



Sexual & Gender Minority Research at NIH: Past, Present, and Future Directions

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(Pronouns: She, Her)

Director, Sexual & Gender Minority Research Office

Division of Program Coordination, Planning & Strategic Initiatives

September 3, 2020

Overview of Presentation

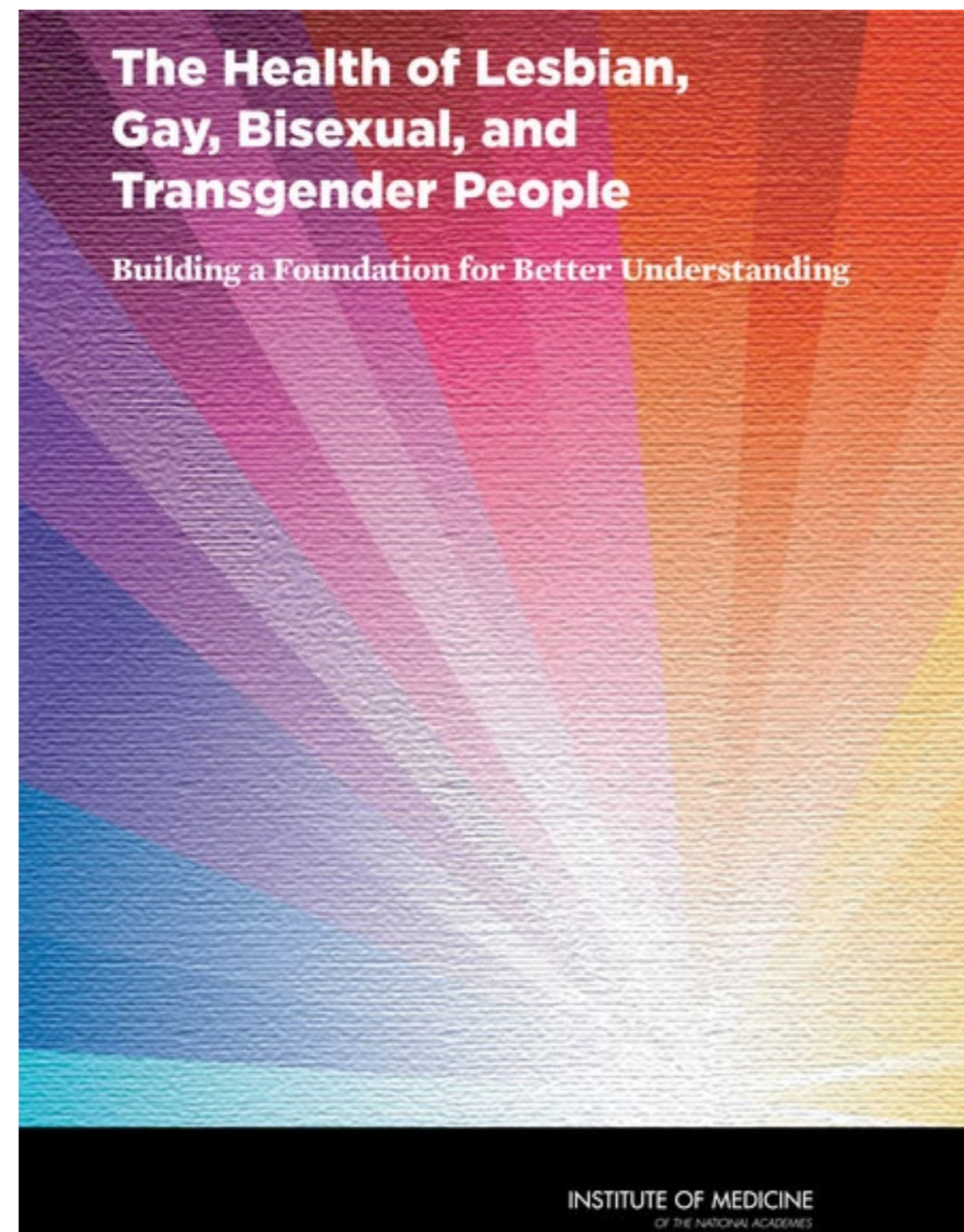
- Development of SGMRO
- NIH SGM Research Strategic Plan
- NIH SGM Grants Portfolio
- Looking Ahead





Development of the SGMRO


The Health of Lesbian, Gay, Bisexual, and Transgender (LGBT) People: Building a Foundation for Better Understanding




- Commissioned by NIH in 2009, published in 2011
- Broad NIH support
- Includes an extensive literature review of existing research on LGBT health
- First-ever comprehensive report on LGBT health

NIH Definition of SGM

“Sexual and gender minority (SGM) populations include, but are not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, Two-Spirit, queer, and/or intersex. Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex.”



SGM as a Health Disparity Population

- In October 2016, NIMHD announced SGM as an officially designated health disparity population for NIH
 - This designation has since facilitated the creation of tailored research projects, programs, and activities intended to tackle the distinct issues encountered by SGM individuals
 - Ascertainment of SGM status in ongoing and planned population studies have been enhanced
- 

SGMRO Establishment

- Created in 2015
- Within the Division of Program Coordination, Planning, and Strategic Initiatives
- Established as a part of NIH's response to the 2011 Institute of Medicine Report on LGBT Health Research



National Institutes of Health

Sexual & Gender Minority Research Office

SGMRO— What We Do

- **Coordinate** sexual and gender minority (SGM) health research activities across NIH
 - **Represent** NIH at conferences and events focused on SGM research
 - **Serve** as a resource for the extramural and NIH communities about SGM-related research activities
 - **Connect** extramural researchers with key NIH contacts
 - **Convene** conferences and workshops to inform priority setting and research activities
 - **Collaborate** with NIH Institutes and Centers on the development of SGM health research reports
 - **Manage** information dissemination related to SGM research
 - **Leverage** resources and develop initiatives to support SGM health research
- 

SGMRO— How We Accomplish Our Goals

- Sexual & Gender Minority Research **Coordinating Committee (SGM RCC)**: representatives from across the Institutes and Centers
- Sexual & Gender Minority Research **Working Group (SGM RWG)**: representatives from extramural institutions; reports to the Council of Councils





Sexual & Gender Minority Research Strategic Plan & Progress to Date

NIH SGM Strategic Plan

- Focuses on FY 2016- FY 2020
- Includes activities across the agency (not just the SGMRO)
- Serves as a blueprint for SGMRO priorities and collaborations



NIH SGM Strategic Plan



Goal 1: Expand the Knowledge Base of SGM Health and Well-being Through NIH-Supported Research



Goal 2: Remove Barriers to Planning, Conducting, and Reporting NIH-Supported Research about SGM Health and Wellbeing

NIH SGM Strategic Plan

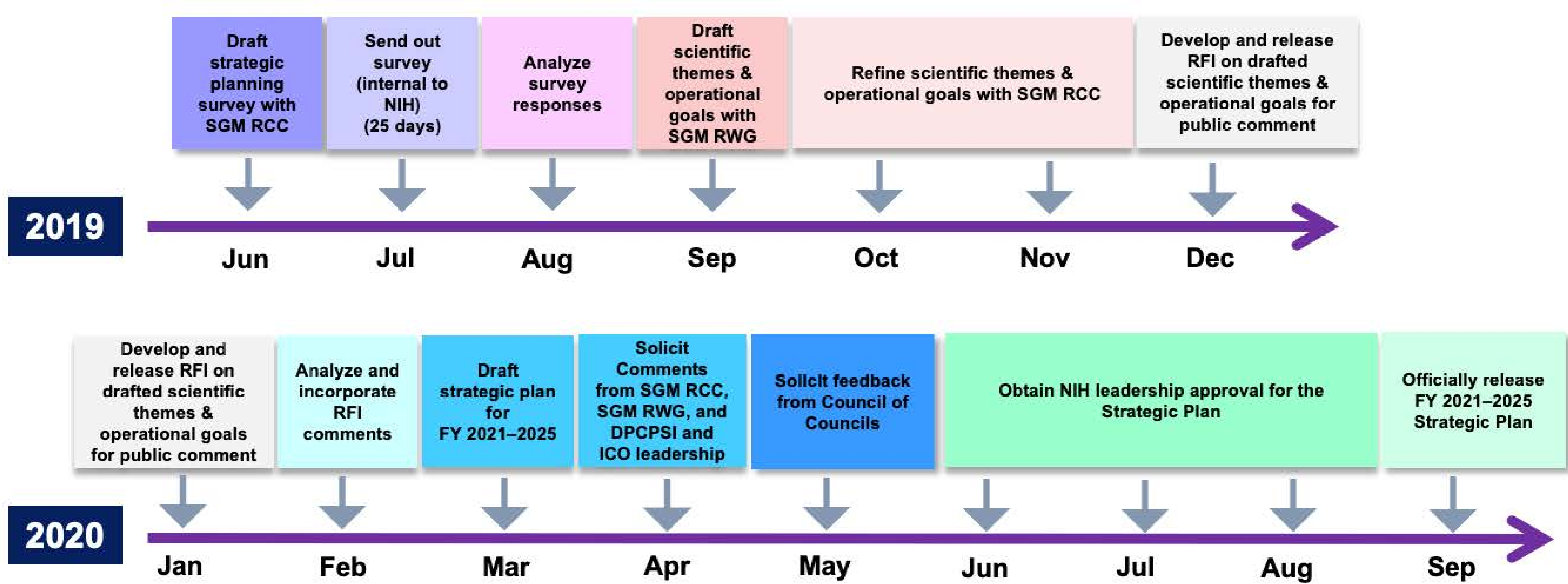


Goal 3: Strengthen the Community of Researchers and Scholars Who Conduct Research Relevant to SGM Health and Wellbeing



Goal 4: Evaluate Progress on Advancing SGM Research

Overview of FY 2021-2025 SGM Strategic Plan Timeline

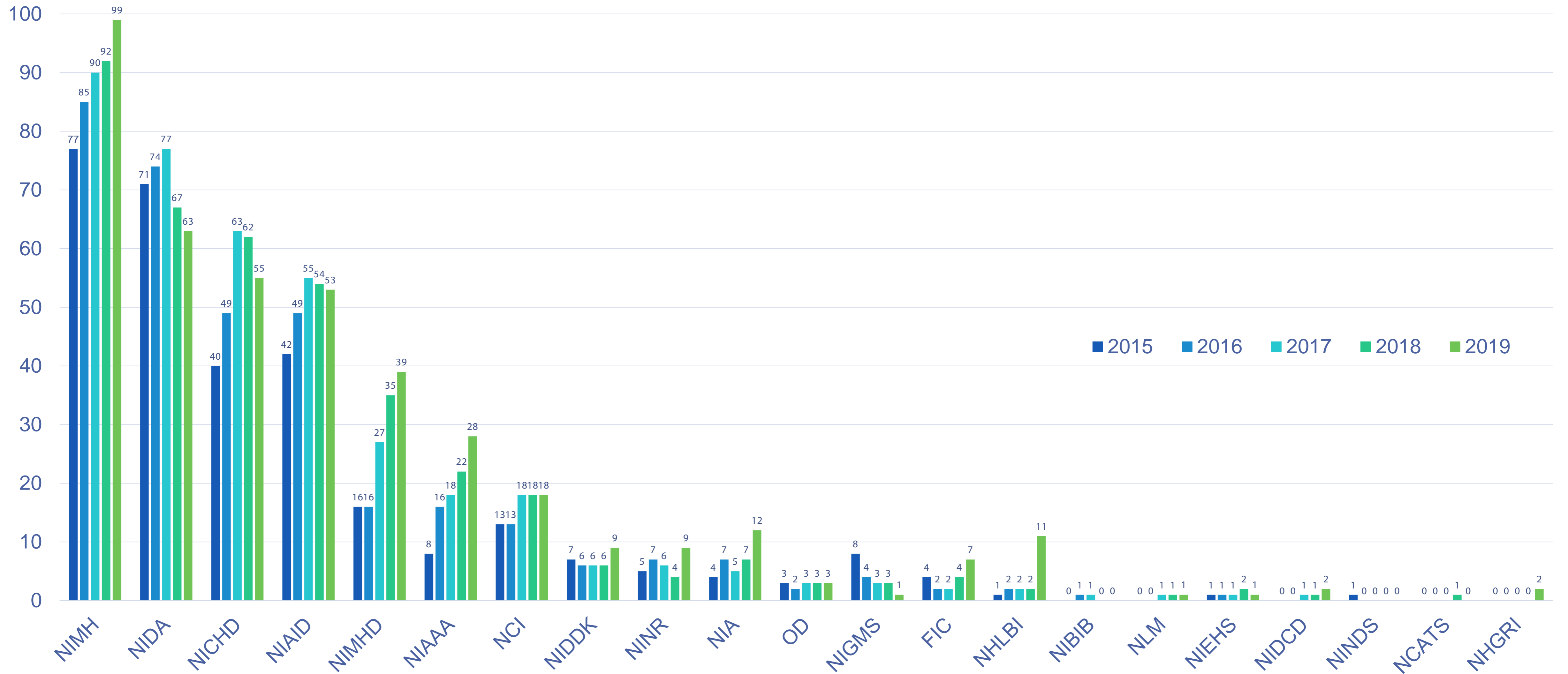


NIH SGM Grants Portfolio



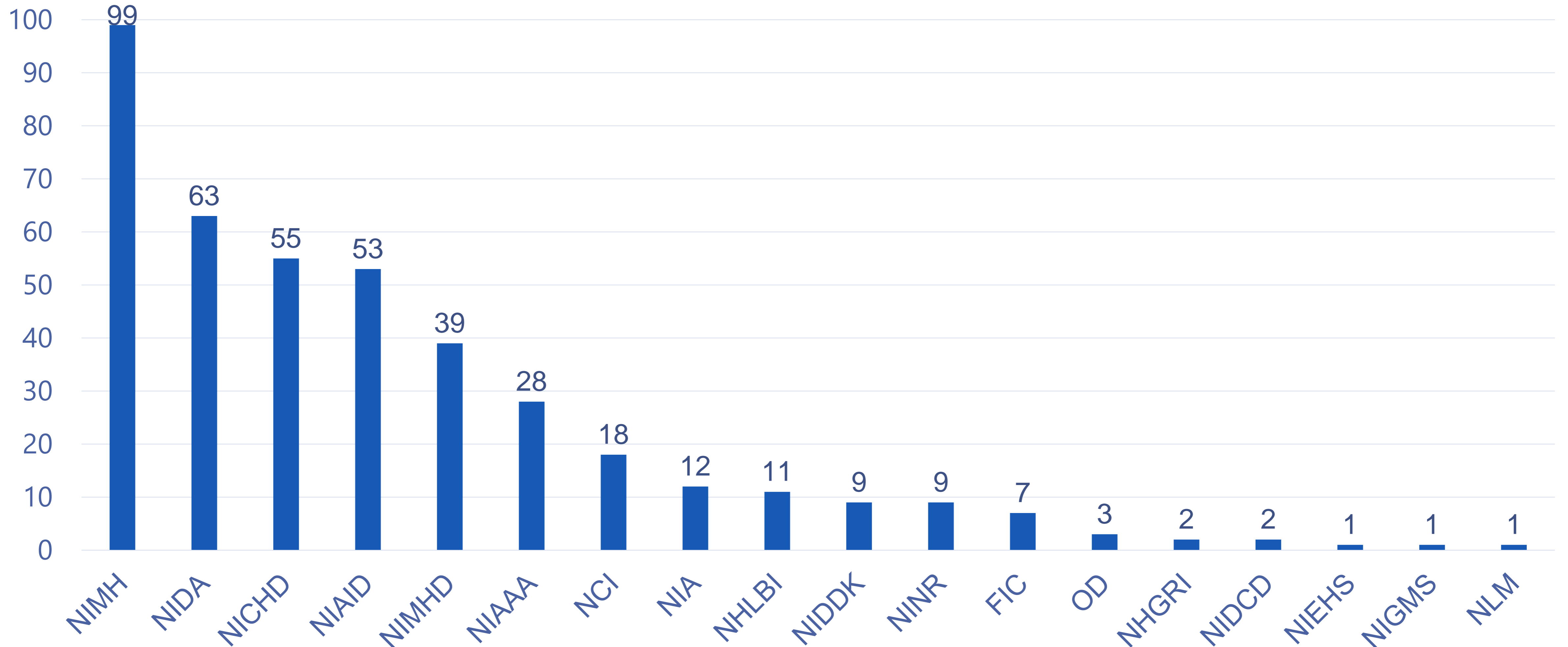
Number of SGM-Related Projects by NIH Institute/Center/Office (FY 2015 -2019)

(FY 2015 N = 301, FY 2016 N = 334, FY 2017 N = 379, FY 2018 N = 384, FY 2019 N = 413)



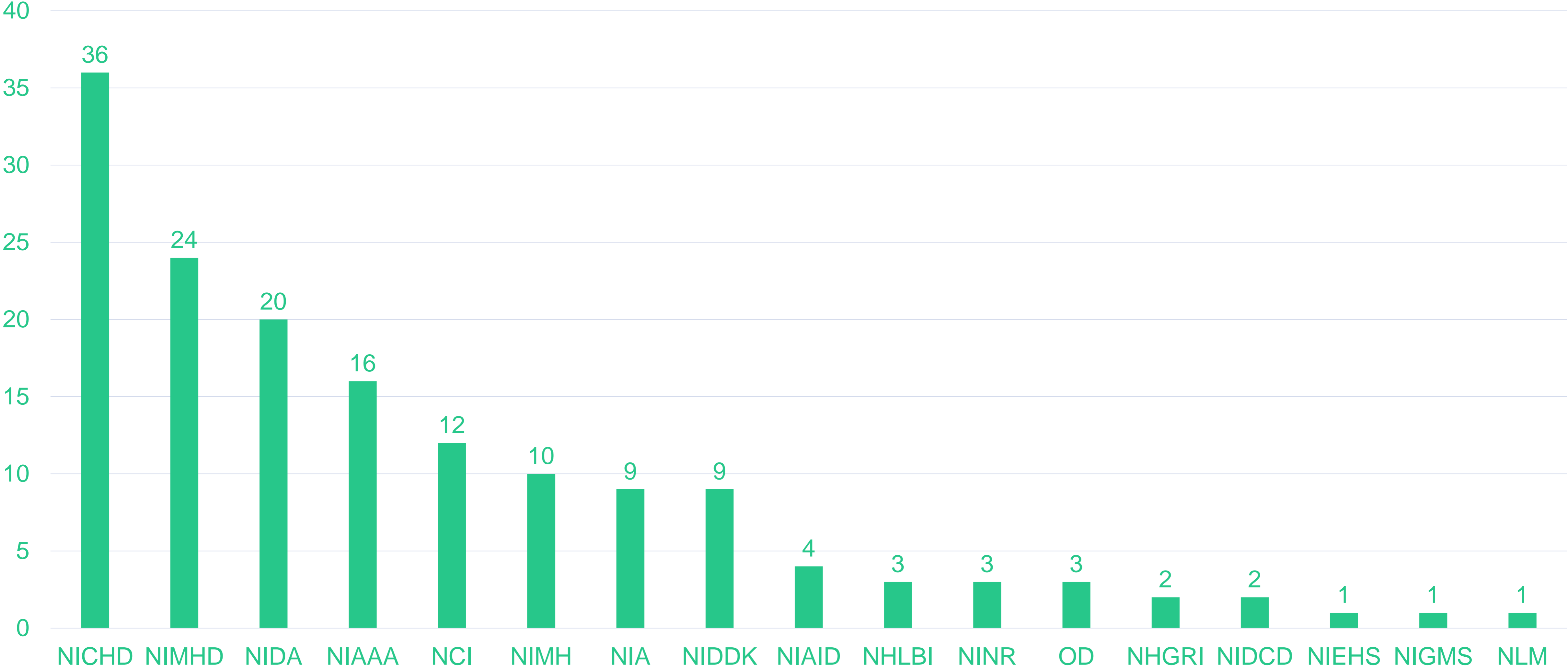
Number of SGM-Related Projects by NIH Institute/Center/Office (FY 2019)

(N = 413)



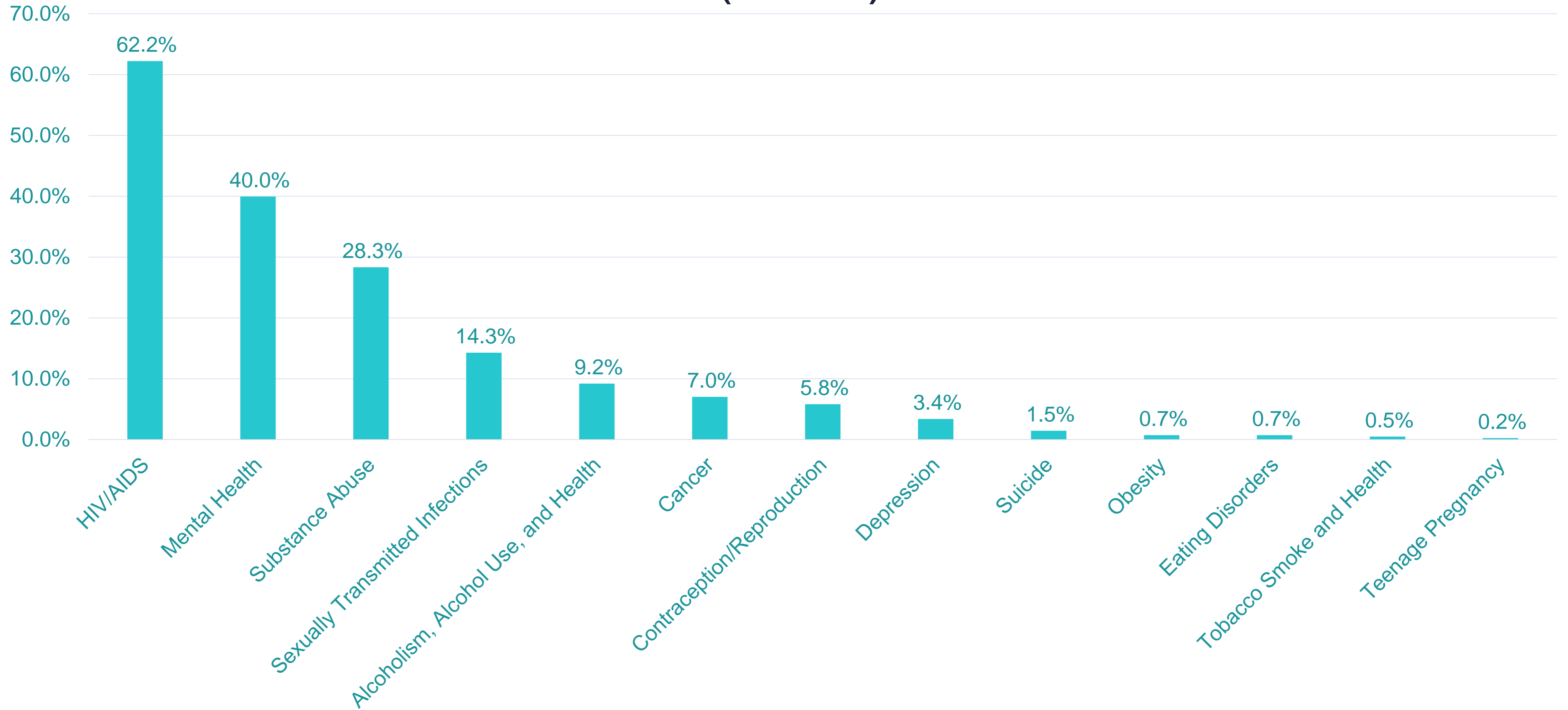
Number of Non-HIV/AIDS-Related SGM-Relevant Projects by NIH Institute/Center/Office (FY 2019)

(N = 156)



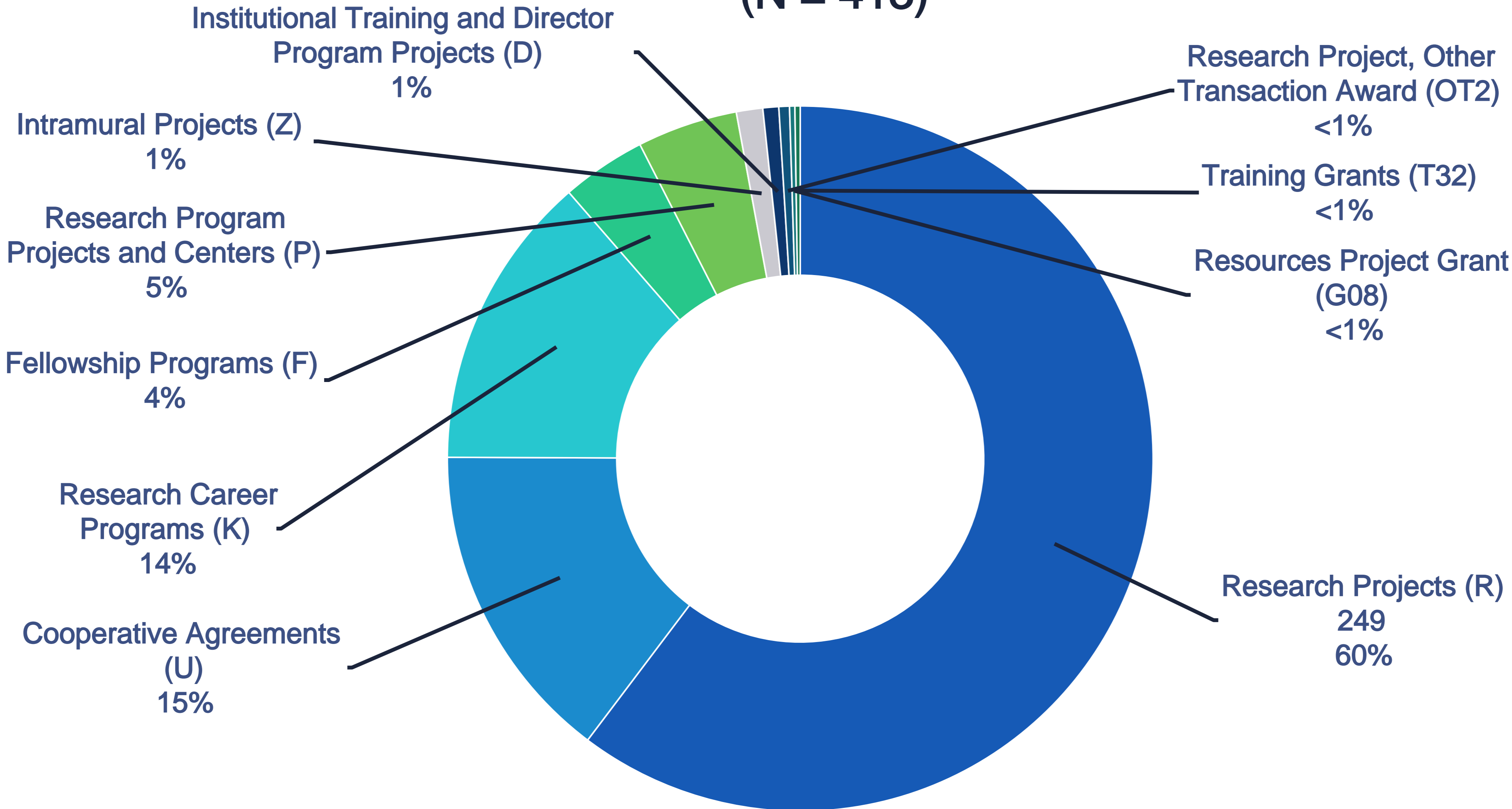
Proportion of SGM-Relevant Projects by Disease Area/Health Condition (FY 2019)

(N = 413)



Proportion of SGM-Related Projects by NIH Grant Type (FY 2019)

(N = 413)





Looking Ahead

Future Plans: 2020 and Beyond



- SGM Research Symposium and Investigator Awards Program (September 17)
- Strategic Plan (FY21-FY25)
- Scientific Webinar Series (TBD Mid-October)
- Listening Session (October 28)

Thank You!

Any Questions?



Visit the SGMRO website at
<https://dpcpsi.nih.gov/sgmro>
to join our listserv!





NIH Grantspersonship Overview: NIH Tools & Resources

Susannah Allison, PhD

Training Director & Program Officer
Division of AIDS Research & Center for Global
Mental Health Research
NIMH/NIH

Sept 3, 2020

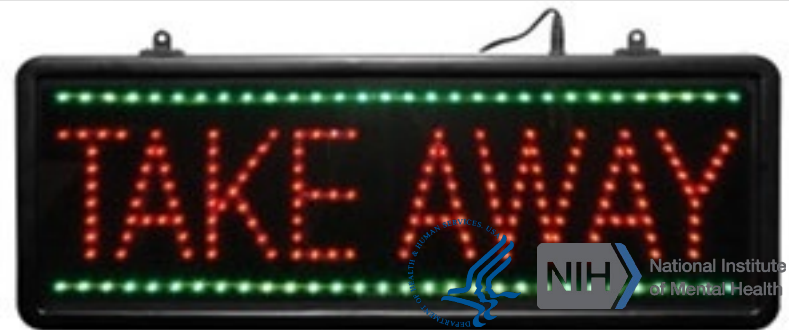


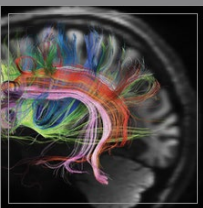
Take home points

E-mail!

✓ Contact Program Staff early!

- ✓ Review Institute/Center priorities and goals ... *each has different research training and career development programs*
- ✓ Learn the NIH application and review process
- ✓ Identify the specific grant programs offered by each Institute/Center ... *see NIH Guide for Grants and Contracts or research training website*
- ✓ Make early contact with program officers
- ✓ Find innovative, well-respected mentors and collaborators
- ✓ Study successful grant applications





Overview of NIH



National Institute
of Mental Health

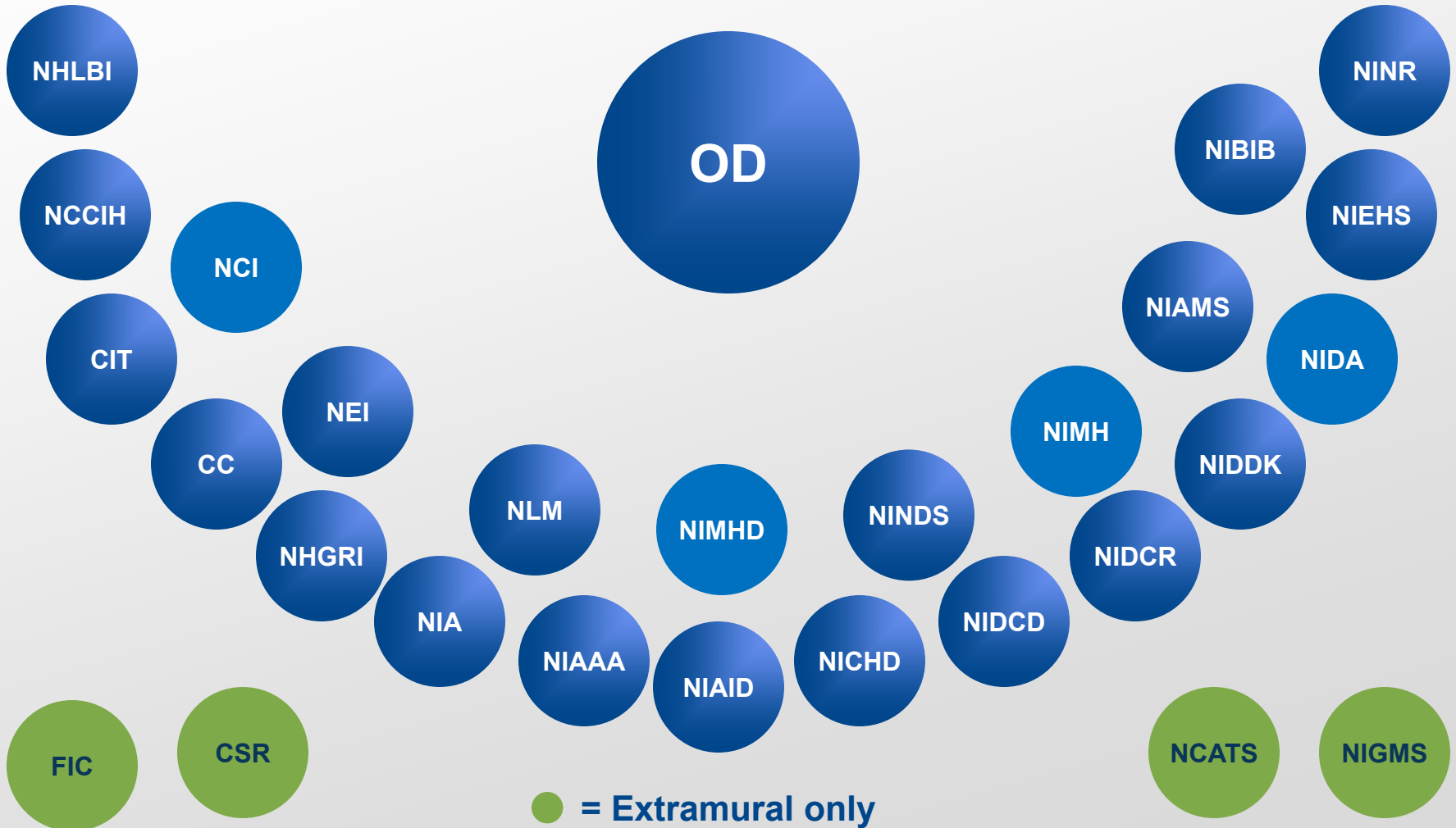
National Institutes of Health

The mission of the NIH is to uncover new knowledge that will lead to better health for everyone by:

- conducting research in its own laboratories (**intramural**)
- providing support for research conducted by scientists in universities, medical schools, hospitals, and other research institutions throughout the country and abroad (**extramural**)
- training research investigators
- fostering the communication of medical information



NIH consists of 27 Institutes and Centers





Overview of the Application Submission Process



National Institute
of Mental Health

Brief Overview of Grant Process



Program Staff



Department of Health and Human Services
Part 1. Overview Information
National Institutes of Health (NIH)
Funding Opportunity Title
NIH Pathway to Independence Award (Parent K99/R00)
PA-16-193

FOA

Application



NIH

CSR

Feedback & Revision



Study Section and Council Review

Award

Institute/Center



Finding Funding Opportunities

HOME

ABOUT GRANTS

FUNDING

POLICY & COMPLIANCE

NEWS & EVENTS

ABOUT OER

CORONAVIRUS DISEASE 2019 (COVID-19) Information for Grantees & Recipients



How to Apply



Find Funding



Funded Research
(RePORT)



Open Mike Blog



News

ABOUT GRANTS

Navigate the NIH grants process.

- Grants Process Overview
- Get Started
- How to Apply
- Application Referral and Review
- Pre-Award and Post-Award Processes
- Forms Library

POLICY & COMPLIANCE

Learn about obligations of your grant award.

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance and Oversight
- Select Policy Topics

INFORMATION FOR...

Find key resources just for you.

- Researchers
- Research Administrators
- Reviewers
- Small Businesses
- Foreign Applicants
- Media and the Public
- NIH Staff

LEARN MORE



Types of Funding Opportunity Announcements (FOAs)

All are **Funding Opportunity Announcements (FOAs)** = A publicly available document by which a Federal agency makes known its intentions to award discretionary grants or cooperative agreements

■ Parent Program Announcement

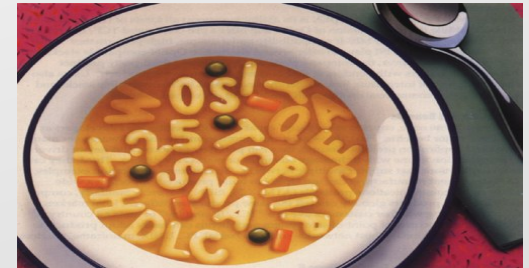
- Broad FOAs (e.g., Parent R01, K01, etc.)
- Generally for “investigator-initiated” or “unsolicited” applications
- Usually active for 3 years
- Uses standard receipt dates

■ Program Announcement (PA)

- Identify an area of scientific interest
- PAR: a PA with special receipt, referral, and/or review considerations

■ Request for Application (RFA)

- Identify a more narrowly defined priority area
- Usually has a single receipt date
- Set aside funds and anticipated number of awards
- Usually reviewed by special review panel convened specifically for the RFA



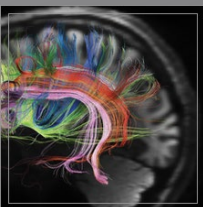
Enjoy the alphabet soup!!



New Direction- Notices of Special Interest (NOSIs)

- NIH Institutes and Centers are increasingly using [Notices of Special Interest](#) as an alternative to issuing or reissuing non-parent program announcements (PAs)
- **PAs** will be limited to parent announcements (e.g., Parent K01, Parent R21, etc.)
- **Notices** will list areas of scientific interest and point to the funding opportunity announcements applicants can use to apply
- NIH will continue to use other types of FOAs (e.g., RFAs, PARs, and PASs)
- Existing non-parent PAs will remain active until their expiration dates
- Enter the NOSI number in the Agency Routing Identifier field (box 4B) of the SF424 R&R form

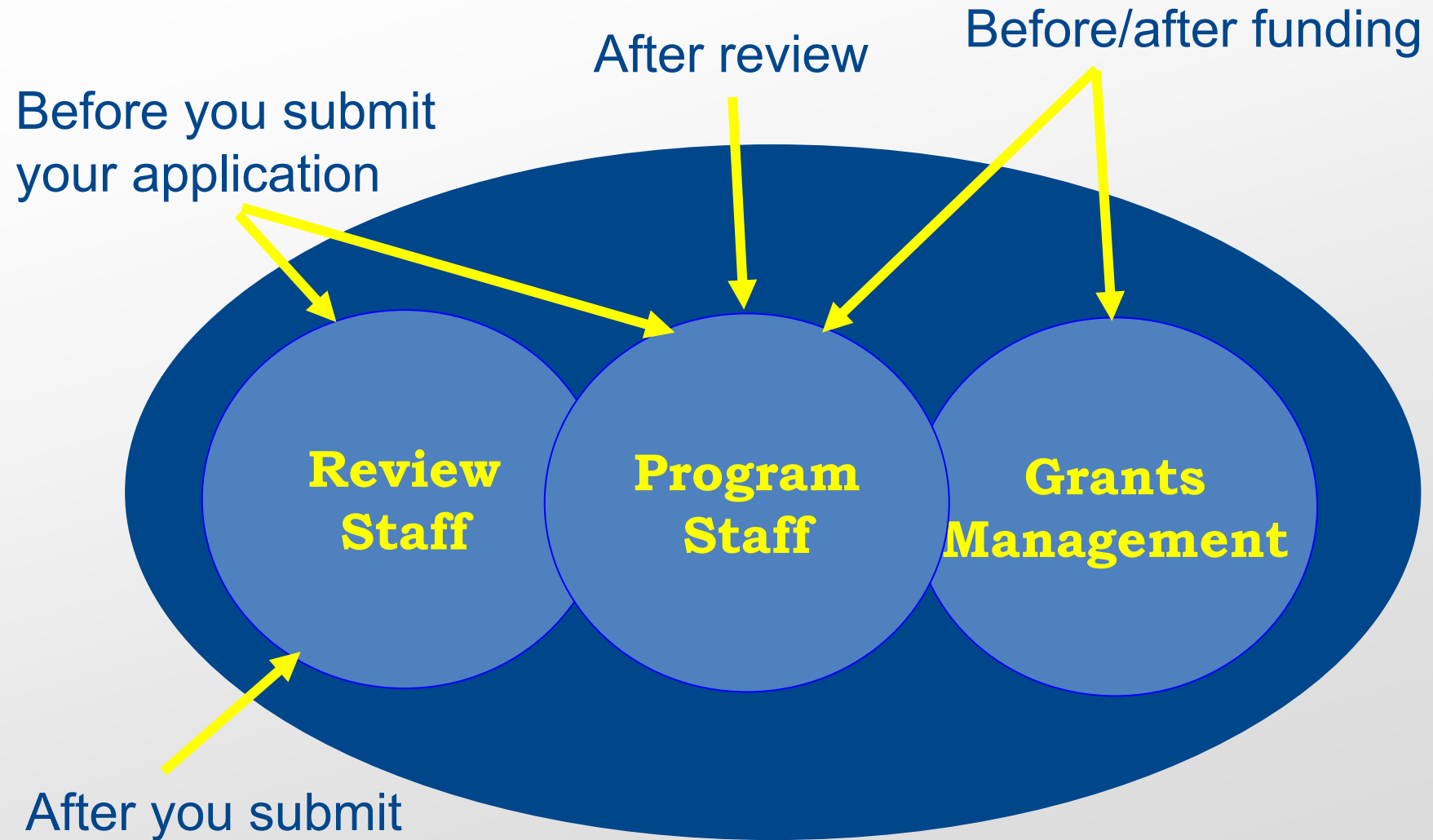




NIH Staff



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of Mental Health



Finding the Right Staff Contacts

- **FOAs** include contact names for program, review and grants management staff.
- **Institute websites** have org charts or contact lists so to help you find a name. www.nih.gov
- **RePORTER** provides the NIH program official's name for funded projects. projectreporter.nih.gov (Demo)
 - **Matchmaker** – a relatively new tool to find a PO
- Use the **NIH Staff Directory** if you already have a name ned.nih.gov
- [Contacting Staff at NIH ICs](#)



Program Officers can help you determine...

- The **relevance** of a research concept to an **Institute/Center's** mission and priorities
- The **best research mechanism** for your project (R01, R21, R34, K awards, etc.)
- The Funding Opportunity Announcement (**FOAs**: PAs, RFAs, etc.) under which to submit – including whether it meets the [NIH definition of a clinical trial](#) (Decision Tool)
- The **Study Section** or group to which the application would likely be assigned for review





More on NIH Grant Mechanisms



National Institute
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Types of Grant Funding Mechanisms

F = Fellowships

G = Resource programs

K = Research Career

P = Research Program Projects & Centers

R = Research Projects

S = Research-related

T = Training Programs

U = Cooperative Agreements



NIMH Supported Training Across Career Stages

Graduate/Medical Student

Dissertation Grant: R36

NRSA Fellowships: F30, F31

● Institutional Training Grant: T32

Research Residency (MDs): R25

Diversity Supplements

Early Career Faculty

K-Awards: K01, K08, K23

● Research Education Grant: R25

Diversity Supplements

Loan Repayment Program

Post-Doctoral Fellow

● NRSA Fellowship: F32

K-Awards: K99/R00

Institutional Training Grant: T32

Research Education Grant: R25

Diversity Supplements

Loan Repayment Program

3 Funding Pathways

1. Individual NIMH Awards
(R36, F, K)

2. Institutional NIMH training
awards (T32, R25)

3. Administrative supplement
to a mentor's NIMH grant



NIH Research Training Website

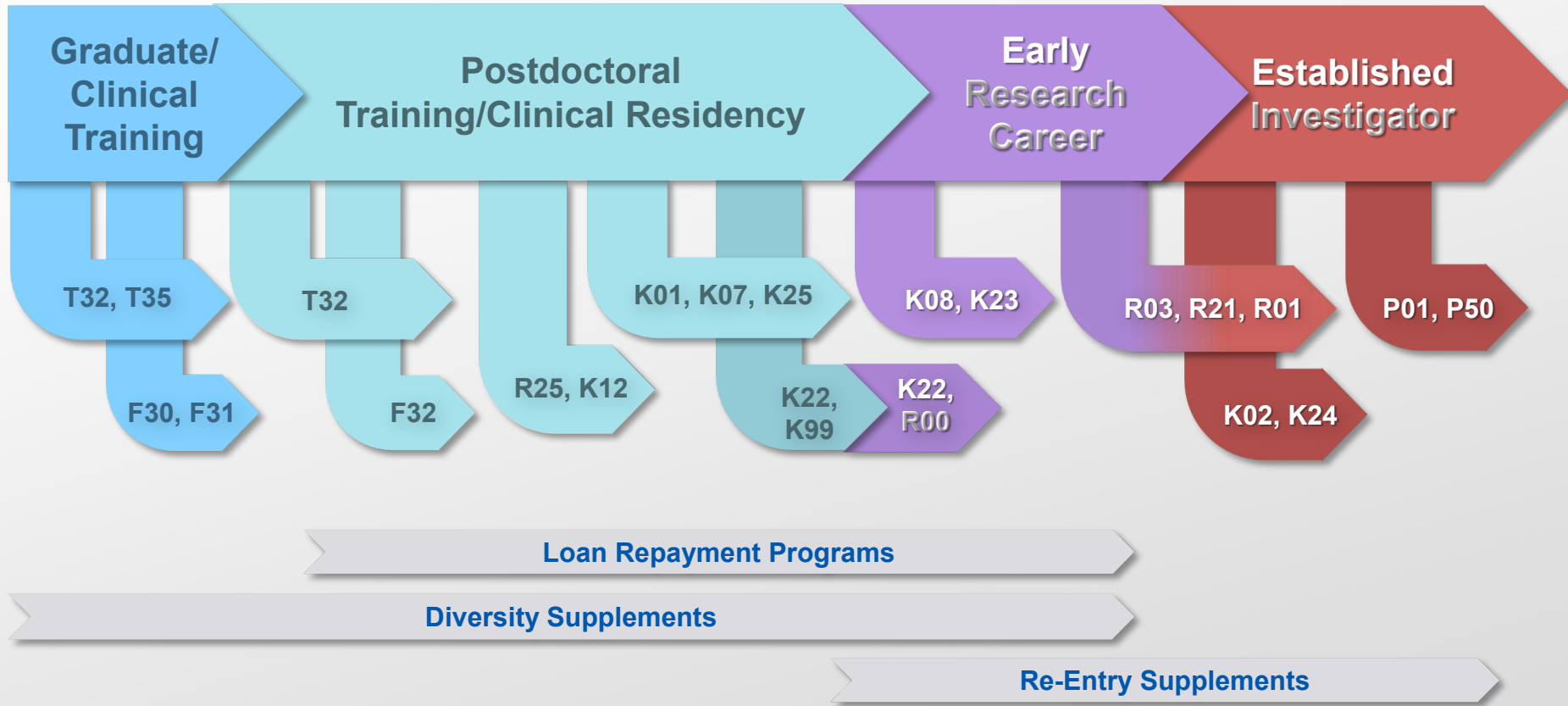
<https://researchtraining.nih.gov>

- Launched in 2015, one stop for funding opportunities
- Useful resource for trainees and early stage faculty
- Modifications and integration with new DBRW website in progress

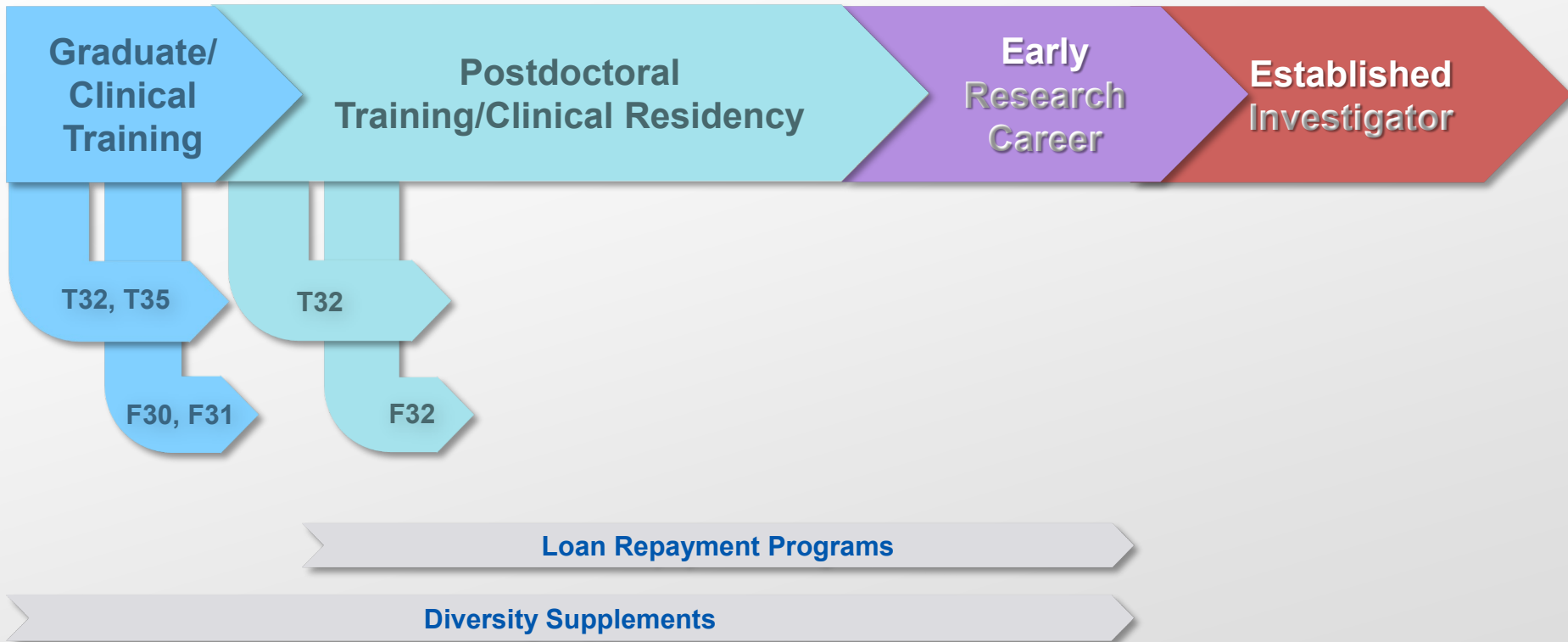
The screenshot shows the homepage of the NIH Research Training Website. At the top right, it says "Division of Biomedical Research Workforce". The NIH logo is on the left, with the text "National Institutes of Health" and "Research Training and Career Development" below it. A search bar with the word "SEARCH" and a magnifying glass icon is on the right. Below the search bar, there are links for "Intramural" and "Contact Us". A blue navigation bar contains the following menu items: "About DBRW", "Career Path", "Programs", "Institute/Program Matrix", and "Resources". The main content area features a large banner with the text "NIH programs help to prepare the skilled, creative and diverse biomedical research workforce of tomorrow". To the right of the text is a circular image of a laboratory with scientists working. Below the banner is a horizontal flowchart with five colored boxes representing career stages: "Undergraduate and Postbaccalaureate Education" (green), "Predoctoral Training/Clinical Doctorate" (blue), "Postdoctoral Training/Clinical Residency" (teal), "Early Research Career Development" (purple), and "Investigator Development and Mentoring" (red).



Career Path Funding Options



Predoctoral and Early Postdoctoral Training

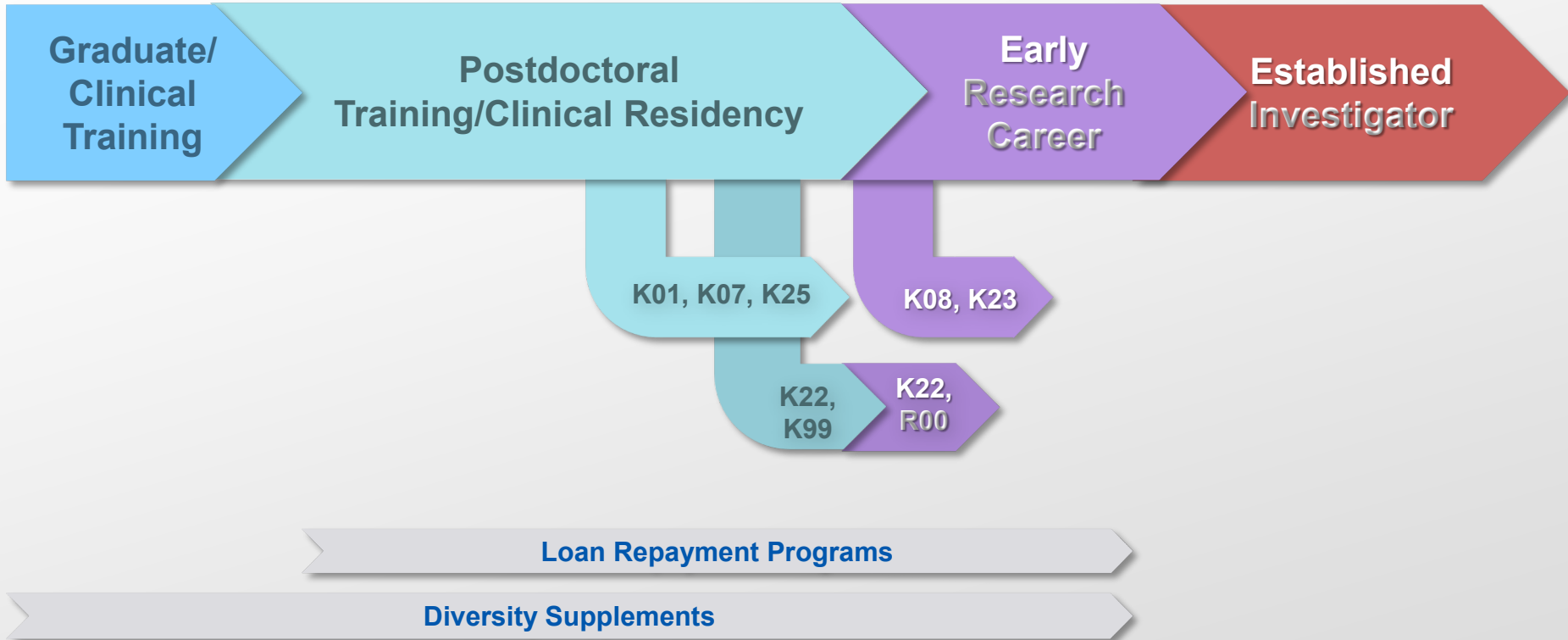


Fellowships

- F30 **Predoctoral** for MD/PhD Training
 - Up to 6 years of support
- F31 **Predoctoral** Fellowship/F31 Predoctoral Diversity Fellowship
 - Up to 5 years of support
- R36 **Dissertation** Grant to Enhance Diversity
 - Not technically fellowships, these grants support dissertation research costs
- F32 **Postdoctoral** Fellowship
 - Up to 3 years of support



Postdoctoral and Early Research Career Training



Individual Mentored *K* Awards

- **Support protected time for** intensive, supervised career development experience : **expectation** for transition to an independent Research Intensive position
- **K01 Research Scientist:** Biomedical or behavioral sciences
- **K08 Clinical Scientist:** Individuals with clinical doctoral degrees pursuing translational research—application of basic research discoveries toward the diagnosis, management, and prevention of human disease
- **K23 Patient Oriented:** Investigators committed to Patient-Oriented Research (POR – direct interaction with human subjects; research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies)
- **K43 Emerging Global Leader:** Individuals from a low- or middle-income country (LMIC) with a junior faculty position at an LMIC academic or research institution*
- **K18 Enhancement Award:** Provides full-time or part-time support for experienced scientists who wish to broaden their research capabilities.
- **K99/R00 Pathway to Independence:** Facilitates **rapid transition** from a mentored postdoctoral position to independent research position (No more than 4 years from doctorate or residency at the time of application)*

* career development awards for which non-US citizens or nationals are eligible



Common Features of *K-Awards*

- By the time of award/appointment, candidates must be citizens, non-citizen nationals, or lawfully admitted for permanent residence in the U.S. (except for K43s and the K99/R00)
- Awardees/appointees must have a research or clinical doctoral degree from an accredited domestic (U.S.) or foreign institution
- Awardees or appointees must have a full-time appointment at the institution, and must commit a minimum of 9 person-months (75% of full-time professional effort) to research career development
- Former PD/PIs on major NIH research grants (e.g., R01), other career development awards (K-awards), or the equivalent are not eligible



K-Kiosk: <https://researchtraining.nih.gov/programs/career-development>



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24

Diversity Supplement

Administrative supplement to an existing, actively funded research grant Designed to:

- Support candidates from underrepresented groups who “wish to develop research capabilities...participate in...career development experiences”
- Support many career stages from undergraduate to faculty
- Add to ongoing research and career development

PA-20-222: <https://grants.nih.gov/grants/guide/pa-files/PA-20-222.html>

Administratively reviewed by the Institute or Center (IC) funding the original grant

- Note: different ICs have different deadlines and policies



Research Grants: R03

R03 – Small Grant

- Small one or two year grant
- Up to \$50k per year in direct costs
- Appropriate for small studies or secondary data analyses



<https://grants.nih.gov/grants/funding/r03.htm>



Research Grants: R21

R21 – Exploratory/Developmental Grant

- Up to **two-year** grant
- Direct costs not to exceed **\$275k** over the course of the two years
- New, exploratory and developmental research
- No preliminary data is generally required



<https://grants.nih.gov/grants/funding/r21.htm>



Research Grants: R34

R34 – Planning Grant (clinical trial or research project)

- Up to a **three-year** grant
- Direct costs limited to **\$225k per year** and **\$450k** over the entire project period
- IC differences re: clinical trial planning grant
- Pilot data is not required



<https://grants.nih.gov/grants/funding/r34.htm>



Research Grants: R15

R15 – NIH Research Enhancement Award

- Supports research at **eligible domestic institutions** that have not been major recipients of NIH research grants
- Includes two programs:
 - **Academic Research Enhancement Award (AREA)** for Undergraduate-Focused Institutions
 - **Research Enhancement Award Program (REAP)** for Health Professional Schools and Graduate Schools
- Up to **3** years with a budget not to exceed **\$300k** over the course of the grant
- Pilot data is not required
- PI cannot be the PI on another NIH grant at the time of the award

<https://area.nih.gov/>



Research Grants: R01

R01 – Mature Award

- Most well known and most commonly used funding mechanism
- Provides **up to 5** years of support with direct costs of up to **\$500k per year**
- Need prior approval to submit an application with a budget over \$500k in any year
- Need preliminary data



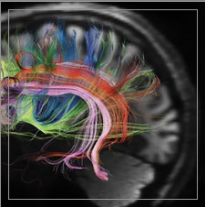
<https://grants.nih.gov/grants/funding/r01.htm>



Early Stage Investigator (ESI)

- An **Early Stage Investigator (ESI)** is within 10 years of completing their terminal research degree or is within 10 years of completing medical residency (or equivalent)
- Has not competed successfully for a substantial NIH-supported research project (R01)
- For multiple PIs, all PIs must meet requirements for ESI status
- Status applies only to R01s
- ESIs are also eligible for the shortened Review Cycle option available to NIs (only applies to non-AIDS-related grant applications)





Tips for Applying

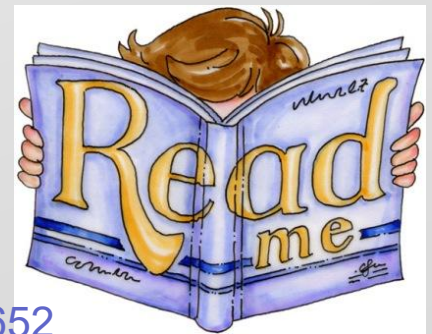


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of Mental Health

You've found a FOA, now what?

Step 1: Read the FOA

- Components of Participating Organizations
- Title
- Activity Code
- Related Notices
- Companion Funding Opportunity
- Purpose
- Key Dates
- Funding Opportunity Description
- Award Information
- Eligibility Information
- Application and Submission Information
- Application Review Information
- Agency Contacts



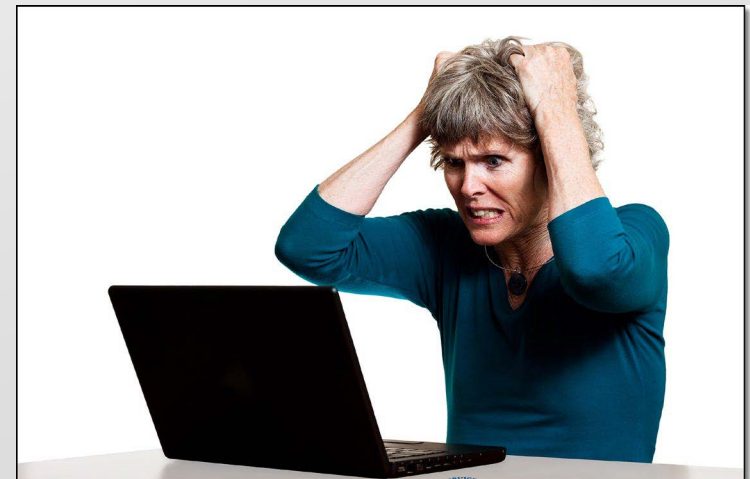
Examples: [RFA-MH-20-201](#); [PA-18-652](#)



You've found a FOA, now what?

Step 2: Write a concept

- Be a “problem solver”
 - Define a significant health problem and research gap
 - Propose a study to address the problem/gap
 - Position your study as one step on the path forward
 - Underscore how this work advances the field
- Write your concept
 - Format: 1-2 pages; can be a draft of Specific Aims
 - Why is the problem you're addressing important?
 - How will you address this problem?



Concept Note Preparation

Key Question/Issue

- What is the specific issue to be addressed in this study
- How is the specific problem/issue defined (**reference**)
- What is known about the specific issue to be addressed (**reference**)
- What are the important factors related to the problem as to its predictors, determinants, causes, consequences... (**reference**)
- What is not known about the issue in general and specifically in the context where you want to study it.
- Why is it important to study the issues (rationale)
- What would the study findings contribute to improving/reducing the issue (significance of the study)



Study Objectives

- State the specific objectives of the study



Methods

- Where would be the study be conducted? Why?
- Proposed Study design
- Study population
- Sample size (**reference**)
- Consider feasibility and cost of the study – take into account the time and resources necessary to conduct the study

You've found a FOA, now what?

Step 3: Contact a Program Officer

- How do I know which Program Officer to contact?
 - Look at the Scientific Contact on the FOA
 - Look at Institute websites for a listing of Program Officers and the types of research in their portfolios
 - Look in NIH RePorter to identify Program Officers on similar research projects
- Can I contact more than one Program Officer? YES
In the same IC? Yes but...
- When should I contact a Program Officer? When you have a concept to share and before you have written the entire application
- How should I reach out? Email
- What should I expect when I speak to a Program Officer?



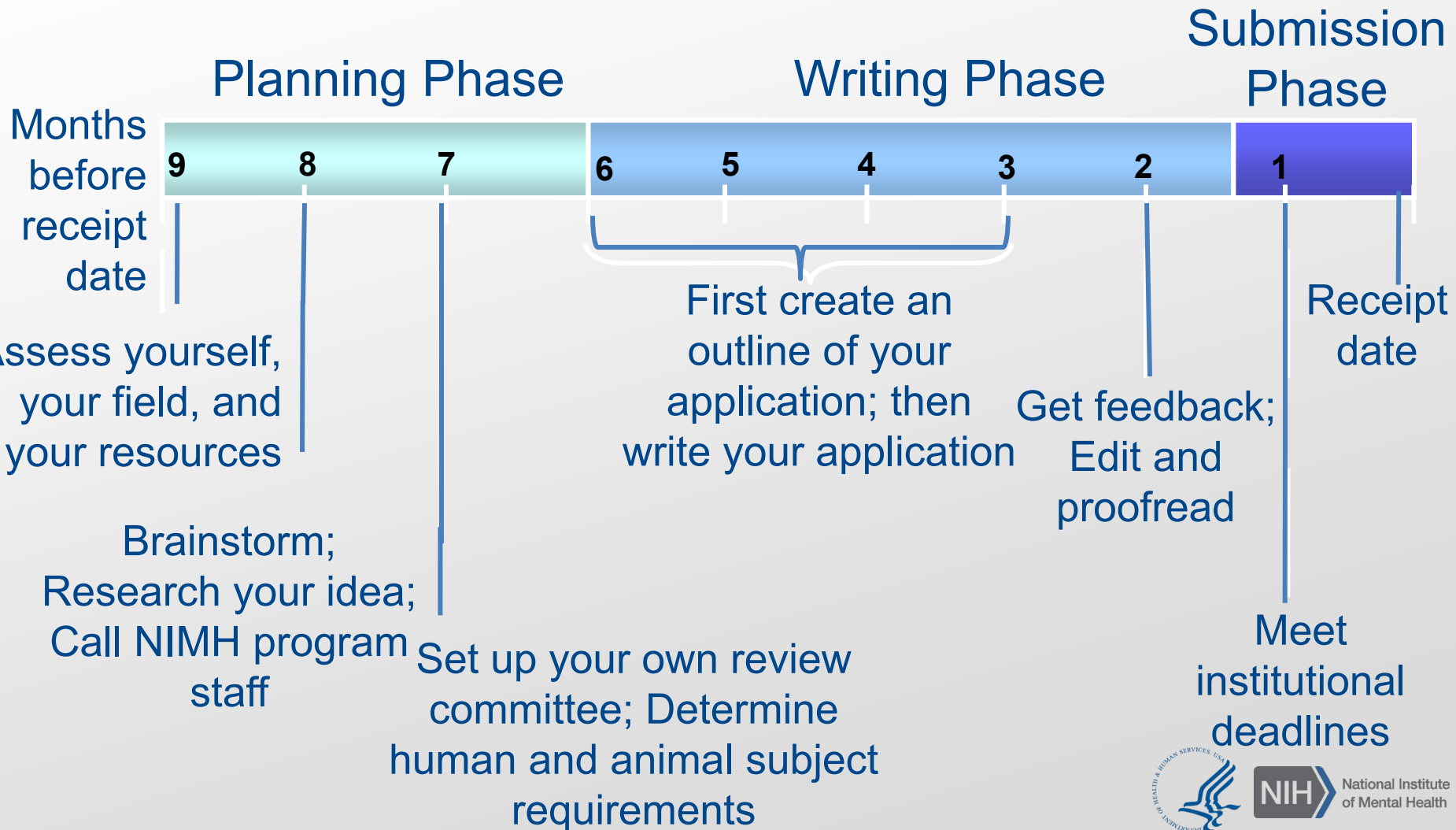
You've found a FOA, now what?

Step 4: Avoid these common pitfalls #1

- Not applying to the correct announcement depending on whether or not you're proposing a clinical trial
- Not paying attention to page limits, expiration date, updates, and other rules and requirements
- Not reading the entire FOA carefully (RFA & PAR in particular)
- Putting important information in an Appendix or other attachment
- Not contacting a Program Officer to discuss your application
- Not giving yourself enough time to prepare the grant application



Preparation Timeline



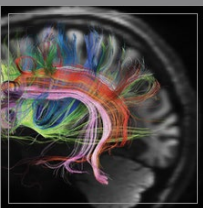
You've found a FOA, now what?

Step 4: Avoid these common pitfalls #2

- Not significant or not new research
- Weak rationale
- Low impact research
- **Too ambitious**
- Unfocused aims
- **Career plan does not match research plan**
- Lacks methodological rigor
- Little feasibility or preliminary data
- Little consideration of mechanisms
- Few publications or collaborators
- Lack of institutional support

Source: <https://www.nimh.nih.gov/funding/grant-writing-and-application-process/common-mistakes-in-writing-applications.shtml>





NIH Resources



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Grant Writing Resources

- ❖ NIH Grant Writing Tips Sheets – links to different Institute’s websites on how to write a grant (http://grants.nih.gov/grants/grant_tips.htm)
- ❖ Preparing Grant Applications (deainfo.nci.nih.gov/extra/extdocs/apprep.htm)
- ❖ Tips for New NIH Grant Applicants (www.nigms.nih.gov/Research/Application/Tips.htm)
- ❖ Grants Process Overview ([Link to site](#))



NIH Peer Review Revealed

View the Videos



- NIH Peer Review Revealed
- Navigating NIH Peer Review
- Jumpstart Your Research Career with CSR's Early Career Reviewer Program
- NIH Tips for Applicants

<http://www.csr.nih.gov/video/video.asp>



About Grants

http://grants.nih.gov/grants/about_grants.htm



Grants Basics



Grants Process Overview



Plan Your Application

How to Apply



Receipt & Referral



Peer Review

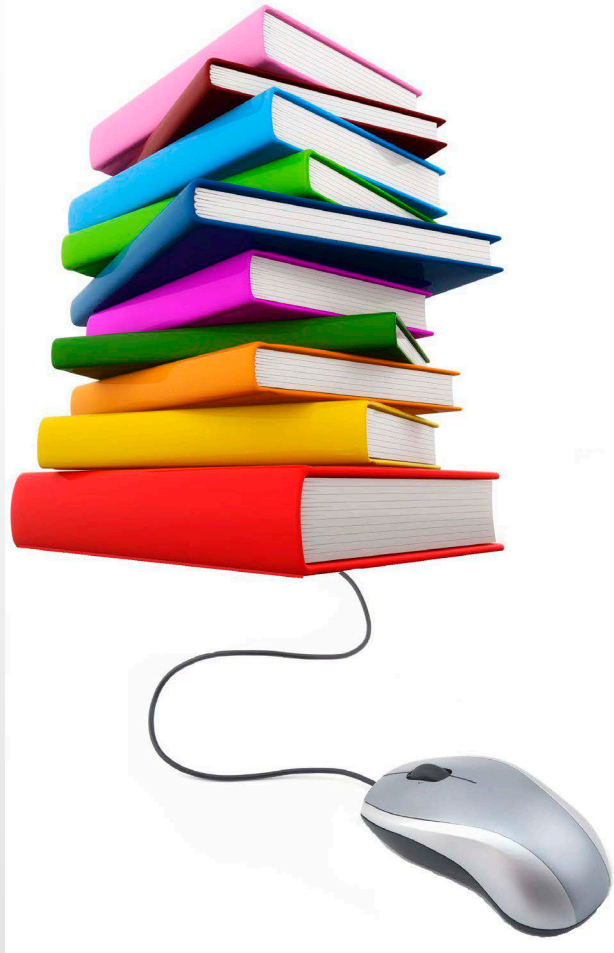


Pre-Award Process

Post-Award Monitoring and Reporting



Additional Resources: e-newsletters



- NIH Grants Policy
 - <https://grants.nih.gov/policy/index.htm>
- NIH Electronic Submission
 - <https://era.nih.gov/>
- Sign up for Inside NIMH
 - Funding news for current and future NIMH awardees
 - Visit the Inside NIMH subscription page: <https://www.nimh.nih.gov/news/e-mail-newsletters/index.shtml>



Additional Resources: Websites

- NIH Research Portfolio Online Reporting Tools (RePORT)
 - Includes an electronic tool that allows users to search a database of NIH-funded research projects
 - <http://projectreporter.nih.gov/reporter.cfm>
- World RePORT website
 - Mapping database system which includes biomedical research studies in sub-Saharan Africa that are funded by 9 funding organizations
 - <http://worldreport.nih.gov>



NIDA HIV/AIDS Priorities & Opportunities

Richard A. Jenkins PhD
National Institute on Drug Abuse

jenkinsri@mail.nih.gov
301-443-1923

SGMRO Research Regional Workshop
September 3, 2020
The Ohio State University (virtual)

National Institute on Drug Abuse (NIDA) Mission

- Lead federal agency supporting scientific research on drug use and its consequences. Our mission is to advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health through:
 - GOAL 1: Identify the biological, environmental, behavioral, and social causes and consequences of drug use and addiction across the lifespan
 - GOAL 2: Develop new and improved strategies to prevent drug use and its consequences
 - GOAL 3: Develop new and improved treatments to help people with substance use disorders achieve and maintain a meaningful and sustained recovery
 - GOAL 4: Increase the public health impact of NIDA research and programs

National Institute on Drug Abuse (NIDA) Mission

- Scope includes:
 - All substances of use/abuse and modes of delivery: injection & non-injection; nicotine/tobacco; vaping; cannabinoids
 - Risk and protective factors for substance use/abuse; prevention; & treatment
 - Social/psychological context of use/abuse: trauma; stigma; pain; family, school and community
 - Co-occurring conditions: mental illness, alcohol and drug use, chronic pain, infectious disease consequences (HIV, HCV, TB)
 - Non-pharmacologic treatment approaches and considerations like physical activity, mindfulness
 - Domestic and international

Research & Training Opportunities for Early Stage Investigators

- F-Awards (F30, F31, F32) for Pre-Doctoral and Post-Doctoral Research Fellowship Training
- K-Awards (K01, K08, K23)
 - Mentored Scientist, Clinical Scientist, & Patient-Oriented Clinical Scientist training (3-5 years)
- K99/R00 - Pathway to Independence Research Award for Postdocs
- B-START (R03) DA-PAR-19-310
 - Large 1 year R03, up to 75K, newly independent PIs
- A-START (R03) PA-18-916
 - New PIs including new to HIV or new to substance use
- Avenir Award RFA-DA-20-024
 - Innovative projects (375K/yr for up to 5 years)

NIDA Research Mechanisms & Resources

- Investigator-Initiated Research R03, R21, R34, R01)
- Accelerating the Pace of Drug Abuse Research Using Existing Data (R01 Clinical Trial Optional) PAR-19-368
- NIDA Research Platforms
 - R25 Training Programs (Ethics Research, Trauma, HIV/AIDS)
 - T32 Programs: Varied topical emphasis (prevention, treatment, methodology, HIV/AIDS)
 - 3PCNO Cohorts
 - Centers of Excellence (P30, P50)
 - CHDUR (NYU)
 - Center for Prevention Intervention Methodology (Northwestern)
 - NAHDAP Archive: <https://www.icpsr.umich.edu/icpsrweb/NAHDAP/>
- Collaborations with Other NIH Institutes
 - Administrative Supplements for Research on Sexual and Gender Minority (SGM) Populations (Clinical Trial Optional) NOT-OD-20-032
 - MACS-WIHS Combined Cohort Study (MWCCS)
 - Centers for AIDS Research (CFARs)
 - Adolescent Trials Network (ATN)

Examples of Current NIDA SGM Grant Topics

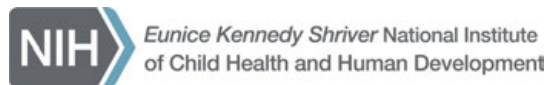
- HIV prevention among gay male couples
- Reducing drug use & sexual risk among bisexual men
- Understanding substance use risk among sexual minority women
- Hormones and GHB metabolism among TG men and women
- Modeling substance use interventions among gay men
- Substance use prevention among sexual minority youth
- mHealth interventions to reduce meth use among MSM
- Intersectional stigma among Black MSM who use substances
- Discrimination, distress and substance use among sexual minority adults

NICHD

Sexual & Gender Minority (SGM) Health Research

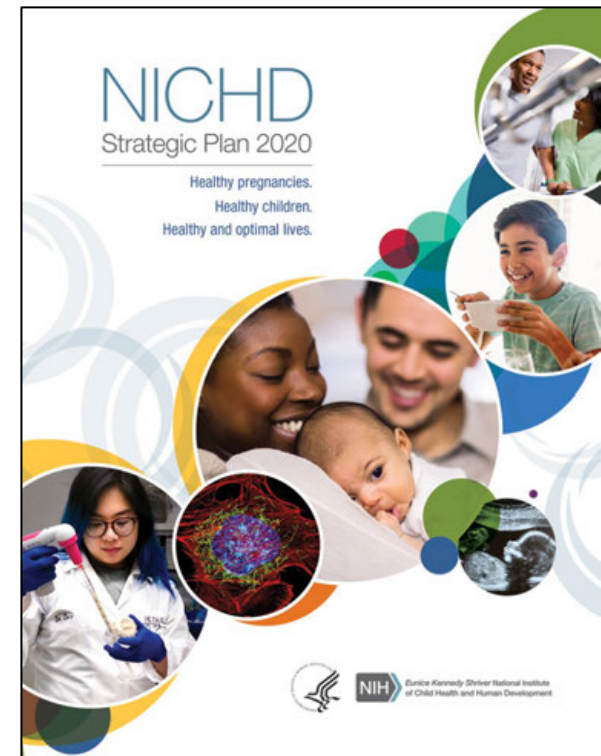
Ronna Popkin, Ph.D.

*SGMRO Regional Workshop, The Ohio State University
September 3, 2020*



NICHD Strategic Plan: Overview

- Guides NICHD's research activities for the next 5 years
- Supports NICHD's new mission and vision statements
- Addresses 5 broad research themes and cross-cutting topics, such as global health
- Lays out NICHD research goals and objectives as well as aspirational goals to drive future activities
- Reaffirms NICHD's commitment to research aimed at improving the health and well-being of women, children, and people with disabilities
- Available at:
<https://www.nichd.nih.gov/about/org/strategicplan>.



NICHD Strategic Plan: Revised Mission and Vision Statements

- **Mission:** NICHD leads research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.
- **Vision:**
Healthy pregnancies.
Healthy children.
Healthy and optimal lives.



NICHD Strategic Plan: Research Themes

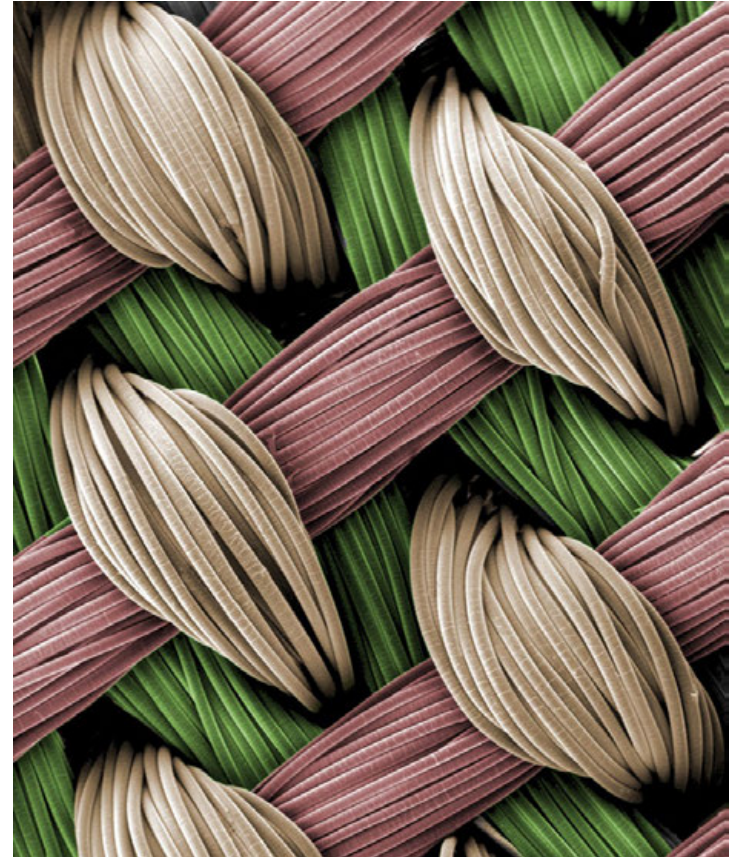
- Understanding the Molecular, Cellular, and Structural Basis of Development
- Promoting Gynecologic, Andrologic, and Reproductive Health
- Setting the Foundation for Healthy Pregnancies and Lifelong Wellness
- Improving Child and Adolescent Health and the Transition to Adulthood
- Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating Women, Children, and People with Disabilities



NICHD Strategic Plan: Cross-Cutting Topics

The following topics are integrated into all research themes:

- Health Disparities
- Disease Prevention
- Infectious Disease
- Nutrition
- Global Health



Credit: Guilak Lab, Washington University



NICHD Populations

infants



children



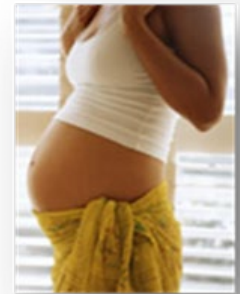
adolescents

emerging/young adults

orphans and vulnerable children



pregnant and non-pregnant women



sexual and gender minorities

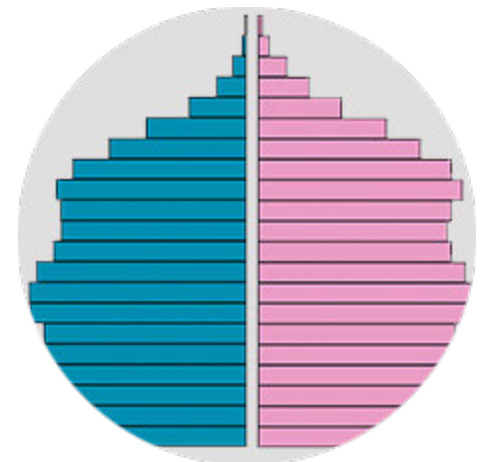


NICHD Areas of SGM Research



Demography and Reproductive Health

- Large-scale population-representative surveys examining the demographic and social characteristics
- Household composition and outcomes for children and families
- Methods for estimating size and characteristics of small and/or hard-to-reach populations
- Studies based on population-representative samples and related to reproductive health or overall health
- Behavioral interventions to improve reproductive health outcomes



Child Development and Behavior

- Social, emotional, psychological, and cognitive development in SGM youth
- Methods of conducting research with SGM youth populations in domains relevant to mission areas
- Identity-related issues and experiences of stigma and discrimination in children, adolescents, and young adults
- Impact of brain development of hormonal therapy in children/adolescents



Gynecologic Health and Fertility/Infertility

- Effects and consequences of surgical procedures and hormone administration on gynecological health outcomes
- Barriers to/options for fertility care, including assisted reproductive technologies
- Impact of hormonal or other therapies on reproductive function, fertility options and fertility preservation, and gamete quality



HIV & AIDS

- Domestic and international research related to the epidemiology, diagnosis, clinical manifestations, pathogenesis, transmission, treatment, and prevention of HIV infection, complications, co-infections, and co-morbidities
- Barriers and facilitators to accessing HIV/AIDS and/or STI care
- Contributions of intimate partner violence and anti-SGM victimization to rates of HIV and STI transmission
- Behavioral and social science; implementation science



DASH Data and Specimen Hub

- Centralized resource for researchers to share de-identified data from studies funded by NICHD. DASH also serves as a portal for requesting biospecimens from selected studies in DASH.
- Data sharing launched in August 2015; biospecimen request launched in March 2019
- Aims to accelerate scientific findings to ultimately improve human health



<https://dash.nichd.nih.gov>

Study Topics in DASH

Adrenal Gland Disorders	Neuroscience
Amenorrhea	Obesity & Overweight
Autism Spectrum Disorders	Obstetrics
Birth Defects	Pediatric Injury
Breastfeeding & Breast Milk*	Pelvic Floor Disorders
Cerebral Palsy	Pharmacology
Child Health*	Preconception & Prenatal Care
Children's Bone Health & Calcium	Preeclampsia & Eclampsia
Delayed Puberty	Pregnancy*
Diabetes	Pregnancy Loss
Driving Risk	Preterm Labor & Birth*
Early Learning	Primary Ovarian Insufficiency
Fertility Problems	Puberty & Precocious Puberty
High-Risk Pregnancy	Rehabilitation Medicine
HIV/AIDS*	Sleep
Infant Care & Health *	Spinal Cord Injury
Infant Mortality	Stillbirth
Infertility & Fertility	Stroke
Labor & Delivery	Sudden Infant Death Syndrome
Men's Reproductive Health	Traumatic Brain Injury
Menkes Disease	Turner Syndrome
Necrotizing Enterocolitis	Women's Health*

*biospecimens available

- DASH has added a new function: managing requests for NICHD biospecimens.
- While not a biorepository itself, DASH serves as a portal for access to biospecimens associated with DASH data collections.
- Investigators worldwide can now request both biospecimens and data for secondary analyses; other than the costs of preparing and shipping biospecimens, these specimens are free to investigators.
- Studies with biospecimens currently available include:
 - Genomic and Proteomic Network for Preterm Birth Research (GPN) – three studies
 - NICHD International Site Development Initiative (NISDI) – four studies
 - Mothers and Infants Cohort Study (MICS)
 - National Children’s Study (NCS)

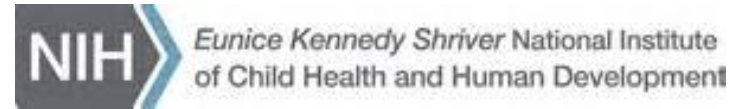
Study Topics Areas of Current Biospecimens

Breastfeeding and Breast Milk	Pregnancy
Child Health	Preterm Labor and Birth
HIV/AIDS	Women’s Health
Infant Care and Infant Health	

Currently Available Biospecimens

Amniotic fluid	Hair
Blood	Lymphocytes
Breast Milk	Meconium
Buffy Coat	Nail
Cord Blood (Buffy Coat, RBC, Plasma, Serum)	Saliva
DNA/RNA/Proteins	Serum/Plasma
Environmental Samples	Tissue samples
Erythrocytes (RBC)	Urine
	Vaginal Fluid

Contact Information:



Ronna Popkin, Ph.D.

NICHD Program Officer

Population Dynamics Branch

ronna.popkin@nih.gov



NICHD Website:

<https://www.nichd.nih.gov/about/org/der/branches>



The *All of Us* Research Program

SGMRO Regional Meeting
September 3, 2020



Sheri Schully, Ph.D.
Chief Medical and Science Officer (Acting)
All of Us Research Program, NIH



Current protocol



Enroll, Consent & Authorize EHR

- Recruiting 18+ years old initially; plan to include children in future
- Online, interactive consent
- Includes authorization to share Electronic Health Record (EHR) data



Answering Surveys

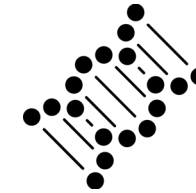
- Initial surveys: The Basics, Overall Health, Personal Habits, Health Care Access & Utilization, Family Medical History
- Additional surveys released on an ongoing basis.



Physical Measurements*

- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

**Based on diverse sampling and capacity*



Provide Biosamples*

- Blood (or saliva, if blood draw is unsuccessful)
- Urine specimen
- Biosamples will be stored at the program's biobank

**Based on diverse sampling and capacity*



Wearables and Digital Apps

- Share data from wearable fitness devices, starting with FitBit
- Share data about mood through integrated apps
- More integrations to come

Fitbit BYOD has started, anticipate mood app soon

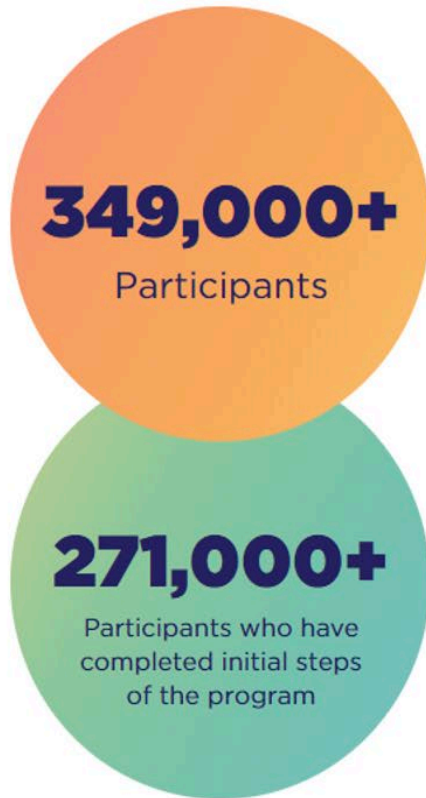
AoURP: a rich resource for SGM health researchers

- From **Day 1** AoU has engaged sexual and gender minority (SGM) communities.
- Comprehensively collects sexual orientation, gender identity, and sex assigned at birth from all participants (1+ million people).
- Previously invisible SGM subgroups (e.g., asexual, gender-fluid) will likely be able to be explicitly included.
- Rich demographics enable studies of intersecting identities among UBR communities.
- Electronic health record (EHR) data enables SGM-specific analyses based on diagnoses, procedures, laboratory tests, imaging studies, medications, etc.

All of Us Data Snapshots and Data Browser

researchallofus.org/data/data-snapshots/

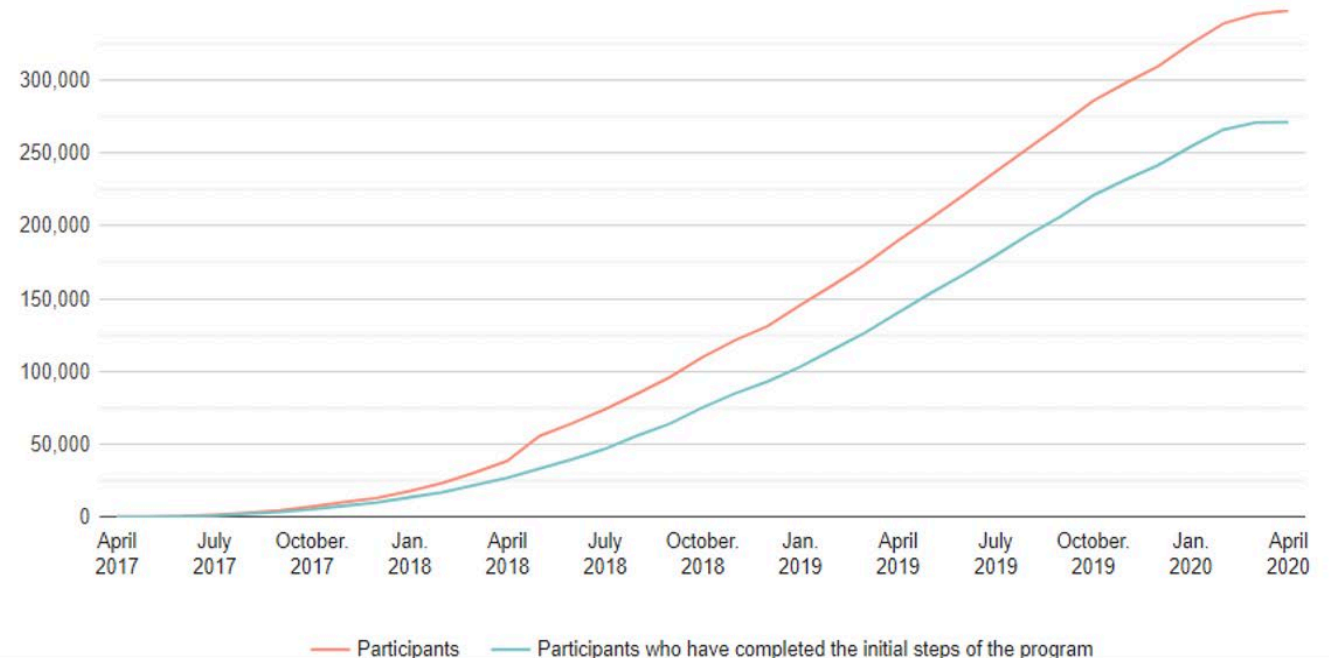
databrowser.researchallofus.org/



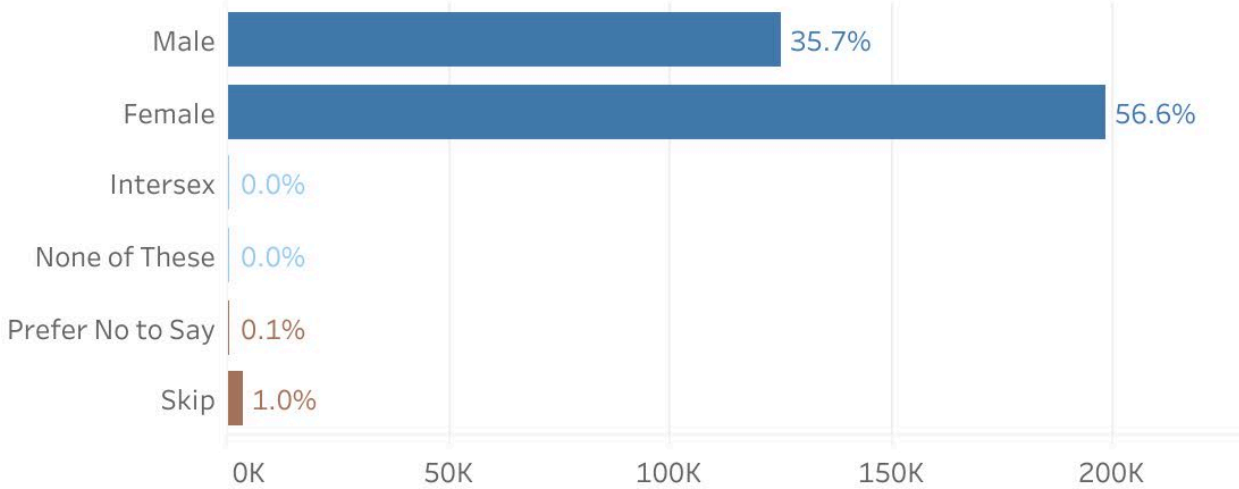
Enrollment Numbers

This graph represents participants who have consented to join the program and participants who have completed all initial steps of the program (i.e., those who have consented, agreed to share their electronic health records, completed the first three surveys, provided physical measurements, and donated at least one biospecimen stored at the biobank).

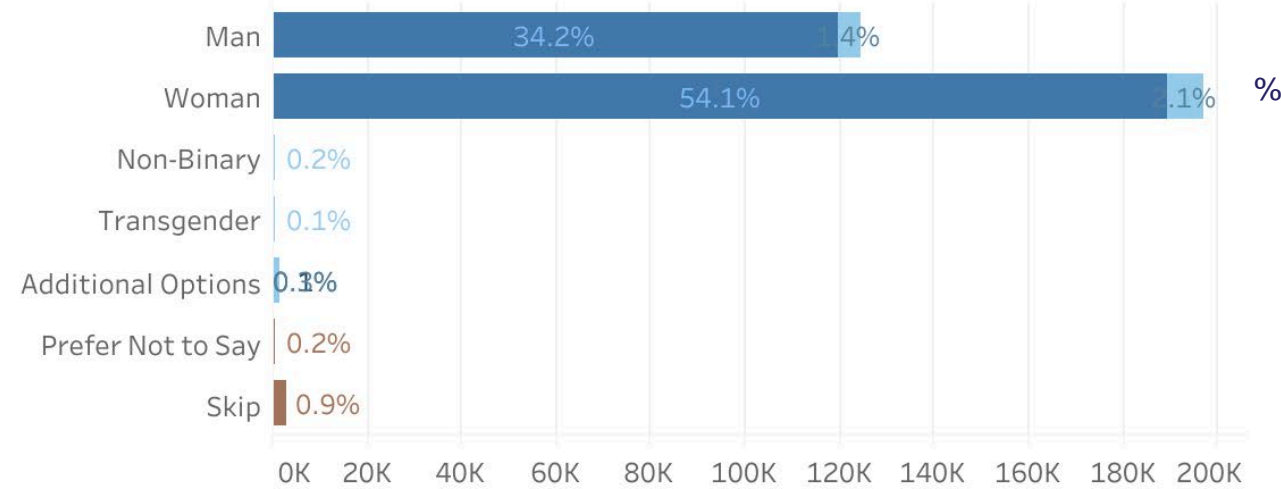
The following numbers are approximated to protect participants' privacy. Numbers are updated as of May 19, 2020.



Sex Assigned at Birth



Gender Identity



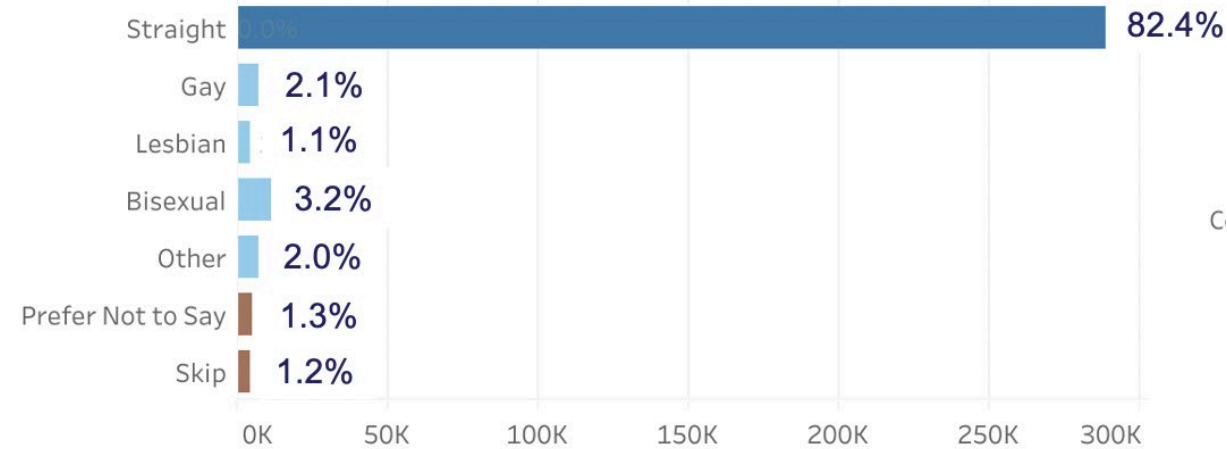
Question 3

What was your biological sex assigned at birth?

[See Answers](#) ▾

	Participant Count	% Answered
Sex At Birth: Female	137,880	61.24%
Sex At Birth: Male	84,260	37.43%
Skip	2,420	1.07%
Prefer Not To Answer	220	0.10%
Did not answer	200	0.09%
Sex At Birth: None Of These	100	0.04%
Sex At Birth: Intersex	60	0.03%

Sexual Orientation



The *All of Us* Research Program's mission is to speed up health research breakthroughs.

People from all walks of life will share their health information. Health data from diverse people will help fill gaps in knowledge about why people get sick or stay healthy. The data could help researchers develop new and better treatments that benefit all of us.

Why is diversity important to the *All of Us* Research Program?

All of Us is asking lots of people to join. Participants are from different races and ethnicities, age groups, and regions of the country. They are also diverse in gender identity, sexual orientation, and health status.

Diversity in a research program is important for several reasons. First, where we live, how we live, and our background can all affect our health. Second, many groups of people have been left out of research in the past. This means we know less about their health.

By studying data from a diverse group of people, researchers can learn more about what makes people sick or keeps them healthy. What researchers learn could lead to better treatment and disease prevention for all of us.

Data from *All of Us* could someday help researchers:

- Identify what makes people more likely to develop a disease.
- Find out how environment, lifestyle, and genes can impact health.
- Build better tools for detecting a health condition and encouraging healthy habits.

Why have some communities not been part of research?

There are different reasons. For example, some communities have not been invited to take part in research. Or, they have been invited but not told what was involved. For these reasons, we need to learn more about them.



The *All of Us* Research Program has learned from this history. We want to be sure we do things right, so many different groups of people can join. We will tell you what we are doing. We will share results. And we will protect your data.

Why is the LGBTQ community important to *All of Us*?

LGBTQ people, like many other groups, have often been left out of research. As a result, we know less about their health and ways to provide them with the best care. The *All of Us* Research Program wants to change this. By joining *All of Us*, LGBTQ people can help ensure their community is included in health studies. These studies could help researchers understand health conditions that are more common among LGBTQ people. What they learn could lead to more tailored approaches for preventing and treating those conditions.

All of Us is working with community partners to educate LGBTQ people about the program and how research has potential benefits for their families and future generations.

All of Us Core Values

- Participation is open to all.
- Participants reflect the rich diversity of the United States.
- Participants are partners.
- Trust will be earned through transparency.
- Participants have access to their information.
- Data will be accessed broadly for research purposes.
- Security and privacy will be of highest importance.
- The program will be a catalyst for positive change in research.

How is *All of Us* addressing concerns about taking part in research?

Here are some of the ways *All of Us* is addressing these concerns:

Becoming a participant

All of Us wants people to make an informed decision about whether to join.

We have worked hard to make the process for joining *All of Us* clear and detailed. Before you decide if you want to join, we will tell you the purpose of the research program. We will also share the risks and benefits of taking part, what to expect in the program, and how to withdraw if you choose to leave. People must agree that they understand the program and their rights as participants before they can join. We have a Support Center and other staff who help answer questions about being a participant.

Ensuring privacy and data security

All of Us is committed to making sure data is kept private. We also want to make sure that data is not misused. The *All of Us* Research Program:

- Follows all federal, state, and local laws and rules for keeping data safe.
- Has strict policies and procedures to prevent misuse of data. See the [Privacy and Trust Principles](#) and [Data Security Policy Principles and Framework](#).
- Has [Certificates of Confidentiality](#) from the U.S. government. These will help the program fight legal demands (such as a court order) to give out information that could identify a participant.
- Continues to test the security of our databases.
- Will tell participants if there is a risk to their privacy because of a data breach.
- Stores data on protected computers. This limits and keeps track of who can see it.
- Removes personal details that could identify participants from the data.
- Requires researchers to agree to follow data use rules, including promising they will not try to identify participants.

Giving information back to participants

The *All of Us* Research Program will give information back to participants. People who join can choose to see their own health information. In the future, this might include information from DNA tests and health records. *All of Us* will post information on its website about the research being done with the data. General demographic information about all participants will be publicly available.



Is the program working with participants and their communities?

Yes. *All of Us* participant representatives shape the program at all levels. Participant representatives are part of local advisory boards and *All of Us* working groups, where they share ideas and help decide what the program does.

All of Us also funds [community organizations](#). They reach groups that have historically been underrepresented in research to tell them about the research and answer questions. They also help spread awareness of the *All of Us* Research Program.

Why should someone consider joining *All of Us*?

People join for many reasons. Some people join because they can:

- Learn more about their health.
- Help improve the health of their communities and future generations.
- Help researchers find the best ways for people to stay healthy.
- Help researchers one day create better tests and treatments.

The longer a person stays involved with *All of Us*, the more they can learn about themselves and help speed up health research and medical breakthroughs.

Where can someone learn more about the *All of Us* Research Program?

Visit JoinAllOfUs.org to learn more about the program, its privacy safeguards, benefits of joining, and how data will be used. The *All of Us* Support Center is open every day (except public holidays) to answer questions. Contact the Support Center at **(844) 842-2855** or help@joinallofus.org.

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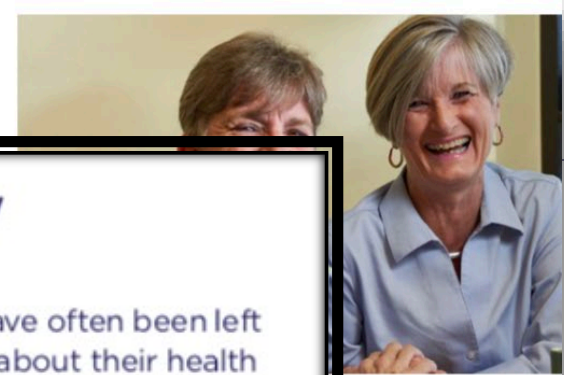
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How participants

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Under joining

people join

Resources

Web: <https://www.joinallofus.org/>

Community Resources: <https://www.joinallofus.org/en/community/community-resources>

Researcher Workbench: <https://workbench.researchallofus.org/login>

Newsletters: <https://www.joinallofus.org/en/newsletters>

Events: <https://www.joinallofus.org/en/events>

Email: Sheri Schully: schullys@mail.nih.gov

Overview of NIMH

Susannah Allison, Ph.D.

SGMRO Regional Workshop
September 3, 2020



National Institute
of Mental Health

About the NIMH



- NIMH is the lead federal agency for research on mental illnesses
- NIMH supports more than 3,000 research grants and contracts at universities and other institutions across the country and overseas
- NIMH Intramural Research Programs support approximately 600 scientists working on the NIH campuses

NIMH Vision and Mission

VISION



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

MISSION



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

NIMH Strategic Plan for Research for the Next 5 Years ... and Beyond

NIMH
2020
STRATEGIC PLAN

The NIMH Strategic Plan for Research outlines the Institute's research goals and priorities over the next five years

[Download PDF](#)

Message from the Director	Overview of NIMH	Stewardship	Accomplishing the Mission	Challenges and Opportunities	Cross-Cutting Research Themes

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.

Define the Brain Mechanisms Underlying Complex Behavior

Goal 1

Examine Mental Illness Trajectories Across the Lifespan

Goal 2

Strive for Prevention and Cures

Goal 3

Strengthen the Public Health Impact of NIMH-Supported Research

Goal 4

NIMH Research Bullets within SGM FOAs at NIH

Notice of Special Interest in Research on the Health of Sexual and Gender Minority (SGM) Populations (NOT-MD-19-001)

- Identification of mutable and mechanistic **causes of disparities in mental health**-related clinical (including suicide thoughts and behaviors) and functional outcomes (including Severe Mental Illness) from which interventions targeting health equity can be developed and tested.
- Studies of how **non-mental health specialty settings** (e.g., SGM social or support groups, human resources or employee assistance programs, educational settings, etc.) can contribute to and support screening, referral, diagnosis and treatment or prevention of mental illness and suicide behavior in SGM populations.
- Studies to better understand **disparities in HIV rates and outcomes** among SGM living with HIV and how to mitigate them as well as a better understanding of the factors impeding scale up of efficacious HIV prevention interventions for SGM and the development of approaches to address these barriers.

<https://grants.nih.gov/grants/guide/notice-files/not-md-19-001.html>

NIMH Research Bullets within SGM FOAs at NIH

Research on the Health of Transgender and Gender Nonconforming Populations: R01 and R21 (PA-18-729; PA-18-728)

- Improved understanding of multivariate risk for, and protection against, the **onset of mental disorders and suicidal behavior** (including studies that look at multiple RDoC domains); with consideration for **transition periods** that may heighten risk. In particular, studies that utilize RDoC-consistent measures could inform the etiological factors for both transgender, gender nonconforming, and other individuals.
- Given the high rates of suicide ideation and attempts, and frequent experiences of harassment, discrimination, violence and rejection among transgender and gender nonconforming individuals, research into what **factors protect against suicide ideation** in this population and **how these factors can inform prevention interventions**.
- **Strategies to improve mental health outcomes** among transgender and gender nonconforming individuals, the effectiveness of strategies for referral and engagement in mental health treatment and services with providers and in settings that are informed about transgender-related care issues.

<https://grants.nih.gov/grants/guide/pa-files/pa-18-729.html>

<https://grants.nih.gov/grants/guide/pa-files/PA-18-728.html>

Prior and Current SGM Administrative Supplement FOAs at NIMH

- Sexual and Gender Minority administrative supplements
 - NIMH has participated for the past 5 years
 - **FY16:** PA-15-329, **FY17:** PA-17-098, **FY18:** PA-18-713
 - **FY19:** NOT-OD-19-102
 - **FY20 & FY21:** NOT-OD-20-032 (still active for FY21)
- Research on the Health of Women of Underrepresented, Understudied and Underreported (U3) Populations – administrative supplements
 - Has included a reference to sexual and gender minorities
 - NIMH has participated for the past 4 years
 - **FY17:** PA-17-101, **FY18:** PA-18-676, **FY19:** PA-19-205
 - **FY20 & FY21:** NOT-OD-20-048 (still active for FY21)

Questions



[Website on the Coordination of SGM Research at NIMH](#)