

# 2019 Inter-CFAR Women and HIV Symposium

Tips and Resources for Early Career Investigators:
A Panel with NIH Representatives

October 22, 2019

# Nothing to Disclose

## **NIH Mission**

Seeks fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

NIH . . . Turning Discovery Into Health®

# **NIH Pursues Its Mission by...**

- Supporting extramural research (~80% of budget) for...
- Research by non-Federal scientists at universities & other research institutions
  - Training research investigators
  - Communicating biomedical information
  - Conducting research, intramural programs (~10% of budget)
    - Performed in NIH's own laboratories
    - Research support and management (~10%)
      - NIH 2019 Budget \$~39 billion

# NATIONAL INSTITUTES OF HEALTH

#### **27 Institutes and Centers** Office of the NIH Director NCI NHLBI NEI NIA NIAAA **Fogarty** NIAID NIAMS **NIDCD NCCIH NHGRI NIDA NICHD NCATS** NIMHD **NIDCR** NIGMS **NIEHS NINR** NIMH **NIDDK NINDS NIBIB** NLM CC **CSR** CIT

# NIH & Women's Health

## NIH Office of Research on Women's Health (ORWH)

- Serves as centralized, national and global leader in forming partnerships across NIH to increase attention and address health research issues focused on women
- Crafts and implements the <u>NIH Strategic Plan for Women's Health Research</u> in partnership with NIH Institutes and Centers (ICs)
- Monitors adherence to NIH's inclusion policies, which ensure that women and minorities are represented in NIH-supported clinical research
- Supports interdisciplinary research and career development initiatives that stimulate research on sex and gender differences to launch promising women's health researchers

# **ORWH**

### Recent highlights

- Addressing intimate partner violence impact of women's health
- Advocating for women in academic medicine
- Bringing diversity to scientific panels

### Current funded programs

- Building Interdisciplinary Research Careers in Women's Health (BIRCWH)
- Specialized Centers of Research Excellence (<u>SCORE</u>)
- <u>U3</u> Interdisciplinary Research
- Co-funding to NIH <u>Global Research Programs</u>: Tobacco Control Network Among Women (Brazil), Fogarty Global Scholars, Medical Education Partnership Initiative (<u>MEPI</u>)
- Administrative Supplements for Research on Sex/Gender Differences

# BIRCWH:

# **Expands the Quality and Number of Researchers who Focus on the Health of Women**

- Congressionally designated program in 1999 remains a priority area (21st Century Cures Act)
- One of ORWH's Signature Programs focuses on career development of junior faculty only trans-NIH Training/Career Development program that focuses broadly on the health of women
- Supports training/career development in interdisciplinary basic, translational, behavioral, clinical and/or health services research relevant to the health of women
- Where appropriate, the inclusion of both sexes (better understand the influence of sex as a variable in health and diseases)
- Mechanism: K12 (Institutional Career Development Award)
  - Clinical trials included: Scholars can lead research projects that fall under NIH definition of clinical trials

# Building Interdisciplinary Research Careers in Women's Health Program uses K12 mechanism & focuses on junior faculty

BIRCWH

#### PIs

### **Scholars**

## **Spotlight on BIRCWH**







Karen M. Freund, M.D., M.P.H.
Jennifer DuPont, Ph.D.
Loss of vascular angiotensin II type 2 receptor
contributes specifically to female vascular aging







Jill M. Goldstein, Ph.D.
Simmie L. Foster, M.D., Ph.D.
Regulation of inflammatory cytokines by pre-exposure to elevated temperatures

### Watch the videocast: https://videocast.nih.gov/Summary.asp?Live=28502&bhcp=1







Kim A. Boggess, M.D. Matthew C. Mauck, M.D., Ph.D. Sex differences in chronic pain development following major thermal burn injury







Ellen B. Gold, Ph.D., M.A.
Laura M. Tully, Ph.D.
Neural mechanisms underlying ↑ psychotic &
mood symptoms in females with schizophrenia

20 BIRCWH Progs. supported by RFA-OD-15-001 & RFA-OD-16-013:

- ORWH
- NICHD
- NCI
- NIA
- NIAAA
- NIAID
- NIAMS
- NIDA
- NIDCR
- NIEHS

Reissued for FY20, RFA-OD-19-020 (HIV/AIDS apps: RFA-HD-20-013)





# OAR Role in NIH HIV/AIDS Research

- Coordinates the largest public investment in HIV/AIDS research globally.
- Establishes scientific priorities.
- Allocates research funds in line with scientific priorities to nearly every NIH IC.
- Manages HIV/AIDS research across the NIH: scientific, budgetary, legislative, and policy components.

## NIH Priorities for HIV and HIV-Related Research



#### **Reduce Incidence**

- Vaccines
- PrEP. U=U
- Microbicides & MPTs
- HIV Testing
- Treatment as Prevention
- Monoclonal Antibodies

## Research Toward A Cure

- ART-free Viral Remission
- Viral Eradication
- Viral Latency & Sanctuaries
- Cure Ethics & Acceptability

#### **Cross-Cutting Areas**

- Virology & Immunology
- Behavioral & Social Sciences
- Epidemiology
- Health Disparities
- Information Dissemination
- Implementation Science
- Infrastructure, Capacity Building

#### **Next-Gen HIV Therapies**

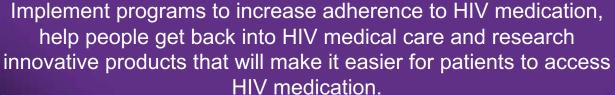
- Less Toxic, Longer Lasting ART
- Novel HIV Targets & Inhibitors
- Novel Immune-Based Therapies
- Adherence & Retention-Care

## Comorbidities, Coinfections, & Complications

- Coinfections
- Neurologic Complications
- Malignancies
- Cardiovascular Complications
- Mental Illness/Substance Use
- Metabolic Disorders
- Across the Lifespan

#### **Treat:**







### Diagnose:

Implement routine testing during key healthcare encounters and increase access to and options for HIV testing.



#### **HIV Health Force:**

A boots-on-the-ground workforce of culturally competent and committed public health professionals that will carry out HIV elimination efforts in HIV hot spots.



Implement extensive provider training, patient awareness and efforts to expand access to PrEP



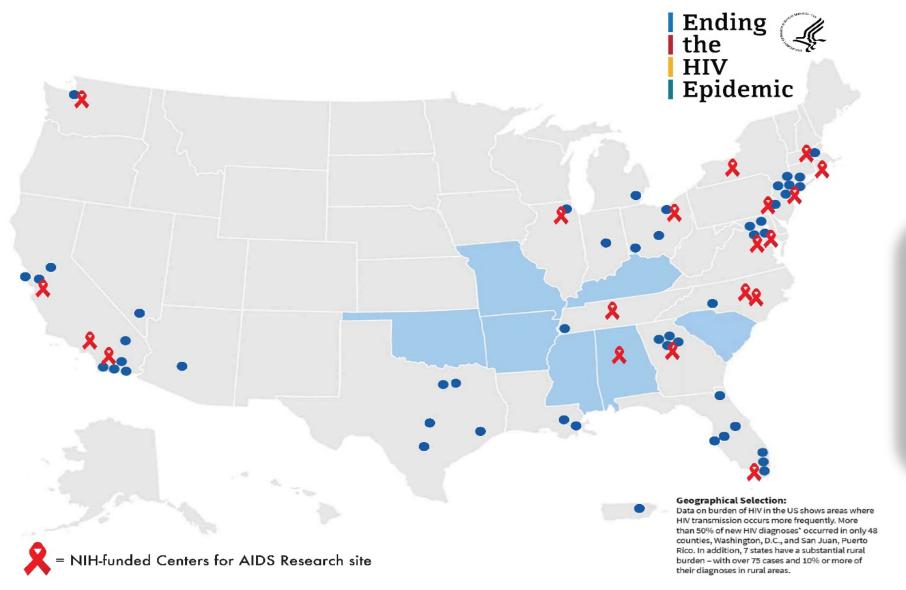
### Respond:

Ensure that states and communities have the technological and personnel resources to investigate all related HIV cases to stop chains of transmission.





# Ending the Epidemic: A Plan for America Multidisciplinary Approach



The Initiative will focus resources in the 48 highest burden counties, Washington, D.C., San Juan, Puerto Rico, and 7 states with a substantial rural HIV burden.

## A Collaborative National Response to the HIV Epidemic

#### **Basic Research to Public Health**

**Basic** Clinical **Translational Implementation Public Health & Policy** 





















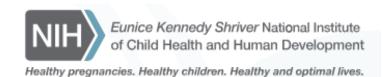












# Diana W. Bianchi, M.D., Director

**Divisions, Centers & Offices** 



Division of Extramural Research (DER) Division of Intramural Population Health Research (DIPHR)

Division of Intramural Research (DIR) National Center for Medical Rehabilitation Research (NCMRR)

## **About NICHD**

#### **Extramural Scientific Branches**

Select a branch to learn more about its research priorities and activities.



<u>Child</u> <u>Development</u> and Behavior Branch (CDBB)



Contraception Research Branch (CRB)



Developmental Biology and Structural Variation Branch (DBSVB)



<u>Fertility and</u> <u>Infertility Branch</u> <u>(FIB)</u>



<u>Gynecologic</u> <u>Health and</u> <u>Disease Branch</u> (<u>GHDB)</u>



Intellectual and Developmental Disabilities Branch (IDDB)



Maternal and Pediatric Infectious Disease Branch (MPIDB)



Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)



Pediatric Growth and Nutrition Branch (PGNB)



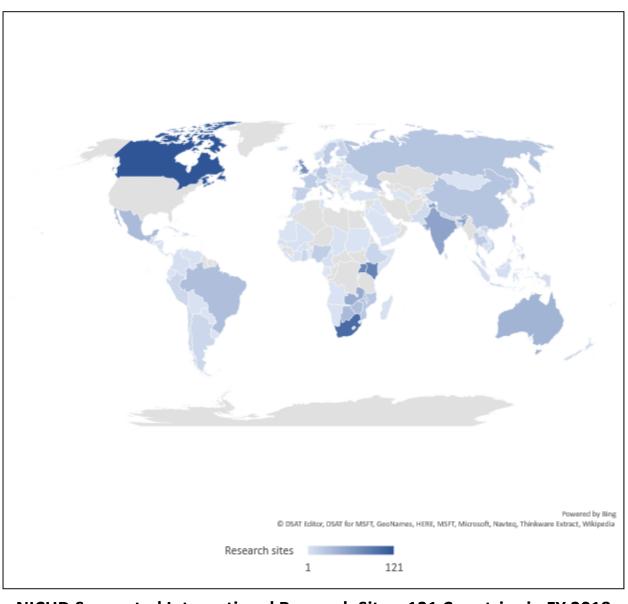
Pediatric Trauma and Critical Illness Branch (PTCIB)



<u>Population</u> <u>Dynamics</u> <u>Branch (PDB)</u>



<u>Pregnancy and</u> <u>Perinatology</u> <u>Branch (PPB</u>)



NICHD Supported International Research Sites: 131 Countries in FY 2018

Source: NIH FACTS Data, FY 2018

# NICHD Strategic Plan: 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.



Available at: <a href="https://www.nichd.nih.gov/about/org/strategicplan">https://www.nichd.nih.gov/about/org/strategicplan</a>

## Cross-Cutting NIH HIV Research Programs

The branch also supports several collaborative programs and networks











#### Critical Infrastructure

- Centers for AIDS Research (CFAR)
- AIDS Research Centers

#### **Clinical Trials Networks**

- Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)
- Microbicide Trials Network (MTN)
- International Maternal, Pediatric, Adolescent AIDS Clinical Trials Network (IMPAACT)
- AIDS Clinical Trials Group
- HIV Prevention Trials Network
- HIV Vaccine Trials Network

#### **Cohort Studies**

- Pediatric HIV/AIDS Cohort Study (PHACS)
- Collaborating Consortium of Cohorts Producing NIDA Opportunities (C3PNO)
- Women's Interagency HIV Cohort Study (WIHS) As of 2019 merged to become:
  - Multicenter AIDS Cohort Study (MACS)/Women's Interagency HIV Study (WIHS) Combined Cohort Study (M/W-CCS)



Interactive Google map to help researchers understand where in the United States each network and program is working

- Select the circle icon in each state to see non-overlapping and overlapping sites for selected networks and programs



#### Study Topics in DASH (\*biospecimens available)

Autism Spectrum Disorders

Birth Defects

Cerebral Palsy

Children's Bone Health

& Calcium

Diabetes

**Driving Risk** 

Early Learning

High-Risk Pregnancy

HIV/AIDS\*

Infant Care & Health

**Infant Mortality** 

Infertility & Fertility

Labor & Delivery

Neuroscience

Necrotizing

Enterocolitis

Obesity & Overweight

**Obstetrics** 

Pediatric Injury

Pelvic Floor Disorder

Pharmacology

Preconception & **Prenatal Care** 

Preeclampsia & Eclampsia

Pregnancy\*

**Pregnancy Loss** 

Preterm Labor & Birth\*

**Primary Ovarian** Insufficiency

Rehabilitation Medicine

Sleep

Spinal Cord Injury

Stillbirth

Stroke

Sudden Infant Death Syndrome

Traumatic Brain Injury

**Turner Syndrome** 

Women's Health



https://dash.nichd.nih.gov

- Centralized resource for researchers to store deidentified data and to access data and associated biospecimens from NICHD supported studies
- Can help investigators meet NIH's data sharing requirements for their own studies
- Data sharing launched in August 2015; biospecimen request launched in March 2019
- Governed by the NICHD DASH Committee
- Aims to accelerate scientific findings to ultimately improve human health







35 Study

**Topics** 





**Publications** 



**142** Studies

Studies Offering Biospecimens



#### Study Topics with Biospecimens in DASH

**HIV/AIDS** Pregnancy Preterm Labor & Birth

More to come!

#### **Biospecimens Currently Available**

Amniotic Fluid

Saliva

Blood

Serum/ Plasma

**Breast Milk** 

Tissue Samples

DNA/RNA/Proteins

Urine

Lymphocytes

Vaginal Fluid

### **New DASH Function: Managing Requests** for NICHD Biospecimens



https://dash.nichd.nih.gov

- Genomic and Proteomic Network for Preterm Birth Research (GPN) Expression profiling, GWAS case control, and longitudinal cohort studies
- NICHD International Site Development Initiative (NISDI) 4 studies of pregnant women with HIV, their infants with and exposed to HIV, and children with and exposed to HIV in Latin American Countries
- Mothers and Infants Cohort Study (MICS) Study of perinatal transmission of HIV and developmental outcomes of children with HIV



8 Studies Offering Biospecimens

## Relevant Funding Opportunity Announcements (FOAs)

Understanding the Early Development of the Immune System (R01 - Clinical Trial Not Allowed) (PAR-18-333)

Scientific Contact: Denise Russo, Ph.D.

Closing Date: December 6, 2019

Zika Virus (ZIKV) Complications (R21 Clinical Trial Optional) (PA-18-048)

Scientific Contact: Nahida Chakhtoura, M.D., M.S.G.H.

Closing Date: January 8, 2020

Promoting NICHD Areas of Research for HIV/AIDS in Maternal and Child Health (R01) (PA-17-262)

Scientific Contact: Samantha C. Calabrese, M.P.H.

Expiration Date: September 8, 2020

Notice of NICHD Participation in "Planning Grant for Fogarty HIV Research Training Program for Low- and Middle-Income Country Institutions
(D71 Clinical Trial Not Allowed)

NICHD Scientific Contact: Denise Russo, Ph.D.

Notice of NICHD Participation in "Fogarty HIV Research Training Program for Low-and Middle-Income Country Institutions (D43 Clinical Trial Optional)

NICHD Scientific Contact: <u>Denise Russo</u>, Ph.D.



## Additional Resources

#### PregSource: Crowdsourcing to Understand Pregnancy

- Research project that aims to help us learn from women like you about what it's like to be pregnant.
  - Learn More and help researchers and healthcare providers understand pregnancy and learn how women experience motherhood.
  - PregSource Sign Up!

#### Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC)

- Established to advise the Secretary of Health and Human Services regarding gaps in knowledge and
  - research on safe and effective therapies for pregnant and lactating women.
    - Additional Information about PRGLAC



## **Additional Resources**

#### Fogarty-leDEA Mentorship Program (FIMP) for D43 Trainees

- Fogarty and the <u>International Epidemiology Databases to Evaluate AIDS (IeDEA) Collaboration</u> will help current and former Fogarty D43 trainees.
  - Information, Participating Regions, Answers to Frequently Asked Questions



Application Deadline: November 4, 2019

#### MPIDB Newsletter Campaign

- Stay up to date with new Funding Opportunity Announcements (FOAs), scientific advances, and grantee highlights by subscribing to the MPIDB Newsletter!
  - <u>Subscription Link!</u> Help us reach 1,000 Subscribers!
  - Newsletter Campaign Archive

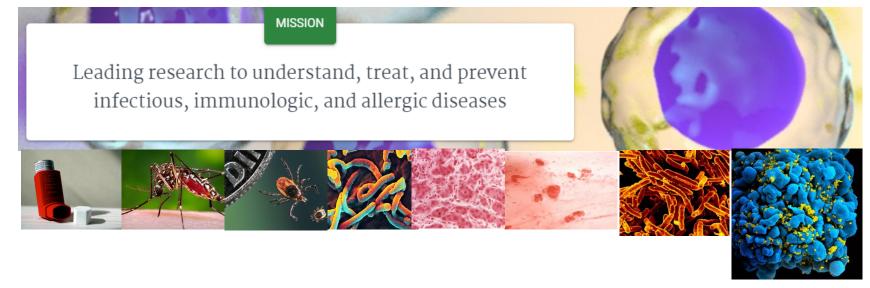




Anthony S. Fauci, M.D. Director



Carl Dieffenbach, Ph.D. DAIDS Director



## Organized by three extramural science divisions

- Division of AIDS (DAIDS)
- Division of Allergy, Immunology, and Transplantation (DAIT)
- <u>Division of Microbiology and Infectious Diseases (DMID)</u>

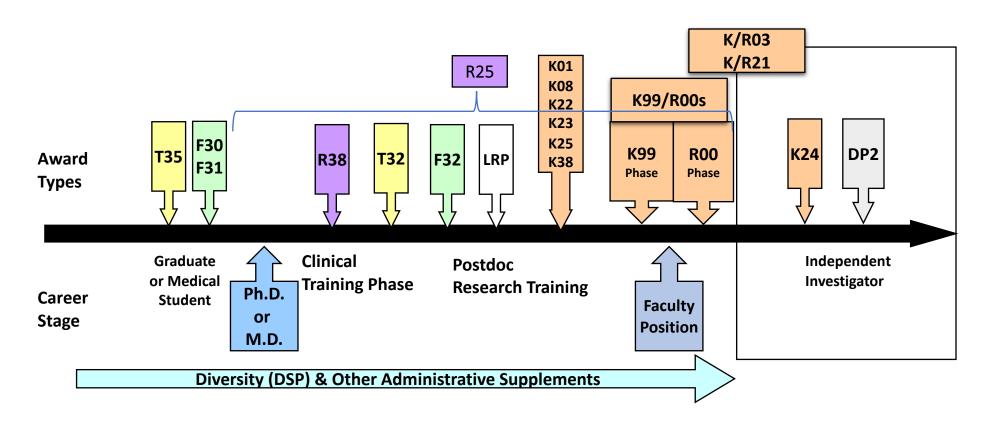
Second largest NIH Institute in terms of annual funding

# National Institutes of Health **Budget Comparison by Institute/Center**(Dollars in Thousands)

			use Mark	Change
\$	6,143,892	\$	6,444,165	4.9%
	5,523,324		5,808,268	5.2%
	3,488,335		3,658,822	4.9%
	575,579		603,710	4.9%
	806,373		845,783	4.9%
	2,872,780		3,033,183	5.6%
	3,083,410		3,286,107	6.6%
	1,419,844		1,489,237	4.9%
	13,080,137	1	3,722,482	4.9%
\$ :	36,993,674	\$ 3	8,891,757	5.1%
	2,112,675		2,206,992	4.5%
	200,000		200,000	0.0%
\$	39,306,349	\$ 4	1,298,749	5.1%
	\$ :	5,523,324 3,488,335 575,579 806,373 2,872,780 3,083,410 1,419,844 13,080,137 \$ 36,993,674 2,112,675	5,523,324 3,488,335 575,579 806,373 2,872,780 3,083,410 1,419,844 13,080,137 1 \$ 36,993,674 \$ 3 2,112,675 200,000	5,523,324       5,808,268         3,488,335       3,658,822         575,579       603,710         806,373       845,783         2,872,780       3,033,183         3,083,410       3,286,107         1,419,844       1,489,237         13,080,137       13,722,482         \$36,993,674       \$38,891,757         2,112,675       2,206,992         200,000       200,000

<sup>\*</sup>Total NIH Program Level (includes estimates for FY 2020 type I diabetes and superfund)

# NIH Training Continuum to Research Independence



## NIMH Supports 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, K99/R00

Research Education Grant: R25

Diversity Supplements

#### 3 Funding Pathways

- Individual NIMH Awards (R36, F, K)
- Institutional NIMH training awards (T32)
- 3. Administrative supplement to a mentor's NIMH grant

#### Post-Doctoral Fellow

NRSA Fellowship: F32

Institutional Training Grant: T32

Research Education Grant: R25

Diversity Supplements

### Mid-Career Faculty +

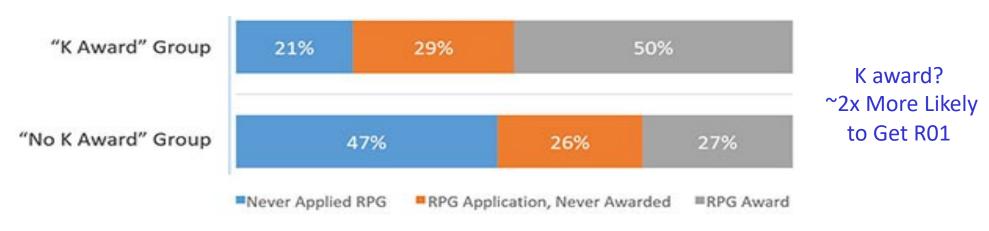
Research Education Grant: R25

Diversity Supplements



# Career "K" Development Awards

- Started 1957; some 20 different "Ks" since inception
- ☐ Goal: Research Independence (e.g., R01 award)
- □ 2018 NIAID Assessment → Ks work!



# NIAID K Trends, FY14 - FY19

FY	# All Ks Competing Applications	# All Ks Competing Awards	*Success Rates	^Total Cost (\$)
2019	299	97	32.4%	\$49.1M
2018	304	74	24.3%	\$44.7 M
2017	288	60	20.8%	\$41.8 M
2016	289	75	25.9%	\$41.2 M
2015	264	73	27.6%	\$38.3 M
2014	258	72	27.9%	\$36.3 M

IMPAC II

<sup>\*</sup>Success Rate = percentage of **reviewed** grant applications that received funding ^Total Costs = T1, T2, T5 and T7 awards

## **StARR - Research in Residency**

- Institutional Program
- Participants conduct research during Residency (R38), directly after med school and prior to subspecialty training (Fellowship)
- Thereafter during Fellowship R38 alumni apply for their own "K" award: K38
- NIAID: Only funded new apps in FY18;
  Duke, Emory and Children's National (DC)

# **Loan Repayment Programs**

- Designed to recruit and retain highly qualified health professionals (MDs, etc.) into biomedical or behavioral research careers
- Pay-off up to \$35K \$50K/year of qualified student load debt; renewable
- LRP is a contract; proposed application research can be same as K award (or other research grant mechanism)
- LRP Programs:
  - I. Clinical Research
  - 2. Pediatric Research
  - 3. Health Disparities Research
  - 4. Contraception and Infertility Research
  - 5. Clinical Research LRP Individuals Disadvantaged Backgrounds



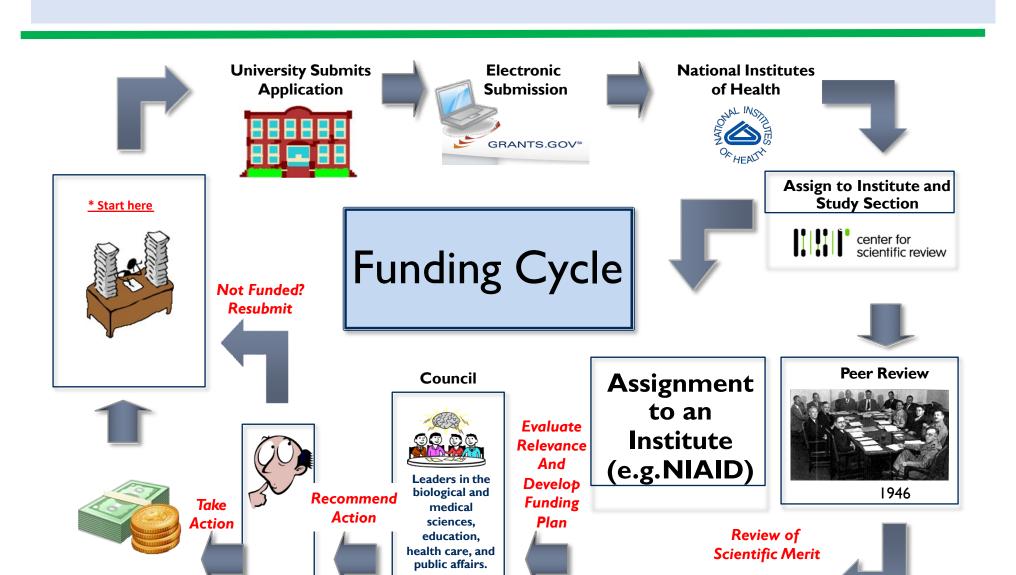
https://www.lrp.nih.gov/

## **Additional Funding Potential**

Consult your Program Officer or the NIH contact about possibilities from:

- NIH OD, Office of Disease Prevention
- NIH OD, Office of Sexual & Gender Minority Research
- NIH OD, Office of Behavioral and Social Sciences Research
  - NIH OD, Office of Dietary Supplements

## **NIH Grant Process**



# **Advice: Before You Start Writing**

Take a step back - view the process of writing the grant not only for funding potential but also to organize your research vision, affirm a timeline for your career development, establish routine engagement with your mentor:

- Define your career goals and research interest
- Outline the techniques, skills, knowledge and relationships necessary to achieve your career goals
- Identify skills gaps and means to address them
- Define your research plan Specific Aims
- Build a career/training plan that is tailored to your needs, strengths
- Complete the application WITH your Mentor

Prepare a complete, consistent, compelling picture of how the **proposed research**, **training plans**, **collaborations** will build upon your accomplishments and help achieve career goals for <u>independent research</u>

# **Avoid Common Pitfalls in "K" and LPR Applications**

Research and career plans not well aligned

Plans for training not well justified

Lack of strong preliminary data

Inadequate alternative strategies proposed

 Lack of mentor training experience in the proposed area, prior collaboration, research expertise or existing funding

## Thank you for your attention!

**Contact Information:** 

<u>OD</u>

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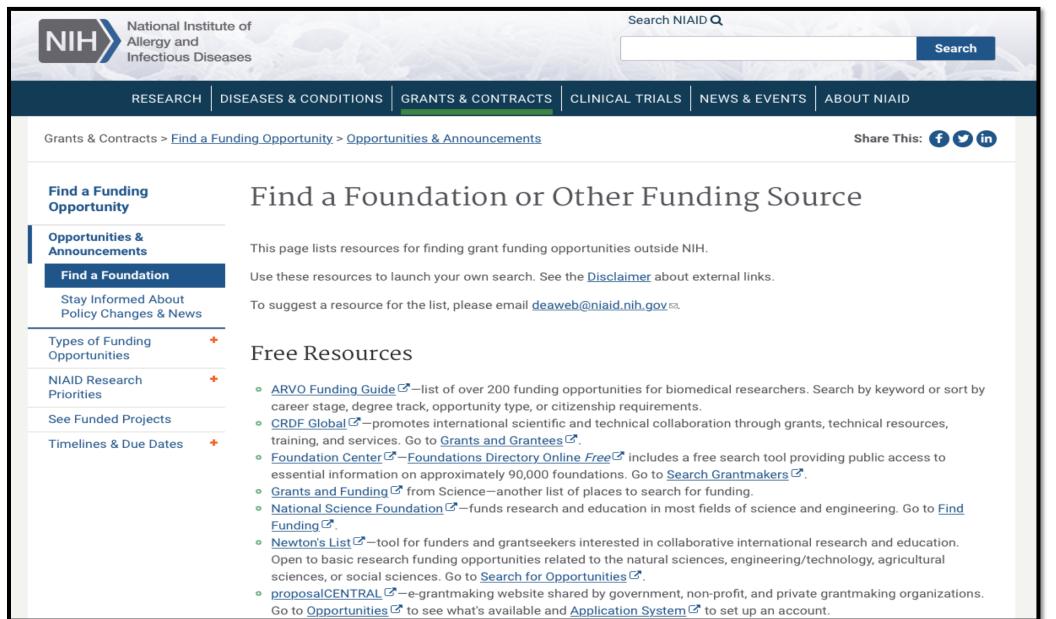


# **Additional Slides of Potential Interest**

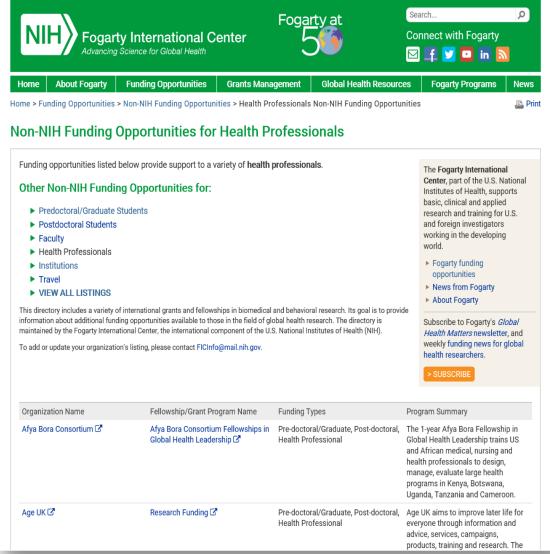
# NIH ORWH: BIRCWH Accomplishments

- Since its creation in 2000, over 700 Scholars graduated from the program
- About 70% of BIRCWH Scholars supported in 2010-2015 submitted at least one subsequent RPG application
  - ~50% who applied were successful
  - ~70% of this cohort had a tenure-track appointment
- Originally focused on reproductive health now includes many areas related to women's health
  - CVD, Aging, Cancer, Neurosciences, Musculoskeletal Conditions, Autoimmunity, Mental Health, and Infectious diseases (HIV/AIDS also)

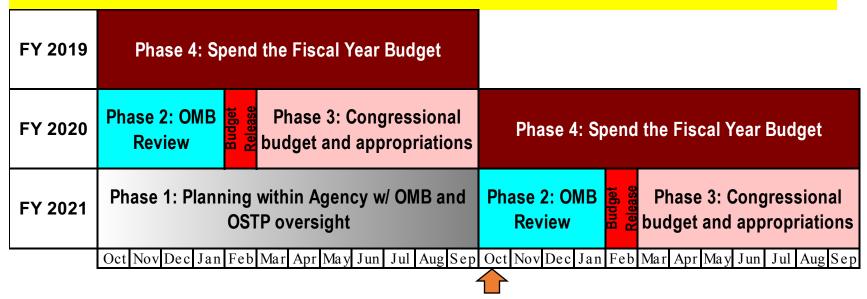
## **Other Funding Sources: Beyond NIH**



# Beyond NIH: Fogarty International Center (FIC) Links



# The Ideal Federal Budget Cycle



Federal agencies work on multiple budgets at any given time

- NIH completes prior fiscal spending by 9/30 of the calendar year
- FY20 Federal government under Continuing Resolution (CR) through Nov 21, 2019
- Agencies/OMB already thinking beyond FY21

Source: AAAS, http://www.aaas.org/page/presentations (June 3, 2019)

# **NIAID K Programs**

K	Program Name	Туре
K22	NIAID Career Transition	Transition to Fac.
~\$250K		
*K99s/R00s	Pathway to Independence Programs	Transition to Fac.
~\$500K	1) Parent NIH	
	2) NIAID Physician-Scientists	hic
K08	2) NIAID Physician-Scientists Variance across ICs R38 NICHD does not support t Mentored Clinical Scientist Research	MDs/Clinicians
~\$750K		
K23	Mentored Patient-Oriented Research	MDs/Clinicians
~\$750K		
K24	Midcareer Investigator Award	MDs/Clinicians
varies		
K25	Mentored Quantitative Research	Specific Research
~\$750K		
K01	Mentored Research Scientist	Specific Research
~\$750K		

## **Important Reminders for Grantees**

#### KNOW THE FUNDING AND SALARY LIMITS – See IC-specific websites (examples below):

- NCI: <a href="https://www.cancer.gov/about-nci/budget">httphttps://www.cancer.gov/about-nci/budget</a>
- NIAID: <a href="https://www.niaid.nih.gov/grants-contracts/paylines-funding">https://www.niaid.nih.gov/grants-contracts/paylines-funding</a>
- NICHD: <a href="https://www.nichd.nih.gov/grants-contracts/process-strategies/strategies/strategies/">https://www.nichd.nih.gov/grants-contracts/process-strategies/strategies/</a>
- NIDA: <a href="https://www.drugabuse.gov/funding/nida-funding-opportunities/nida-funding-strategy">https://www.drugabuse.gov/funding/nida-funding-opportunities/nida-funding-strategy</a>
- NIMH: <a href="https://www.nimh.nih.gov/funding/funding-strategy-for-research-grants/index.shtml">https://www.nimh.nih.gov/funding/funding-strategy-for-research-grants/index.shtml</a>
- NHLBI: <a href="https://www.nhlbi.nih.gov/current-operating-guidelines">https://www.nhlbi.nih.gov/current-operating-guidelines</a>
- FIC: https://www.fic.nih.gov/About/FundingStrategy/Pages/default.aspx

**NIH PEER REVIEW** – Make sure you note page limits, required forms, allowable supplemental/appendix materials, review criteria, human subjects inclusion, and clinical trials requirements, etc. - <a href="http://grants.nih.gov/grants/peer/peer.htm">http://grants.nih.gov/grants/peer/peer.htm</a>

**NIH POLICY ON CLINICAL TRIALS** – Avoid rejection of your application by keeping informed on funding opportunity announcement (FOA) requirements and any recent revisions to policies: <a href="https://grants.nih.gov/policy/notices.htm">https://grants.nih.gov/policy/notices.htm</a>

NIH POLICY ON SINGLE IRB REVIEW FOR MULTI-SITE RESEARCH – Full details are available: <a href="https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm">https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm</a>

NIH PUBLIC ACCESS POLICY — Adequate preparation, and using NCBI's MyBibliography to monitor your publications, are keys to avoiding delays in funding awards due to non-compliance issues. If you aren't sure how to use MyNCBI, see: <a href="http://publicaccess.nih.gov/communications.htm">http://publicaccess.nih.gov/communications.htm</a>

NIH PROGRESS REPORTING (RPPR) & GRANT CLOSEOUT - Don't submit the wrong grant closeout report, a final/F-RPPR or interim/I-RPPR may be needed (see the NIH RPPR Page)

**Administrative, budgeting actions requiring NIH approval** (per <u>NIH Grants Policy Statement</u>): Ask your PO, ask your budget office! Start the process early.