alzheimer's association®

Business Consortium

Alzheimer's Association Business Consortium (AABC)

Federal Grant Funding Webinar

March 1, 2023

AABC Leadership

Co-Chairs:

Codi Gharagouzloo, Ph.D., CEO, Imaginostics

Jacob Donoghue, M.D., CEO & Co-Founder, Beacon Biosignals

Alzheimer's Association:

Christopher Weber, Ph.D.- Director, Global Science Initiatives
Ashley Hansen, Senior Specialist, Research Projects

Agenda

Time		Name
10:00 - 10:05 a.m.	Welcome	Christopher Weber, PhD Director, Global Science Initiatives Alzheimer's Association
10:05 – 10:20 a.m.	NIA Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Seed Funding PRograms	**Todd Haim, PhD** Director of the Office of Strategic Extramural Programs Division of Extramural Activities (DEA) National Institute on Aging (NIA)
10:20 - 10:35 a.m.	NINDS Small Business Program	**Annette Gilchrist, PhD** Program Officer NINDS Small Business Program Division of Translational Research National Institute of Neurological Disorders and Stroke (NINDS)
10:35 - 10:50 a.m.	Department of Defense Congressionally Directed Medical Research Programs (CDMRP)	**Sarah Fontaine, PhD** Health Science Program Manager U.S. Army Medical Research and Development Command (USAMRDC)
10:50 – 11:20 a.m.	All	Panel Q&A
11:20 – 11:25 a.m.	Closing	Christopher Weber, PhD

AABC Election & Announcements

- Co-Chair Election:
  - Dr. Ornit C Falek (CLAIRIgene)
  - Dr. Adrian Noriega (Perceiv AI)
  - **Voting ends March 10**
- Call for Newsletter items
- Company Logos
- AAIC 2023
  - Save-the-Date **July 16-20**, Amsterdam, Netherlands
  - AABC Networking Lunch **July 18**

Thank you!

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NIA Small Business SEED Fund:

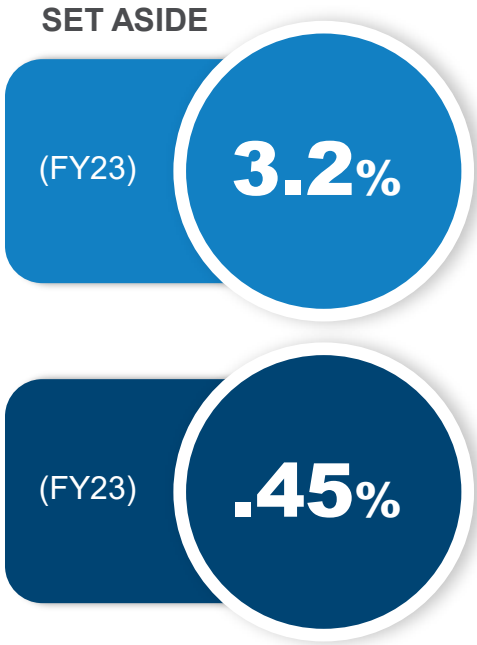
Accelerating Alzheimer's and Aging Research

National Institute on Aging

JLABS December 2022

About SBIR and STTR

Congressionally Mandated Programs



Small Business Innovation Research (SBIR) Program
Set-aside program for small businesses to engage in federal R&D — with potential for commercialization

Small Business Technology Transfer (STTR) Program
Set-aside program to facilitate cooperative R&D between small businesses and U.S. research institutions — with potential for commercialization

Why Seek SBIR/STTR Funding

- Provides seed funding for innovative technology development
  - ❖ **Not a loan**
  - ❖ **No repayment required**
  - ❖ **No impact on stock or shares (non-dilutive)**
- Small business retains intellectual property rights
- Provides recognition, verification, and visibility
- Helps attract additional funding or support (e.g., venture capital, strategic partner)

Eligibility

- Applicant must be a small business
- Organized for-profit U.S. business
- 500 or fewer employees, including affiliates
- > 50% U.S.-owned by individuals and independently operated

OR

> 50% owned and controlled by another (one) business that is > 50% owned and controlled by one or more individuals

OR (*SBIR ONLY*)

> 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

Critical Differences

AWARD IS STILL MADE TO THE SMALL BUSINESS!

SBIR	STTR
Permits research institution partners (e.g., universities)	**Requires** research institution partners (e.g., universities)
Small business may outsource ~33% of Phase I activities and 50% of Phase II activities	The for-profit small business should conduct a minimum of 40% of the work, and a non-profit U.S. research institution should conduct a minimum of 30% of the work
Eligibility: Project Director/Principal Investigator's primary employment (> 50%) **must** be with the small business for the duration of the project	**Eligibility:** An agreement providing necessary intellectual property (IP) rights to the small business is required to carry out follow-on R&D and commercialization
	Principal Investigator primary employment not stipulated (at least 10% effort to project)

NIA SBIR & STTR Program Phases and Funding Levels

Phase I	Discovery & Feasibility	• Typically 1 year in length • Awards up to $300,000, or up to $500,000 for AD/ADRD • Establish technical merit, feasibility, and potential for commercialization
Phase II	Development & Full R&D	• Typically 2 years in length • Awards up to $2 million, or up to $2.5 million for AD/ADRD • Continues Phase I R&D efforts • Requires a commercialization plan
Fast Track		• One combined application for Phases I and II
Direct-to-Phase II (SBIR only)		• Apply directly for Phase II funding • Demonstrated feasibility through other funding sources
Commercialization Readiness Pilot		• Funding for late-stage R&D and technical assistance for commercialization
Phase IIB	Competing Renewal	• Up to 3 years • Awards up to $3 million

Budget Specifics

TOTAL COSTS

- SBIR/STTR budgets are defined by **total costs,** and subcontracting is limited. Know the rules and the criteria.
- Check the budget allowance in each funding opportunity.

- **Can request a 7% fee:**
  - Company profit
  - Part of total budget

- **Fee for service: CRO-type activities can count as small business costs, providing that:**
  1) It is a commercially available service.
  2) All analysis is done by the small business.
  3) It is a fee per basis (no indirect costs by fee for service providers).

NIH Funding Mechanisms

Investigator-Initiated Grants

1.

Omnibus Solicitation

3 receipt dates:
January 5 • April 5
September 5

Other Funding Opportunities

2.

Targeted Solicitations

Focused priority areas with variable receipt dates

Contracts

3.

Targeted Solicitations

Specified deliverable with 1 receipt date per year

NIA Small Business Programs: Core Activities

Central Coordination

Administer all SBIR/STTR awards at NIA

Guidance

Help applicants prepare for application/resubmission, and discuss funding options

Outreach

Attend conference/workshops and visit regional organizations to raise awareness of the program

Funding

Seed emerging technology areas by developing targeted funding opportunities and Omnibus interest topics

Networking

Facilitate connections between awardees and potential strategic partners (NIA programs/external partners)

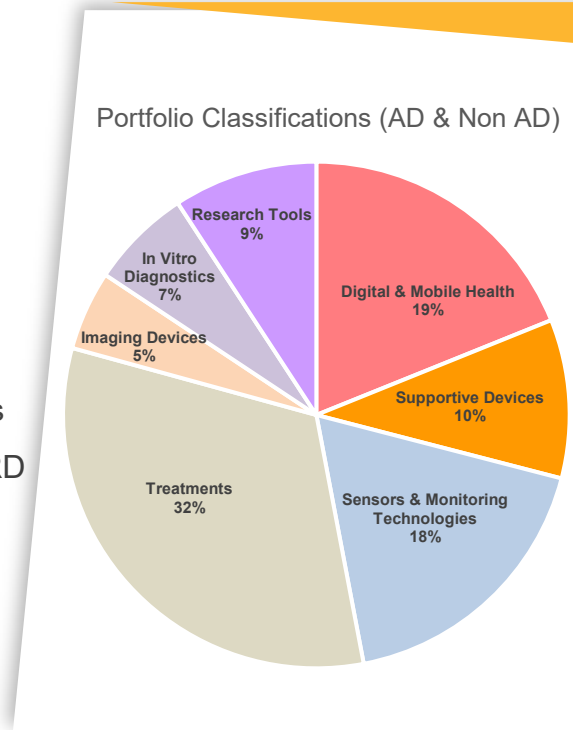
Entrepreneurship

Provide entrepreneurship training as well as webinars on key commercialization-related topics

Stakeholder Engagement for Cross-Leverage: ADDF SBIR Bridge Funding and Longevity Innovation Summits

We *Strategically* Fund Innovations for:

- Alzheimer's disease (AD), AD-related dementias (ADRD), and age-related change in brain function
- Aging in place
- Age-related diseases and conditions
- Research tools



Additional Areas of Interest

- Companion diagnostics and other forms of personalized medicine
- Bioinformatics, public health informatics, or data science technologies/methods (e.g., machine learning, artificial intelligence) to better understand and predict health outcomes
- Novel cell and gene therapies, as well as other novel therapeutic approaches to AD/ADRD
- Biomarkers and diagnostic tools for the early detection of disease
- Prevention and therapeutics that directly target mechanisms related to aging biology
- Assistive technology, devices, and mobile applications for older adults and caregivers
- Tools, technologies, and analytic methods to address health disparities among older adults

NIA Funding Opportunities

	Omnibus FOAs	AD/ADRD-Focused FOAs
SBIR	**PA-22-176** (clinical trial not allowed) **PA-22-177** (clinical trial required) *Budget limits: Phase I $300,000; Phase II $2 million*	**PAS-22-196** (Advancing Research on AD/ADRD) *Budget limits: Phase I $500,000; Phase II $2.5 million*
STTR	**PA-22-178** (clinical trial not allowed) **PA-22-179** (clinical trial required) *Budget limits: Phase I $300,000; Phase II $2 million*	**PAS-22-197** (Advancing Research on AD/ADRD) *Budget limits: Phase I $500,000; Phase II $2.5 million*

NIA Funding Opportunities (Continued)

Commercial Readiness Pilot (CRP) Program	Budget Limits
PAR-20-128 (CRP Technical Assistance; clinical trial not allowed)	$300,000
PAR-20-129 (CRP Technical Assistance and Late Stage Development; clinical trial not allowed)	$1.75 million/year for 2 years ($3.3 million total)
PAR-20-130 (CRP Technical Assistance and Late Stage Development; clinical trial required)	$1.75 million/year for 2 years ($3.3 million total)
Supplements & NIA Participating Initiatives	**Budget Limits**
PA-21-345 (Administrative Supplements to Promote Diversity in Research and Development Small Business; clinical trial not allowed)	$250,000 in direct costs
NOT-NS-017 (SBIR Technology Transfer; clinical trial not allowed)	Phase I $300,000; Phase II $2 million

More funding opportunities: www.nia.nih.gov/research/sbir/nia-small-business-funding-opportunities

NIA Entrepreneurial Development Funding Opportunities

	FOAs	Due Dates	Budget Limits
SBIR	RFA-AG-23-029 (REDI Entrepreneurial Small Business Transition Award; clinical trial optional)	Letter of Intent: January 17, 2023 Application: February 17, 2023	Phase I $400,000; Fast-Track $2 million
STTR	RFA-AG-23-030 (REDI Entrepreneurial Small Business Transition Award; clinical trial optional)	Letter of Intent: January 17, 2023 Application: February 17, 2023	Phase I $400,000; Fast-Track $2 million
R25	PAR-22-226 (REDI Entrepreneurship Enhancement Award; clinical trial not allowed)	Letter of Intent: 30 days before due date Applications: November 15, 2022; October 18, 2023; October 17, 2024	$250,000/year in direct costs
K01	PAR-22-227 (REDI Mentored Entrepreneurial Career Development Award; clinical trial not allowed)	Letter of Intent: N/A Applications: November 15, 2022; October 18, 2023; October 17, 2024	$90,000/year in salary; $50,000/year in other program-related expenses

Research and Entrepreneurial Development Immersion (REDI)

Empowering spin-offs is critical to biomedical innovation, the economy, and the NIA mission. REDI provides bio-entrepreneurship training to further enrich and diversify NIA training programs. REDI-supported trainees acquire additional non-academic skills for success, such as science communications; intellectual property; regulatory affairs; science policy; consulting; drug discovery, approval, and production; and the business of science, science education, and health care. **Participants from diverse backgrounds are particularly encouraged to apply.**

Visit: https://www.nia.nih.gov/research/sbir/nia-research-and-entrepreneurial-development-immersion-redi

NIA Resources to Help Research Entrepreneurs

Everyone	
Webinars & Events. Watch archived presentations including a mock peer review session on our website and sign up for future events.	
Applicants	
Sample Applications. Review other successful applications on our website to see what information other applicants included and how they presented it.	**Applicant Assistance Program.** A 10-week coaching program to help prepare your Phase I application. Offered once each standard funding period. Open to first-time and never-funded applicants.
Phase I Awardees	
Diversity Supplement. Funds to recruit and support students, postdocs, and eligible investigators from underrepresented groups that enhance the diversity of the research and entrepreneurial workforce.	
Innovator Support. Support from the NIA Entrepreneurs-in-Residence including business consults, pitch coaching, and company showcase opportunities.	
Additional Resources and Support for Grantees. Companies that receive SBIR/STTR awards are eligible to apply for additional funding, technical assistance, and training programs such as the I-Corps™ at NIH program, C3i Medical Device Entrepreneurial Training Program, and training programs designed for diverse applicants.	

NIH Applicant Assistance Program

Goal:
Provide a mentor for applicants with great technology but little NIH experience and limited NIH experience in their network.

- Free application preparation **assistance** for 10 weeks
- Participating ICs: NIA, NCI, NHLBI, NINDS, NCCIH, NCATS, NIEHS and NINR

PROVIDED	NOT PROVIDED
Phase I preparation support and review	Grant writer
Specific Aims page review and advice	Development of research plan
Submission process coaching	Register small business for you Apply to NIH for you

NIH Applicant Assistance Program: Eligibility and Process

- Simple eligibility criteria:
  - **Never received a small business grant award from NIH**

    OR
  - **Received an award prior to 2010**
- Interested in applicants who are currently underrepresented in the biosciences (not a requirement)
  - Women-owned small businesses
  - Minority-owned small businesses
  - Small businesses operating in an underrepresented (IDeA) state
- **Contact:** Joshua Hooks

AAP application portal

- Answer a series of structured questions
- Upload supporting documents (e.g., abstract)
- Submit here

Submissions due May 22, 2023!

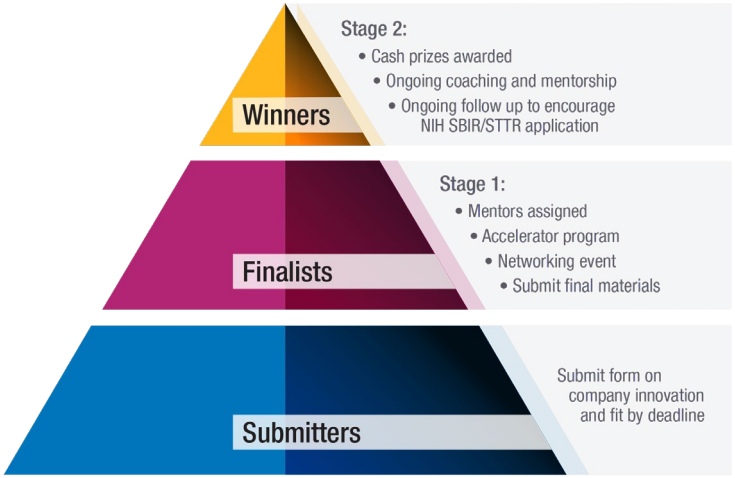
NIH National Institute on Aging

2023 NIA Start-Up Challenge and Accelerator

Fostering Entrepreneurial Diversity

This Challenge seeks submissions from aging researchers and entrepreneurs from diverse backgrounds who have a demonstrated need for support and innovative ideas for research-driven technologies and products that align with the NIA small business research priorities. Submit your idea by April 20, 2023, to participate in a 5-month accelerator program with mentorship, networking opportunities, and a chance to compete for a $60,000 cash prize.

Read the full Challenge announcement here and register to attend the Pre-Submission Webinar to learn more.



IMPORTANT DATES

Pre-Submission Webinar: March 16, 2023

Registration and Submission Period Ends: April 20, 2023

Stage 1 Finalists Announced: July 2023

Stage 1 Accelerator Program: July–December 2023

Final Submission and Pitch Due: December 2023

Stage 2 Winners Announced: February 2024

For more information, contact the NIA Challenge Team at niastartupchallenge@mail.nih.gov.

2022 NIA Startup Challenge Winners

Mayowa Agbaje-Williams, PharmD, MPH

Co-Founder

Moremee VA, LLC

Wheaton, IL

Non-hormonal therapeutic for vulvo-vaginal atrophy in post-menopausal women

Cameron Carter, MS, ECHM

Co-Founder & CEO

Rose Management Group, LLC

Centennial, CO

ML-driven platform to match providers and patients to affordable and vetted home modification products and services

Denice Wharton, MBA

Founder & CEO

Suma

Oxnard, CA

Online management system that simplifies and streamlines the licensing and renewal process for CNAs, HHAs, and other medical professionals

Christin Glorioso, MD, PhD

Founder & CEO

NeuroAge Therapeutics

San Francisco, CA

Therapeutic leveraging proprietary screening platforms using multi-omics biologics aging clocks to rejuvenate biological brain aging and treat neurodegenerative disorders

Devita Stallings, PhD, RN

Founder & CEO

Pressure Points, LLC

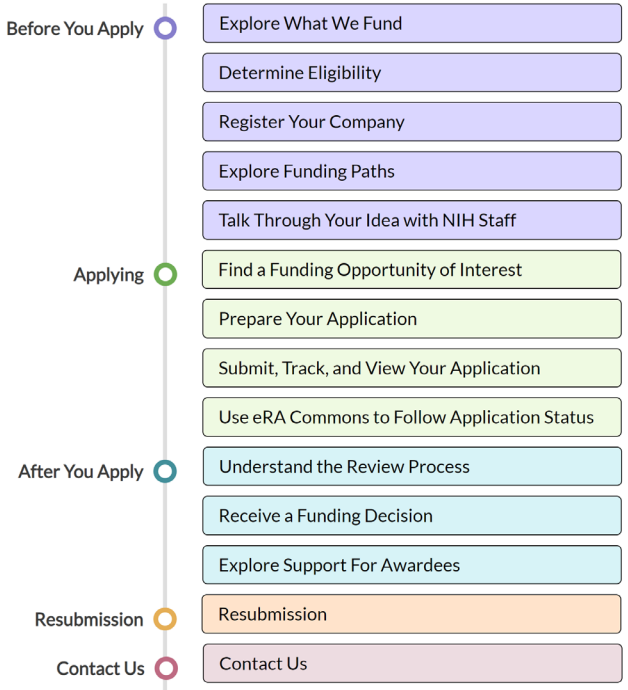
St. Louis, MO

Digital health app for the self-management of hypertension in African American older adults

Tips for a Successful Application

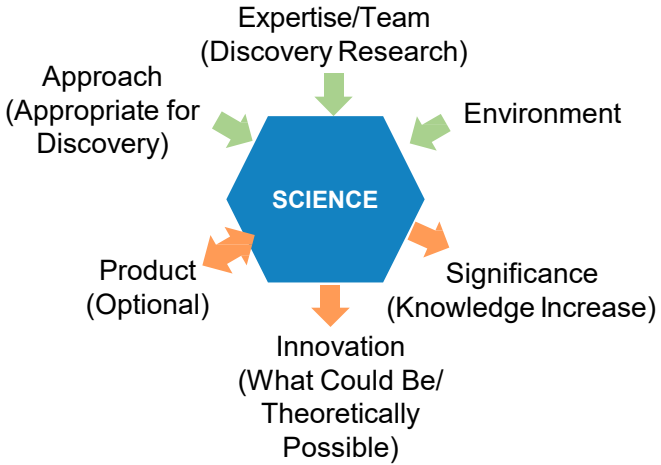
Start Early

- **Strong proposals take time to develop.**
  - ❖ Carefully read the funding solicitation and allow time to address all of the key requirements.
  - ❖ Assemble a strong scientific team.
  - ❖ Gain access to equipment, facilities, and other resources.
  - ❖ Obtain letters of support from collaborators.
- **Complete the necessary administrative registrations.**
  - ❖ Start at least 2 months before deadline.
  - ❖ Follow the SF 424 application guide.
  - ❖ Process and electronic submission information: https://seed.nih.gov/small-business-funding/how-to-apply

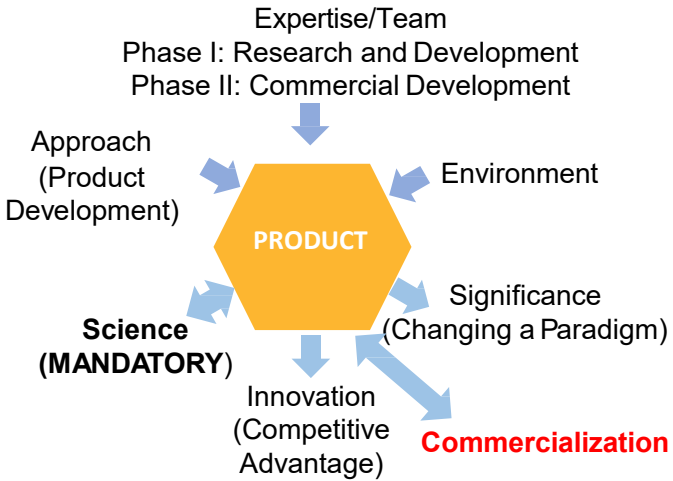


Remember: Focus on Product

ACADEMIC GRANT



SBIR/STTR GRANT



Tip 4: Draft a Clear Application

Specific Aims (1 page): The Executive Summary and First Impression

First 1/2 to 2/3:

The Elevator Pitch—Why Is It Meritorious?

1. The technology prototype or therapeutic to be developed;
2. The technical innovation the development would represent, the unmet need it addresses, and technical challenges to overcome;
3. The value proposition and competition, and how the technology builds on current scientific premise and/or preliminary data;
4. The proposed specific research aims, including key models, assays, metrics, and quantitative performance milestones; and
5. The relevance of the research and development to NIA's mission.

Last 1/3 to 1/2:

The Specific Aims for the Proposed Project

- Key models, assays, and metrics
- Quantitative performance milestones

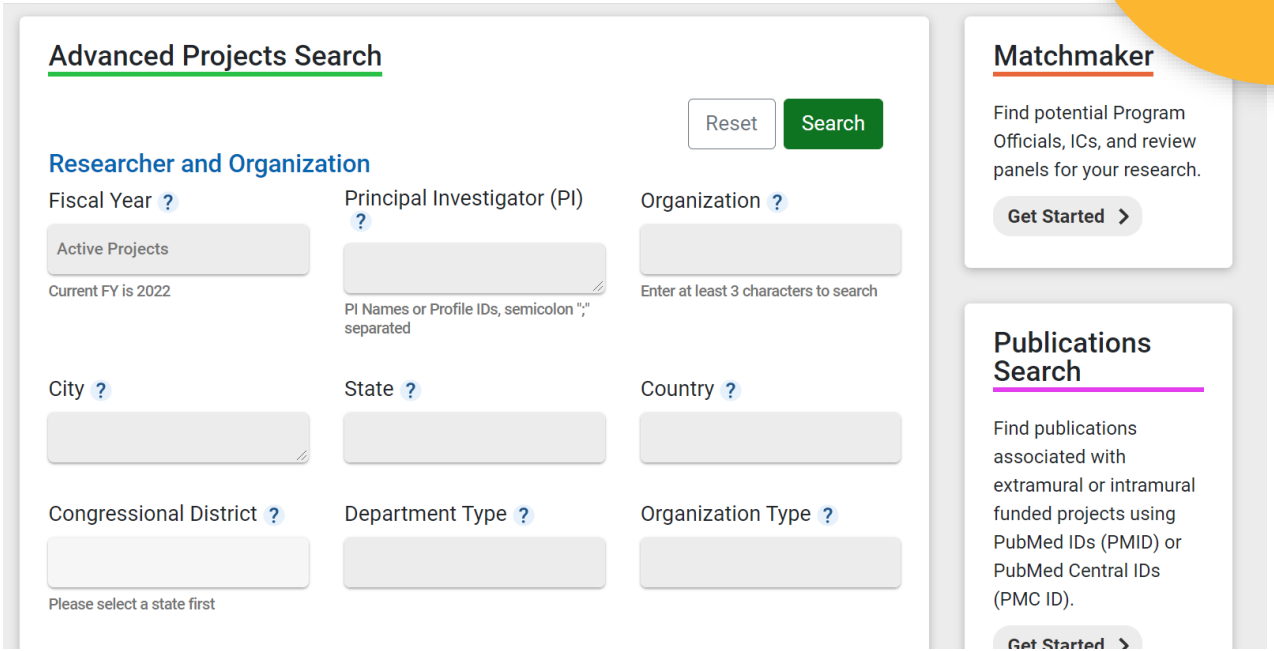
Provide your draft Specific Aims page to NIA Small Business Programs staff for feedback.

Sample Applications: A Great Resource

Funded Company	Submission Type	Program and Phase	Application Links
Amprion	Original (Funded)	STTR, Phase II	Full Application Summary Statement
CareBand	Original	SBIR, Phase I	Full Application Summary Statement
CareBand	Resubmission (Funded)	SBIR, Phase I	Full Application Summary Statement
care.coach Corporation	Original	SBIR, Fast-Track	Full Application Summary Statement
care.coach Corporation	Resubmission (Funded)	SBIR, Fast-Track	Full Application Summary Statement
CorticoMetrics	Original	STTR, Fast-Track	Full Application Summary Statement
CorticoMetrics	Resubmission (Funded)	STTR, Fast-Track	Full Application Summary Statement
Crossroads Consulting	Original (Funded)	SBIR, Phase II	Full Application Summary Statement
StarWise	Original (Funded)	STTR, Phase I	Full Application Summary Statement

NIH RePORTER

- Database of NIH-supported research
- In general, updated weekly with most up-to-date project information

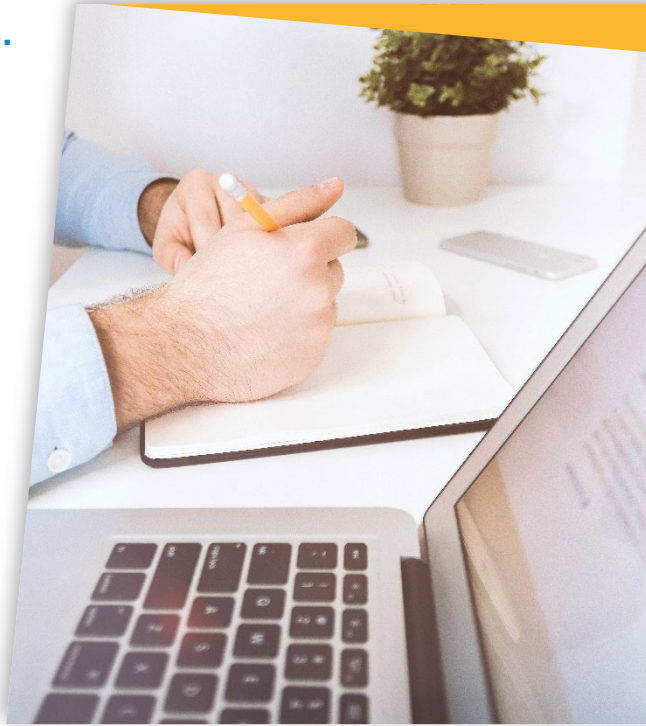


https://reporter.nih.gov/advanced-search

If You Weren't Funded on the First Try

Rejection is painful, but feedback provides a roadmap for next steps.

- **Carefully review the Summary Statement (written critiques).**
  - Discuss the Summary Statement with your NIH Program Officer.
  - Use reviewer comments to improve your application.
- **Revise and resubmit the application.**
  - Introduction Page: Respond to reviewer critiques.
  - Be constructive, NOT defensive.
  - Award rate for resubmissions was **15.8%** compared to **8.3%** for non-resubmissions in FY20
- **Learn more about SBIR/STTR grants.**
  - Talk to successful applicants.
  - Understand the review process and dynamics: http://csr.nih.gov



Connect with NIA


Visit nia.nih.gov/sbir


Follow us on Twitter: @NIA_SBIR


Follow us on LinkedIn: NIA Small Business Programs


View upcoming events and funding opportunities


Join our mailing list


Email NIAsmallbusiness@mail.nih.gov

Thank you

National Institute of Neurological Disorders and Stroke

NINDS Small Business Program

Enabling Startups To Reach Key Value Inflection Points

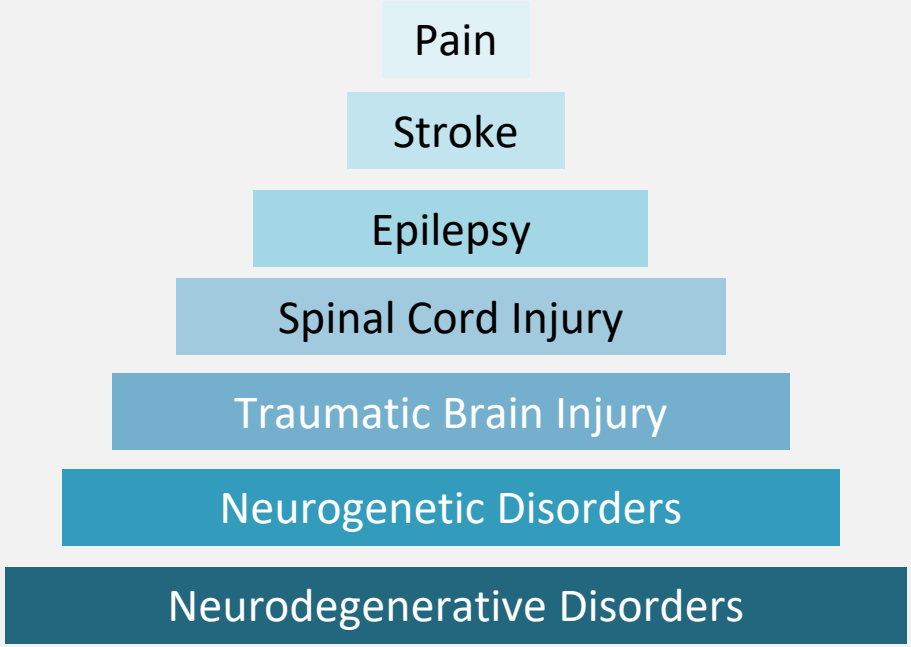
Annette Gilchrist, Ph.D.

Program Officer
NINDS Small Business Program
Division of Translational Research
annette.gilchrist@nih.gov

National Institute of Neurological Disorders and Stroke

NINDS Mission

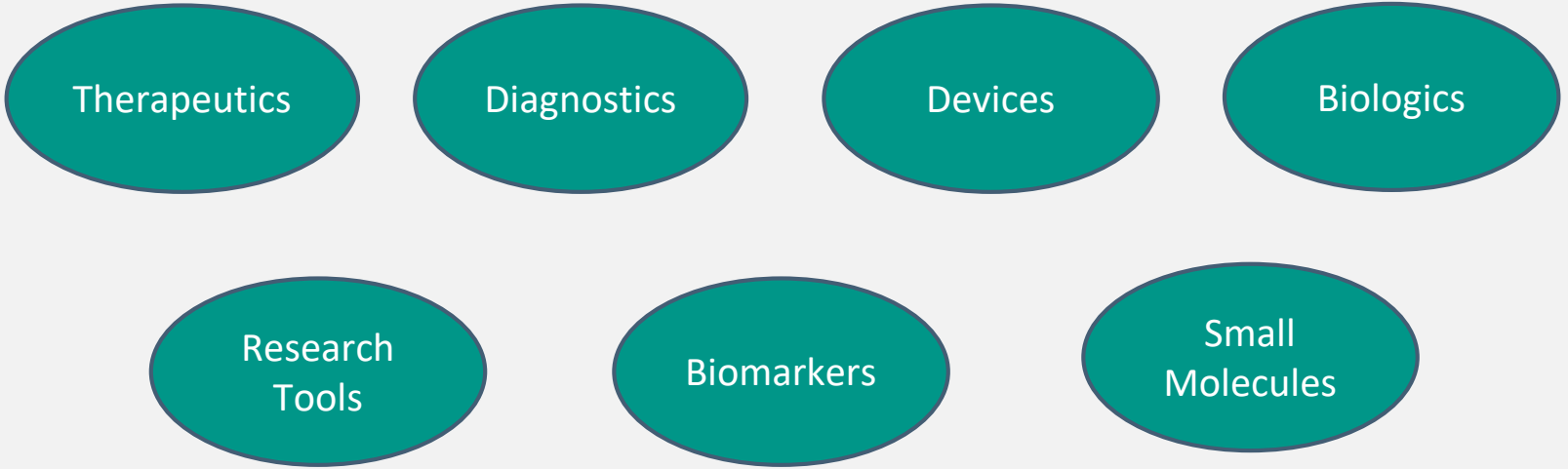
Seek fundamental knowledge about the brain and nervous system and use that knowledge to reduce the burden of neurological disease for all people



Our mission space encompasses hundreds of neurological disorders including AD/ADRD

National Institute of Neurological Disorders and Stroke

Small Business Portfolio

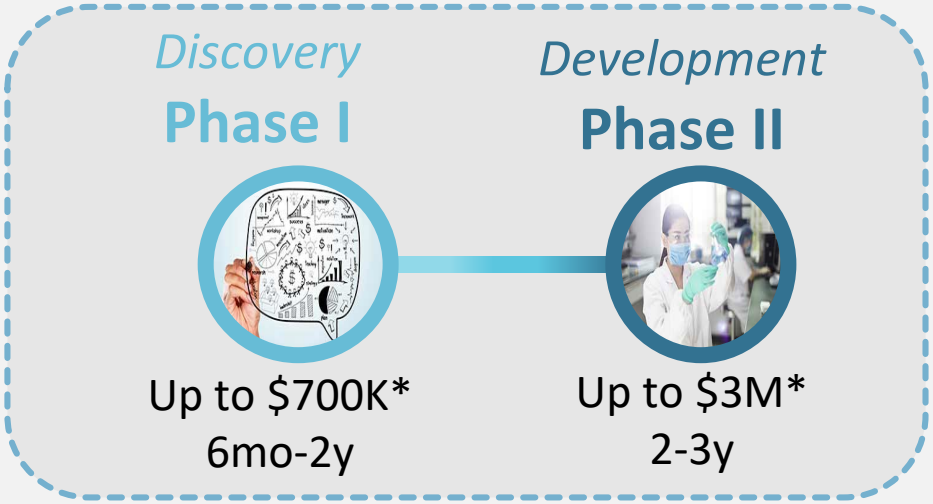


NINDS offers ~$70M in annual funding for small businesses

National Institute of Neurological Disorders and Stroke

Range of Translational R&D Activities

National Institute of Neurological Disorders and Stroke



** With a Waiver and appropriate justification*

SBIR/STTR direct funding CAN be used for:

- US-based R&D activities: labor, materials, vendor contracts, etc.
- Small amount of commercialization activities (eg market or IP analysis) through TABA funding

SBIR/STTR direct funding CAN'T be used for:

- Patent or License fees
- Foreign-based work, including consulting services, except in rare circumstances

National Institute of Neurological Disorders and Stroke

NINDS Waiver Topics

1. In vivo animal testing required for therapeutics and diagnostics development.
2. Drug and biologics preclinical discovery and development activities for regulatory submission, such as lead identification/optimization, preclinical efficacy testing, IND-enabling studies, and manufacturing for clinical trials.
3. Device preclinical discovery and development activities for regulatory submission, such as hardware prototyping, device/software verification, biocompatibility/sterilization testing, pre-clinical efficacy testing, large animal GLP safety testing, and preparing material/devices for human testing.
4. Clinical testing of therapeutics (drugs, devices, or biologics), diagnostics, clinical and rehabilitation tools (i.e. intraoperative technologies, rehabilitation devices and programs, and brain monitoring systems), and technologies for clinical research. This would include clinical research studies to test scientific hypothesis that are not feasible or practical to conduct in animal models but would inform a final device design.
5. In vivo animal testing of technologies for animal research and development of animal models for drug development and neuroscience research.
6. Research that requires special facilities to contain hazardous or infectious materials.
7. Development and validation of biomarkers and the technologies and approaches for measuring them. Biomarkers may include diagnostic, prognostic, monitoring, pharmacodynamic/response, risk, safety, and predictive biomarkers.

National Institute of Neurological Disorders and Stroke

Omnibus Funding Opportunities

- PA-22-177 Parent Omnibus Solicitation SBIR [R43/R44] Clinical Trial Required
- PA-22-178 Parent Omnibus Solicitation STTR [R41/R42] Clinical Trial Not Allowed
- PA-22-179 Parent Omnibus Solicitation STTR [R41/R42] Clinical Trial Required
- PA-22-176 Parent Omnibus Solicitation SBIR [R43/R44] Clinical Trial Not Allowed

Find Funding Opportunities | National Institute of Neurological Disorders and Stroke (nih.gov)

National Institute of Neurological Disorders and Stroke

Specific Funding Opportunities

- PAS-22-197 Advancing Research on Alzheimer's Disease (AD) and AD-Related Dementias (ADRD) (R41/R42 Clinical Trial Optional)
- PAS-22-196 Advancing Research on Alzheimer's Disease (AD) and AD-Related Dementias (ADRD) (R43/R44 Clinical Trial Optional)
- RFA-NS-24-001 Using Multimodal Biomarkers to Differentially Diagnose ADRDs for Clinical Trials (U19 Clinical Trial Optional)
- RFA-NS-23-002 Tools and resources to understand the vascular pathophysiology of in vivo neuroimaging findings in TBI-related dementia and/or VCID (U24 - Clinical Trials Not Allowed)

Find Funding Opportunities | National Institute of Neurological Disorders and Stroke (nih.gov)

National Institute of Neurological Disorders and Stroke

U44 Funding Opportunities

- Small Molecules: Blueprint Neurotherapeutics Network (BPN)
- Biologics: Cooperative Research to Enable and Advance Translational Enterprises for Biotechnology Products and Biologics (CREATE Bio) program
- Biomarkers: Biomarkers Research
- Devices: Translational Devices and BRAIN Initiative Next Generation Devices
- Clinical Trials: NeuroNEXT and StrokeNet

National Institute of Neurological Disorders and Stroke

Review Criteria

01 Significance

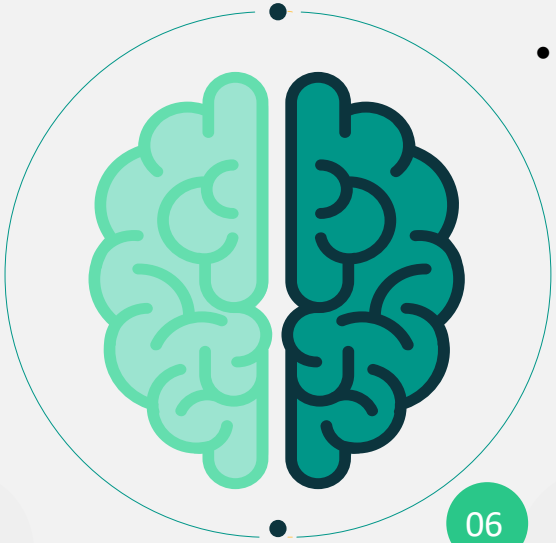
- Does product address significant problem?
- Is there a realistic market?

02 Approach

- Are design and methods well developed and appropriate?
- Potential pitfalls and alternative approaches provided?

03 Innovation

- Is product novel?
- Does product fill a market gap?



04 Investigators

- Does team have all the expertise needed for the project?

05 Environment

- Are there appropriate facilities and equipment to conduct the studies?

06 Commercialization

- Does product have commercial potential?
- Does business strategy have a high potential for success?

National Institute of Neurological Disorders and Stroke

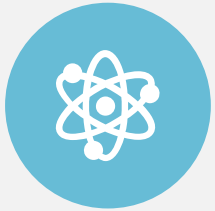
Examples of Funded Applications

NEURODEX INC

Development of a Blood-based Test for Identifying Synucleinopathy in Patients with Dementia

SHIFT PHARMACEUTICALS

Development of novel ASO-based therapeutics for CMT1A



LUCERNA, INC

Fluorescent IRE sensor for synucleinopathy drug discovery

REGENNOVA, INC

Therapeutic Reduction of Cerebral Amyloid Angiopathy Pathologies in ADRD

OUR TEAM

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National Institute of Neurological Disorders and Stroke

"Ever tried. Ever failed. No matter. Try again. Fail again. Fail better."

—Samuel Beckett

Questions?

Contact Us

NINDS Small Business Program

NINDS_SBIR@ninds.nih.gov

The Congressionally Directed Medical Research Programs

Presented by

Sarah N. Fontaine, Ph.D.

1 March 2023

*Transforming Healthcare through Innovative and **Impactful** Research*

CDMRP
DEPARTMENT OF DEFENSE
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

Vision and Mission

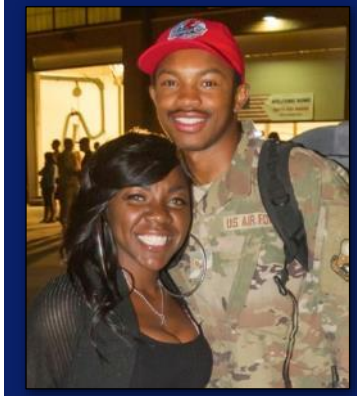
Vision

Transforming healthcare through innovative and impactful research

Mission

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

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 publicly 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 FY23 Appropriations

Research Program	FY23 $M	Research Program	FY23 $M
Alcohol and Substance Use Disorders	$4.0	Orthotics and Prosthetics Outcomes	$15.0
Amyotrophic Lateral Sclerosis	$40.0	Ovarian Cancer	$45.0
Autism	$15.0	Pancreatic Cancer	$15.0
Bone Marrow Failure	$7.5	Parkinson's	$16.0
Breast Cancer	$150.0	Peer Reviewed Alzheimer's	$15.0
Chronic Pain Management	$15.0	Peer Reviewed Cancer (20 Topics)	$130.0
Combat Readiness Medical	$5.0	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	$5.0	Rare Cancers	$17.5
Joint Warfighter Medical	$25.0	Reconstructive Transplant	$12.0
Kidney Cancer	$50.0	Spinal Cord Injury	$40.0
Lung Cancer	$25.0	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	$25.0	**TOTAL = $1.52B**	

CDMRP Relevance and Impact

- Every program aligns with CDMRP's overarching vision of transforming healthcare for Service Members (SMs), Veterans and the American public

Select examples of incidence in the military:

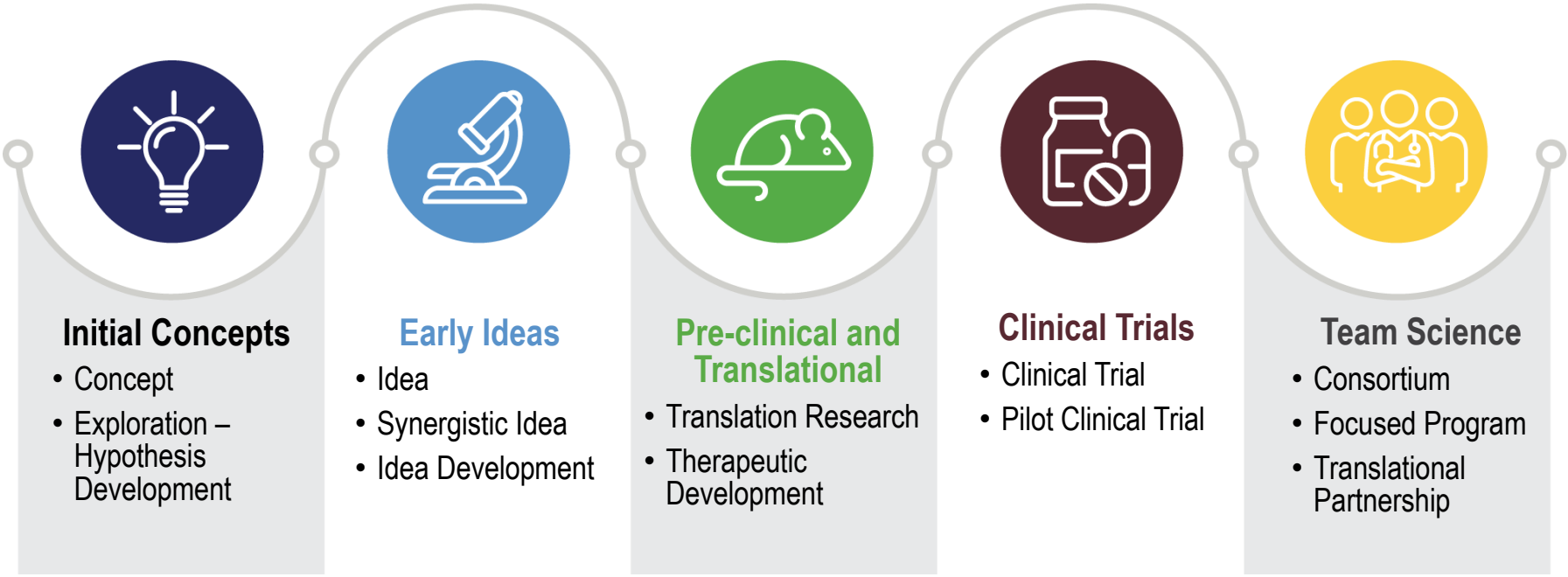
- SMs are at a 50% greater risk for ALS
- Substance abuse responsible for ~30% of Army's suicide deaths
- Female active duty SMs have a 20-40% higher incidence of breast cancer
- Post-traumatic epilepsy affects ~2,187 Iraq/Afghanistan Veterans, with a 5 times higher mortality
- 1.8-fold SM increased risk of Parkinson's

- Commitment to the health and wellbeing of DoD families also directly contributes to the ***readiness*** of Service Members by allowing them to focus on their military mission

- CDMRP-funded research generates products that provide better preventions, novel diagnostics and prognostics, improved treatments and therapies, and more effective rehabilitation and restorative strategies – ***to improve lives***

CDMRP Award Mechanisms

- Funding Opportunities are Program Announcements (PAs) or program-specific Broad Agency Announcements (BAAs)
  - Grants/Cooperative Agreements (few contracts/other transactions)
- 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



First Tier: Peer Review

- How the evaluation process works
  - Technical merit assessment based on an ideal application
  - Criteria-based evaluation of entire application
- Peer reviewers
  - Panels comprised of scientific and consumer reviewers
  - No standing panels
  - Reviewers are recruited based on expertise needed and may include specialists
  - Identities are unknown to applicants; contact between applicants, reviewers, and program staff are not permitted

Outcome: Summary Statements

Prior year peer reviewer lists are available on the CDMRP website

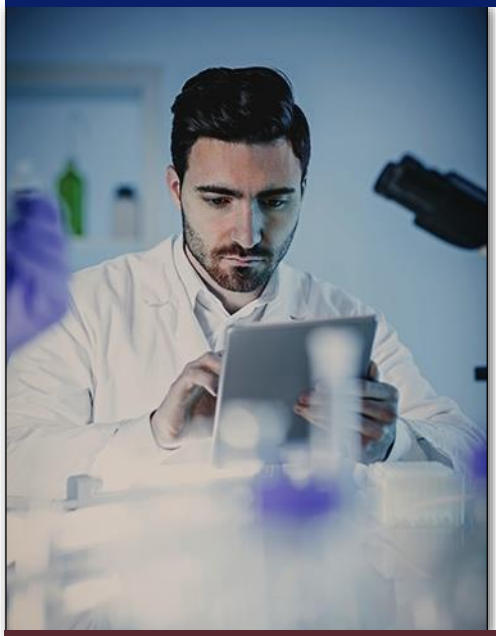
Second Tier: Programmatic Review

- How the evaluation process works
  - Comparison among proposals of high scientific merit
    - ➤ Adherence to award mechanism's intent
    - ➤ Relative innovation and/or impact
    - ➤ Relevance to program goals
    - ➤ Consideration of portfolio composition
  - No "pay line" (portfolio balance)
- Programmatic reviewers
  - Programmatic Panel members comprised of consumers, clinicians, researchers, and program staff from a wide variety of representative organizations
  - Ad hoc reviewers

Outcome:
Funding Recommendations

Applying for Funding

Understanding the *goals of the program, intent of the award mechanism*, and *review criteria* is critical for a successful application



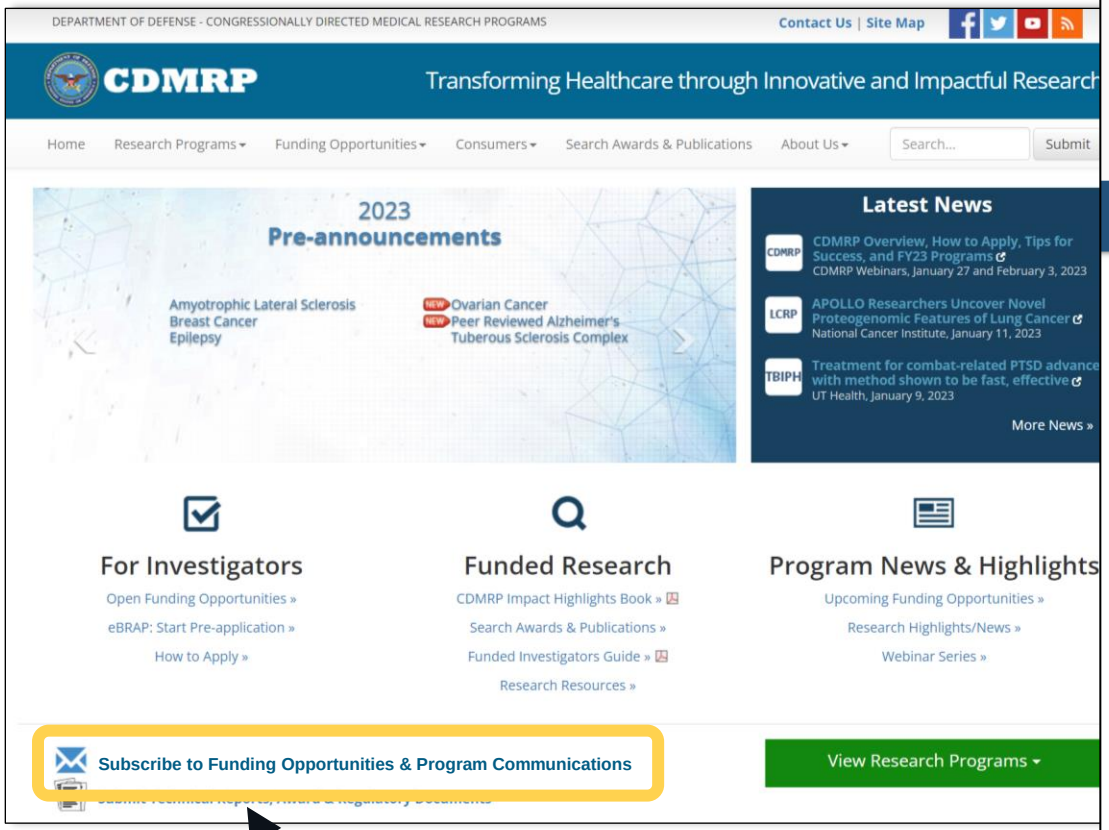
- The funding opportunity announcement contains information on:
  - Program Goals
  - Focus Areas/Topics
  - Award Intent
  - Required Elements, Eligibility, and Funding
  - Review Criteria
  - Deadlines

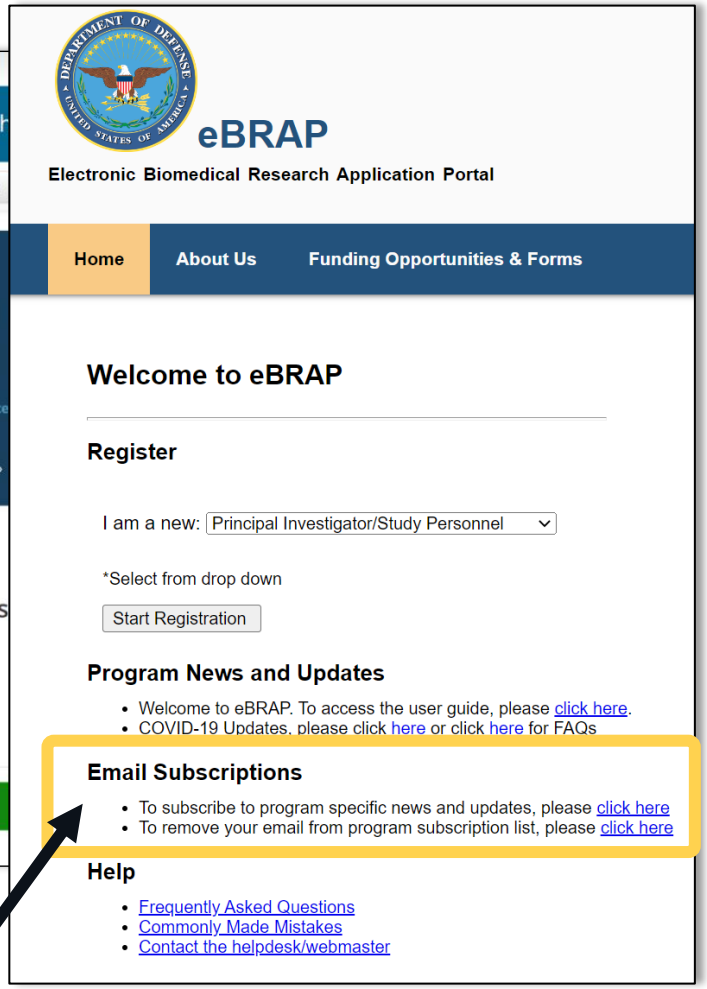
Single most important tip:
Read the announcement carefully

Funding Opportunities

- Pre-announcements and funding opportunity release notifications
  - CDMRP website and email blasts
- Funding opportunity postings
  - Grants.gov (CFDA 12.420)
  - CDMRP website (cdmrp.health.mil)
  - electronic Biomedical Research Application Portal (eBRAP) system (ebrap.org)
  - SAM.gov (BAAs)
- Quickly find open CDMRP Funding Opportunities on the CDMRP website here:
  - Home > Funding Opportunities > Synopsis of Open Program Funding Opportunities

Subscribe to Email Notifications





Sign up for listserve through CDMRP website or in eBRAP

Application Process Overview

Preliminary Steps

PI BO

Review Program Announcement/ Broad Agency Announcement

PI BO

Register/Update eBRAP Account

Verify/Update SAM Registration

BO

Step 1

Submit Pre-Application in eBRAP

PI

Preproposal

Letter of Intent

Receive Invitation to Submit Proposal/ Application

Step 2

Submit Proposal/Application….

BO

Extramural to Grants.gov

Intramural to eBRAP

BO PI

Step 3

PI BO

Verify Application in eBRAP

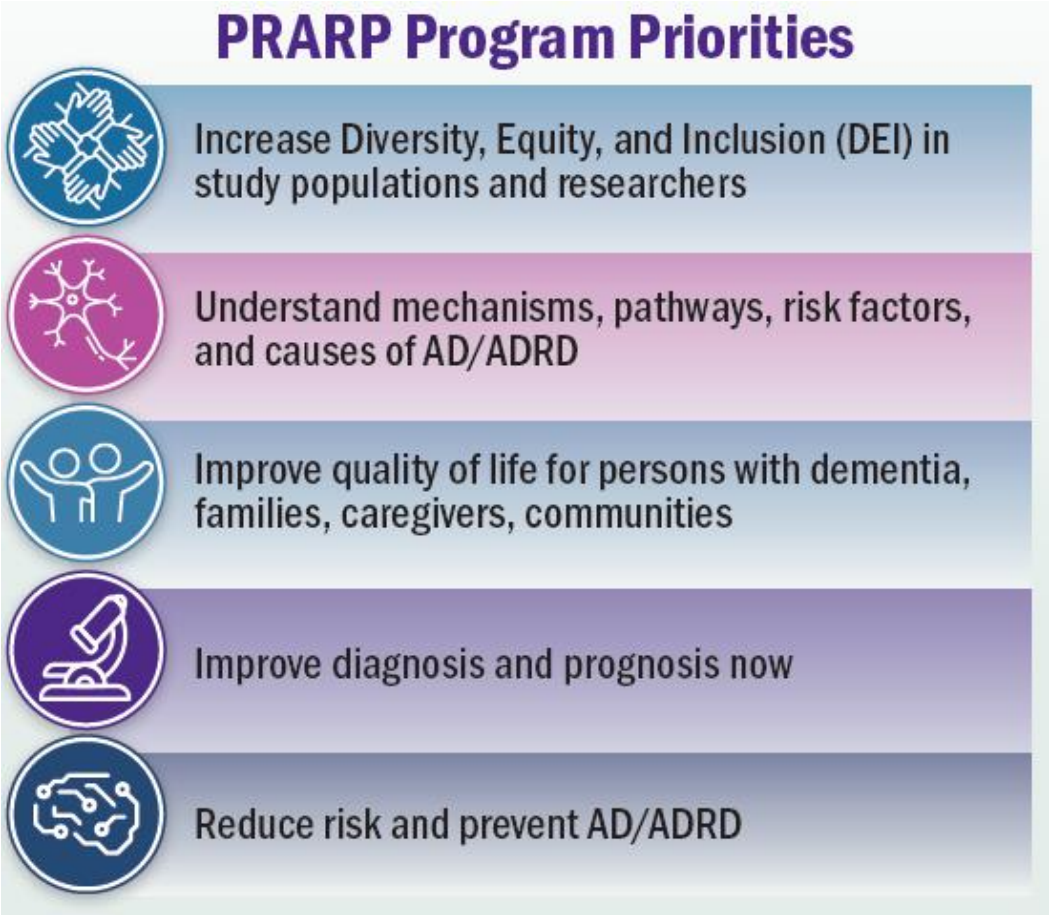
BO: Business Official from applicant organization
PI: Principal Investigator from applicant organization

eBRAP: electronic Biomedical Research Application Portal
SAM: System of Award Management

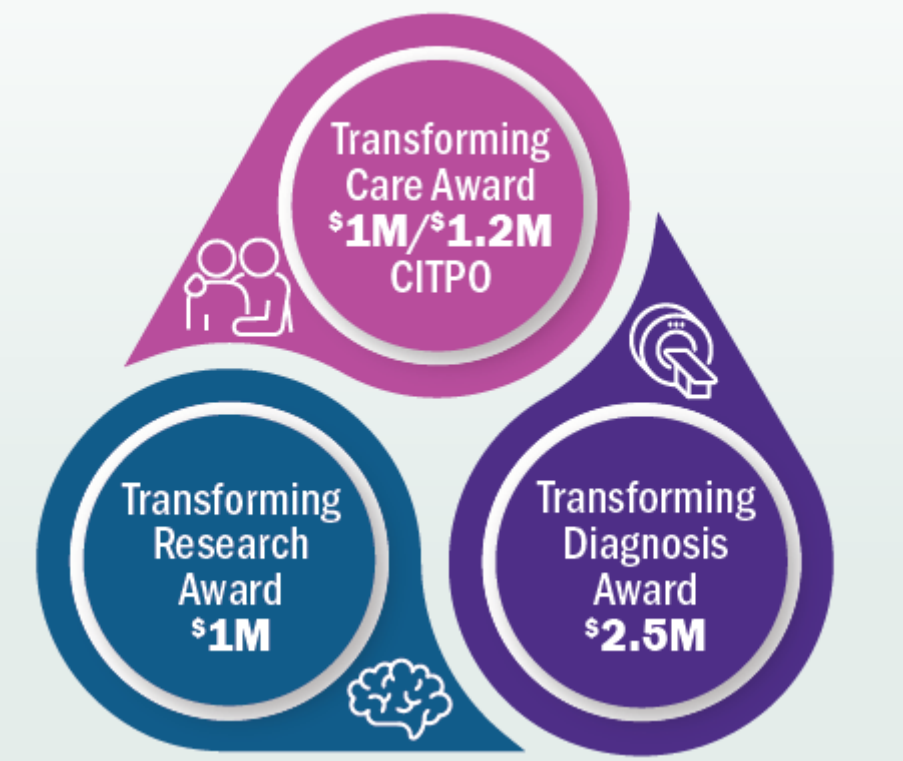
Peer Reviewed Alzheimer's Research Program (PRARP)

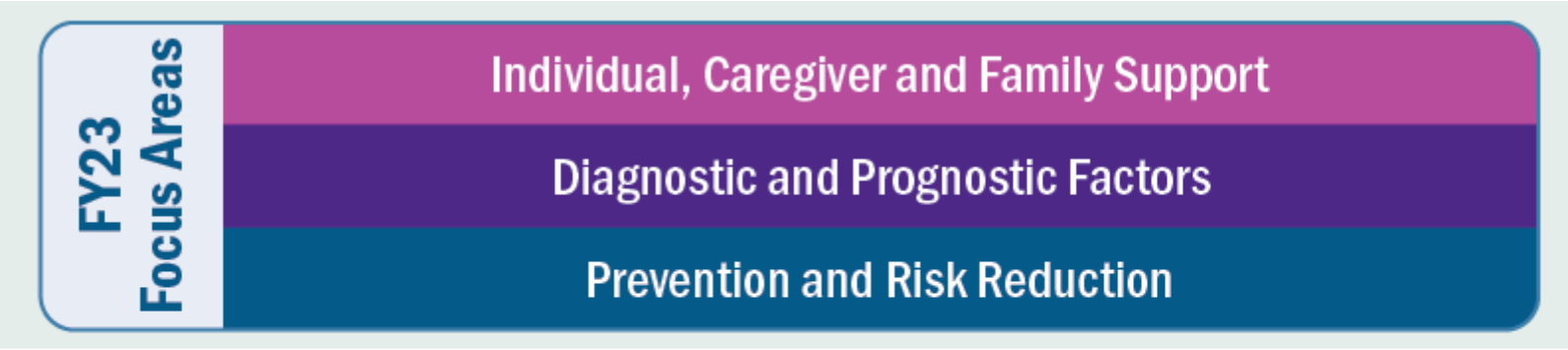
Vision: *To address and mitigate long-term implications of traumatic brain injury and military service as they pertain to Alzheimer's disease and Alzheimer's disease-related dementias*

Mission: *Support research to (1) understand the association between TBI and other military service-related risk factors and Alzheimer's disease/Alzheimer's disease-related dementias, and (2) improve quality of life and reduce the burden on affected individuals and caregivers for the military, Veterans, and the public*



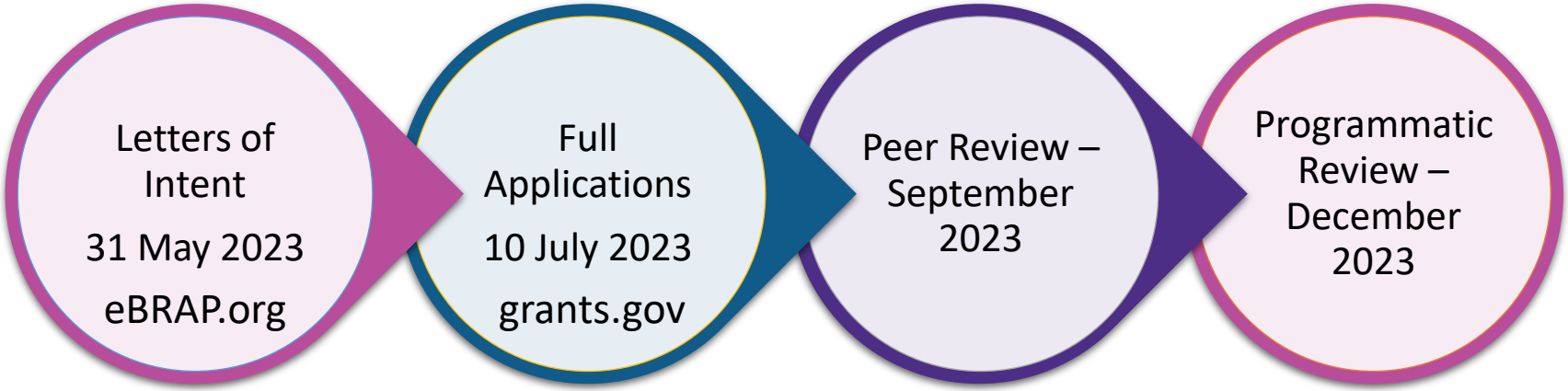
FY23 PRARP Funding Opportunities





FY23 PRARP Anticipated Deadlines

- Deadlines are not yet finalized and therefore subject to change
- Final deadlines will be posted in the FOA



An invitation to submit a full application is NOT provided after LOI submission and applicants are not required to have such an invitation in order to proceed to submitting a full application.

Start early!

- ❑ Registration in SAM.gov
- ❑ Register in eBRAP.org
- ❑ Subscribe to email alerts for PRARP
- ❑ Read the pre-announcement and start planning!

Questions?
For more information, please visit:

cdmrp.health.mil

CDMRP
DEPARTMENT OF DEFENSE
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

Additional information

Submit Your Pre-Application

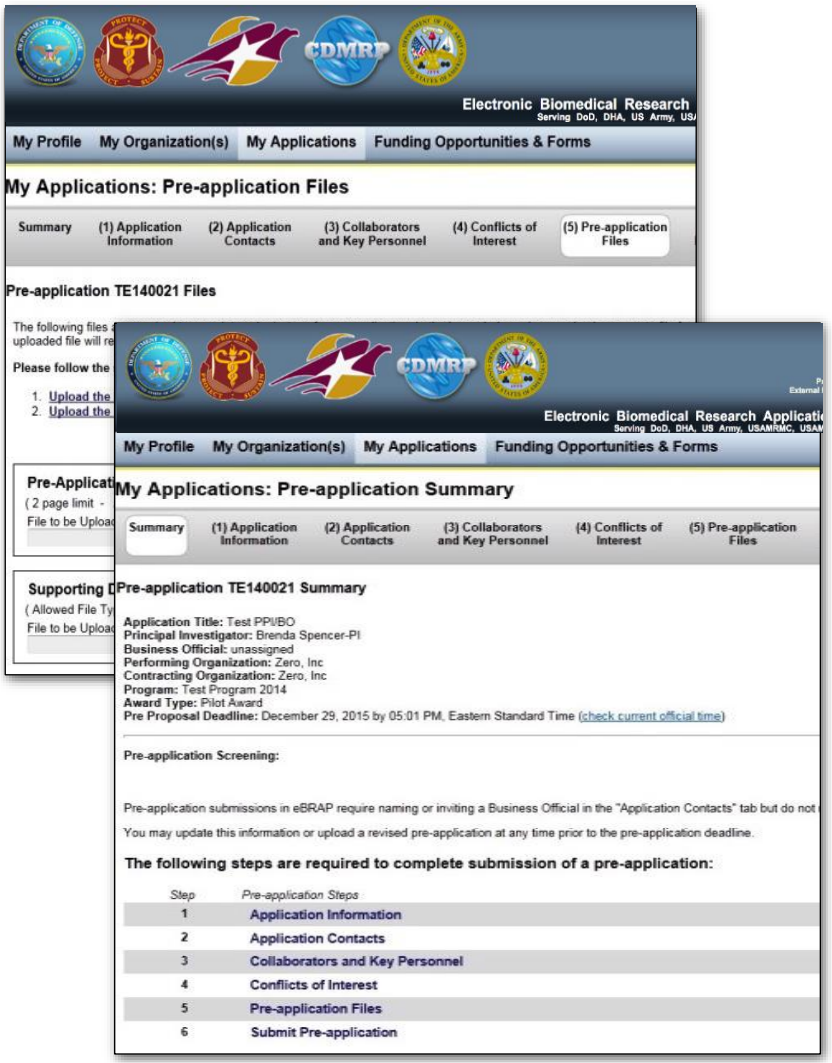
STEP 1: Pre-Application submission in eBRAP **(required!)**

- Type of pre-application depends on the award mechanism
  - **Letter of Intent**
    - ➤ Will not be reviewed
    - ➤ No invitation is required for application submission
  - **Preproposal**
    - ➤ Will be reviewed
    - ➤ Invitation is required for application submission
- Tips for success!
  - Review funding opportunity – address all pre-app requirements
  - Choose the correct funding opportunity and "option" in the pre-application process
  - Start the process **early** to allow time to resolve issues

Pre-Application Files in eBRAP

STEP 1:

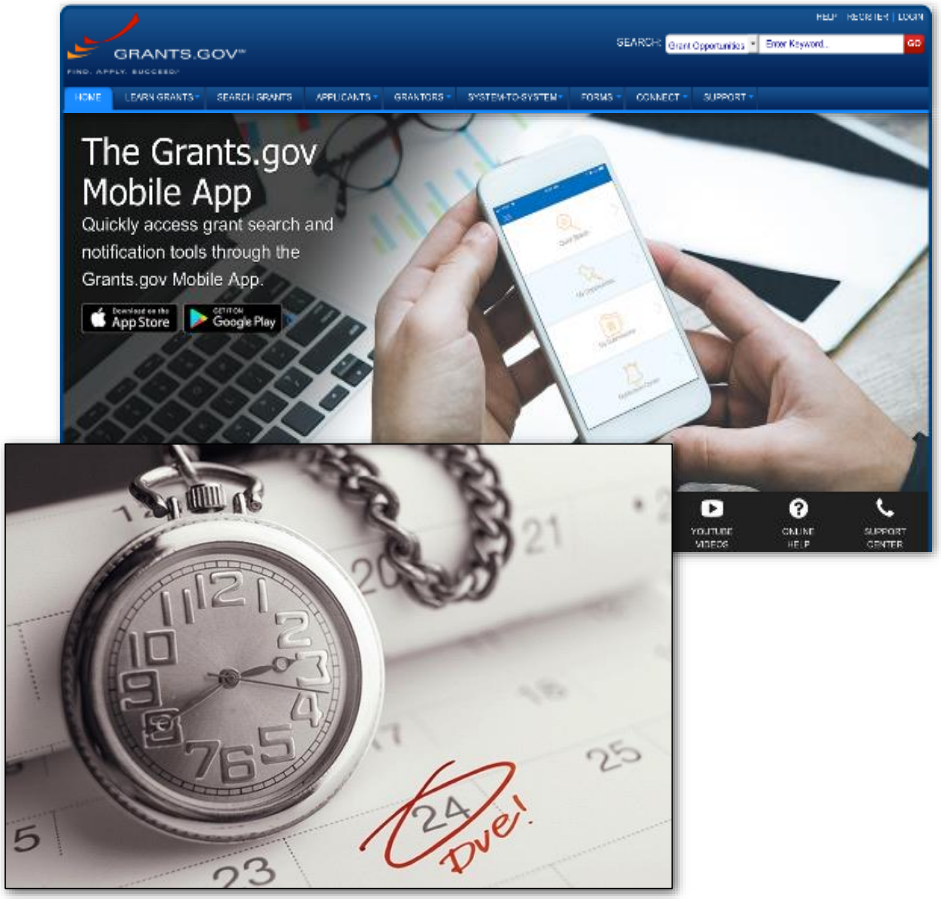
- Specified in announcement
- Page and/or text field limits
- Adhere strictly to the announcement requirements
- Follow Tabs 2-5, in any order
- Real-time auto-compliance
- Pre-application is submitted by the PI in Tab 6
- Auto-email notification
- Pre-application submission is MANDATORY and must be ON TIME
  - Remember to press “Submit” on draft pre-applications



Submit Extramural Application to Grants.gov

STEP 2:

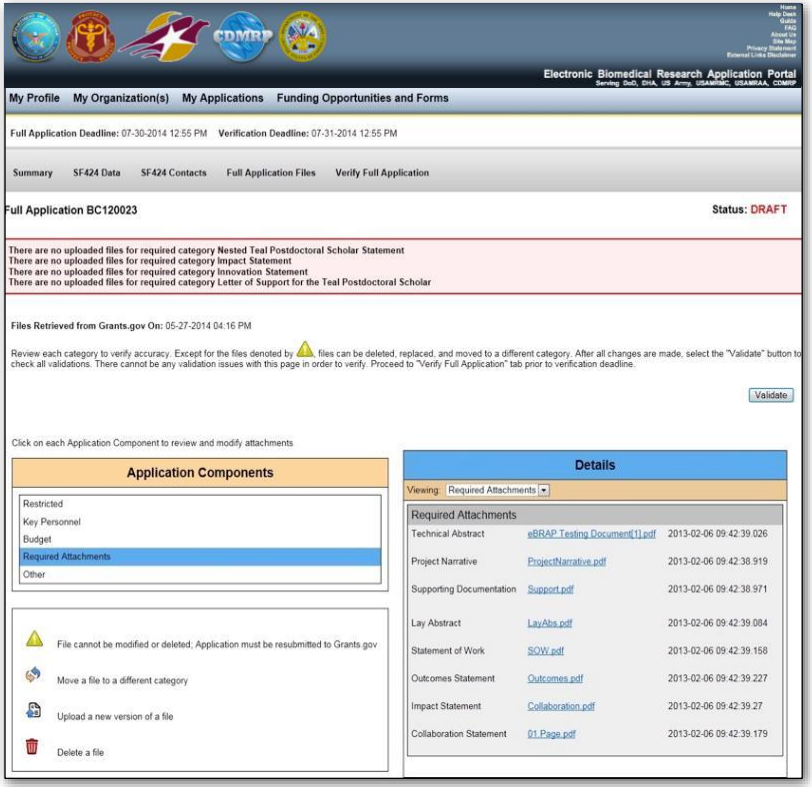
- LOIs – submit any time after pre-application and before deadline for application
- Pre-proposals – ensure you have received an invitation to apply
- Sponsored Program Office *(or equivalent)* submits through **Grants.gov**
- Adhere strictly to the announcement requirements
- Application submission is mandatory and must be ON TIME



Application Verification in eBRAP

STEP 3:

- Review & Modify Full Application
- Verification Period
  - Auto-email notification after eBRAP has processed the Grants.gov application
  - Intramural Lab Commander designee must approve submission in eBRAP
  - Review and modify allowable components
    - ➤ Not Project Narrative or Budget
  - Affiliation with organization is required



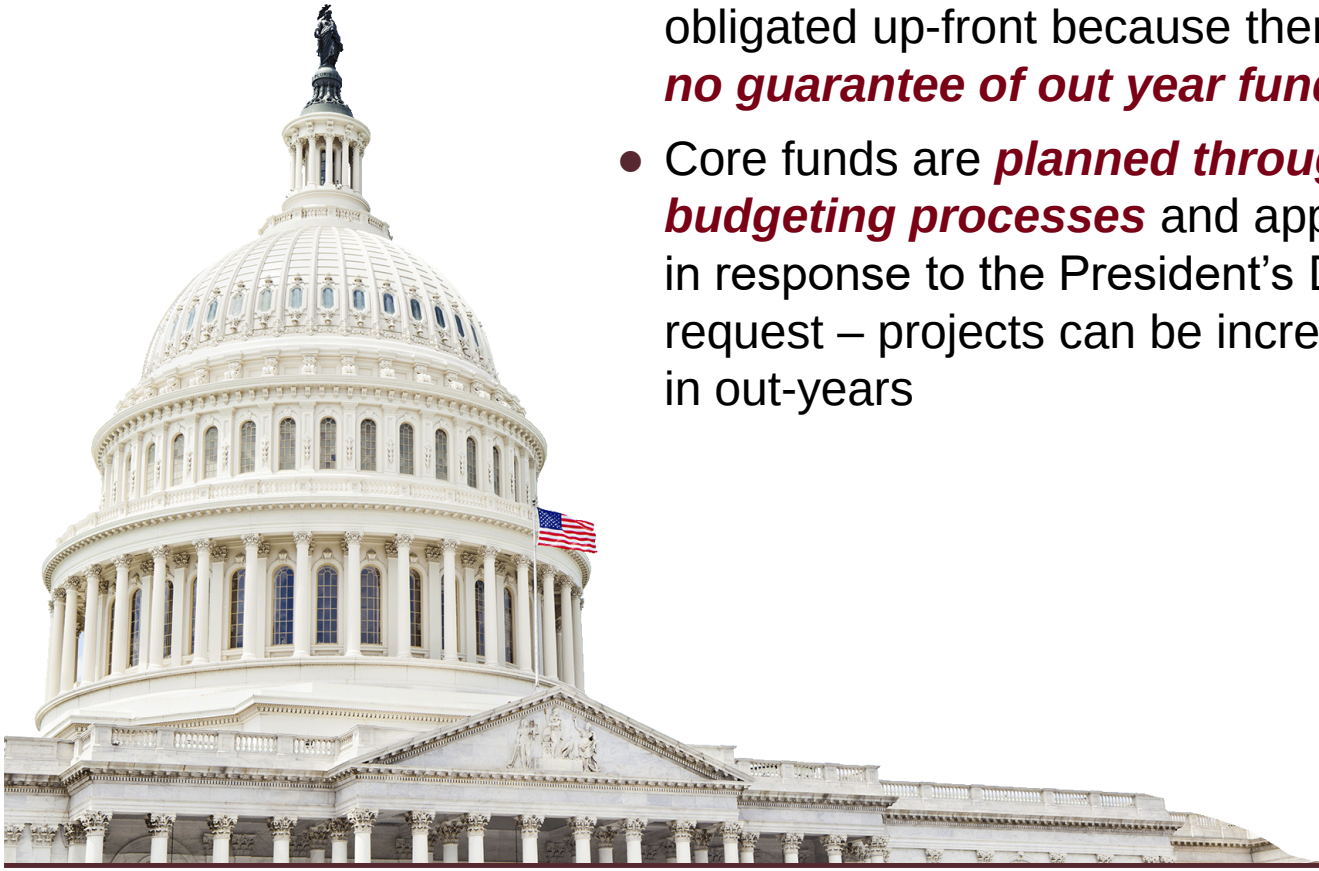
- Tips for success!
  - Extramural: Choose correct Grants.gov application package
    - ➤ Check spelling of names and emails; must match those in pre-application
    - ➤ Include eBRAP log number
  - Intramural: Lab Commander designee must approve submission or reset to draft for modification

Things to Check in Application Submission

- Do not include Programmatic Panel members for the program and fiscal year to which you are applying
- Stay within the page limits; check files after creating PDF version
- Submit before the deadline
  - Grants.gov validation may take up to 72 hours
  - System-to-system submissions are sometimes problematic
  - Application verification in eBRAP is possible before the deadline
- Submit the correct Project Narrative and Budget
  - These components cannot be modified during the verification period in eBRAP

Understand DOD Funding

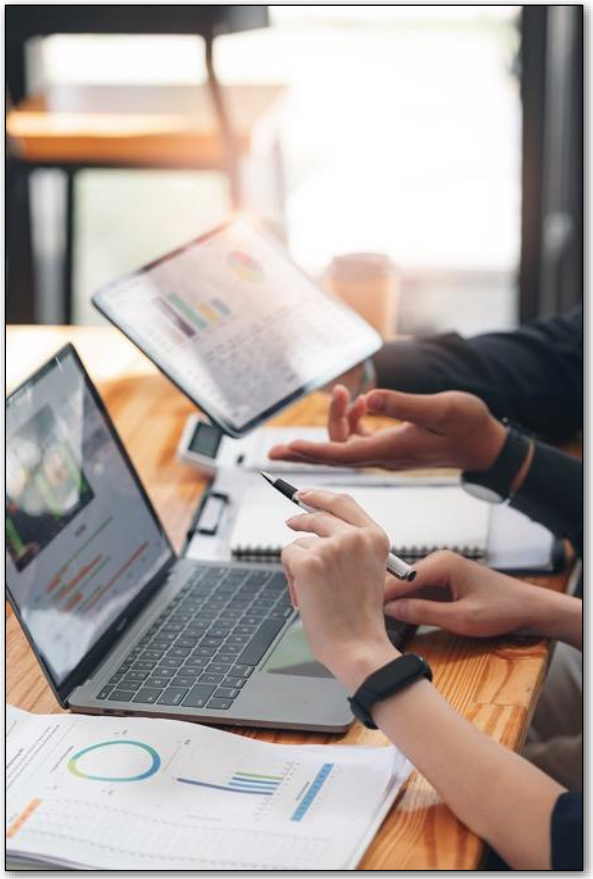
Congressional Special Interest (CSI) versus DOD Core funding



- CDMRP's CSI funds are ***directed by Congress*** and appropriated through the DOD budget – obligated up-front because there is ***no guarantee of out year funding***
- Core funds are ***planned through specific budgeting processes*** and appropriated yearly in response to the President's DOD budget request – projects can be incrementally funded in out-years

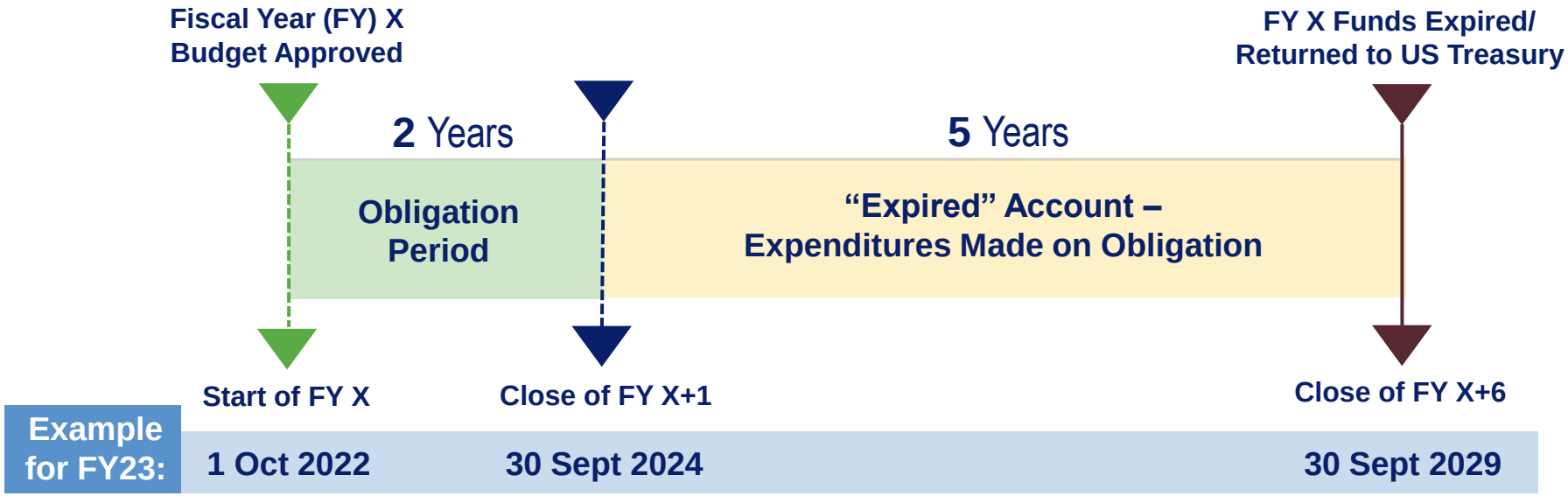
Understand DOD Funding

- Funding strategy and restrictions described in each Funding Opportunity Announcement
  - Type of award (grant, cooperative agreement, contract, other)
  - **Direct** costs versus **total** costs – cost limits
  - Include direct ***and*** indirect costs of any subaward in the direct costs of the primary award
  - Budgeting for DOD sites and collaborators (use of foundations vs. direct funding)
    - ➤ Funding obligated up-front for entire period of performance
    - ➤ Plan for managing out-year funding
  - Interagency and interservice agreements, including support agreements



Plan for Funding Timelines

- Manage/monitor financial burn rate, patient enrollment, invoicing, and other factors unique to the project to avoid funds expiring
- All research, development, test, and evaluation (RDT&E) funds:
  - Have a 2-year period to obligate (make or add to an existing award)
  - Have 5 years to expend, but funds cannot be used to make new or different obligations
  - Expire if not expended after 7 years



Unique Budget Considerations

- DOD intramural submissions
  - Funding is transferred directly via MIPR or FAD with a support agreement
  - Intramural applicants must coordinate through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators

- Extramural submissions with intramural component
  - Extramural prime applicant - intramural **performer**
    - ➤ Typically foundation support arrangements (e.g., Geneva, HJF)
  - Extramural prime applicant - intramural **collaborator**
  - Funds for travel, animal facility per diem, biospecimen storage, institutional review board (IRB) fees, clinical care costs, CT scans, etc. are sent to the organization via **direct funds transfer** (e.g., MIPR, FAD) rather than being placed on the extramural award

Reference:
http://www.usamraa.army.mil/Shared%20Documents/PAN_15-01.pdf

Plan for Access and Approvals

- Active-duty military or Veteran patient populations and resources (databases, specimens, etc.)
  - Clearly define DOD or VA collaborator role: conducting research may require higher level approval
    - ➤ Key collaborators should be research partners and publication co-authors
    - ➤ Plan for IRB review
    - ➤ Create a contingency plan if PI is military (many move every few years)
  - Know what legal instruments are available for collaborative research; e.g., Cooperative Research and Development Agreement (CRADA), Memorandum of Understanding (MOU), Material Transfer Agreement (MTA)
  - Know the requirements and timelines for human or animal subjects research approvals and consult early when planning collaboration

References:
- Conducting DOD Funded Human Research with Military Populations (https://cdmrp.health.mil/pubs/pdf/Conducting%20Research%20Military%20Pop%20DoD_funded_7NOV2022.pdf)
- "Expanding Use of Technology Transfer Mechanisms Within the Army's Medical Treatment Facilities" US Army Med Dep J. Jan-Mar 2012;32-6.

CDMRP Website

Information available:

- Program pages
  - Strategic Plans
  - Program booklets, summary sheets, information papers, etc.
  - Other program-specific resources
- Pre-announcements and Funding Opportunities
- Research and Consumer Highlights
- Search awards
- Annual reports
- Webinar series and videos
- Other guides and resources

cdmrp.health.mil

Program Pages

News & Highlights

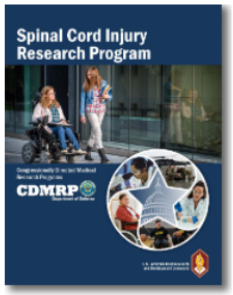
- Monitoring Upper Limb Movement in Individuals with Cervical SCI (external link)
- Department of Defense Spinal Cord Injury Research Program Anticipated Funding Opportunities for Fiscal Year 2022 (FY22)
- FY21 SCIRP Recommended for Funding List
- Update on TRACK-SCI: Toward Better Biomarkers and Data Accessibility for Spinal Cord Injury Research
- UCSF Researchers Introduce Promising New Treatment for Spinal Injuries (external link)
- Synchron Ste… as one of the… Inventions of… link)
- Stentrode: A… Device to Fa… Independenc… Paralysis
- Spinal Cord I… Management… Military Healt… System

Spinal Cord Injury

Vision - *Advance the treatment and management of spinal cord injury and ameliorate its consequences relevant to injured Service members*

Spinal cord injuries (SCIs) are complex neurotraumatic wounds affecting military Service members, their families, Veterans, and the general population. These are serious injuries with long-term consequences requiring lifelong care. It is estimated that about 300,000 individuals are living with an SCI, and this number continues to grow as over 17,000 new cases occur in the U.S. each year. For military populations, the current rate of SCI is relatively low; however, these injuries are still a major cause of medical discharge from Service. Furthermore, between 2000 and 2009, during the height of the conflicts in Iraq and Afghanistan, the rate of SCI in the military was nearly eight times that of the civilian population. As a result, the Department of Veterans Affairs is the largest single SCI care network, providing services for 10%–20% of all individuals living with an SCI in the U.S.

The Spinal Cord Injury Research Program (SCIRP) was established by Congress in fiscal year 2009 (FY09), in part as a response to the high rates of SCI observed in Warfighters returning home from duty. The Congressional intent was to establish a program to enhance the long-term care of wounded Soldiers. To this end, the SCIRP has invested over $200 million (M) into research and development efforts guided by the vision to advance the



» Click on Image to View Program Booklet

Vision

Advance the treatment and management of spinal cord injury and ameliorate its consequences relevant to injured Service members

Mission

To fund research and encourage multidisciplinary collaborations for the development and translation of more effective strategies to improve the health and well-being of Service members, Veterans, and other individuals with spinal cord injury

Congressional Appropriations

$357.9 million FY09-21

$40 million FY22

Funding Summary

278 Awards in FY09-20

Recent Applications Recommended for Funding

Programmatic Panels

FY22 Programmatic Panel

Previous Years' Programmatic Panels

Peer Review Participants

FY21 Peer Review Participants

Previous Years' Peer Review Participants

Strategies for Success

✓ Relevance

- Address program-specific goals
- **Align** the proposed work with specific guidance from the announcement

✓ Impact

- Propose **solutions** to important problems or gaps
- Clearly articulate translatability – how will this work **make a difference**?

✓ Innovation

- Provide clear rationale if proposing to test new, potentially high-risk ideas or use novel approaches

✓ Feasibility

- Justify a technically sound plan with clear approaches for contingencies
- Include evidence of appropriate **expertise** (collaboration, consultants, etc.)
- Ensure the study is **appropriately powered** for the proposed research outcome
- Demonstrate **availability** and **access** to critical resources, reagents, and/or subject populations

Strategies for Success

✓ Planning/Timelines

- Include and allow adequate time in project plan for **regulatory approvals** if required
- For multi-organizational efforts, show a clear plan for **coordination** and communication
- For DOD collaborations, understand rules and plan for differences in funding process

✓ Grantsmanship

- Explain the proposed work with **clarity** and **unburdened** by jargon
- Understand the different audiences of the peer and programmatic reviews and **communicate** effectively
- **Review** application documents carefully before submission – Enlist experienced colleagues to help
- Don’t break the rules for deadlines or requirements – **be compliant**

Questions?
For more information, please visit:

cdmrp.health.mil

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