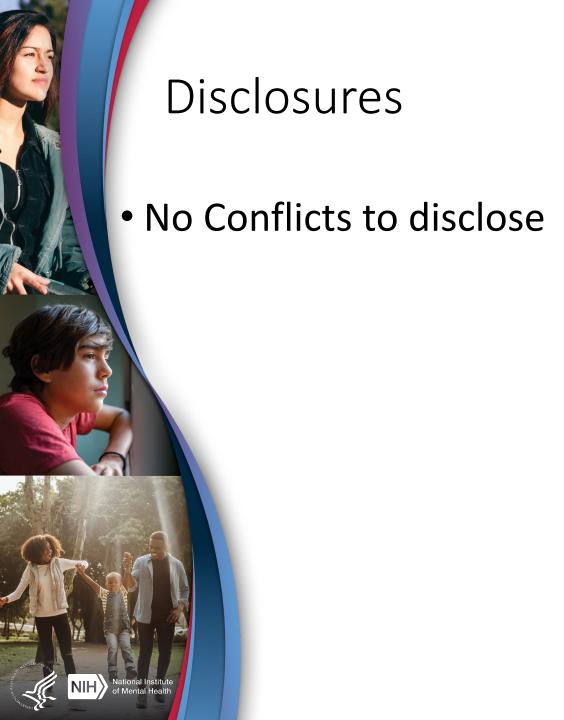


NIMH Update Succeeding in Mental Health and Aging Research March Webinar

March, 19,2024

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NIMH, Division of Translational Research
Geriatrics and Aging Processes Research Branch



AGENDA

- NIMH Budget for Fiscal 2024
- Institute Priorities and Initiatives
- Geriatrics & Aging Processes Branch
- Open Discussion

NIMH Vision and Mission



NIMH envisions a world in which mental illnesses are prevented and cured.



To transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure.

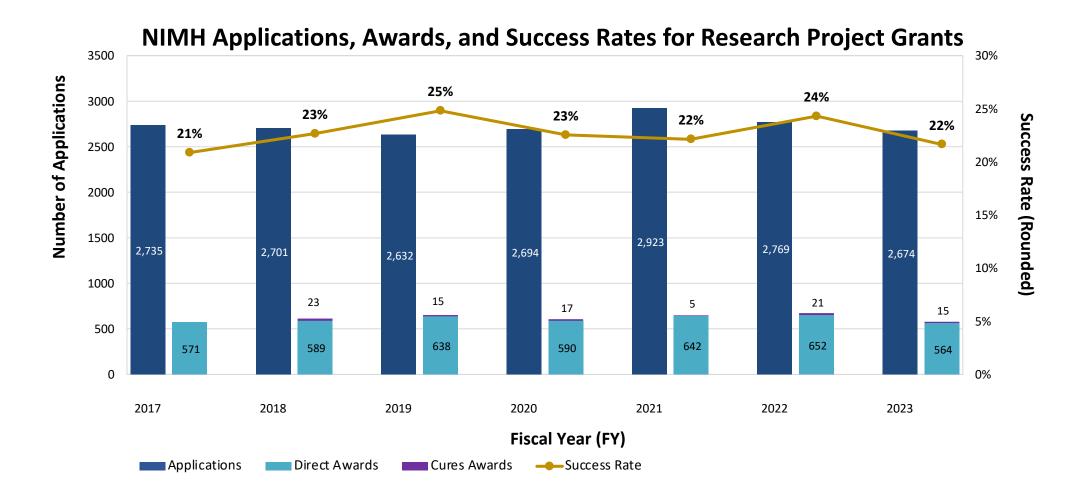


Appropriations Update

- On January 18, 2024, Congress passed a second two-step continuing resolution that provides funding for NIH through March 8, 2024
- On January 7, 2024, lawmakers announced an agreement on Fiscal Year 2024 (FY24) topline funding levels
 - It provides \$886.3 billion for defense and \$772.7 billion for nondefense programs, representing a flat budget for many nondefense programs
 - Lawmakers continue to negotiate funding levels for the 12 annual appropriation bills

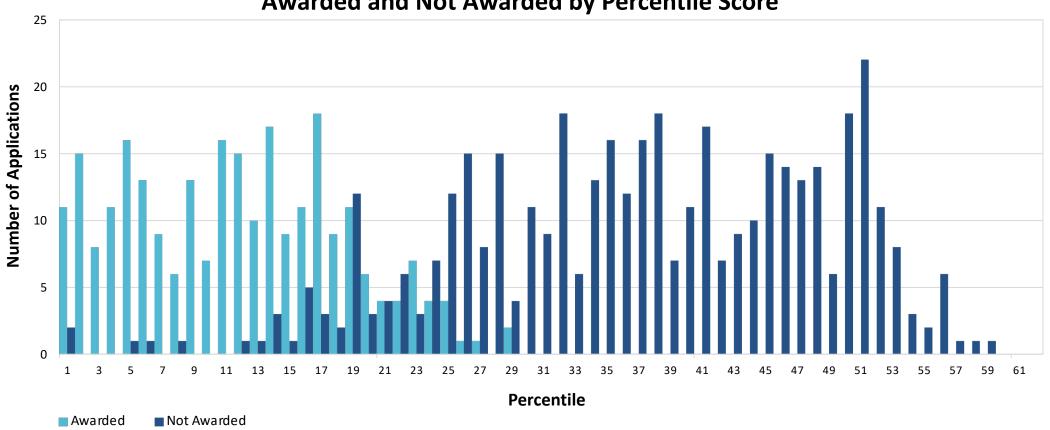


NIMH Budget



NIMH Budget Update

NIMH FY23 Competing R01 and Equivalent Applications Awarded and Not Awarded by Percentile Score



NIMH FY24 INTERIM FUNDING STRATEGY

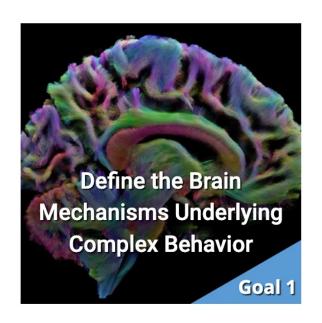
https://www.nimh.nih.gov/funding/grant-writing-and-application-process/fy-2022-funding-strategy-for-research-grant

- Fund roughly 3/4 of new/competing applications under the 20th percentile (under 25th percentile for ESIs)
 - No specific payline; support <u>most</u> applications below 10th percentile, <u>many</u> in 10-20th percentile range, <u>some</u> beyond 20th percentile
- Support the Next Generation Initiative, prioritizing support for Early Stage Investigators (ESI)
- Decisions based on:
 - Alignment with NIMH Strategic Plan (Institute priorities)
 - Programmatic portfolio considerations
 - ESI investigator status
 - Availability of funds
- This funding strategy will be updated when FY 2024 appropriations are enacted, and final funding policies are determined.



NIMH Strategic Plan for Research

The four Strategic Plan Goals form a broad roadmap for the Institute's research priorities, spanning fundamental science to public health impact.









NIMH Priority Research Areas

Suicide

Suicide is an urgent, complex public health crisis. The Suicide Research Team was formed as part of NIMH's commitment to helping reduce the suicide rate by 20% by 2025.

Mental Health Disparities

The Disparities Team promotes innovative and high-impact mental health research that enhances our understanding of minority mental health and health disparities, reduces mental health disparities and their impact on individuals and communities, and moves us toward achieving mental health equity.

Genomics

The Genomics Team helps shape the field of genomic psychiatry, the study of genes to improve risk prediction, prevention, diagnosis, treatment selection, and causes of mental illnesses. The Genomics Team has initiated many programs from basic gene discovery to clinical translational efforts.

Global Mental Health

The Global Mental Health Team helps shape and advance NIMH's efforts to improve the lives of people living with or at risk for mental illnesses in low-resource settings worldwide.

https://www.nimh.nih.gov/research/priority-research-areas

NIMH Suicide Research Priorities

Progress since 2010: More evidence-based practices

- Valid risk identification approaches in healthcare settings
 - Risk Identification: Screening; Risk Algorithms
- Intervention & implementation examples
 - Safety planning
 - Pragmatic trials in healthcare systems
 - Collaborative care to address opioid comorbidity

Improved US estimates of suicide decedents & their characteristics

Healthcare access and mental health diagnoses

How can we better implement what we know to reduce the suicide rate?

- Telehealth enabled suicide prevention
- Rapid-acting interventions



NIMH Suicide Prevention Opportunities

- Notice of Special Interest (NOSI): Priority Research Opportunities in Crisis Response Services
 - NOT-MH-23-140 Expires May 8, 2025
- Notice of Special Interest (NOSI): Firearm Injury and Mortality Prevention Research
 - NOT-OD-23-039 Expires February 5, 2026

NIMH Clinical Trials Funding Opportunities

Clinical Trial Pipeline - Phase of Intervention Development

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First in Human	Exploratory Experimental Therapeutics	Confirmatory Efficacy	Effectiveness (Prevention, Treatment, Services)
First in Human and Early Stage Clinical Trials of Novel Investigational Drugs or Devices for Psychiatric Disorders (U01)*			Pilot Effectiveness Trials for Treatment, Preventive and Services Interventions (R34)
	Early Stage Testing of Pharmacologic or Device- based Interventions for the Treatment of Mental Disorders (R61/R33) and (R33)*	Confirmatory Efficacy Clinical Trials of Non- Pharmacological Interventions for Mental Disorders (R01)	Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (R01)
	Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders (R61/R33) and (R33)		Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (Collaborative R01)

Reminder: New NIH Data Management and Sharing (DMS) Policy

- NIH has issued a new DMS Policy (effective for due dates on/after January 25, 2023) to promote the sharing of scientific data (NOT-OD-21-013)
- Under the DMS policy, NIH expects investigators and institutions to:
 - Plan and budget for the managing and sharing of data
 - Submit a DMS plan for review when applying for funding
 - Comply with the approved DMS plan
- Visit <u>sharing.nih.gov</u> for more information, including samples of DMS Plans



NIMH Data Sharing Requirements

- All NIMH human subjects studies must specify data-sharing plans
- Generally expected to include depositing study data into the NIMH Data Archive (NDA) periodically during the study
- Notice of Data Sharing Policy for the National Institute of Mental Health (NOT-MH-23-100)
- Recent notice around the collection of Common Data Elements (NOT-MH-20-067)

Requirements in Grant Applications

- Rigor and Transparency: Must specify how the study will address/enhance research rigor and transparency (NOT-OD-15-103)
- Sex as a Biological Variable: Must account for the possible role of sex as a biological variable in vertebrate animal and human studies (NOT-OD-15-102)
- Inclusion Across the Lifespan: Policy requires justifying exclusion of potential study participants by age:
 - https://grants.nih.gov/grants/funding/lifespan/lifespan.htm



NIMH Structure

Division of
Neuroscience and
Basic Behavioral
Science
(DNBBS)

Division of Translational Research (DTR) Division of Services and Interventions Research (DSIR)

Division of AIDS Research (DAR)

Global Mental Health Research (CGMHR)

Disparities Research and Workforce Diversity (ODWD)



Strategic Objective 1

Define mechanisms of complex behaviors



Strategic Objective 2

Determine when, where, & how to intervene



Strategic Objective 3

Strive for prevention and cures



Strategic Objective 4

Strengthen the public health impact



Division of Translational Research (DTR)

Director: Sarah Hollingsworth Lisanby, MD

Deputy Director: Mi Hillefors, MD, PhD

- "Adult Programs"
 - Adult Psychopathology & Psychosocial Interventions Branch
 - Adult Pathophysiology & Biological Interventions Development Branch
 - Geriatrics & Aging Processes Research Branch
 - Traumatic Stress Program
- "Developmental Programs"
 - Developmental Mechanisms and Trajectories of Psychopathology Branch
 - Biomarker and Intervention Development for Childhood-Onset Mental Disorders Branch
- Research Training & Career Development Program
- Small Business Research Program



Geriatrics and Aging Processes Research Branch: Areas of Emphasis

- Predictors and mechanisms of late-life mental disorders (esp. genetic, neurobiological, physiological, cognitive, psychosocial, and disability)
- Trajectories of chronic mental illnesses across the lifespan; pathways of influence of earlier life trauma
- Novel treatment development and approaches
- Predictors and mechanisms of variability in treatment response (esp. genetic and brain structure/function factors)



Geriatrics and Aging Processes Research Branch: Programs

 Behavioral Science of Mental Disorders and Aging Psychosocial Intervention and Aging

 Neuroscience of Mental Disorders and Aging Pharmacologic and Somatic Intervention and Aging

http://www.nimh.nih.gov/about/organization/datr/geriatrics-and-aging-processes-research-branch/index.shtml



Geriatric Intervention Research

- Observational and experimental outcome studies:
 - pharmacologic and somatic interventions
 - behavioral and psychosocial interventions
 - algorithms for combining or sequencing multiple interventions
- Treatment, prevention, or rehabilitation
- Acute, continuation, or maintenance phases
- Primary outcomes can include:
 - relapse prevention
 - enhancement of function or reduction of disability
 - enhancement of treatment access, acceptance, adherence



Behavioral Science of Mental Disorders and Aging

Approaches:

- Basic and translational social and behavioral science
- Clinical geropsychology
- Cognitive, affective, and decision sciences

• Focus:

- Social, behavioral, and cognitive:
 - Risk factors contributing to mid-to-late life vulnerability/resilience to mental illness
 - Mechanisms of mid-to-late life mental illness pathophysiology
 - Phenotypes of mid-to-late life mental disorders
 - Processes that shape trajectories of mental illness across the adult lifespan

Areas of emphasis and opportunity:

- Social Isolation
- Suicide
- Predictive Coding and Reward Processing
- Emotion Regulation



Social disconnection and Suicide Risk in Late Life

- PAR-MH-23-238 (R01) and PAR-MH-23-239 (R21)
- Aim: encourage research that addresses the link between social disconnection in late-life and late-life suicidal thoughts and behaviors.
- Of specific interest is research that identifies mechanisms by which social disconnection confers risk for, and social integration protects against, suicidal thoughts and behaviors in late life.
- Mechanisms to be considered exist at multiple levels of analysis, including but not limited to neurobiological, behavioral, and environmental.

Neuroscience of Mental Disorders and Aging Program

- Basic and translational neuroscience applications to understand risk factors, presentation, course, and outcome of mid to late-life mental illness
- Understand aging-related neural processes that contribute to vulnerability and resilience to mental illness across the adult lifespan
- Neural mechanisms that contribute to
 - the pathogenesis or worsening of mid to late life mental illnesses
 - treatment response variation in mid to late-life mental illnesses
 - domains of function relevant to mental illnesses in mid to late-life
- Molecular, cellular, and systems level of brain function, state-of-the-art neuroimaging, magneto/electrophysiology, and stimulation methods like ECT and TMS are supported



Novel Mechanism Research on Neuropsychiatric Symptoms (NPS) in Alzheimer's Dementia

- PAR-23-207 (R01) and PAR-23-208 (R21)
- Aim: to encourage applications for studies that will enhance knowledge of mechanisms associated with neuropsychiatric symptoms (NPS) in persons with Alzheimer's disease (AD) or Alzheimer's disease-related dementias (ADRD)
- The findings are expected to advance mechanistic understanding of both biobehavioral and neurobiological pathways leading to NPS. Findings may also provide insight into novel therapeutic targets that can be advanced into interventions to treat and prevent the development of NPS in AD and/or ADRD
- NIA and NIMH sponsored FOA



Mood and Psychosis Symptoms during the Menopause Transition

- PAR-MH-23-097 (R01) and PAR-MH-23-102 (R21)
- Aim: To encourage research that will advance mechanistic and translational research on the onset and worsening of mood and psychotic disorders during the menopausal transition (or perimenopause)
- Research is solicited that will advance understanding of the underlying neurobiological and behavioral mechanisms of mood disruption and psychosis during the menopausal transition and that will identify novel targets for future mental health interventions or prevention efforts

Schizophrenia and related disorder during mid- to late-life

- PAR-MH-24-023 (R01) and PAR-MH-24-026 (R21)
- Aim: To encourage research that will advance translational work to better understand the emergence, trajectory, and outcomes of schizophrenia and related psychotic disorders in mid- to late-life, and to identify targets for future treatment development.

Mailing Lists about NIMH and NIH-related News

- NIMH Website updates: www.nimh.nih.gov
- Inside NIMH (newsletter, 3X per year):
 https://www.nimh.nih.gov/research/research-funded-by-nimh/inside-nimh
- NIMH Funding Opportunities: https://www.nimh.nih.gov/funding/opportunities-announcements
- NIH Guide to Grants and Contracts: http://grants.nih.gov/grants/guide/index.html

Please Contact Program Staff



Contact us early... and often! We provide assistance prior to submission to ensure your application...

- ✓ Meets referral guidelines and is consistent with NIH/NIMH grant policies
- ✓ Aligns well with the Institute priorities (find the right home for your research)
- ✓ Uses the funding mechanism most appropriate for your research career stage, needs, and training/research goals
- ✓ Meets review criteria (research plan, training plan, mentors, environment)
- ✓ Will optimally set you up for subsequent funding and future success



