Advancing the Science of Community Engaged Research

Innovative and Effective Methods of Stakeholder Engagement in Translational Research

Washington, DC; Association of American Medical Colleges

# Novel Approaches to Training Researchers and Stakeholders in Community Engaged Research

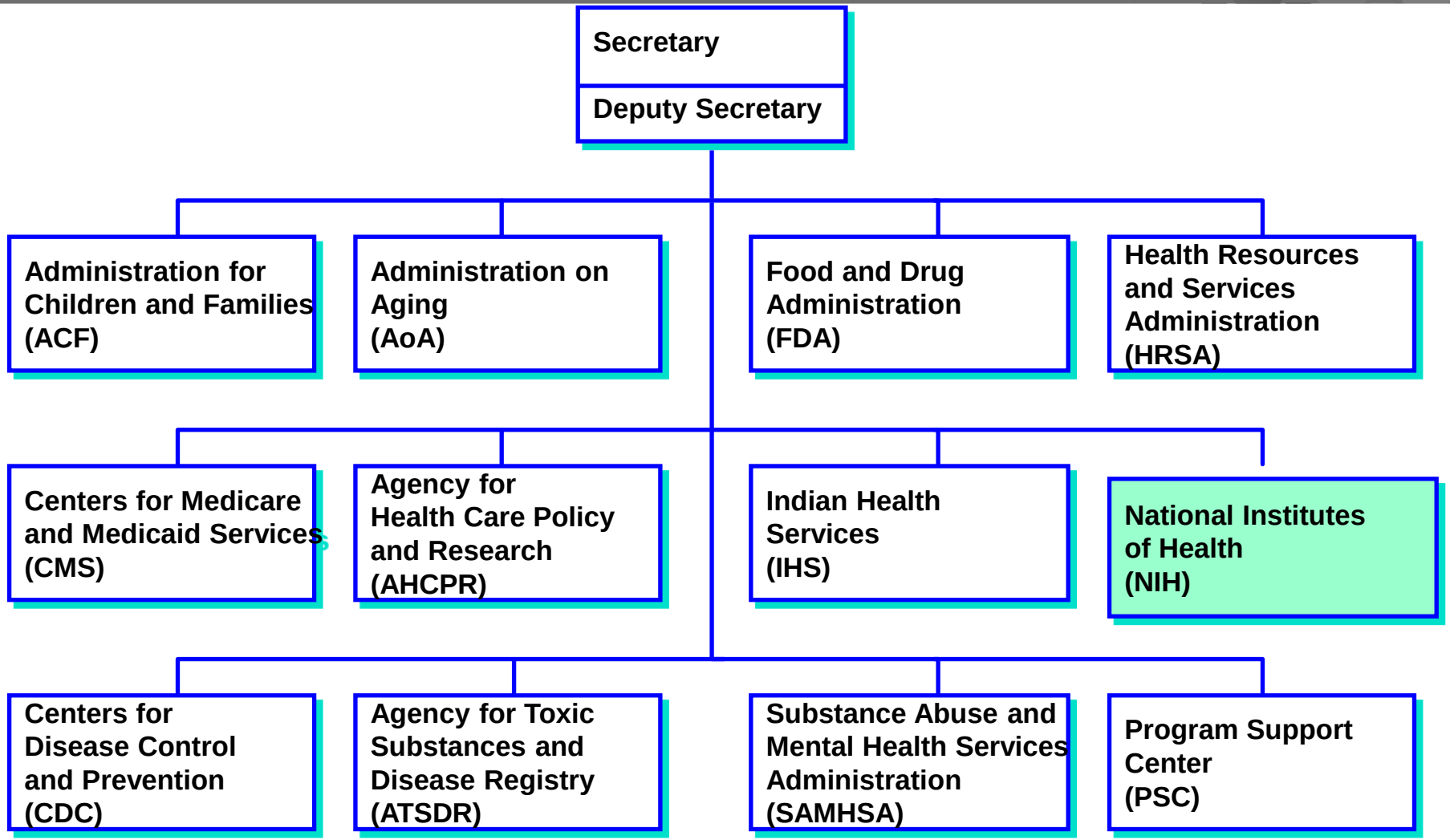
Cheryl Anne Boyce, Ph.D.
Chief, Implementation Science Branch,
Center for Translation Research and Implementation Science

**The views expressed are those of the author and do not necessarily reflect the views of the National Institutes of Health (NIH), Department of Health and Human Services (DHHS).*

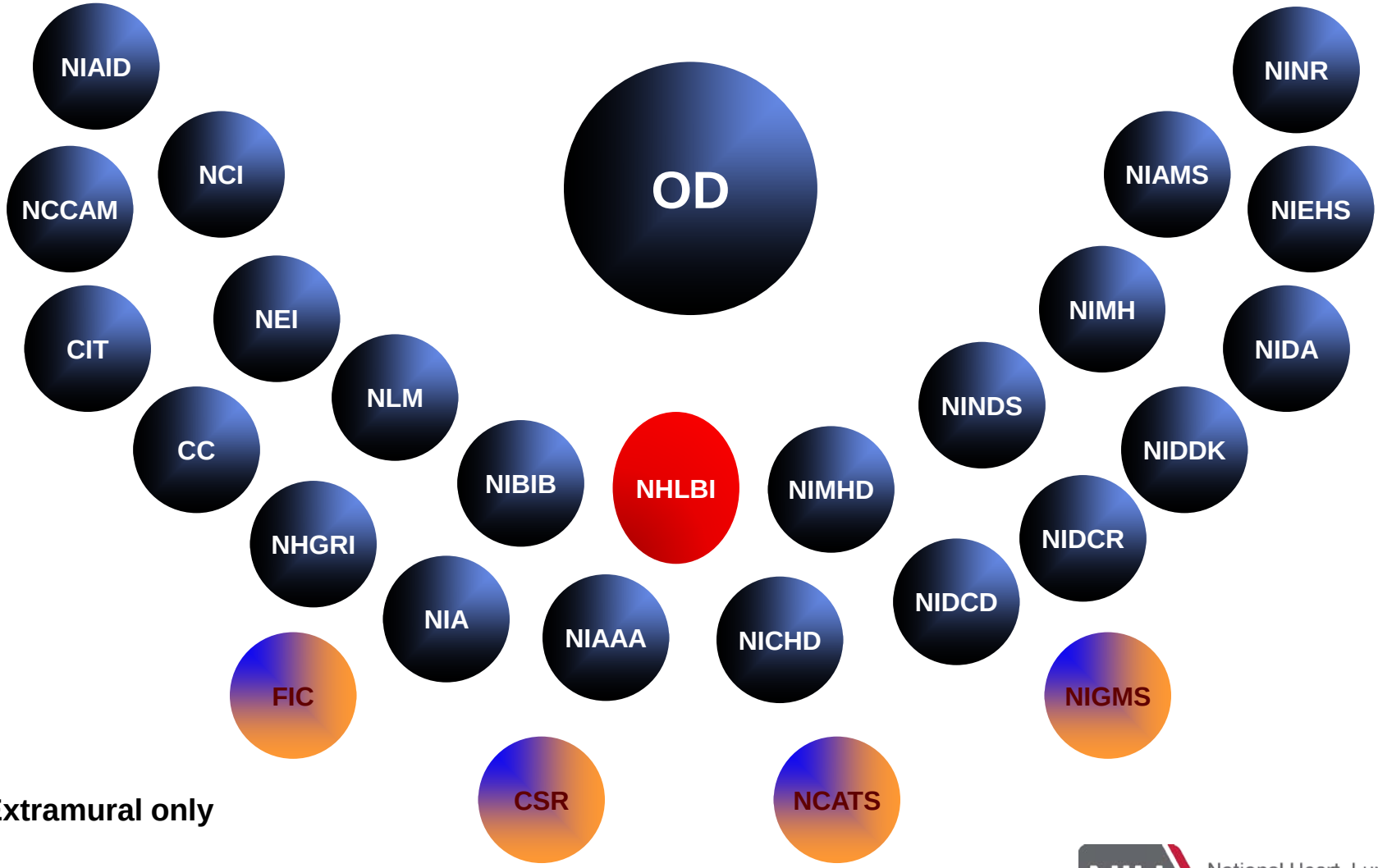
August 26, 2016

National Heart, Lung, and Blood Institute

# US Department of Health and Human Services (DHHS)



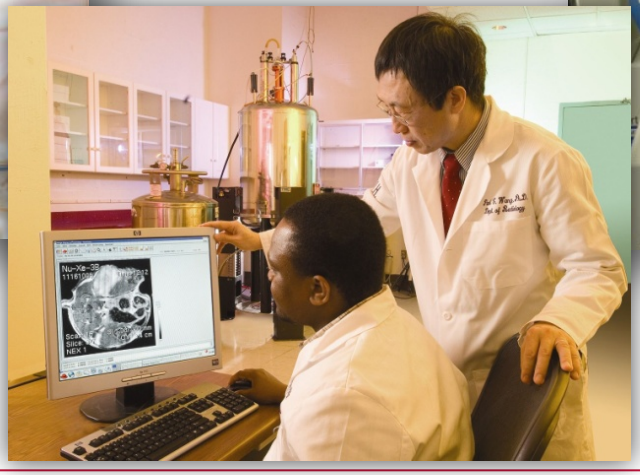
# Structure of the NIH: 27 Institutes and Centers

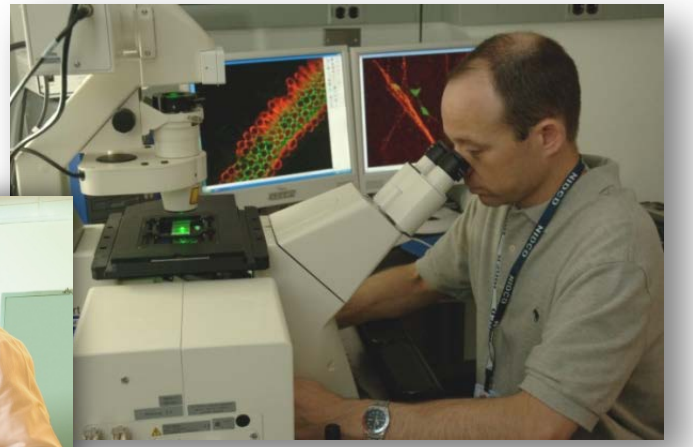


# National Heart, Lung and Blood Institute

**Mission:**

Provide global leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.





# NHLBI Strategic Goals

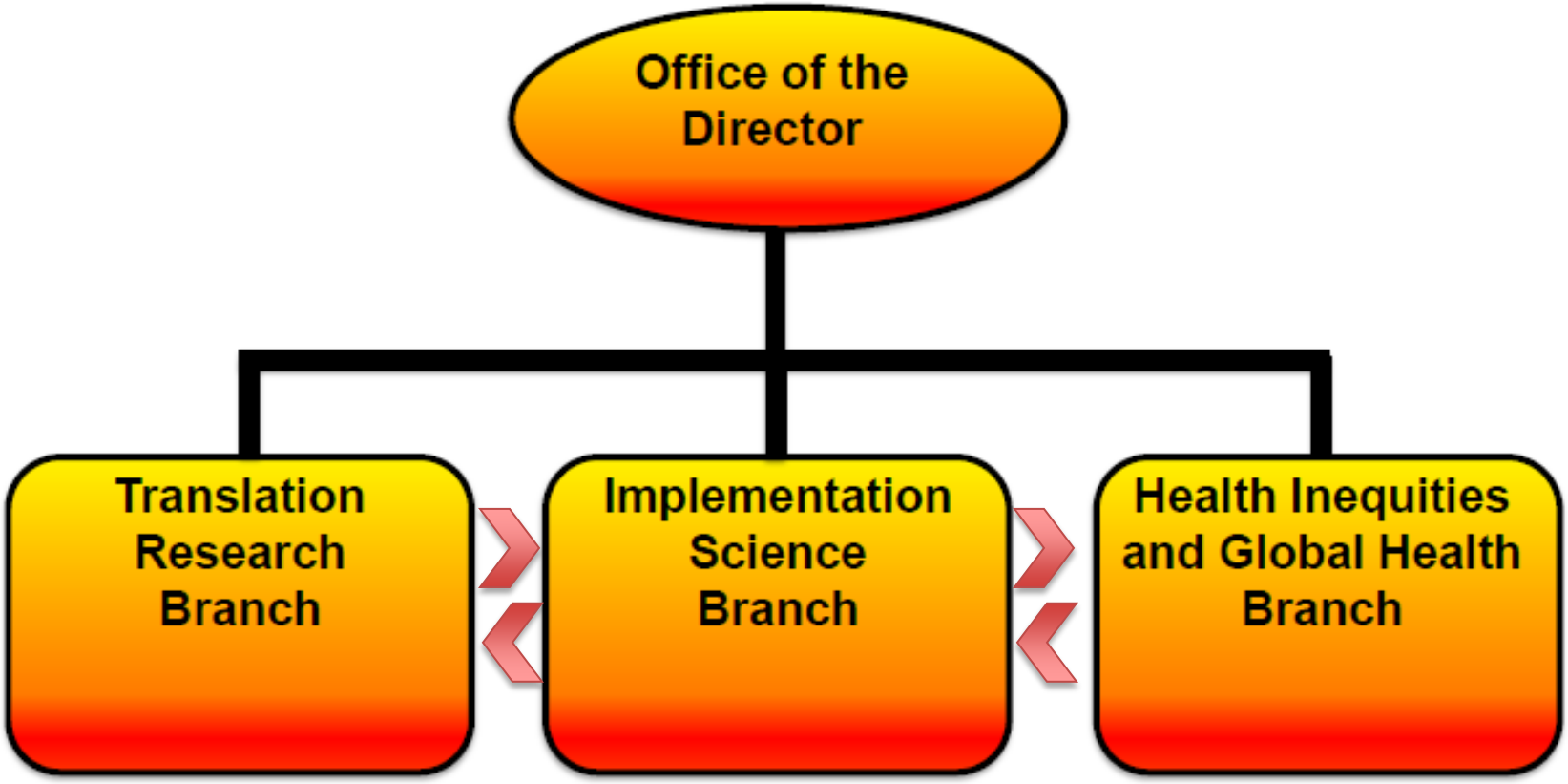
The four Strategic Goals for the Strategic Visioning process span the NHLBI mission and include research on normal health and disease in heart, lung, blood, and sleep (HLBS) systems, the *translation of research for prevention, diagnosis, and treatment of diseases, and the support of training and resources for biomedical researchers across the NHLBI landscape.*

http://www.nhlbi.nih.gov/about/documents/strategic-visioning/strategic-goals
Accessed 3/9/2016

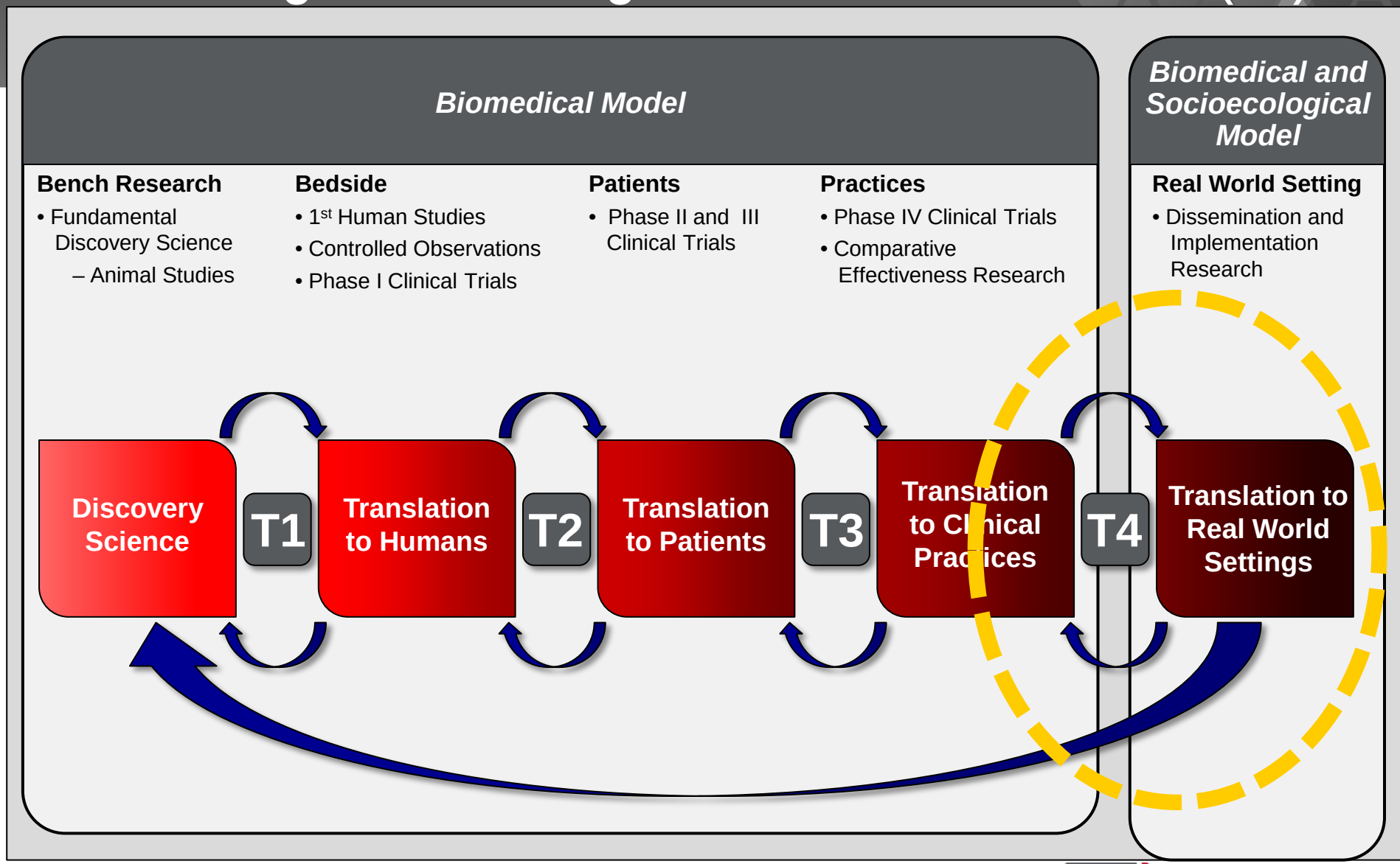
# CTRIS Announcement, January 23, 2014

*The Center for Translation Research and Implementation Science (CTRIS) will serve as a strategic focal point for* ***T4 translation research****,* ***implementation science****, and a* ***research agenda*** *that addresses both* ***domestic and global health inequities****, and* ***research training*** *for a workforce to achieve these goals.*

# Center for Translation Research and Implementation Science (CTRIS)



# Focusing on Late Stage Translation Research (T4)




Mensah. *Global Heart* September 2013;8(3): 283-284. Based on and informed by the models of Khoury et al. *Genet Med* 2007;9:665-74, and the Harvard Catalyst; The Harvard Clinical and Translational Science Center, available at: http://catalyst.harvard.edu/pathfinder/. Accessed August 28, 2013.

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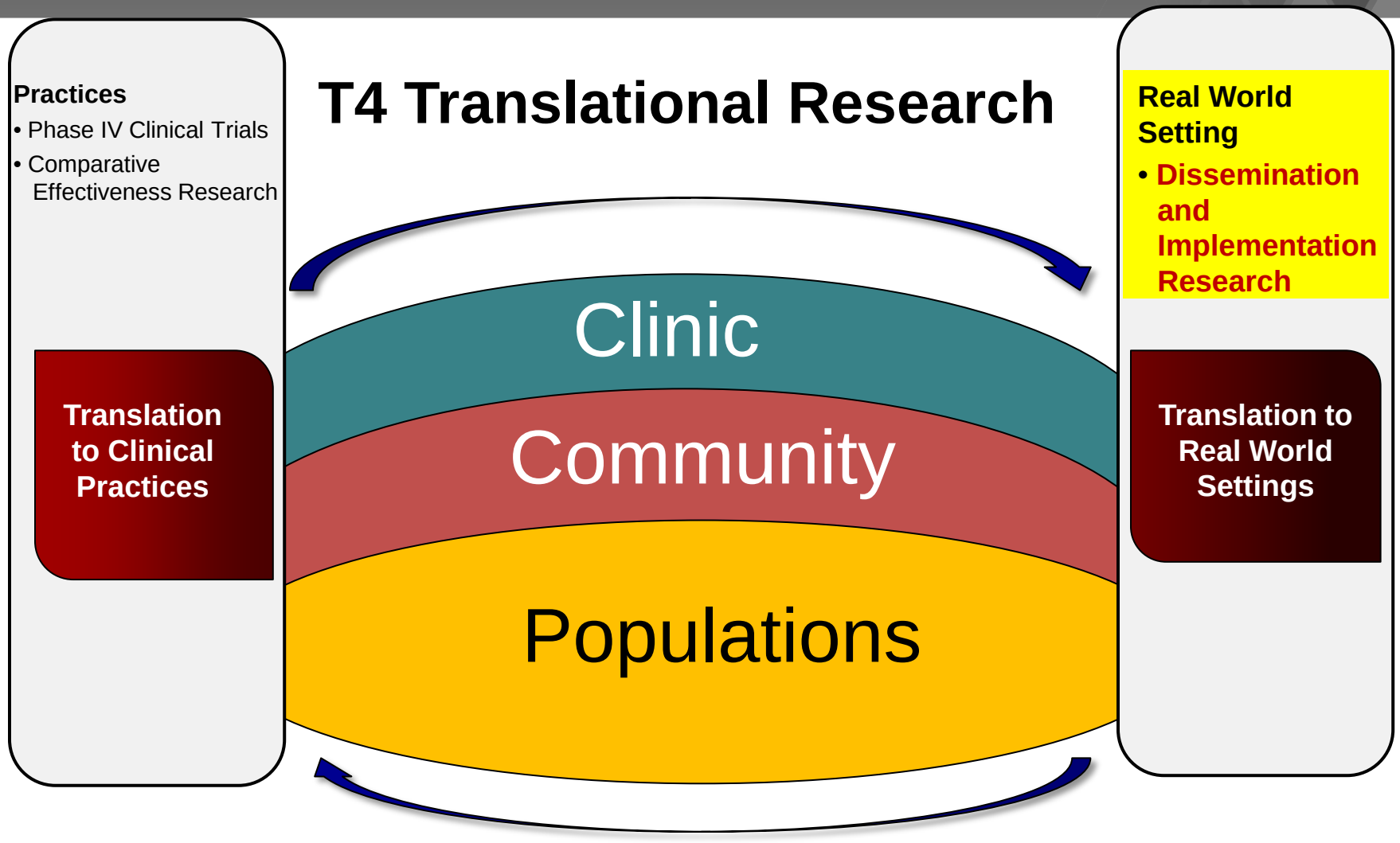
# Late Stage T4 Translation Research




* Authors conclusion – T4 research occurs in other settings but these are key for population impact

# T4 Translation Research - Approach

- Multilayered
  - Community
  - Health care system
  - Providers
  - Patients
  - Families
- Multifaceted
  - Interventions at several layers
  - Aligned with common outcome
  - Specific targets at each level
- Engages stakeholders/key partners at each level
- Population-level impact

# Funding Opportunities

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# NHLBI Research Career Development Programs in T4 Implementation Research (K12)- **RFA**

**Program Goal**

- Build a new trans-disciplinary implementation research workforce to investigate strategies that, when scaled up improve health outcomes for NHLBI-related diseases and conditions.
- https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-17-016.html

- RFA-HL-17-016
- Letter of Intent Due Date(s):
  - **September 13, 2016**
    (not required)
- Application Receipt Date:
  - **October 13, 2016**
- Earliest Start Date:
  - **September 2017**

Programmatic Contact:
Helena O. Mishoe, PhD, MPH
mishoeh@nhlbi.nih.gov
(301) 451-5078

# NHLBI Research Career Development Programs in T4 Implementation Research (K12)- **RFA**

- Year 1: Planning; Years 2-5: Implementation
- Mentoring by a multidisciplinary research team
- Scholars must hold a research or health-professional doctoral degree
- Scientific and training environments beyond disciplines.
- Collaborations across diverse and non-academic institutions
- Partnerships/collaborative training linkages with practice settings

# Strategies to Increase Delivery of Guideline-Based Care to Populations with Health Disparities (R01)- **PAR**

**Program Goal**

- Innovative and feasible studies to test strategies to accelerate the adoption of guideline-based recommendations into clinical practice among populations with health disparities.
- http://grants.nih.gov/grants/guide/pa-files/PAR-15-279.html#sthash.uMjziN1h.dpu

- PAR-15-279
- Application Receipt Dates:
  - **October 21, 2016**
  - **June 21, 2017**
  - **October 20, 2017**
  - **June 21, 2018**
- Expiration Date:
  - June 22, 2018

R01

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# NIH Support for Conferences and Scientific Meetings (Parent R13)- **PA**

**Program Goal**

- Support high quality scientific conferences that are relevant to the NIH's mission and to the public health. A conference is defined as a symposium, seminar, workshop, or any other organized and formal meeting, whether conducted face-to-face or via the internet, where individuals assemble (or meet virtually).

- PA-16-294
- Standard Application Receipt Dates (three times per year)
- http://grants.nih.gov/grants/guide/pa-files/PA-16-294.html

R13

# NHLBI Program Project Applications (P01)- **PAR**

**Program Goal**

- Support minimum of three interrelated research projects that investigate a complex biomedical theme or research question. Program Project Grants support collaborative research effort can accelerate the acquisition of knowledge more effectively than a simple aggregate of research projects that have no interaction or thematic integration.

- PAR-16-402
- Standard Application Receipt Dates (three times per year)
- http://grants.nih.gov/grants/guide/pa-files/PAR-16-402.html

P01

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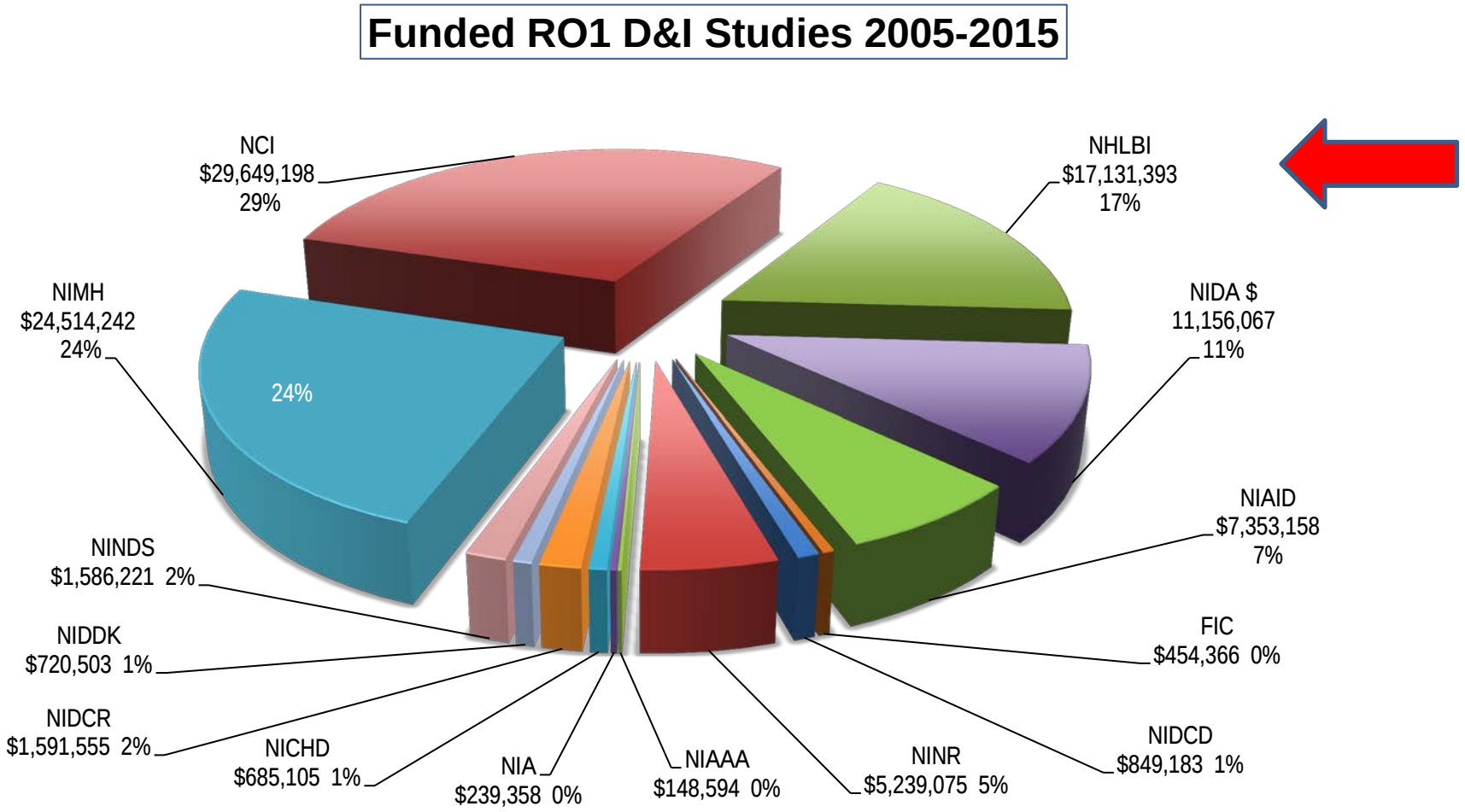
# R01 Funded D & I Studies 2005-2015




(Method from Tinkle et al, 2013 using data from NIH Reporter Accessed February, 2016)

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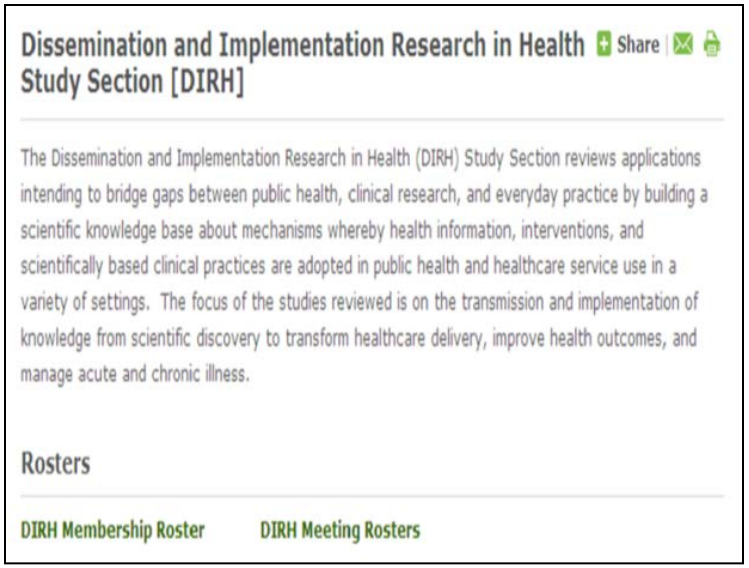
# DIRH Study Section (Review Committee)

- The Dissemination and Implementation Research in Health (DIRH) Study Section reviews applications intending to bridge gaps between public health, clinical research, and everyday practice.
- The focus of the studies reviewed is on the transmission and implementation of knowledge from scientific discovery to transform healthcare delivery, improve health outcomes, and manage acute and chronic illness.

NIH Center for Scientific Review



**Dissemination and Implementation Research in Health Study Section [DIRH]** Share

The Dissemination and Implementation Research in Health (DIRH) Study Section reviews applications intending to bridge gaps between public health, clinical research, and everyday practice by building a scientific knowledge base about mechanisms whereby health information, interventions, and scientifically based clinical practices are adopted in public health and healthcare service use in a variety of settings. The focus of the studies reviewed is on the transmission and implementation of knowledge from scientific discovery to transform healthcare delivery, improve health outcomes, and manage acute and chronic illness.

Rosters

DIRH Membership Roster  DIRH Meeting Rosters

*"How will this study advance the field of implementation science?"*

http://public.csr.nih.gov/StudySections/IntegratedReviewGroups/HDMIRG/DIRH/Pages/default.aspx

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# Dissemination and Implementation Research in Health (R01)

## Program Goal

- Support grant applications that will identify, develop, test, evaluate and/or refine strategies to disseminate and implement evidence-based practices (e.g. behavioral interventions, prevention, early detection, diagnosis, treatment, disease management interventions, quality improvement programs) into public health, clinical practice, and the community.
- http://grants.nih.gov/grants/guide/pa-files/PAR-16-238.html

- PAR-16-238 , R01
  Research Project Grant

R01

- Companion grants
  - PAR-16-236, R21
    Exploratory/Developmental Grant

R21

  - PAR-16-237, R03
    Small Grant Program

R03

- Standard Application Receipt Dates (three times per year)

# Non-HHS Agency D & I Partners

- Patient-Centered Outcomes Research Institute
- Department of Education
  - Pediatric populations
  - School health clinics
- Department of Justice
- Department of State
- Department of Veterans Administration

# Research and Training Opportunities and Resources

# D&I RESEARCH TRAINING: TIDIRH

July 26-31, 2015

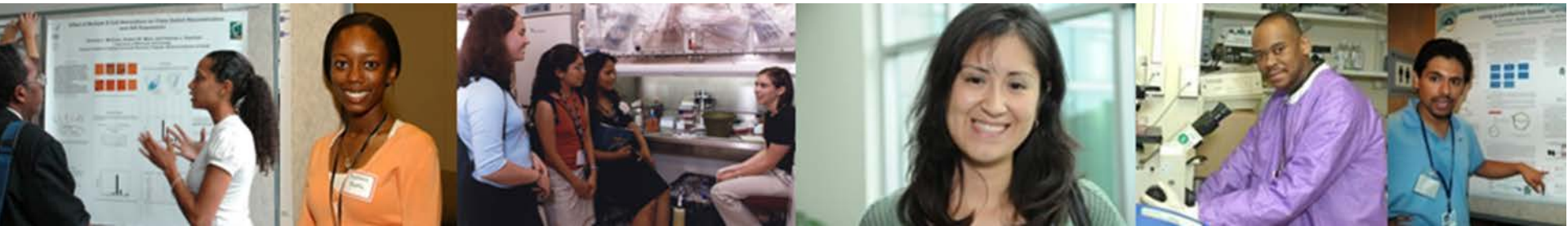
TIDIRH Training Institute for Dissemination and Implementation Research in Health

Pasadena, California

Applications are due on **August 26, 2016.**

- Initiated in 2011: The TIDIRH used a 5-day residential immersion to maximize opportunities for trainees and faculty to interact. Over 200 have been trained.
- Harvard University and the Dana-Farber Cancer Institute with support from NCI, NHLBI, NIDDK, NIMH, OBSSR, ODP, and VA.

https://researchtoreality.cancer.gov/discussions/marking-five-great-years-di-training.
http://obssr.od.nih.gov/about_obssr/about.aspx



# 9th Annual D&I Conference

NIH Sponsored in Partnership with OBSSR, VA and now Academy Health "State of the Science" Venue

- 2007: "Showcase," ~350 participants
- 2009: "Building Capacity," > 500 registrants
- 2010: "Methods and Measures," 900 registrants
- 2011: "Policy and Practice," 1200 registrants
- 2012: "D and I at the Crossroads," 1200 registrants
- 2014: "Transforming Health Systems to Optimize Individual and Population Health," 1200 registrants
- 2015: "Optimizing Personal and Population Health," 1200 registrants

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# Developing Successful Research Grants

"**How to Write a Successful Research Grant Application: A Guide for Social and Behavioral Scientists**" (Pequegnat, Stover & Boyce, 2011).

- *Developed from HIV/AIDS grant research workshops.*
- *The only collaborative book written by federal personnel and research investigators who have participated in the process of reviewing research grants.*

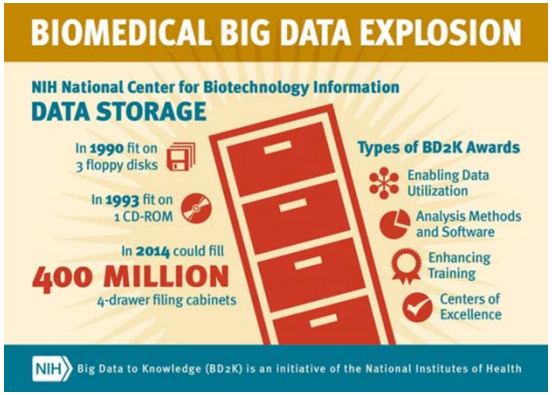
## Chapters of interest:

- "Community-Based Collaborations: Designing, Conducting and Sustaining Prevention Programs" (McKay, Bell & Blake, 2011)
- Selecting the Appropriate Research Mechanism: Finding the Right Match (Boyce & Ferrell Aklin, 2011).

http://www.springer.com/medicine/book/978-1-4419-1453-8

# Future Prospects and Innovations

- Precision Medicine Initiative
- Team Science
- Big Data
- Data Harmonization
- Affordable Health Care
- Electronic Health Records
- Neuroepidemiology
- Population neuroscience




SciTS | Building the knowledge base for effective team science

eHR INCENTIVE PROGRAM

Heart, Lung, ɔd Institute

# NIH Precision Medicine Initiative

## WHAT IS IT?

**Precision medicine** is a groundbreaking approach to disease prevention and treatment based on people's individual differences in environment, genes and lifestyle.

The Precision Medicine Initiative® Cohort Program will lay the foundation for using this approach in **clinical practice.**

## WHAT ARE THE GOALS?

Engage a group of **1 million or more U.S. research participants** who will share biological samples, genetic data and diet/lifestyle information, all linked to their electronic health records. This data will allow researchers to develop more precise treatments for **many diseases and conditions.**

Pioneer a new model of research that emphasizes **engaged research participants, responsible data sharing and privacy protection.**

Research based on the cohort data will:

- Lay **scientific foundation** for precision medicine
- Help identify new ways to **treat and prevent disease**
- Test whether **mobile devices**, such as phones and tablets, can encourage healthy behaviors
- Help develop the **right drug** for the **right person** at the **right dose**

https://www.nih.gov/precision-medicine-initiative-cohort-program

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# Data Harmonization and Toolkits

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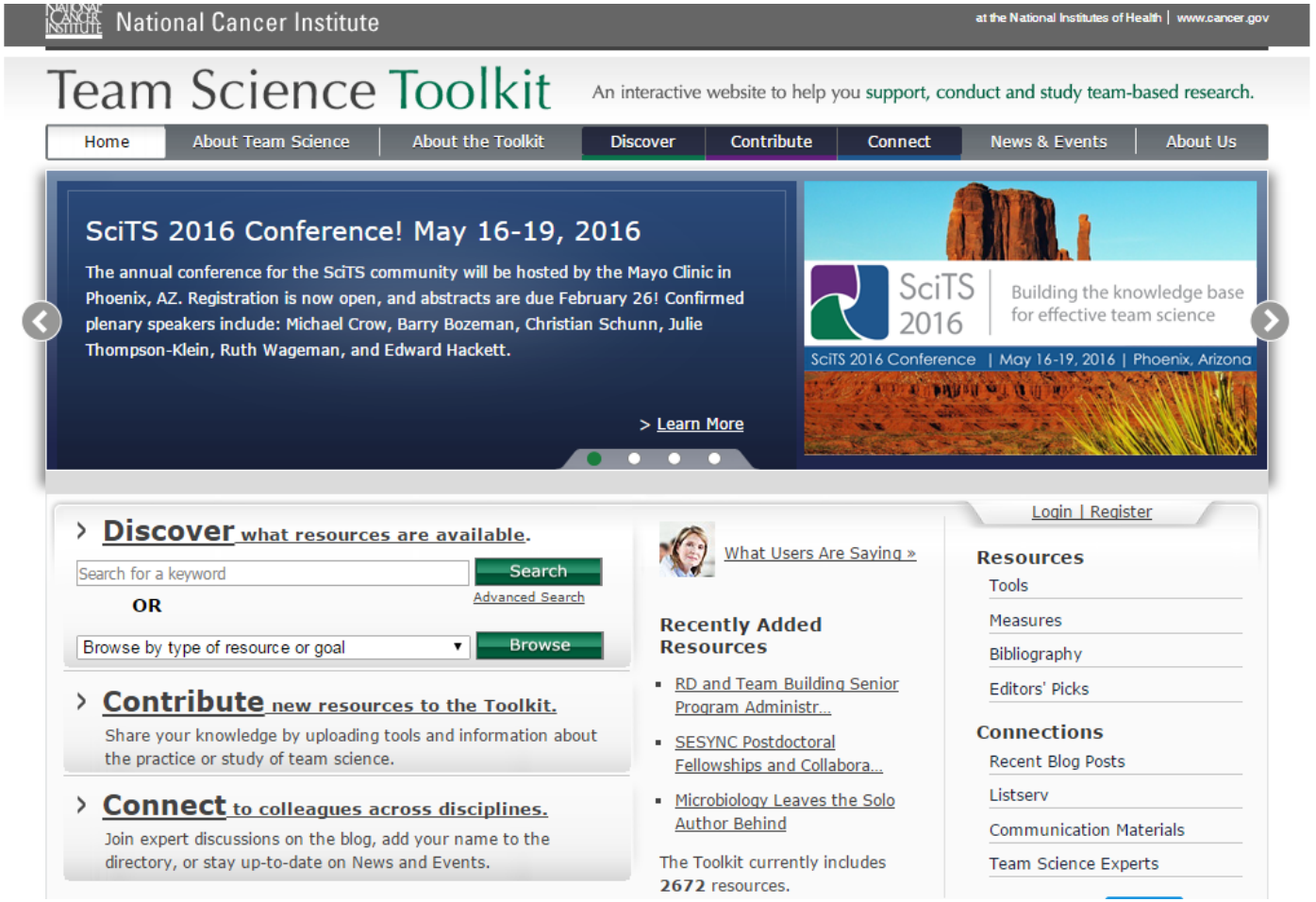
# Team Science Toolkit




https://www.teamsciencetoolkit.cancer.gov/Public/Home.aspx

# Common Data Element (CDE)

- **Common Data Element** (CDE) - A data element that is common to multiple data sets across different studies.
- Commonality may be intentional or unintentional
- CDEs improve data quality and promote data sharing. .

- Types
  - **Universal** - may be used in studies, regardless of the specific disease or condition of interest, e.g., demographic information of study subjects, medical history, certain patient-reported outcomes.
  - **Domain-specific** - designed and intended for use in studies of a particular topic, disease or condition, body system, or other classification, e.g., sickle cell disease, etc.
  - **Required** - required or expected, as a matter of institutional policy (e.g., research funder or performer), to be collected for all subjects in studies of a particular type.
  - **Core** - required or expected to be collected in particular classes of studies.

https://www.nlm.nih.gov/cde/glossary.html

# **Pheno**types and e**X**posures **(PhenX)** Toolkit

https://www.phenxtoolkit.org

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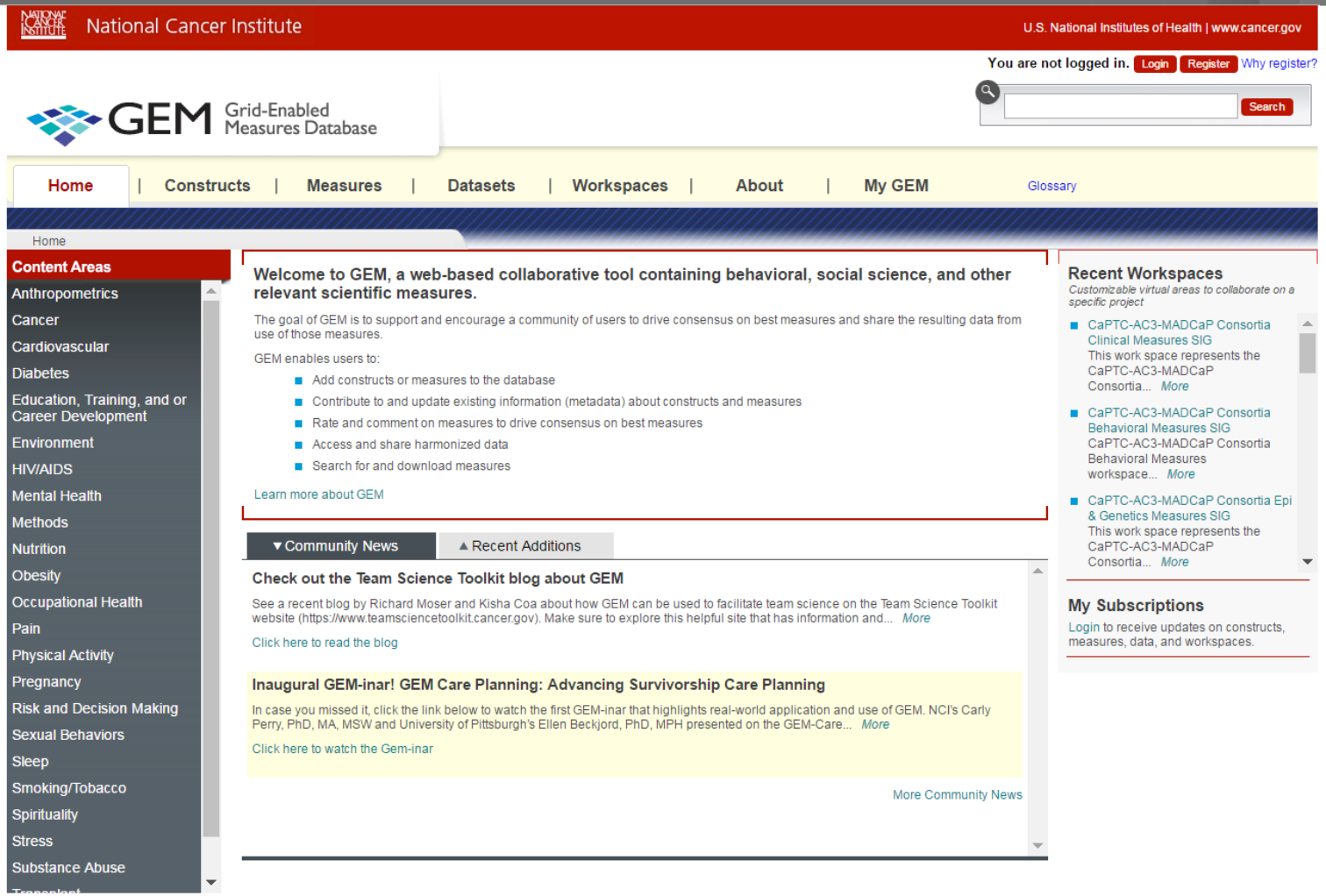
# Grid-Enabled Measures Database (GEM)




https://www.gem-beta.org/Public/Home.aspx

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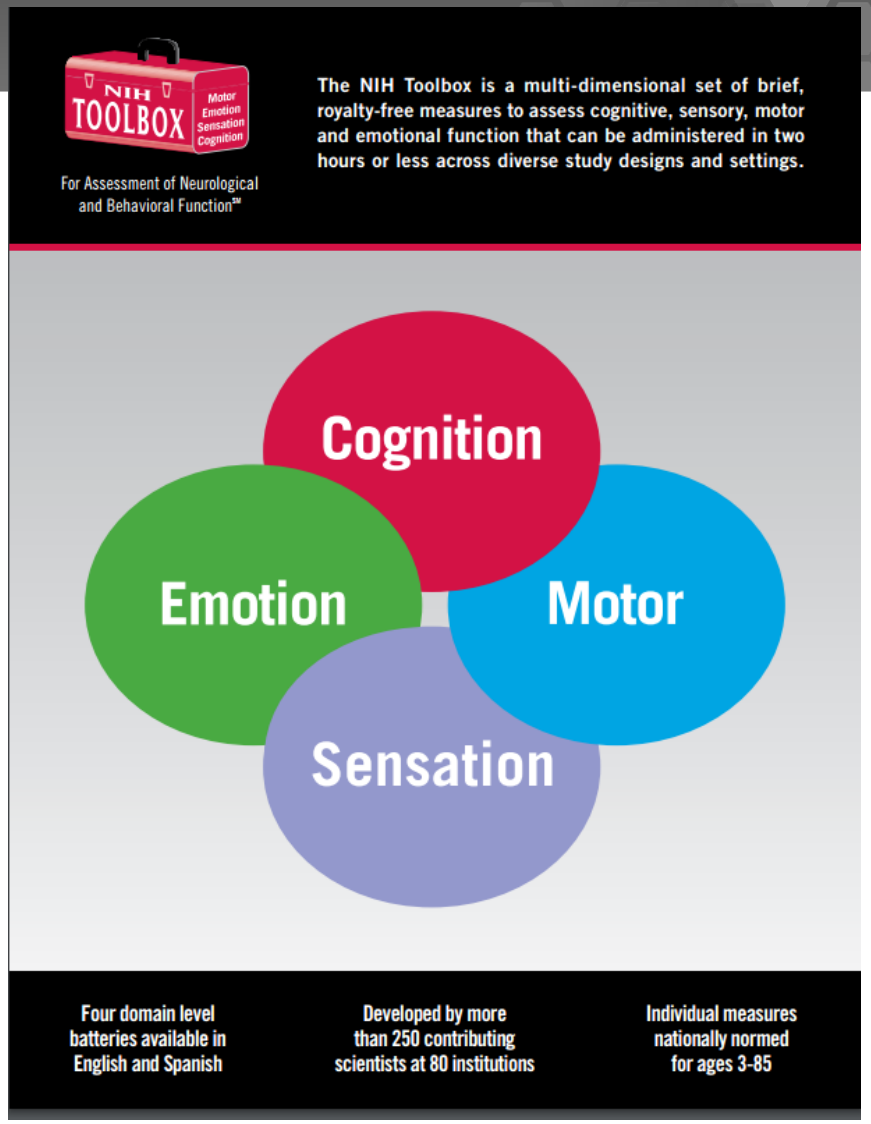
# NIH Toolbox

- Monitors neurological and behavioral function over time, and measures the domain constructs across developmental stages.
- Facilitates the study of functional changes across the lifespan, including evaluating intervention and treatment effectiveness.
- App available on iTunes
  https://itunes.apple.com/us/app/nih-toolbox/id1002228307?mt=8



# **PROMIS** (Patient-Reported Outcomes Measurement Information System)*

PROMIS® (Patient-Reported Outcomes Measurement Information System) is a set of person-centered measures that evaluates and monitors physical, social, and emotional health in adults and children. It can be used with the general population and with individuals living with chronic conditions.

**INTRO TO PROMIS**

**OBTAIN & ADMINISTER MEASURES**

**MEASURE DEVELOPMENT & RESEARCH**

## Why Use PROMIS?

- Developed and validated with state-of-the-science methods to be psychometrically sound and to transform how life domains are measured
- Designed to enhance communication between clinicians and patients in diverse research and clinical settings
- Created to be relevant across all conditions for the assessment of symptoms and functions
- Translations available in Spanish and many other languages

*PROMIS, Patient-Reported Outcomes Measurement Information System, and the PROMIS logo are marks owned by the U. S. Department of Health and Human Services.*

http://www.healthmeasures.net/explore-measurement-systems/promis

*Northwestern University, NIH grant U2C CA186878

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# **ASCQ-Me** (Adult Sickle Cell Quality of Life Measurement Information System)*

**ASCQ-Me℠ (Adult Sickle Cell Quality of Life Measurement Information System) is a patient-reported outcome measurement system that evaluates and monitors the physical, social, and emotional well-being of adults with sickle cell disease (SCD).**

**INTRO TO ASCQ-ME**

**OBTAIN & ADMINISTER MEASURES**

**MEASURE DEVELOPMENT & RESEARCH**

## Why Use ASCQ-Me?

- Developed and validated with state-of-the-science methods to be psychometrically sound
- Designed to be comprehensive when used with PROMIS®
- Created to be complementary with physiological measures of disease severity
- Supports treatment planning as well as clinical and health services research

*ASCQ-Me, the Adult Sickle Cell Quality of Life Measurement Information System, and the ASCQ-Me logo are marks owned by the U. S. Department of Health and Human Services.*

http://www.healthmeasures.net/explore-measurement-systems/ascq-me

*Northwestern University, NIH grant U2C CA186878

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# NHLBI: People…Science…Health

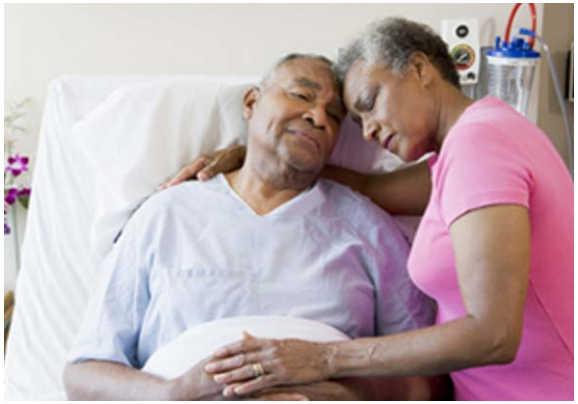
**Please keep in touch with us:**

- Website: http://www.nhlbi.nih.gov
- Facebook: http://www.facebook.com/nhlbi
- Twitter: @nhlbi_nih

**For more information:**

- NIH Website: http://www.nih.gov
- NIH Office of Extramural Research Website: http://grants.nih.gov/grants/oer.htm

# Thank You, Gracias, Merci, Shukran, Xièxie, Obrigado, Ngiyabonga, Teşekkürler



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