Advanced Research Institute (ARI)
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June 23, 2020

NIMH Update

Jovier D. Evans, PhD

NIMH, Division of Translational Research

Geriatrics and Aging Processes Research Branch

National Institute of Mental Health

DISCLOSURES

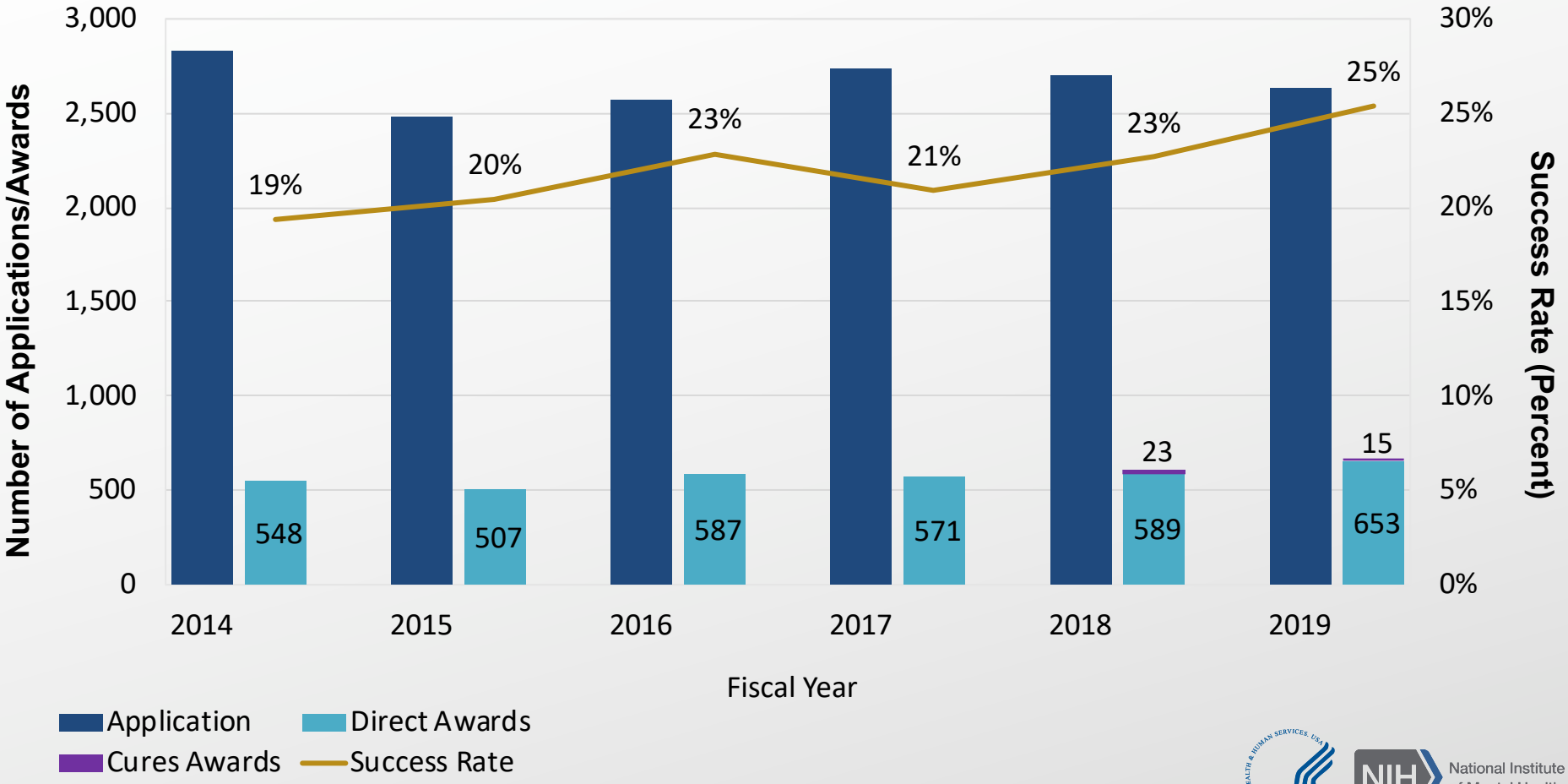
No conflicts to disclose

AGENDA

- NIMH Funding Strategy
- NIMH Strategic Plan Updates
- Priorities and Initiatives
- Geriatrics & Aging Processes Branch
- Future Directions for the Branch
- Open Discussion

NIMH Budget Update

NIMH Applications, Awards, and Success Rates for Research Project Grants



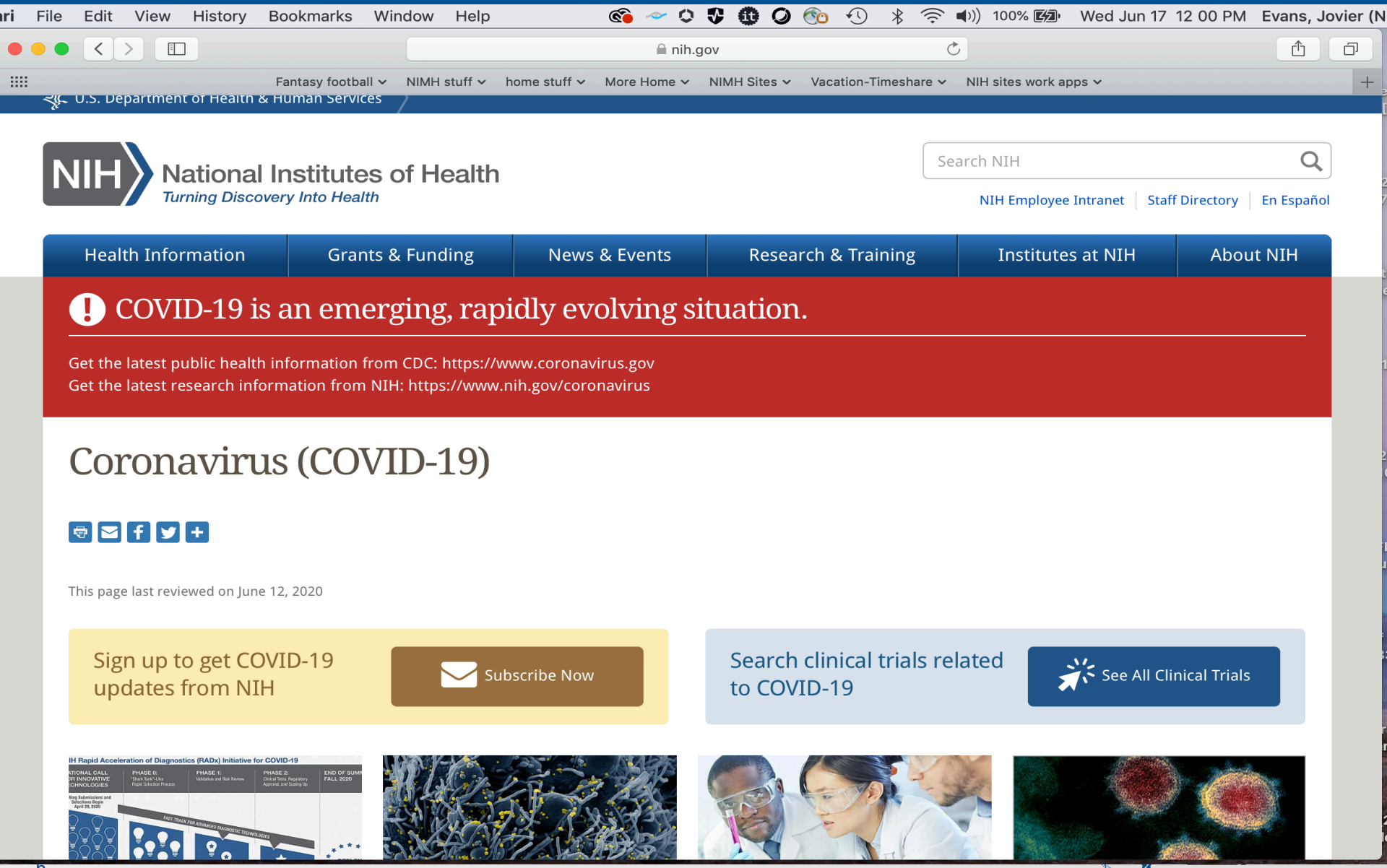
National Institute of Mental Health

NIMH FY20 FUNDING STRATEGY

(https://www.nimh.nih.gov/funding/grant-writing-and-application-process/fy-2020-interim-funding-strategy-for-research-grants.shtml)

- Fund roughly 3/4 of new/competing applications under the 20th percentile (under 25th percentile for ESIs/EEIs)
  - No specific payline; support **most** applications below 10th percentile, **many** in 10-20th percentile range, **some** beyond 20th percentile
- Support the Next Generation Initiative, prioritizing support for Early Stage Investigators (ESI) and Early Established Investigators (EEI)
- Decisions based on:
  - Alignment with NIMH Strategic Plan (Institute priorities)
  - Programmatic portfolio considerations
  - ESI or EEI investigator status
  - Availability of funds

COVID – 19 NIH Resources



COVID-19 Funding Opportunity Announcements

- Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Mental Health Research on the 2019 Novel Coronavirus(NOT-MH-20-047)
- Notice of Special Interest (NOSI): Emergency Competitive Revisions for Social, Ethical, and Behavioral Implications (SEBI) Research on COVID-19 Testing among Underserved and/or Vulnerable Populations(NOT-OD-20-119)
- Notice of Special Interest (NOSI): Emergency Competitive Revisions for Community-Engaged Research on COVID-19 Testing among Underserved and/or Vulnerable Populations(NOT-OD-20-120)

COVID-19 Funding Opportunity Announcements cont'd

- Notice of Special Interest (NOSI): Limited Competition for Emergency Competitive Revisions for Community-Engaged Research on COVID-19 Testing among Underserved and/or Vulnerable Populations(NOT-OD-20-121)
- Notice of Special Interest (NOSI): Competitive and Administrative Supplements for Community Interventions to Reduce the Impact of COVID-19 on Health Disparity and Other Vulnerable Populations(NOT-MD-20-022)
- Notice of Intent to Publish a Funding Opportunity Announcement for Community Interventions to Address the Consequences of the COVID-19 Pandemic for Health Disparity and Vulnerable Populations (R01-Clinical Trial Optional)(NOT-MD-20-023)

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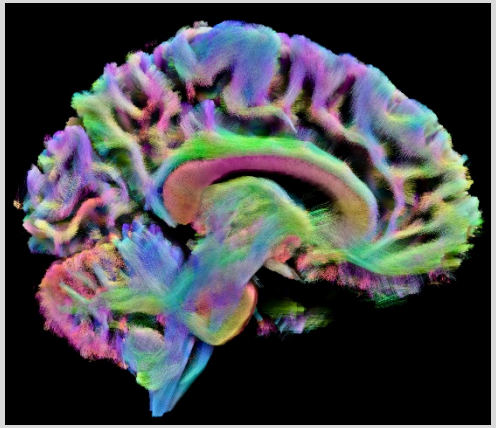
NIMH 2020 Strategic Plan

2020 NIMH Strategic Plan for Research: Updates

Goal 1:
Define the Brain Mechanisms Underlying Complex Behaviors



Goal 2:
Examine Mental Illness Trajectories Across the Lifespan

Goal 3:
Strive for Prevention and Cures

Goal 4:
Strengthen the Public Health Impact of NIMH-Supported Research

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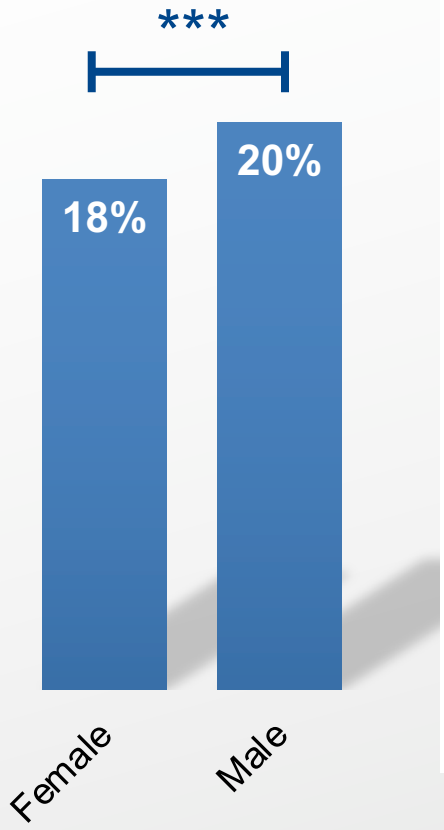
NIMH Principal Investigator (PI) Diversity Analysis

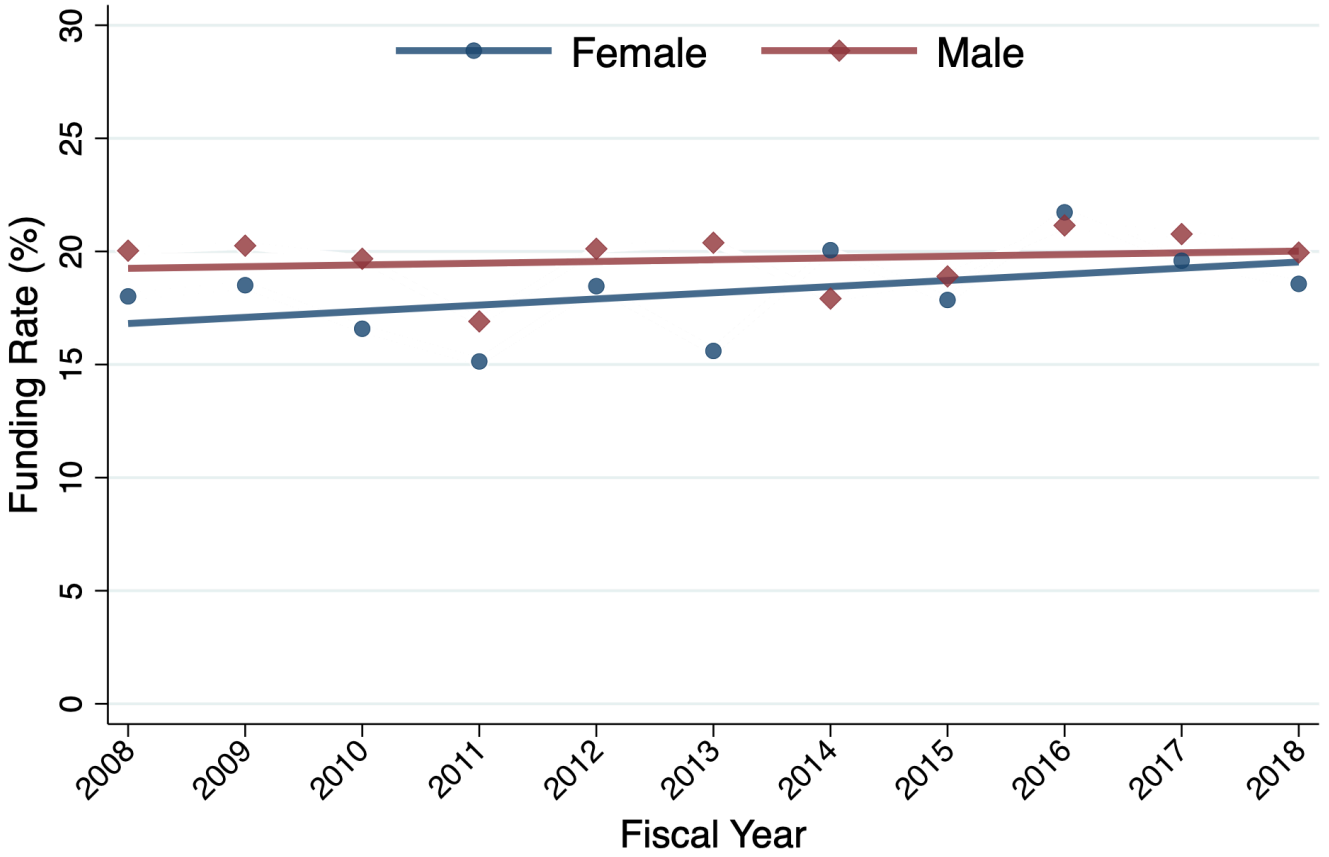
- Promoting equity in the research workforce is a priority
- Evaluating the application counts and funding rates allows us to see the overall demographic landscape
- The goal is to identify and understand gaps, and to develop strategies to address areas for improvement

- <u>Current Analysis</u>:
  - For fiscal years (FYs) 2008-2018, compared application counts (including multiple PIs) and funding rates* by gender, race, and ethnicity**

* Funding Rate: Percentage of unique application/PI combinations receiving funding
** All demographic data is self-report

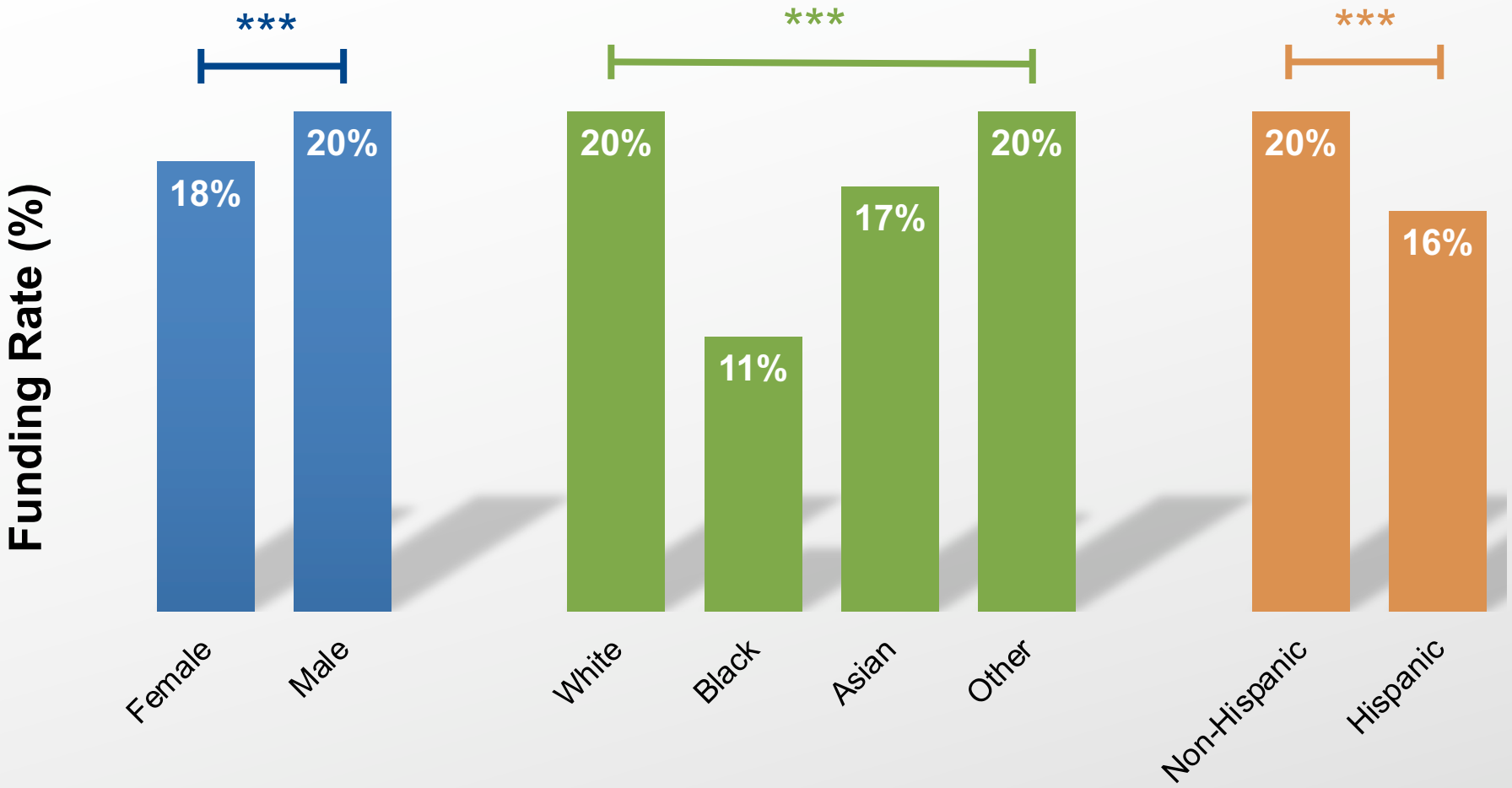
NIMH PI Diversity Analysis





- Funding Rate: Percentage of unique application/PI combinations receiving funding
- All demographic data are self-report

NIMH PI Diversity Analysis



- Funding Rate: Percentage of unique application/PI combinations receiving funding
- All demographic data are self-report
  - "Other": American Indian/Alaskan Native, Pacific Islander, More than 1 Race Reported

Current Efforts to Advance Workforce Diversity

- **Individual Supplement Awards**
  - Research Supplements to Promote Diversity
- **Predoctoral Awards**
  - Individual Predoctoral Fellowship to Promote Diversity (F31)
  - Mental Health Dissertation Research Grant to Increase Diversity (R36)
  - NIH Blueprint Diversity Specialized Predoctoral to Postdoctoral Advancement in Neuroscience (D-SPAN) Award (F99/K00)
- **Postdoctoral/Career Development Awards:**
  - BRAIN Initiative Advanced Postdoctoral Career Transition Award to Promote Diversity (K99/R00)
- **Other Programs**
  - NIH Blueprint initiative - Enhancing Neuroscience Diversity through Undergraduate Research Education Experiences (ENDURE)
  - NIMH Support for Scientific Conferences to Promote Inclusion
  - Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Institutionally-Focused Research Education Award to Promote Diversity
  - Faculty Institutional Recruitment for Sustainable Transformation (FIRST)

Toward a Balanced Research Portfolio

Diversity in scientific workforce, study participants, subject matter, and timeframes

- Short-term
- Medium-term
- Long-term

NIMH Research Priorities

- Suicide Prevention
  - Identify implementable evidence-based practices and knowledge gaps
- Computational Psychiatry
  - Develop computational perspectives and approaches to improve the understanding and treatment of mental health disorders
- Genomics
  - Develop novel approaches to understanding the pathophysiology of complex mental disorders

NIMH Suicide Research

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

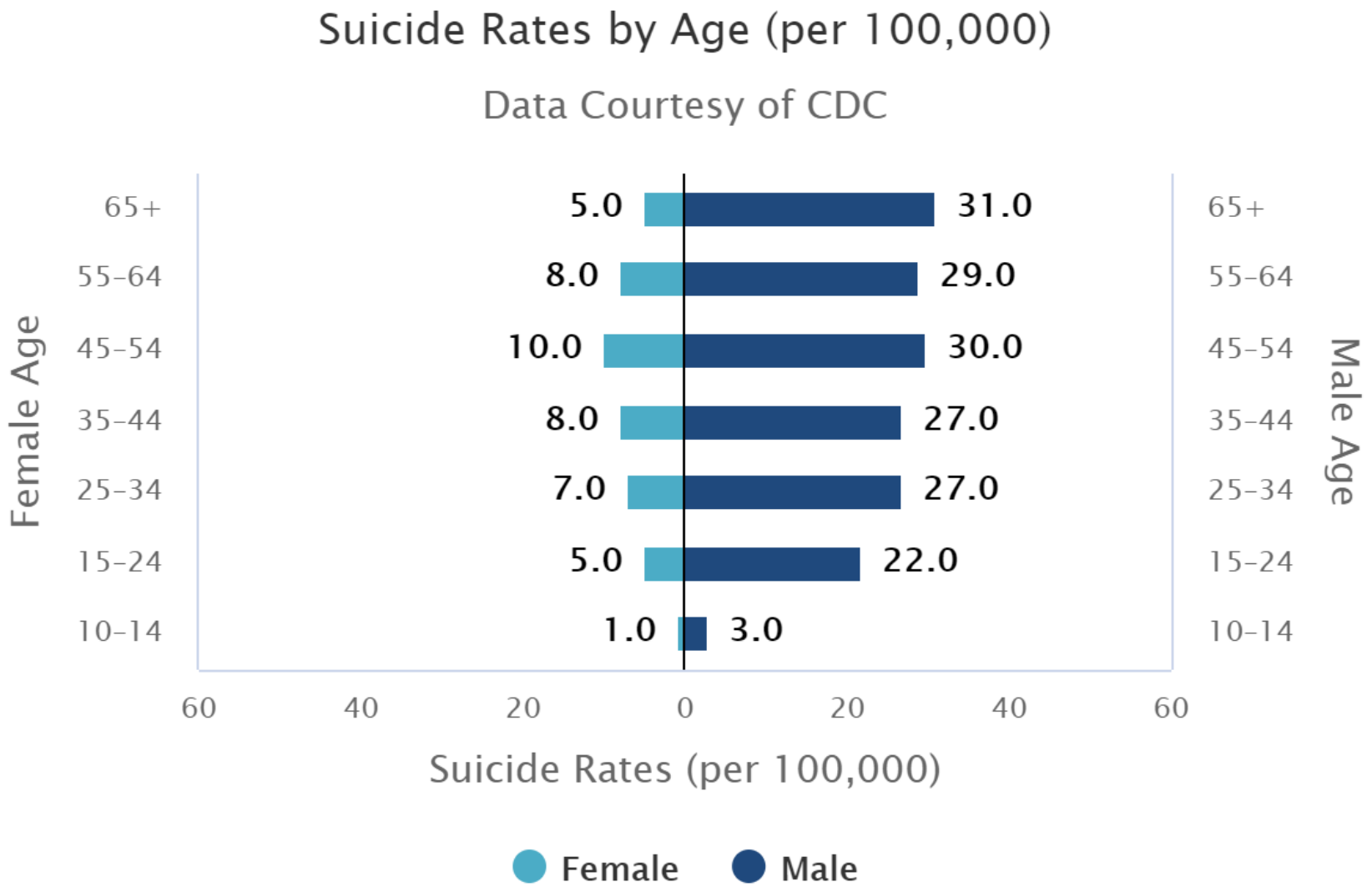
Improved US estimates of suicide decedents & their characteristics

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

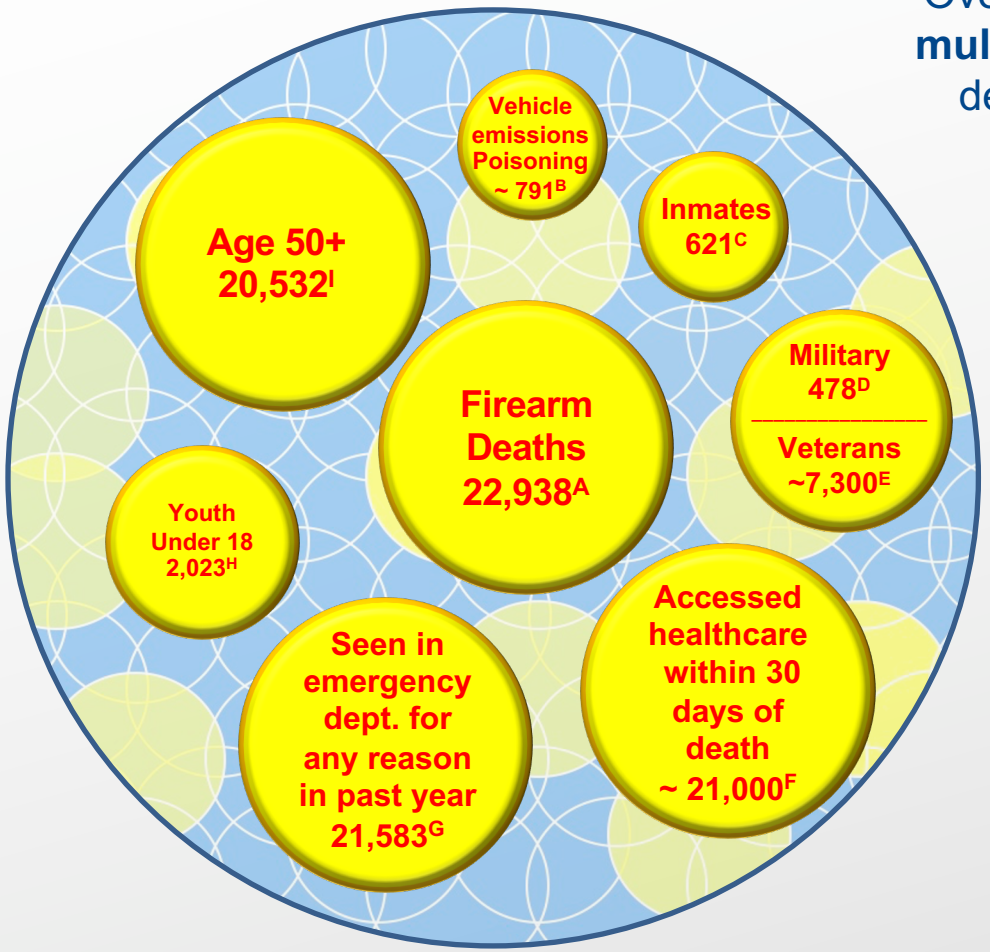
2017 US Suicide Rates by Age and Sex



https://www.nimh.nih.gov/health/statistics/suicide.shtml

Identifying 47,173 Suicide Decedents in the United States (2017)[1]

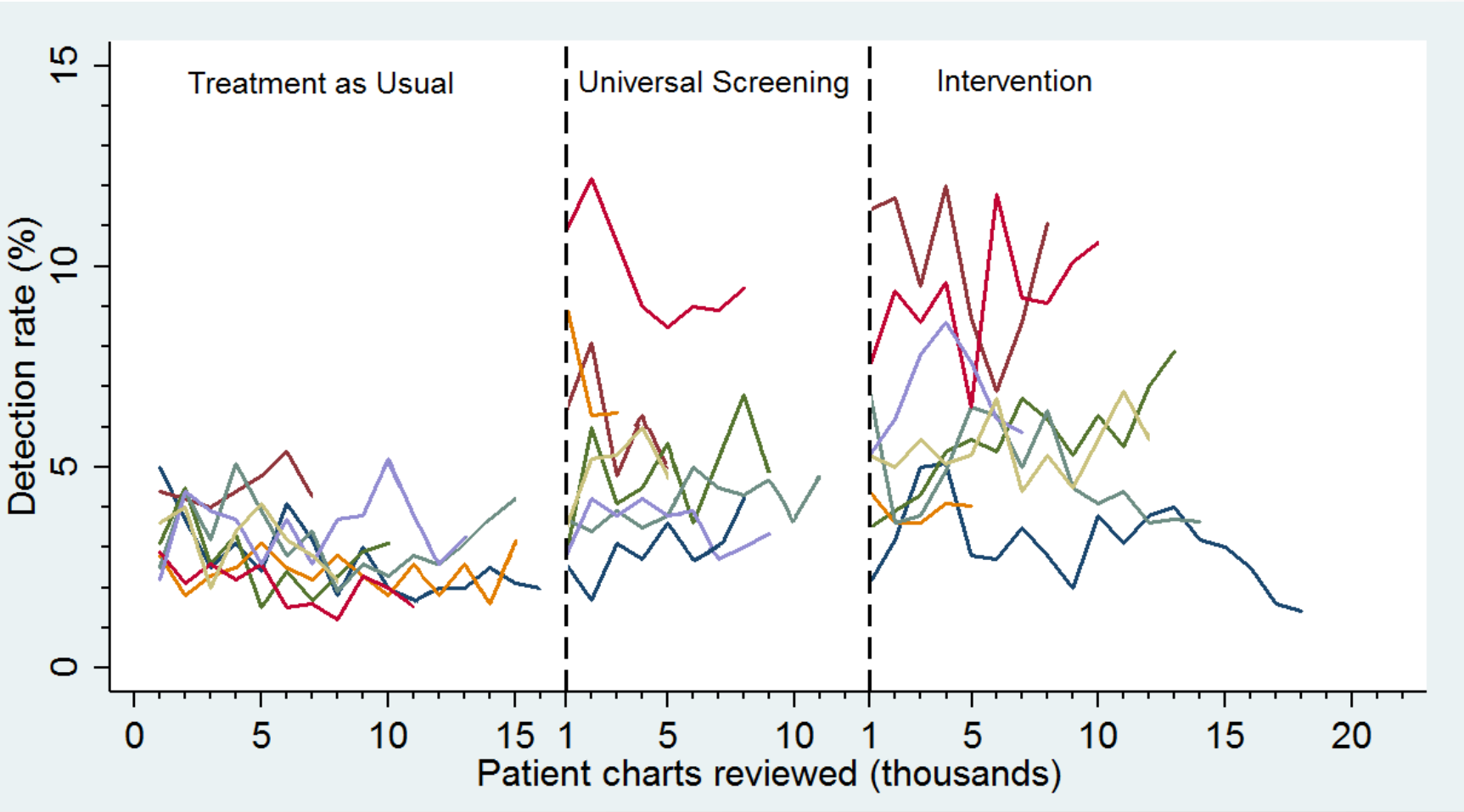
Overlap in subgroups and **multiple opportunities** to detect individuals at risk



1. NCHS Data Brief 330. Suicide Mortality in the United States, 1999-2017; (https://www.cdc.gov/nchs/products/databriefs/db330.htm)

National Institute of Mental Health

ED-SAFE: Universal Suicide Screening Doubles the Rate of Suicide Risk Detection



Boudreaux et al., *Am J Prev Med*, 2016

Electronic Health Record Algorithms Identify Suicide Risk

Integrating Predictive Modeling Into Mental Health Care: An Example in Suicide Prevention

Greg M. Reger, Ph.D., M.A., Mary Lou McClure, R.N., B.S.N., David Ruskin, M.D., Sarah P. Carter, Ph.D., Mark A. Reger, Ph.D.

Recent advances in statistical methods and computing power have improved the ability to predict risks associated with mental illness with more efficiency and accuracy. However, integrating statistical prediction into a clinical setting poses new challenges that need creative solutions. A case example explores the challenges and innovations that emerged at a Department of Veterans Affairs hospital while implementing REACH VET (Recovery Engagement and Coordination for Health—Veterans Enhanced Treatment), a suicide prevention program that is based on a predictive model that identifies veterans at statistical risk for suicide.

Psychiatric Services 2019; 70:71–74; doi: 10.1176/appi.ps.201800242

Predicting Suicide Attempts and Suicide Deaths Following Outpatient Visits Using Electronic Health Records

Gregory E. Simon, M.D., M.P.H., Eric Johnson, M.S., Jean M. Lawrence, Sc.D., Rebecca C. Rossom, M.D., M.S., Brian Ahmedani, Ph.D., Frances L. Lynch, Ph.D., Arne Beck, Ph.D., Beth Waitzfelder, Ph.D., Rebecca Ziebell, Robert B. Penfold, Ph.D., Susan M. Shortreed, Ph.D.

PROSPECT Study

ORIGINAL CONTRIBUTION

Reducing Suicidal Ideation and Depressive Symptoms in Depressed Older Primary Care Patients

A Randomized Controlled Trial

Martha L. Bruce, PhD, MPH
Thomas R. Ten Have, PhD
Charles F. Reynolds III, MD
Ira I. Katz, MD, PhD
Herbert C. Schulberg, PhD
Benoit H. Mulsant, MD
Gregory K. Brown, PhD
Gail J. McAvay, PhD
Jane L. Pearson, PhD
George S. Alexopoulos, MD

Context Suicide rates are highest in late life; the majority of older adults who die by suicide have seen a primary care physician in preceding months. Depression is the strongest risk factor for late-life suicide and for suicide's precursor, suicidal ideation.

Objective To determine the effect of a primary care intervention on suicidal ideation and depression in older patients.

Design and Setting Randomized controlled trial known as PROSPECT (Prevention of Suicide in Primary Care Elderly: Collaborative Trial) with patient recruitment from 20 primary care practices in New York City, Philadelphia, and Pittsburgh regions, May 1999 through August 2001.

Participants Two-stage, age-stratified (60-74, ≥75 years) depression screening of randomly sampled patients; enrollment included patients who screened positive and a random sample of screened negative patients. This analysis included patients with a depression diagnosis (N=598).

NIMH Suicide Prevention Opportunities

- Practice-Based Research for Implementing Scalable Evidence-Based Prevention Interventions in Primary Care Settings (R01 Clinical Trial Optional) RFA MH-20-505
- Practice-Based Research for Implementing Scalable Evidence-Based Prevention Interventions in Primary Care Settings (R34 Clinical Trial Optional)RFA-MH-20-506
- Enhancing Suicide Prevention in Emergency Care via Telehealth (R01 Clinical Trial Optional).RFA-MH-20-226
- Notice of Special Interest to Highlight Research Priorities for Risk Algorithms Applications in Healthcare Settings to Improve Suicide Prevention. (NOT-MH-20-031)

Computational Psychiatry

- Biophysical Modeling
- Computational Phenotyping
- Data Mining

- Test links across multiple levels of analyses (genetic, molecular, cellular, circuit, behavior)
- Formalize behavioral analysis, defining underlying algorithms and facilitating neurobiological and clinical studies
- Provide quantitative assessment of utility of biomarkers
- Enhanced understanding of brain mechanisms

NIMH Initiatives for Computational Psychiatry

- Computational Approaches for Validating Dimensional Constructs of Relevance to Psychopathology (RFA-MH-19-242)
- Computationally-Defined Behaviors in Psychiatry (RFA-MH-19-240)
- Explainable Artificial Intelligence for Decoding and Modulating Neural Circuit Activity Linked to Behavior (R01 Clinical Trial Optional) (PAR-19-344)
- Notice of Availability of Administrative Supplements for Advancing Computational Modeling and Data Analytics Relevant to Mental Health (NOT-MH-19-004)

Genomics

https://www.nimh.nih.gov/research-priorities/policies/guidance-for-applicants-following-the-report-of-the-national-advisory-mental-health-council-workgroup-on-genomics.shtml

National Institute of Mental Health

Transforming the understanding and treatment of mental illnesses.

Sea

MENTAL HEALTH INFORMATION | OUTREACH | RESEARCH PRIORITIES | FUNDING | LABS AT N

Research Areas | Policies and Procedures | Research Resources | Res

Home > Research Priorities > Policies and Procedures

Guidance for Applicants Following the Report of the National Advisory Mental Health Council Workgroup on Genomics

NIH Clinical Trials

Website with interactive tools: https://grants.nih.gov/policy/clinical-trials.htm

The NIH definition of a clinical trial was revised in 2014 and the revised changes have now been formally implemented across all NIH Institutes. The NIH definition of a clinical trial is very broad. The definition now extends beyond just treatment studies, and many mechanistic studies involving human subjects now fall under the definition of a clinical trial.

NIMH Clinical Trials
Funding Opportunity Announcements

Clinical Trial Pipeline - Phase of Intervention Development

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)

Recent Concept: Mechanistic Clinical Trials

- NIH issued “Parent Announcements” for R01s and R21s that involve clinical trials
- NIMH joined in these PAs (NOT-MH-18-006 and NOT-MH-18-005), while specifying that under them it will accept only applications proposing “mechanistic” studies (NOT-18-004)
- The basic concept is quite similar to that of NIMH’s previous “probe” and “biomarker” studies
- Applicants submit standard R01s or R21s, which are reviewed by CSR review committees

Independent Clinical Trial or Independent Basic Experimental Studies with Humans Required

Key Consideration: Is the study itself applied (i.e., with a process or product in mind), or is the study looking to gain a fundamental understanding of a process that may have translational potential in the future?

- If the purpose of the study is to gain a fundamental understanding of a phenomenon, even if it is using an intervention or experimental manipulation as a probe to do this = Basic Experimental Studies with Humans (BESH) Required FOA.
  - Example: Findings from the study are used to understand a phenomenon, which may eventually (aspirational) be used to improve treatment options (BESH)
- If the purpose of the study is actually translational or applied with process in mind, and/or is focused on how the intervention or treatment produces its effects = Clinical Trial (CT) Required FOA.
  - Example: The findings from the study are designed to study how a treatment target can be modified.

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-19-033)

Increased 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:** Expect to see increasing attention directed toward this
- **Inclusion Across the Lifespan:** New policy requires justifying exclusion of potential study participants by age : https://grants.nih.gov/grants/funding/lifespan/lifespan.htm

AGENDA

- NIMH Budget for Fiscal 2020
- NIMH Strategic Plan Updates
- Priorities and Initiatives
- Geriatrics & Aging Processes Branch
- Future Directions for the Branch
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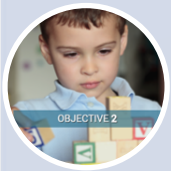
NIMH Structure

- 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

National Institute of Mental Health

Division of Translational Research (DTR)

Director: Sarah Hollingsworth Lisanby, MD
Acting 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 factors)
- Biomarkers, assessments, and phenotypic characterizations of late-life disorders
- Novel treatment development and approaches
- Predictors and mechanisms of variability in treatment response (esp. genetic and brain structure/function factors)
- Trajectories of course and resilience from mid to late life

Geriatrics and Aging Processes Research Branch: Programs

- Behavioral Science of Mental Disorders and Aging
- Neuroscience of Mental Disorders and Aging
- Psychosocial Intervention and Aging
- Pharmacologic and Somatic Intervention and Aging

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

Welcome New DTR AAAS Fellow – Elizabeth Necka, PhD

- PhD in Psychology from the University of Chicago
- She completed a Postdoctoral fellowship at NCCIH with Dr. Lauren Atlas in the Section on Affective Neuroscience and Pain
- Research interests: mechanisms underlying social influences on health, perception, and cognitive function, and psychophysiological regulation of social behavior
- Manages the Behavioral Science portfolio in the Geriatrics and Aging Processes Research Branch, explores interests across the division, and fosters the influence of science and robust research practices on public policy

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

Emotion Regulation, Aging and Mental Disorder

- PA-19-094 (R01)and PA-19-095 (R21)
- Aim: to stimulate mechanistic research on how aging-related changes in emotion processing over the adult life course interact with and may inform the understanding of affective dysregulation in adult mental disorders
- The branch maintains active interest in affective neuroscience research on emotion regulation; future announcements forthcoming.

Welcome New DTR Program Officer – Laura Rowland, PhD

- Joined DTR in November 2019 as Chief of the Neuroscience of Mental Disorders and Aging Program in the Geriatrics and Aging Processes Research Branch.
- Ph.D. in Experimental Psychology, Behavioral Neuroscience from the University of New Mexico. Postdoctoral Fellowship at the Maryland Psychiatric Research Center.
- Prior to DTR, she was a tenured Associate Professor at the University of Maryland School of Medicine, Department of Psychiatry and the Director of the Post-doctoral training program funded through the NIMH.
- Her research program integrated spectroscopic neurochemistry measures with functional paradigms, multimodal neuroimaging, and translational behavioral neuroscience to better understand learning mechanisms, clinical high-risk, aging/illness course, and novel treatments in schizophrenia and related disorders

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 support

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

- PAR-20-157(R01) and PAR-20-159(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

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

Encourage Innovation in Intervention Development

- Capitalize on basic science discoveries in formulating new intervention targets
- Foster collaborations between neuroscience and behavioral science in treatment development
- Identify and enhance mechanisms of change
- Develop new preventive as well as treatment interventions
- Support effectiveness as well as efficacy studies
- Produce practical information (findings applicable in current health care context)
- Emphasize research with potential to “change practice”
- Emphasize interventions with high likelihood of broad usage
- Expand range of outcomes assessed (e.g., not only symptoms, but also functioning, quality of life, use of other services, etc.)

Areas of Special Interest

- Refocusing traditional lines of research on all forms of mental disorder according to RDoC constructs; increasing attention to heterogeneity within any grouping
- Trajectories of chronic mental illnesses across the lifespan; pathways of influence of earlier life trauma
- Mechanisms underlying psychiatric and behavioral disturbances in late-life neurodegenerative disorders
- Long-term consequences of mental disorder (e.g., increased risk of dementia or premature mortality, accelerated biological aging)

NIMH FOAs that may be of Interest

- Effectiveness of Implementing Sustainable Evidence-Based Mental Health Practices in Low-Resource Settings to Achieve Mental Health Equity for Traditionally Underserved Populations (R01 Clinical Trial Optional) (RFA-MH-20-400)
- Implementing and Sustaining Evidence-Based Mental Health Practices in Low-Resource Settings to Achieve Equity in Outcomes (R34 Clinical Trial Required) (RFA-MH-20-401)
- Laboratories to Optimize Digital Health (R01 Clinical Trial Required) (RFA-MH-20-510)

Future Directions for the Branch

- The next generation of researchers
- Understanding molecular, cellular, and systems levels of brain function
- Aging biology and its relationship to mental illness
- Translation of science into practice
- Encouraging studies on underrepresented populations
- Implementation strategies
- Innovative partnerships, consortia, etc

Mailing Lists about NIMH and NIH-related News

- NIMH Website updates: www.nimh.nih.gov
- Inside NIMH (newsletter, 3X per year): http://www.nimh.nih.gov/site-info/listserv.jsp?listServName=INSIDE-NIMH-L
- NIMH Funding Opportunities: http://www.nimh.nih.gov/site-info/listserv.jsp?listServName=NIMHFUNDINGOPPS
- NIH Guide to Grants and Contracts: http://grants.nih.gov/grants/guide/index.html

Please Contact Program Staff

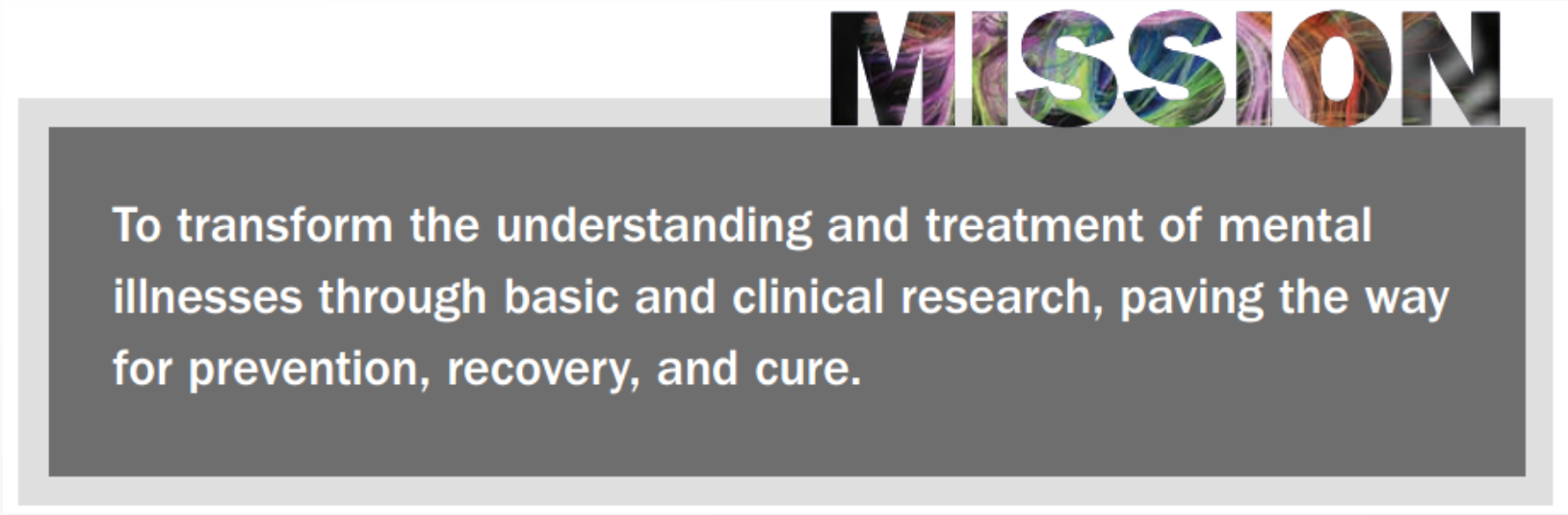
Contact us early… and often!

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

Questions

NIMH's Mission



www.nimh.nih.gov

Research = Hope