Update from the National Institute of Mental Health (NIMH)

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National Institute of Mental Health

Disclaimer

- I have no conflicts of interest, financial or otherwise, to disclose.
- The opinions expressed during this presentation are solely my own and do not necessarily reflect the views of NIH / NIMH, the Department of Health and Human Services, or the Federal Government.

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.

Strategic Plan Goals

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

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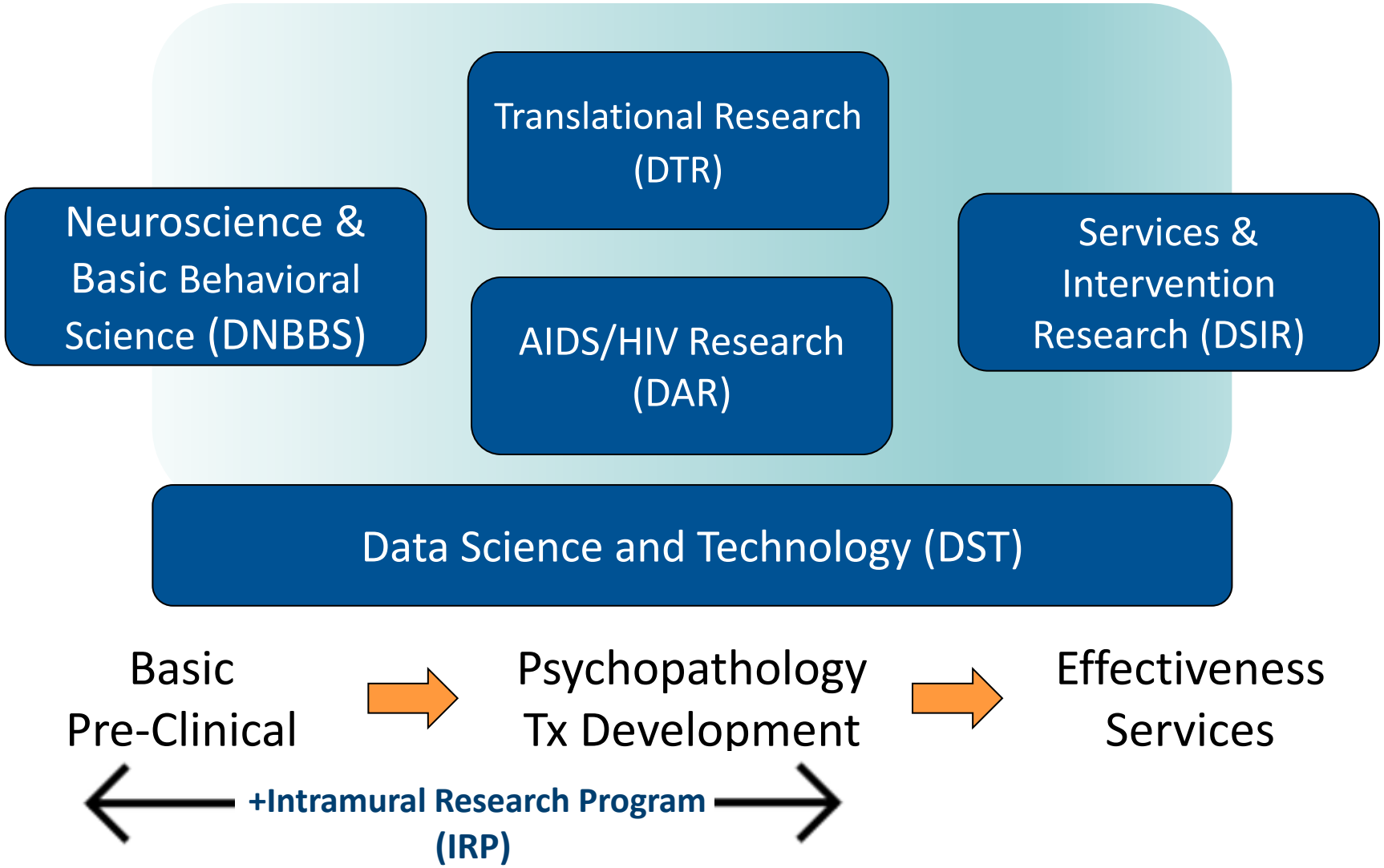
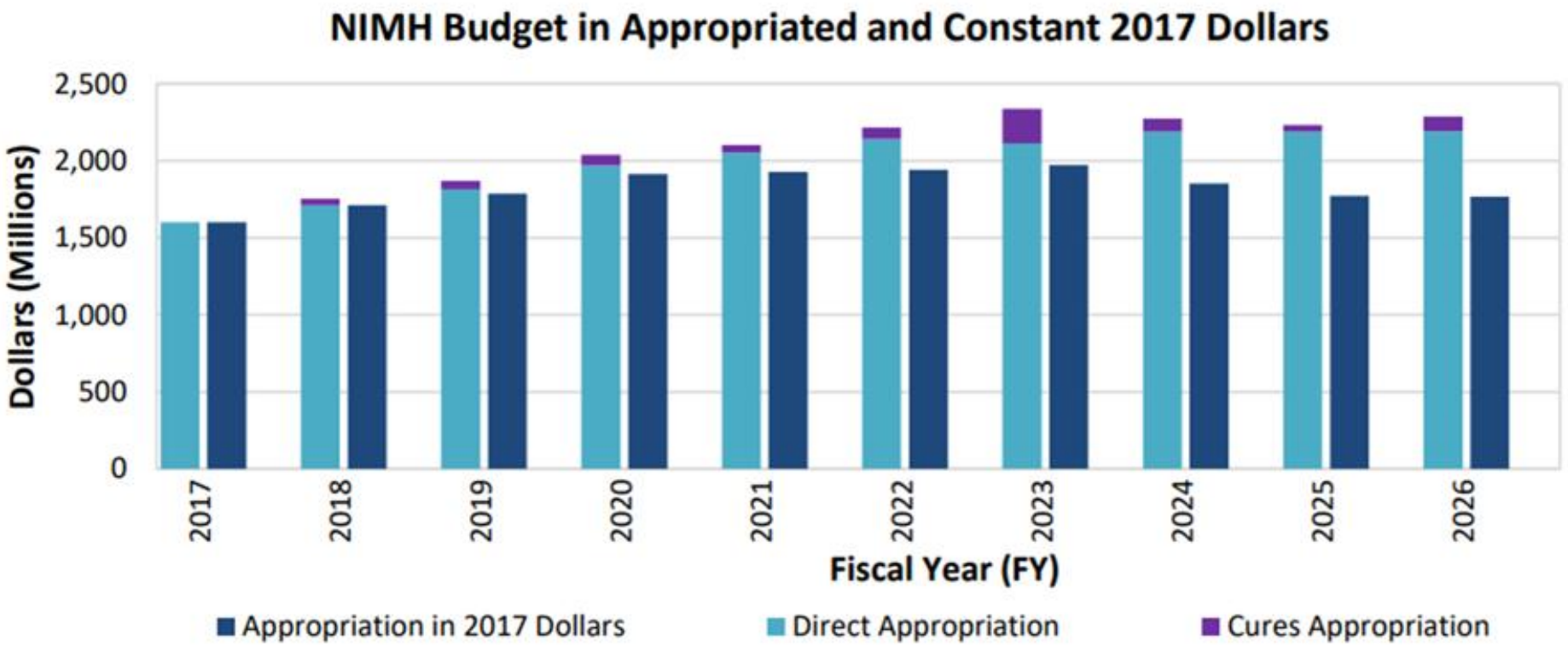
NIMH Extramural Scientific Divisions



NIMH Budget Update

NIMH's FY26 budget is nearly identical to NIMH's FY25 enacted budget except for the planned increase from the 21st Century Cures.



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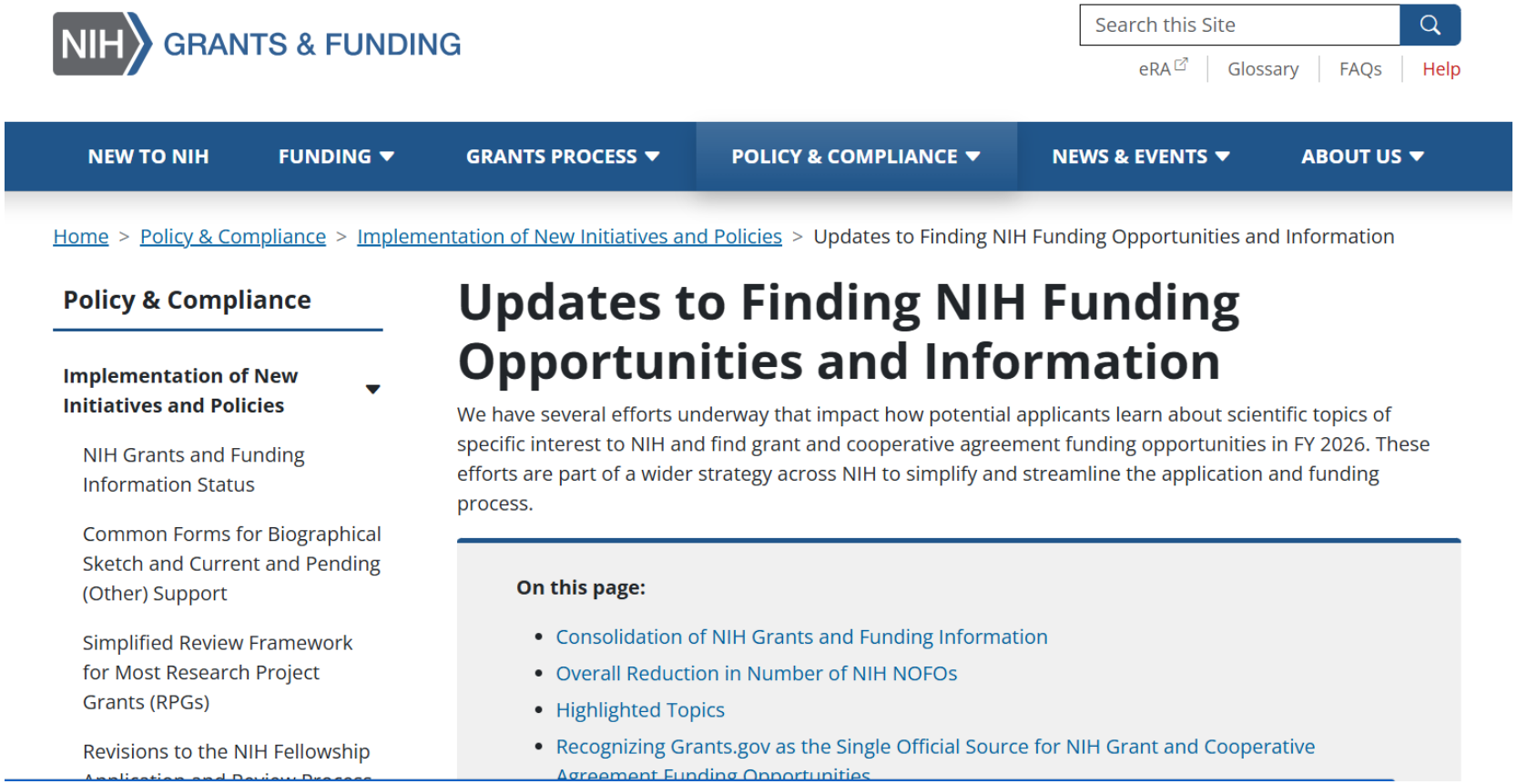
Major Changes in Funding Opportunities

- Consolidation of Information
- Reduction in Number of NIH NOFOs
- Highlighted Topics
- Grants.gov single official source for grant funding



 https://grants.nih.gov/policy-and-compliance/implementation-of-new-initiatives-and-policies/updates-to-finding-nih-funding-opportunities-and-information

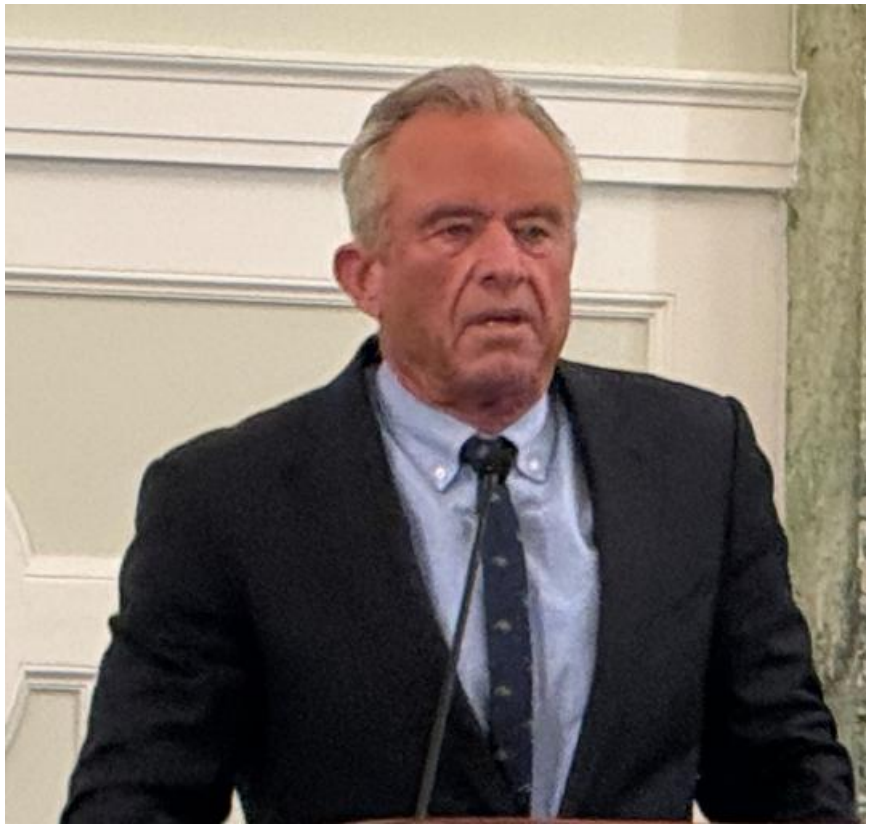
NIH Funding Opportunities

- Simplifying how the research community learns about NIH grants and funding processes
  - 

  - *https://simpler.grants.gov/*
  - Explore NIH Grant Opportunities tool: *grants.nih.gov/funding/explore-nih-opportunities*

 https://grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices/NIMH

Make America Healthy Again (MAHA)



Robert F. Kennedy, Jr., Secretary
Dep't of Health and Human Services

"Psychiatric medications have a role in care, but we will no longer treat them as the default, we will treat them as one option, to be used when appropriate, with full transparency and with a clear path off when they are no longer needed," Mr. Kennedy said at a Mental Health and Overmedicalization Summit organized by the MAHA Institute.

May 4, 2026

NIMH Clinical Trials

Clinical Trial Pipeline - Phase of Intervention Development

First in Human	Exploratory Experimental Therapeutics	Confirmatory Efficacy	Effectiveness/Implementation (Prevention, Treatment, Services Interventions)
First in Human and Early Stage Clinical Trials of Novel Investigational Drugs or Device-Based Interventions for Psychiatric Disorders (U01 - Clinical Trial Required)			Pilot Hybrid Effectiveness-Implementation Trials for Mental health Interventions (R01 – Clinical Trial Required)
	Early Stage Testing of Pharmacologic or Neuromodulatory Device-based Interventions for the Treatment of Mental Disorders (R33- Clinical Trial Required) (R61/R33-Clinical Trial Required)		Full-Scale Hybrid Effectiveness-Implementation Trials for Mental Health Interventions (R01 – Clinical Trial Required)
	Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders (R61/R33- Clinical Trial Required) and (R33 Clinical Trial Required)	Confirmatory Efficacy Clinical Trials of Non-Pharmacological and Pharmacological Interventions for Mental Disorders (R01 Clinical Trial Required)	Effectiveness Trials to Test Mental Health System Interventions (R61/R33 Clinical Trial Required)

Basic Experimental Studies Involving Humans (BESH)

https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/besh

https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml

Optimizing Treatment Strategies for Adult Attention-Deficit Hyperactivity Disorder (ADHD) (R01 Clinical Trial Required)

- *Funding Opportunity Number (FON):* **RFA-MH-26-195** [EXPIRED]
- This notice of funding opportunity (NOFO) seeks applications for clinical research to adapt, optimize and test empirically-supported non-stimulant pharmacological, device-based, and/or psychosocial interventions to augment or replace stimulant medication in the treatment of ADHD in adults when stimulant monotherapy has proven clinically insufficient, undesirable (e.g., due to adverse effects or concern about tolerance or dependence), or unavailable. Proposed clinical trials may include multiple treatments used in combination or sequentially in a stepped-care design.
- **Common for all Clinical Trial applications:** Consistent with the NIMH experimental therapeutics approach, this NOFO supports studies that not only test the intervention effects on outcomes of interest in real world settings, but also inform understanding of the intervention's mechanisms of action. As such, applications must include an assessment of target engagement …
- Proposed clinical trials research should fit an **effectiveness** model designed to test the therapeutic value of interventions for which there is already evidence of efficacy … for use in community and practice settings. Consistent with an effectiveness approach, NIMH encourages research studies that take place in generalizable community practice settings (i.e., outside academic laboratories or research clinics)…

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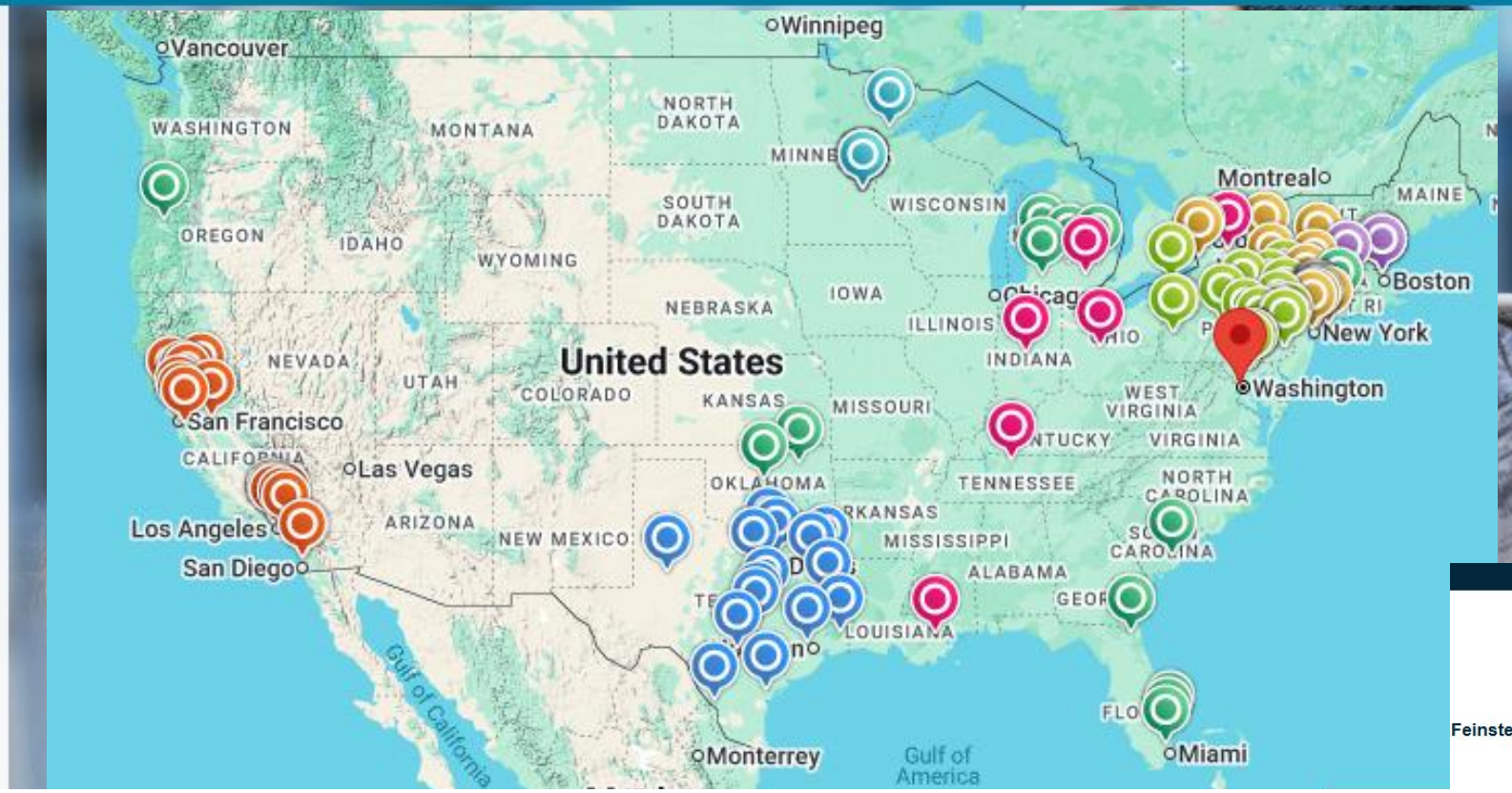
EPINET
Early Psychosis Intervention Network

Accelerating advances in early psychosis care, recovery outcomes, and scientific discovery through a national early psychosis learning health care partnership

ABOUT | CORE ASSESSMENT BATTERY (CAB) | RESOURCES | WEBCAB | CONTACT US | COMMUNITY PORTAL

Welcome

The Early Psychosis Intervention Network (EPINET) is a learning health care system for early psychosis. Initiated in 2019 and sponsored by the National Institute of Mental Health (NIMH), EPINET links early psychosis clinics through regional scientific hubs. The EPINET National Data Coordinating Center (ENDCC) supports the network with standardized data collection, data integration, and other networking opportunities.



LEAP

McLean Hospital
Belmont, MA
6 clinics

Connection LHS

University of Maryland
Baltimore, MD
22 clinics

ESPRITO2

ESPRITO2
Feinstein Institute for Medical Research
Manhasset, NY
12 clinics

AC-EPINET

INDIANA UNIVERSITY
PURDUE UNIVERSITY
INDIANAPOLIS
Indiana University – Purdue University of Indianapolis
Indianapolis, IN
6 clinics

Each of the Regional Hubs collaborates with multiple Coordinated Specialty Care (CSC) clinics. These clinics provide treatment and services to individuals with early psychosis. The Regional Hubs work with clinic staff to coordinate data collection and conduct research to improve health outcomes.

NIH

Core Assessment Battery (CAB)

- The **EPINET Core Assessment Battery (CAB),** collected at baseline and every 6 months, includes standardized measures and individual items that assess key domains of early psychosis psychopathology, recovery, contextual factors, and treatment.

CLIENT SELF-ADMINISTERED

Staying Well (Questionnaire about the Process of Recovery (QPR))

In each row, mark one box that best describes your experience over the last 7 days.

Your experience over the last 7 days	Disagree strongly	Disagree	Neither agree nor disagree	Agree	Agree strongly
1. I feel better about myself					
2. I feel able to take chances in life					
3. I am able to develop positive relationships with other people					
4. I feel part of society rather than isolated					
5. I am able to assert myself					
6. I feel that my life has a purpose					
7. My experiences have changed me for the better					
8. I have been able to come to terms with things that have happened to me in the past and move on with my life					
9. I am basically strongly motivated to get better					
10. I can recognize the positive things I have done					

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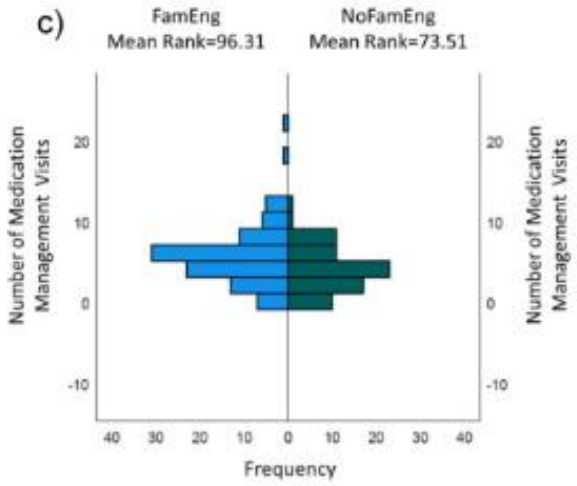
Demarais *et al. BMC Psychiatry* (2024) 24:686
https://doi.org/10.1186/s12888-024-06126-y

BMC Psychiatry

RESEARCH Open Access

Impact of family engagement on client participation in coordinated specialty care for first episodes of psychosis

Marielle Demarais[1*], Melissa Fisher[2], Anne Williams-Wengerd[3], Christie Alexandre[2], Piper Meyer-Kalos[2] and Sophia Vinogradov[2]



Using data from the Early Psychosis Intervention Network (EPINET) research hub in Minnesota (**EPI-MINN**), the Vinogradov investigators compared two groups of individuals: clients who had a family member(s) engaged in their treatment vs. clients who did not. Family engagement in any CSC treatment service was associated with a larger number of total visit attendance in the first six months of treatment, as well as increases to specific visit types, including **Medication Management** appointments.

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Non-pharmacologic interventions in SMI: Enhance physical health and cognition?

Schizophrenia Research 203 (2019) 24–31

Contents lists available at ScienceDirect

Schizophrenia Research

journal homepage: www.elsevier.com/locate/schres

Cognitive remediation can improve negative symptoms and social functioning in first-episode schizophrenia: A randomized controlled trial

Joseph Ventura [a,*], Kenneth L. Subotnik [a], Denise Gretchen-Doorly [a], Laurie Casaus [a], Michael Boucher [a], Alice Medalia [c], Morris D. Bell [d], Gerhard S. Hellemann [a], Keith H. Nuechterlein [a,b]

Browne *et al. BMC Psychiatry* (2024) 24:790
https://doi.org/10.1186/s12888-024-06250-9

BMC Psychiatry

The NEW ENGLAND JOURNAL of MEDICINE

CURRENT ISSUE SPECIALTIES TOPICS

ORIGINAL ARTICLE

A Behavioral Weight-Loss Intervention in Persons with Serious Mental Illness

Authors: Gail L. Daumit, M.D., M.H.S., Faith B. Dickerson, Ph.D., M.P.H., Nae-Yuh Wang, Ph.D., Arlene Dalcin, R.D., Gerald J. Jerome, Ph.D., Cheryl A.M. Anderson, Ph.D., Deborah R. Young, Ph.D., +10 , and Lawrence J. Appel, M.D., M.P.H. Author Info & Affiliations

Published April 25, 2013 | **N Engl J Med 2013;368:1594-1602** | **DOI: 10.1056/NEJMoa1214530** | **VOL. 368 NO. 17**

RESEARCH Open Access

Engagement in a virtual group-based walking intervention for persons with schizophrenia: a qualitative study

Julia Browne[1,2*], Claudio Battaglini[3], Aslihan Imamoglu[4], Bryan Stiles[4], L. Fredrik Jarskog[5], Paschal Sheeran[4], Ana M. Abrantes[2], Tonya Elliott[5], Oscar Gonzalez[4] and David L. Penn[5,6]

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Suicide Prevention Research remains a high priority for NIMH

Connecting Research and Practice: Implementation of Suicide Prevention Strategies in Learning Health Care Systems

Rebecca C. Rossom, M.D., M.S., Julie E. Richards, Ph.D., M.P.H., Stacy Sterling, Dr.P.H., M.S.W., Brian Ahmedani, Ph.D., L.M.S.W., Jennifer M. Boggs, Ph.D., Bobbi Jo H. Yarborough, Psy.D., Arne Beck, Ph.D., Karen Lloyd, Ph.D., Cathy Frank, M.D., Vincent Liu, M.D., M.S., Sam B. Clinch, M.D., Laura D. Patke, Psy.D., Greg E. Simon, M.D., M.P.H.

The health care systems affiliated with the Mental Health Research Network strive to be learning health care systems that identify and address evidence gaps of importance to clinicians, patients, and funders. This column describes how research guides clinical care and clinical care guides research in the area of suicide prevention as well as some of the challenges of conducting embedded research.

Psychiatric Services 2022; 73:219–222; doi: 10.1176/appi.ps.202000596

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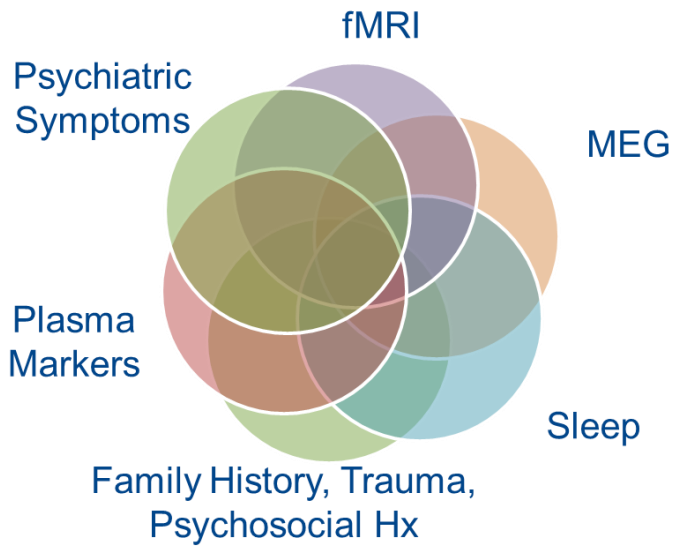
NIMH Intramural Research Program

Neurobiology of Suicide Protocol: Enrolling at NIMH Clinical Center

Multi-modal biomarkers of acute as compared to chronic suicide risk
Preliminary identification of biomarkers of suicide ideation (SI) response to ketamine



Evaluate markers of electrophysiological response to ketamine

- Recent NARSAD grant to Dr. Steve Lamontagne: *Neural correlates of chronic suicide risk: Examining effects of stress on neural oscillatory patterns and their modulation by ketamine*
- Recent NARSAD grant to Dr. Adam Fijtman: *A Study of Ketamine's Impact on Cognition and Magnetoencephalography Changes in Bipolar Depression*
- Recent paper on the role of suicide risk and aggression/impulsivity suggests that glutamatergic-mediated sensory and emotional regulation processes may underlie suicide risk (Lee et al., 2024).

OXFORD

Social Cognitive and Affective Neuroscience, 2024, 19(1), nsae041
DOI: https://doi.org/10.1093/scan/nsae041
Advance Access Publication Date: 14 June 2024
Original Research – Neuroscience

Potential association between suicide risk, aggression, impulsivity, and the somatosensory system

Yoojin Lee, Jessica R. Gilbert, Laura R. Waldman, Carlos A. Zarate Jr, and Elizabeth D. Ballard*

Experimental Therapeutics and Pathophysiology Branch, Intramural Research Program, National Institute of Mental Health, National Institutes of Health, Bethesda, MD 20892, United States
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Neuron
NeuroView

CellPress

Advancing Translational Research Using NIMH Research Domain Criteria and Computational Methods

Charles A. Sanislow,[1,2] Michele Ferrante,[3,4] Jennifer Pacheco,[3,5] Matthew V. Rudorfer,[6]
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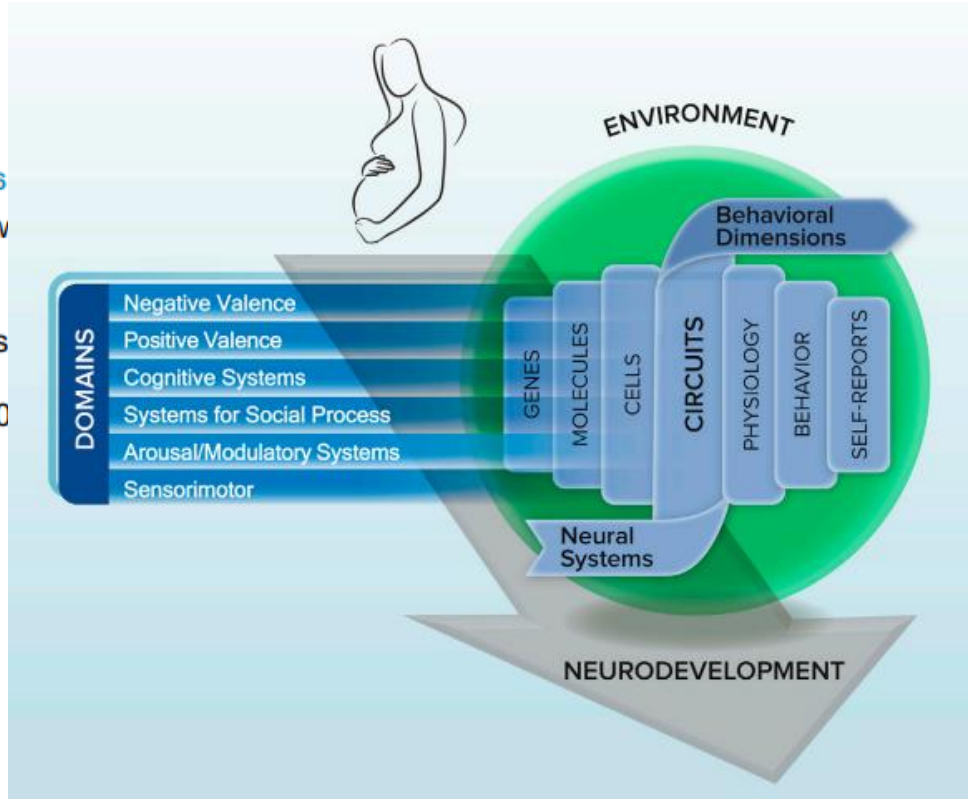
https://doi.org/10.1016/j.neuron.2019.02.024



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Expanding the reach of studied interventions

- *Live therapist via telehealth* (e.g., **BetterHelp**)
  - Prospective patients are matched with therapists for video, audio, and live chat sessions at a flat fee

- *Self-help via mobile app (e.g.,* **CBT-i Coach**, *targeting sleep problems, from the Dep't of Veterans Affairs)*

- *Integration with healthcare professionals (e.g.,* **LiveWell** *for bipolar disorder, developed with NIMH support)*
  - Self-monitoring and adaptive feedback, with live coaches and provider involvement as needed.

Title	Issuing Organization	Participating Organization(s)	Activity Codes	Release Date ▼	Expiration Date	Grants.gov Record
Addressing Methodological Challenges with Clinical Trials of Rapid-Acting Psychotropic Interventional Drugs (RAPIDs) (R01 Clinical Trial Required)	NIMH	NIDA	R01	April 29, 2026	October 12, 2026	RFA-MH-27-135

Purpose: The purpose of this notice of funding opportunity (NOFO) is to elucidate the key components of the therapeutic effects of rapid-acting psychotropic interventional drugs (RAPIDs) by addressing the methodological challenges involved with these clinical trials. In addition, this NOFO seeks to advance understanding of how RAPIDs and adjunctive psychosocial interventions can be optimally delivered, monitored, and sustained over time to enhance effectiveness and generalizability. The NOFO will support studies designed to enhance the rigor of RAPID clinical trial design, which will ultimately increase the interpretability of the data and the generalizability of the results.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
October 10, 2026	Not Applicable	Not Applicable	March 2027	May 2027	July 2027

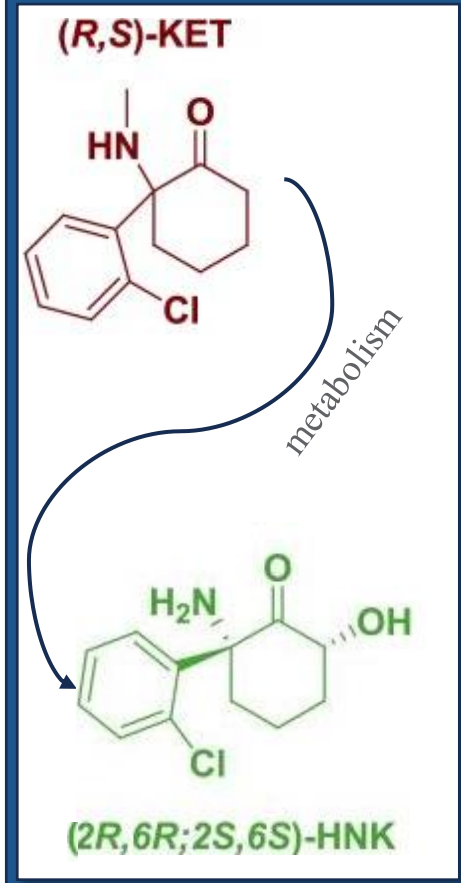
NIMH Intramural Research Program

(2*R*,6*R*)-HNK for Treatment-Resistant Depression

Ongoing NIH placebo-controlled crossover trial

National Institutes of Health

Why (2*R*,6*R*)-hydroxynorketamine?

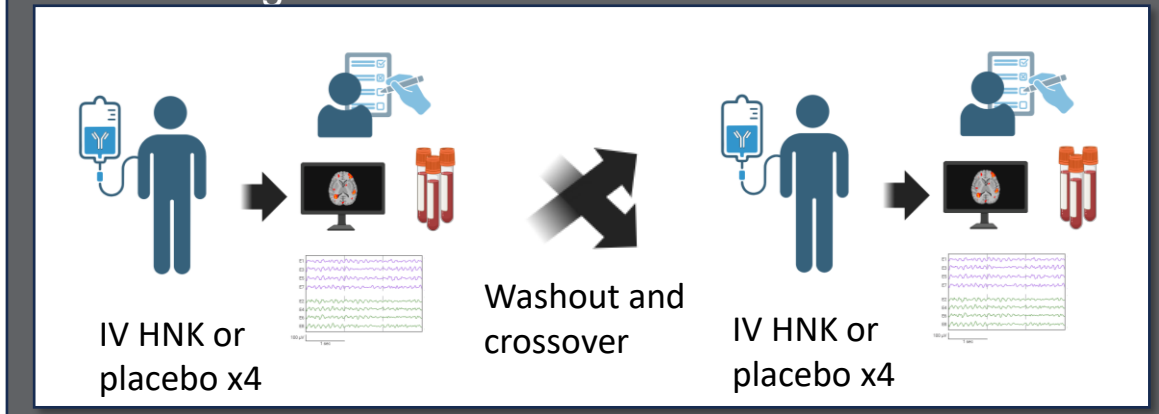


- Long-lasting metabolite of ketamine
- Strong rapid efficacy in multiple rodent models of depression/anhedonia
- Does not exhibit ketamine-like dissociation, locomotor activation, abuse potential, or NMDAR-mediated adverse effects
- Novel NMDAR-independent glutamate-based rapid antidepressant potential

Phase IIa Crossover RCT

Treatment-resistant depression participants (ages 18-70)

- N=50 target enrollment



- Single ascending doses: 0.25-2.0 mg/kg as tolerated
- Outcomes: Depression, Suicidal Ideation, Anxiety, Anhedonia, MEG, fMRI, peripheral blood biomarkers, safety and tolerability
- Duration: 7-14 weeks total

Currently recruiting NCT06511908
NIMH, NIH Clinical Center, Bethesda, MD, USA
PI: Zarate, Lead AI: Kvarta

NIMH-supported clinical trials: Studies in progress

- Ongoing clinical trials: ***Appropriate for future "stepped-care" or combination-treatment studies with pharmacotherapy?***
  - ➢ Randomized effectiveness-implementation trial of an asynchronous texting version of Cognitive Processing Therapy (CPT) for PTSD on the **Talkspace** platform.
  - ➢ **fMRI-based Neurofeedback** for Major Depression, aimed at normalizing low amygdala activity at baseline
  - ➢ **Resistance exercise** for depression, complementing positive findings from aerobic exercise

- A multisite trial of depression treatment is underway, using **Automated Self-Association Training (ASAT)**, a 20-minute twice-daily automated task, pairing positive self-referential words and images. This follows an initial series of intravenous ketamine infusions, which serve to temporarily increase neural plasticity, allowing the automated training to efficiently rewire negative self-associations into positive ones.