic shoulder pain in persons with SCI could be used as a preventative program to decrease the rate of shoulder pain onset
- a site-specific, double-blind, placebo controlled randomized clinical trial of an evidence-based cognitive rehabilitation intervention for learning and memory deficits following TBI

#### • RERC:

 A randomized clinical trial of a serious game developed to enhance selfmanagement ability among adolescents and young adults with spinal cord dysfunction

#### • RRTC:

 The RRTC on Health and Function for People with Physical Disabilities focuses on people with physical disability who have neurogenic lower urinary tract dysfunction (NLUTD) - Assessment of neuromodulation of the bladder using transcutaneous tibial nerve stimulation in a randomized controlled trial

## Engage with NIDILRR

#### Learn about NIDILRR

https://www.acl.gov/about-acl/about-national-institute-disability-independent-living-and-rehabilitation-researchhttps://acl.gov/news-and-events/announcements/new-nidilrr-long-range-plan

Receive Funding Opportunity Announcements <a href="http://www.naric.com/?q=node/33">http://www.naric.com/?q=node/33</a>

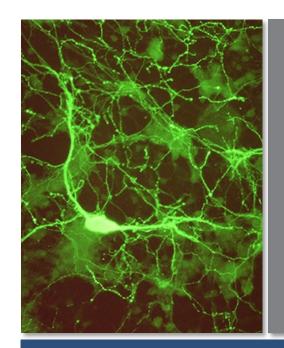
Review NIDILRR grant forecast/open grant competitions

http://www.grants.gov/web/grants/search-grants.html?cfda=93.433

## Engage with NIDILRR

Search NARIC to learn about NIDILRRfunded research in your topic areas https://www.naric.com/?q=en/ProgramDatabase Engage with NIDILRR grantees Become a NIDILRR Peer Reviewer https://rrm.grantsolutions.gov/AgencyPortal/acl.aspx Contact Information:
Radha Holavanahalli, PhD
Rehabilitation Program Specialist
Radha.Holavanahalli@acl.hhs.gov







## Foundation Funding in SCI Rehabilitation Research

Jacob Shreckengost, PhD Program Officer Craig H. Neilsen Foundation www.chnfoundation.org/



### Neilsen Mission and Values

#### **Mission**

Funding is dedicated to supporting both programs and scientific research to improve the quality of life for those affected by and living with spinal cord injury

Our values are inspired by Craig H. Neilsen

They are the lens we use in making funding and decisions

Leadership

Lead by example

**Inclusion** 

Expand opportunity

**Excellence** 

Transparency, rigor Results

Collaboration

Leverage knowledge Creativity

Take bold initiatives

#### What We Fund – Grants to U.S. and Canadian Organizations

Research: cells to psychosocial; dishes to animals to people

- SCI Research on the Translational Spectrum (SCIRTS)
- Psychosocial Research (PSR)

**Programs:** nonprofit/community activities and resources

- Creating Opportunity & Independence (CO&I)
  - Arts, Sports & Recreation; Assistive Tech; Education;
     Employment; Independent Living; Rehabilitation

#### **Education:**

- SCI Medicine Fellowships (SCIMF) specialty rehab training in SCI medicine
- Neilsen Scholarship Program (NSP) support for students with SCI

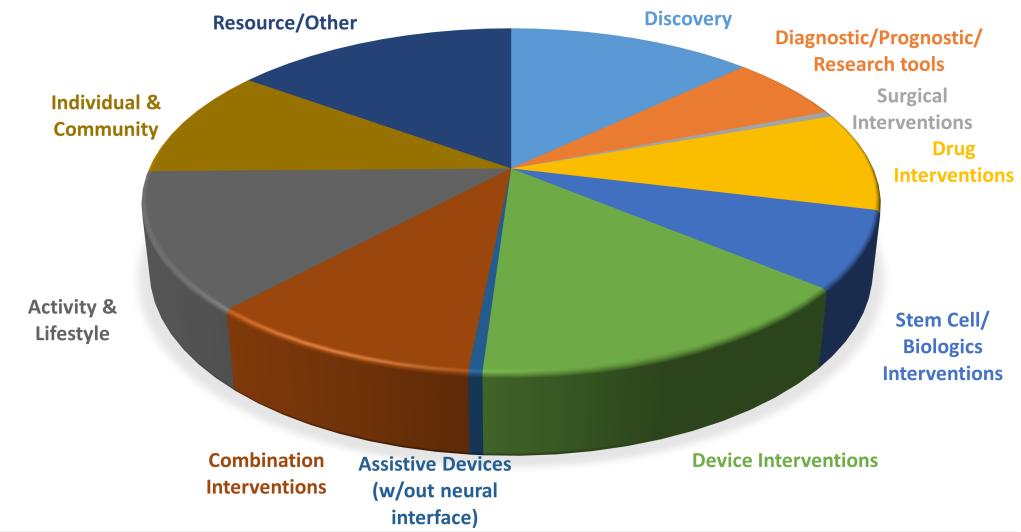
#### **Strategic Grants:**

Invited programs to meet specific needs

## Research Funding Areas

#### **RESEARCH APPROACH AND INTERVENTION - 2021 GRANTS**





Both current and previously funded studies can be reviewed through our searchable database: <a href="https://chn.dimensions.ai/discover/grant">https://chn.dimensions.ai/discover/grant</a>

## Program Staff; deadline structures

#### **Portfolios**

- SCI Research on the Translational Spectrum (SCIRTS)
  - Letter of Intent OPEN April
  - Letter of Intent Results September
  - Full Grant Applications DUE November 11,2022
  - Awards Announced June, 2023
- Psychosocial Research
  - Letter of Intent OPEN January
  - Letter of Intent CLOSES March
  - Letter of Intent Results May
  - Full Grant Application DUE July
  - Awards Announced December

#### **Program Staff**

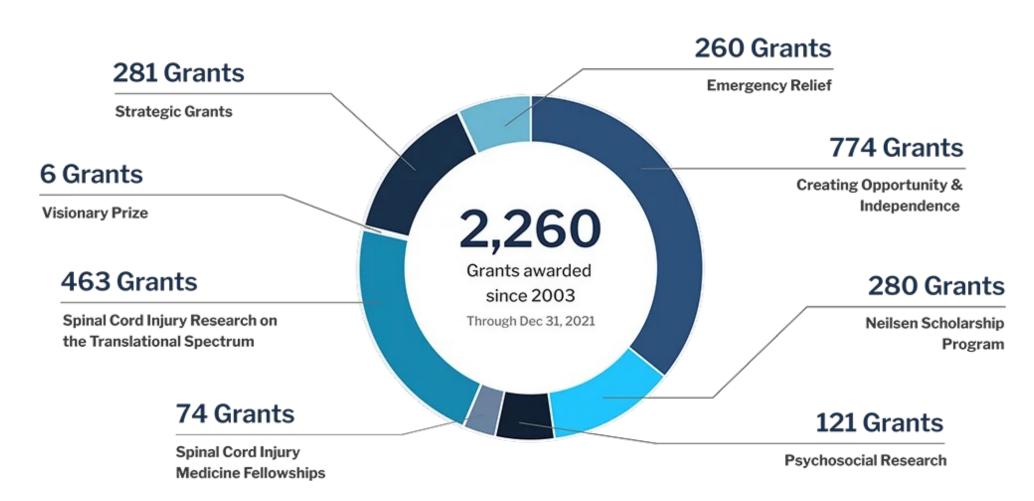
- Jacob Shreckengost
- jacob@chnfoundation.org
- Tracey Wheeler
- tracey@chnfoundation.org

- Constanza Svidler
- constanza@chnfoundation.org

# Thank you!!!

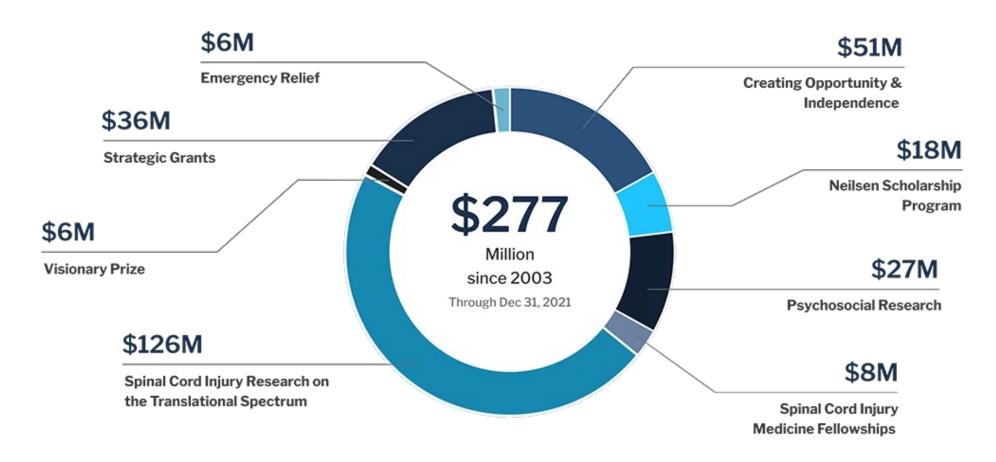
# Funding Overview – Grant Numbers





# Funding Overview – Dollars





# The Congressionally Directed Medical Research Programs

Overview & FY22 Funding Opportunities





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. Future use of this presentation does not constitute, express, or imply endorsement of the user by the Department of the Army.

GH-IMPACT RESEARCH







#### **About CDMRP**



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



Transforming
Healthcare for
Service Members,
their Families,
and the
American
Public



#### WHERE

Research Conducted in Institutions
Around the World

#### HOW

Two-Tier Review Process Involving Scientists, Clinicians, and Consumers



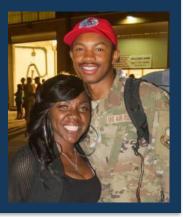




#### **Hallmarks**







- 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





## **CDMRP FY22 Appropriations**

Research Program	FY22 \$M	Research Program	FY22 \$M	
Alcohol and Substance Abuse Disorders	\$4.0	Orthotics and Prosthetics Outcomes	\$20.0	
Amyotrophic Lateral Sclerosis	\$40.0	Ovarian Cancer	\$45.0	
Autism	\$15.0	Pancreatic Cancer		
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	





#### **Major Changes for FY22**

- Overall CDMRP funding increased by \$43M
- ◆ No appropriation for Scleroderma Research Program (\$4M in FY21)
- New topic areas under Peer Reviewed Medical
- ◆ New Peer Reviewed <u>Toxic Exposures Research Program (TERP)</u>

#### **TERP Congressional language excerpt:**

"Transitioning related research to a new, broader program, including <u>neurotoxin</u> <u>exposure treatment</u> research, research on <u>Gulf War illness</u>, exposures to <u>burn pits</u>, and other service-related exposures to potentially <u>toxic chemicals and materials</u> 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."

# FY22 Topic Areas for CDMRP Department of Defense Peer Reviewed Cancer Research (20 total)

- Bladder Cancer
- Blood Cancer
- Brain Cancer
- ◆ Colorectal Cancer
- Endometrial Cancer
- Esophageal Cancer
- Germ Cell Cancers
- Head and Neck Cancers
- Liver Cancer
- Lymphoma
- Mesothelioma
- Metastatic Cancer
- Myeloma
- Neuroblastoma
- Pediatric, Adolescent and Young Adult Cancers
- Pediatric Brain Tumors

- Sarcoma
- Stomach Cancer
- ◆ Thyroid Cancer
- Von Hippel-Lindau
   Syndrome Malignancies
   (excluding cancers of the kidney and pancreas)



The inclusion of the individual Rare Cancers Research Program shall not prohibit the PRCRP from funding the above mentioned cancers or cancer subtypes that may be rare by definition

Applicants must address at least one of these Topic Areas, as directed by Congress

Funds may not be used for research into breast, kidney, lung, ovarian, pancreatic, prostate, rare cancers, or melanoma

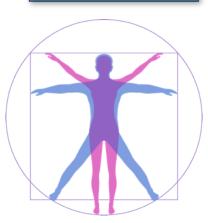
Research must be relevant to Service Members, their Families, Veterans, and other military beneficiaries

#### HIGH-IMPACT RESEARCH **FY22 Topic Areas for** Peer Reviewed Medical Research (50 total)

- **Arthritis**
- Cardiomyopathy
- Congenital Heart Disease
- **Diabetes**
- Dystonia
- **Eating Disorders**
- **Ehlers-Danlos Syndrome\***
- **Endometriosis**
- Epidermolysis Bullosa
- Familial Hypercholesterolemia
- Fibrous Dysplasia
- Focal Segmental Glomerulosclerosis
- **Food Allergies**
- Fragile X
- Friedreich's Ataxia\*
- Frontotemporal Degeneration
- Guillain-Barre Syndrome\*\*
- Hemorrhage Control
- Hepatitis B
- Hydrocephalus
- Hvpercholesterolemia\*
- Hypertension
- **Inflammatory Bowel Diseases**
- Interstitial Cystitis\*\*
- Malaria
- Mitochondrial Disease

- **Musculoskeletal Disorders Related to Acute** and Chronic Bone Conditions and Injuries\*
- Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome
- Myotonic Dystrophy
- **Nephrotic Syndrome\***
- Non-Opioid Therapy for Pain Management
- **Nutrition Optimization**
- Pancreatitis\*\*
- Pathogen-Inactivated Blood Products
- Peripheral Neuropathy
- Plant-Based Vaccines
- Platelet-like Cell Production
- Polycystic Kidney Disease
- **Pressure Ulcers**
- **Pulmonary Fibrosis**
- Respiratory Health
- Rett Syndrome\*\*
- Rheumatoid Arthritis
- Sleep Disorders and Restriction
- Suicide Prevention
- Sustained Release Drug Delivery
- Trauma\*
- Vascular Malformations
- Viral Diseases (Previously Emerging Viral Disease)
- Women's Heart Disease

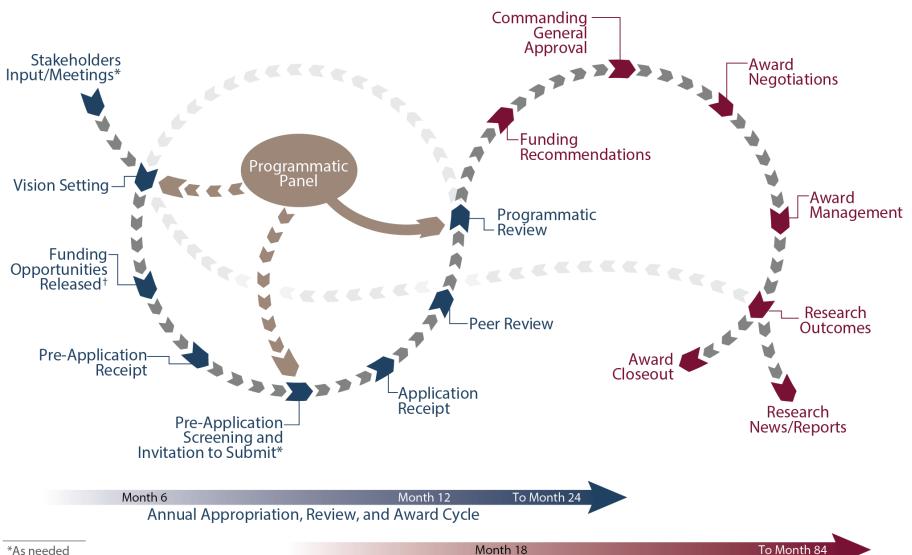
**Applicants** must address at least one of these **Topic** Areas, which are directed by Congress







#### **Program Cycle**



<sup>&</sup>lt;sup>†</sup>Pending Congressional appropriation





#### **Award Mechanisms**

- Funding Opportunities are Program Announcements (PAs) or program-specific Broad Agency Announcements (BAAs)
  - Grants/Cooperative Agreements (few contracts, OTAs)
- Numerous types of award mechanisms
  - Tailored to the goals of each program
  - Programs, topics, and focus areas may vary from year to year
  - Fund the full continuum of research

Development of Ideas									
Initial Concepts		Early Ideas	Clinic Translat	COMMON CO.	Clinical Trials	$\overline{}$	Team Science		
Concept Exploration - Hypothesis Development	<ul><li>Idea</li><li>Synergistic Idea</li><li>Idea</li><li>Development</li></ul>		<ul><li>Transla Resear</li><li>Therap Develo</li></ul>	rch • eutic	<ul><li>Clinical Trial</li><li>Pilot Clinical Trial</li></ul>		<ul> <li>Consortium</li> <li>Multi-Team</li> <li>Synergistic Idea</li> <li>Translational Partnership</li> </ul>		





#### **Funding Opportunities**

- Pre-announcements and funding opportunity release notifications
  - CDMRP website and email blasts
- Funding opportunity postings
  - Grants.gov (CFDA 12.420)
  - electronic Biomedical Research Application Portal (eBRAP) system (ebrap.org)
  - CDMRP website (cdmrp.health.mil)
  - SAM.gov (BAAs)







#### **Applying for Funding**

Understanding the <u>goals of the program</u>, <u>intent of the award mechanism</u>, and <u>review criteria</u> is critical for a successful grant application



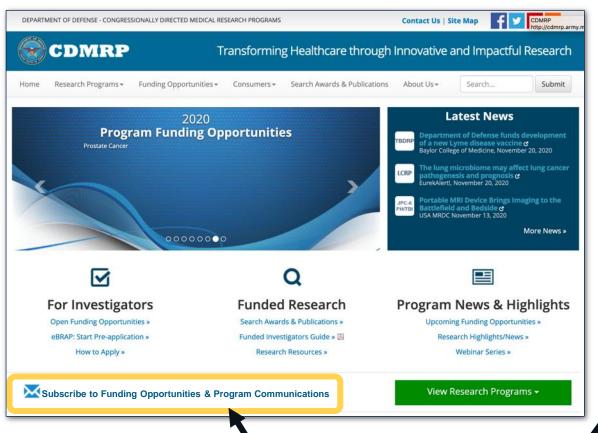
- The announcement (PA or BAA) contains information on:
  - Program Goals
  - Focus Areas
  - Award Intent
  - Required Elements, Eligibility, and Funding
  - \* Review Criteria
  - Deadlines

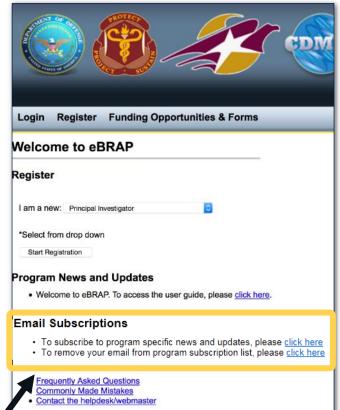
Single most important tip: Read the announcement carefully





#### **Subscribe to Email Notifications**





Sign up for listserve through CDMRP website or in eBRAP













# Disability and Rehabilitation Engineering (DARE) Research at the National Science Foundation

Engineering Directorate (ENG)
Chemical, Bioengineering, Environmental, and Transport Systems (CBET)
Division



Grace M. Hwang, Ph.D. Program Director, PD DARE



September 29, 2022













# NSF Supports Disability & Rehabilitation Research

From the NSF Proposal & Award Policies & Procedures Guide (PAPPG):

Biological research on mechanisms of disease in humans, including on the etiology, diagnosis, or treatment of disease or disorder, is normally not supported. . [...] However, research with etiology, diagnosis- or treatment-related goals that advances knowledge in engineering, mathematical, physical, computer, or information sciences is eligible for support. Bioengineering and assistive information technology research to aid persons with disabilities also is eligible.













# NSF Supports Disability & Rehabilitation Research

From the Disability and Rehabilitation Engineering (DARE) Program Description:

The **DARE** program supports fundamental engineering research that will improve the quality of life of persons with disabilities through: the development of new technologies, devices, or software combined with advancement of knowledge regarding healthy or pathological human motion, or advancement in understanding of injury mechanisms.

NSF does <u>not</u> support clinical trials, however, feasibility studies involving human volunteers may be supported if appropriate to the project objectives.













# Disability & Rehabilitation Engineering (DARE)

#### **Program Objectives:**

- Develop fundamental understanding, technologies, & models to improve the quality of life of persons with disabilities - cognitive, sensory, physical, others
- Support research directed to the characterization, restoration, and/or substitution of human functional ability or cognition
- Novel engineering approaches to understanding human motion
- Understanding injury at the tissue or system-level

#### **Key Components:**

- Fundamental engineering research
- Transformative outcomes
- High-risk/High-reward

#### **Typical award**

(2-3 years)

1 PI 200-300K

2 Pls 400-440K



Grace Hwang ghwang@nsf.gov













# Origin of the DARE Program

1972 1978 1980 ~2010 2018

PL 93-112
Rehabilitation
Act of 1972

Congressman from TX



Olin Earl Teague 1910-1981

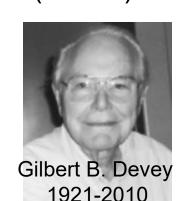
PL 95-434

Congress authorized a Handicapped Research

Program:
Science
& Technology
to Aid the
Physically
Disabled

(STAPH)

STAPH was renamed to Research to Aid People with Disability (RAPD)



RAPD was renamed to General and Age-Related Disabilities Engineering (GARDE)

2006-2008: Robert J. Jager, currently at NIDILRR 2008-2010: Ted A. Conway GARDE was renamed to Disability and Rehabilitation Engineering (DARE)

2010-2014: Ted A. Conway 2014-2016: Alex Leonessa

2016-2018: Michelle J. Grimm 2019-2020: Aleksandr Simonian

2020-now: Grace M. Hwang











# DARE Presidential Early Career Awards for Scientists and Engineers (PECASE) Awardees

1997

CAREER:

Mechanical

Function of

Residual Stresses

in Anulus

Fibrosus

9703299

1998

CAREER:

**Universal Access** 

to the Graphical

User Interface:

Design for the

**Partially Sighted** 

0196030

2010

**CAREER: Using** 

**Control Systems** 

to Quantify Limbic

Dysregulation for

Neurobiologically-

Based Diagnoses

of Psychiatric

Disabilities.

0954643

2012

CAREER:

Advancing

Treatment of Pelvic

Floor Disorders

through Discoveries

in Elasticity and

Viscoelasticity of

Uterosacral and

Cardinal Ligaments.

1150397















**Funding** 

Awards

**Document Library** 

News

**About NSF** 

Home > Research Areas > Engineering









#### Rehabilitation Research at NSF



Image credit: Auttapon Wongtakeaw/Shutterstock.com.

NSF has many funding opportunities for research related to rehabilitation.

https://www.nsf.gov/eng/rehab.jsp









PD: Laurel Kuxhaus, PhD; lkuxhaus@nsf.gov





#### Programs supporting rehabilitation research

#### Biomechanics and Mechanobiology (ENG/CMMI/BMMB)

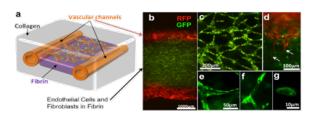
The BMMB program supports fundamental research in biomechanics and mechanobiology. The program emphasizes multiscale mechanics approaches that integrate across molecular, cell, tissue, and organ domains in the study of organisms. Projects may include theoretical, computational, and experimental approaches. Projects relevant to rehabilitation are welcome

8 1 100

New understanding of bones could lead to stronger engineered materials for osteoporosis treatment

#### Engineering of Biomedical Systems (ENG/CBET/EBMS)

The EBMS program supports research projects that integrate engineering and life sciences to solve biomedical problems and serve humanity in the long term. Projects use an engineering framework (for example, design or modeling) that supports increased understanding of physiological or pathophysiological processes. Areas include: methods, models, and enabling tools applied to understand or control living systems; fundamental improvements in deriving information from cells, tissues, organs, and organ systems; or new approaches to the design of systems that include both living and non-living components for eventual medical use.



In vitro vascularization



CNS Regeneration



PD: Stephanie George, PhD; stgeorge@nsf.gov

#### Mind, Machine and Motor Nexus (ENG/CMMI/M3X)

PD (temporary): Alex Leonessa, PhD; aleoness@nsf.gov

The M3X program supports fundamental studies of bidirectional dynamic interactions between humans and intelligent machines. Interactions between humans and assistive devices are within the scope of M3X, however the focus of an M3X project should be on emergent behavior arising from dynamic interactions, rather than on advances in rehabilitation technologies.

https://www.nsf.gov/eng/rehab.jsp









#### Cross-directorate programs

#### Collaborative Research in Computational Neuroscience (CRCNS)

The CRCNS program supports collaborative activities that advance understanding of nervous system structure and function, mechanisms underlying nervous system disorders, and computational strategies used by the nervous system, including Research Proposals describing collaborative research and Data Sharing Proposals to enable sharing of data and other resources. Domestic and international projects will be considered. Funders include NSF, NIH, DOE, and partners in Germany, France, Israel, Japan, and Spain.

- Joint with NIH, DoE, and international partners
- Must relate to computational neuroscience from synapse through cognition/behavior
- Can include clinically relevant projects
- PD: Ken Whang, PhD; <a href="mailto:kwhang@nsf.gov">kwhang@nsf.gov</a>
- Next due date: 11/22/2022

#### Integrative Strategies for Understanding Neural and Cognitive Systems (NCS)

The NCS program calls for innovative, convergent, boundary-crossing proposals seeking to understand complex aspects of neural and cognitive systems through integrative multidisciplinary approaches. NCS projects advance the foundations of one or more of the following areas: 1) Neuroengineering and Brain-Inspired Concepts and Designs; 2) Individuality and Variation; 3) Cognitive and Neural Processes in Realistic, Complex Environments; and 4) Data-Intensive Neuroscience and Cognitive Science. Projects relevant to rehabilitation are welcome.

FY23 Frontier and Foundation competition due date: 2/15/2023

Questions, email ncs@nsf.gov

https://www.nsf.gov/eng/rehab.jsp













# Key consideration for Intellectual Merit (IM)

- 1. What is the potential for the proposed activity to advance knowledge and understanding within its own field or across different fields?
- 2. To what extent do the proposed activities suggest and explore creative, original, high-risk/high-payoff, or potentially transformative concepts?
- 3. Is the plan for carrying out the proposed activities well-reasoned, well-organized, and based on a sound rationale? Does the plan incorporate a mechanism to assess success?
- 4. How well qualified is the individual, team, or organization to conduct the proposed activities?
- 5. Are there adequate resources available to the PI (either at the home organization or through collaborations) to carry out the proposed activities?











# Key consideration for Broader Impact (BI)

- 1. Broader Impacts do not need to be innovative
- 2. There is no checklist, e.g., the impact of the research itself may be sufficient
- 3. There is no requirement that a proposal addresses any particular item on the example list, e.g., K-12/STEM education, diversity, underrepresented minorities, outreach, but these types of activities are encouraged
- 4. DARE strongly encourages the inclusion of trainees with disabilities and participatory design
- 5. Useful link on BI: https://www.nsf.gov/pubs/2002/nsf022/bicexamples.pdf













# **One-page Whitepaper**

#### **Overview**

- •What is the problem?
- •Why should we care?
- •What's the proposed solution?
- •What's the potential impact?
- •Why is the PI/Team the best to do this work?

#### **Intellectual Merit**

- What high-risk/high-reward innovation or transformative fundamental science are you proposing to advance?
- What are competing scientific methods and the current state-of-the-art? How is your innovation significantly better, and what scientific obstacles/barriers does it overcome?
- What is your high-level research plan? Highlight just the major milestones. How will success be assessed?
- The preliminary evidence you have that can convince reviewers that although the proposed research is high risk and innovative, there is indication that it has a chance to succeed!

# **Broader Impact** (optional during white paper phase)

- Describe the activities that will advance the project's objectives to have broad impact
- DARE strongly encourages the inclusion of trainees with disabilities and participatory design
- Discuss how success of impact will be addressed







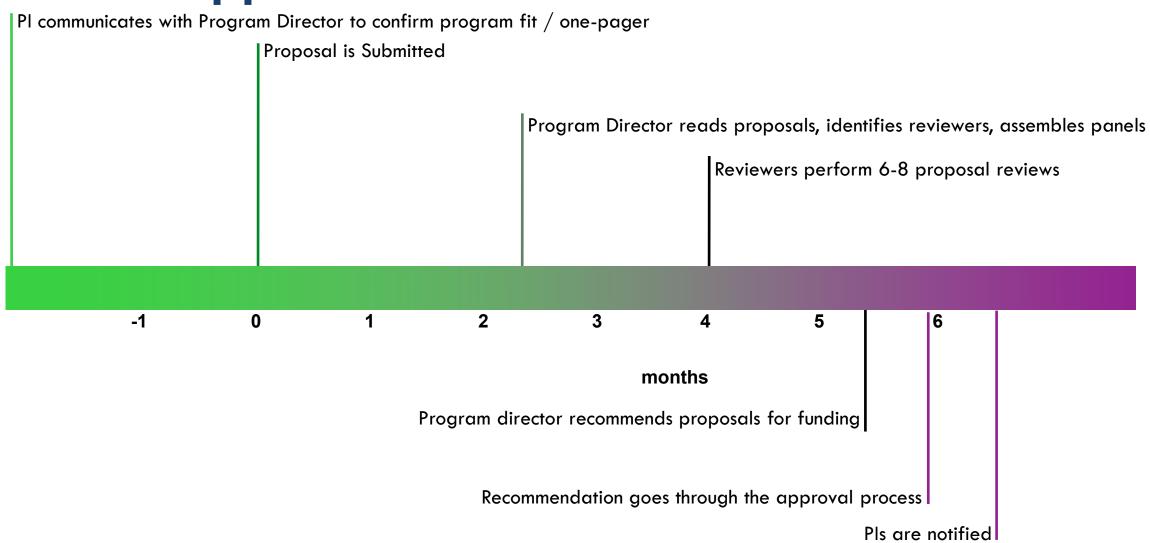








# **Approximate Review Timeline**















## **NSF vs. NIH**

- Advancement of foundational knowledge
- Engineering projects will involve some translation
- Feasibility studies may include limited human volunteers
- Budgets in ENG are typically ~\$100k/year (Direct + Indirect Costs); higher budgets allowed

- Basic research
- Translational research with direct medical applications
- Much larger budget possibilities for most funding mechanisms
- Budget limits are typically for Direct costs only.
- The structure of NSF and NIH proposals is different!
  - (Reviewers recognize a cut-andpaste....)

Proof of concept

...totally different proposals....

Proof of practice













# Key take-home messages

- Understand the goals and requirements of the program.
   Locate the program description and read it thoroughly and carefully. Look at recently funded proposals for additional insight.
- Contact the program director early. Get to know your program director!
- NSF does not support clinical trials, however, feasibility studies involving human volunteers may be supported if appropriate to the project objectives.











## **Become a Reviewer**

- Learn and understand the merit review process
- Read good proposals and see other ways of writing proposals
- Read about and discuss interesting leading-edge work
- Network with other experts in your field
- Provide service to the science and innovation community

How? Reach out to Program Directors from divisions close to your expertise and volunteer.











# Thank you for your attention! Grace Hwang ghwang@nsf.gov