

National Institutes of Health Research into ME/CFS

Vicky Whittemore, PhD

National Institute of Neurological Disorders and Stroke

National Institutes of Health

Bethesda, MD, USA

IACFS/ME Conference

Ft. Lauderdale, FL

October 26-30, 2016

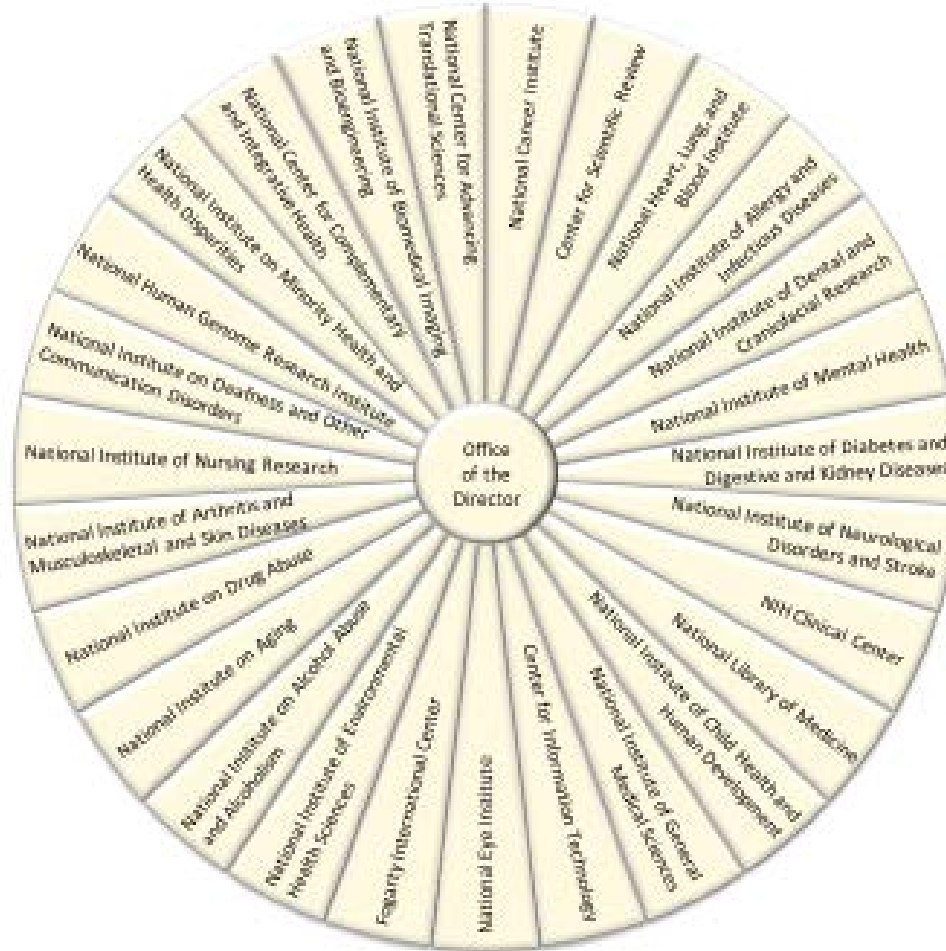
National Institutes of Health

- NIH's mission is to seek 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 is made up of **27 Institutes and Centers**, each with a specific research agenda, often focusing on particular diseases or body systems.

Trans-NIH

27 Institutes, Centers and Offices

National Institutes of Health



National Institutes of Health

- Intramural Research – Research laboratories and NIH Clinical Center on NIH campus in Bethesda, MD
- Extramural Research – Research done by investigators located at institutions outside NIH and located in USA and throughout the world, supported by NIH grant awards



NIH ME/CFS Intramural Study

- Led by Dr. Avi Nath, Clinical Director at NINDS
- IRB approval received
- Studies at the NIH Clinical Center in Bethesda, MD
- Protocol includes detailed phenotyping, neurological and immunological studies
- First healthy control study participant has been to NIH
- Once all procedures are finalized, will begin recruiting 40 individuals with post-infectious ME/CFS who are within 5 years of the onset of the disease
- Extensive analysis and biospecimen collection
- <http://mecfs.ctss.nih.gov/>



ME/CFS Special Interest Group (SIG)

- Seminars organized by NIH intramural investigators
- Designed to educate and provide perspective for intramural staff and extramural program staff
- Information at:
<http://mecfs.ctss.nih.gov/sig.html>

Trans-NIH ME/CFS Working Group

- Revitalized in October 2015
- Chaired by Walter Koroshetz, MD, Director of NINDS
- Coordinated by Vicky Whittemore, PhD
- Representatives from 24 Institutes, Offices and Centers across NIH
- Developing short-, intermediate- and long-term goals and strategies to stimulate and support research on ME/CFS

Trans-NIH ME/CFS Working Group

Walter Koroshetz, M.D., Chair

National Institute of Neurological Disorders and Stroke

Vicky Whittemore, Ph.D., NIH Representative to HHS CFS Advisory Committee

National Institute of Neurological Disorders and Stroke

Harvey J. Alter, M.D., MACP

NIH Clinical Center

Catherine Bennett, Ph.D.

(Alternate: Christine Melchior, Ph.D.)

NIH Center for Scientific Review

Joseph Breen, Ph.D.

(Alternate: Joshua Milner, M.D.)

National Institute of Allergy and Infectious Diseases

Milton Corn, M.D.

National Library of Medicine

Emmeline Edwards, Ph.D.

National Center for Complementary and Integrative Health

Basil Eldadah, M.D., Ph.D.

National Institute on Aging

Bill Elwood, Ph.D.

Office of Behavioral and Social Science Research

Yolanda Vallejo-Estrada, Ph.D.

National Institute of Dental and Craniofacial Research

Adam Felsenfeld, Ph.D.

National Human Genome Research Institute

Rohan Hazra, M.D.

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Mike Humble, Ph.D.

(Alternate: Jonathan Hollander, Ph.D.)

National Institute of Environmental Health Sciences

Joyce Hunter, Ph.D.

National Institute on Minority Health and Health Disparities

Kathy Jung, Ph.D.

National Institute on Alcohol Abuse and Alcoholism

Cheryl Kitt, Ph.D.

NIH Office of Extramural Research

Martha Matocha, Ph.D.

(Alternate: Leorey Saligan, Ph.D., RN, CRNP)

National Institute of Nursing Research

Cheryl L. McDonald, M.D.

(Alternate: Shimian Zou, Ph.D.)

National Heart, Lung, and Blood Institute

Christopher Mullins, Ph.D.

National Institute of Diabetes and Digestive and Kidney Diseases

Ann O'Mara, Ph.D., R.N., M.P.H.

National Cancer Institute

Matthew Rudorfer, M.D.

National Institute of Mental Health

David Thomas, Ph.D.

National Institute on Drug Abuse

Todd Wilson, D.O.

(Alternate: David Eckstein, Ph.D.)

National Center for Advancing Translational Research

James Witter, M.D., Ph.D.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Steve Zullo, Ph.D.

National Institute on Biomedical Imaging and Bioengineering

Trans-NIH ME/CFS Working Group Goals

Short Term Goals

FY16-FY17

Complete detailed portfolio analysis
Issue Notice soliciting Administrative Supplements (NINDS, NIAID, others) and fund awards
Issue Request for Information (RFI) to solicit input on areas of research priorities
Develop inventory of available biospecimens and linked phenotypic data for use in research
Organize P2P Federal Partners meeting in Spring 2016
Initiate collaboration for Common Data Elements for ME/CFS (Workshop in October 2016) with the CDC
Develop plan for communication with and engagement of ME/CFS stakeholders
Develop FOAs for ME/CFS Collaborative Research Centers and ME/CFS Data Management and Coordinating Center

Intermediate Goals

FY17-FY18

NIH Program Staff attend ME/CFS conference in 2016 and participate in grant workshop
Work with FDA to develop clearly defined endpoints for treatment trials and interventions
Develop mechanisms for access to available biospecimens for potential identification of biomarkers
Launch ME/CFS Collaborative Research Centers and ME/CFS Data Management and Coordinating Center
Foster and develop international collaborations and partnerships to foster ME/CFS research
Assess clinical trial readiness and potential treatment and intervention trials for ME/CFS
Leverage CDC health care provider educational materials

Long Term Goals

FY18-FY22


Support meritorious clinical trial applications
Ongoing support of ME/CFS Collaborative Research Centers and Coordinating Center
Develop new RFAs as appropriate

Short-Term Goals

- Stimulate research: Notice of Availability of Administrative Supplements on ME/CFS: Released April 7, 2016 [by NIAID, NINDS, NIDCR, NINR, NCCIH]
 - 7 awards supported by NIAID and NINDS in FY16
- Foster collaboration: Federal Partners meeting held on May 24, 2016 as follow-up to Pathways to Prevention ME/CFS Workshop in December 2014 (NIH, FDA, CDC, AHRQ, HRSA, SSA, CMS)
 - Collaborations identified and initiated. Summary of meeting in preparation.
- Identify research priorities: Request for Information released on May 25, 2016 and responses received on research priorities for ME/CFS
- Common Data Elements Project initiated – session on Friday evening
- Foster international discussion and collaboration
 - Discussions held with Canadian Institute for Health Research about partnering opportunities

ME/CFS Common Data Elements

PROJECT OVERVIEW CDE SEARCH CRF SEARCH FORM BUILDER CONTACT



NINDS Common Data Elements

Harmonizing Information. Streamlining Research.

▼ CDEs ▼ Tools ▼ Learn

Streamline Your Neuroscience Clinical Research

using content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community.

The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with these common data elements (CDEs). [Learn more about the CDE Project.](#)

CDEs Now Available	CDEs Under Review	CDEs in Development
General (CDEs that cross diseases)		
Amyotrophic Lateral Sclerosis		
Epilepsy		
Friedreich's Ataxia		
Headache		
Huntington's Disease		
Mitochondrial Disease <i>NEW!</i>		
Multiple Sclerosis		
Neuromuscular Diseases		

Launch Your Own Studies Faster

- ▶ Case report form modules
- ▶ Standardized data element definitions
- ▶ Instrument recommendations




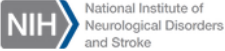

Incorporate CDEs Into Systems

- ▶ Search for current CDEs
- ▶ Download CDE metadata
- ▶ Download Case Report Forms

Learn About the CDE Project

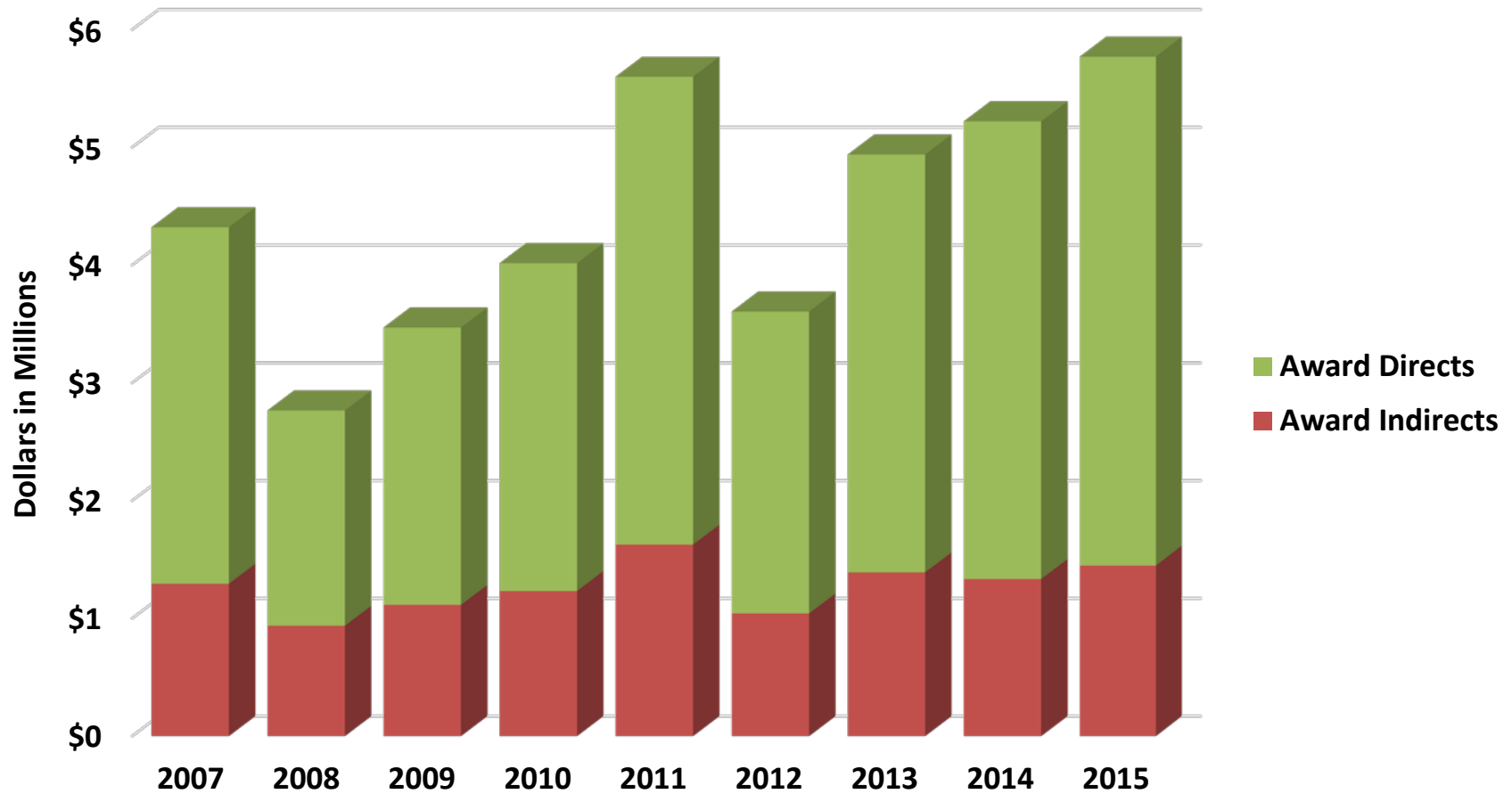
- ▶ Project overview and background
- ▶ Meetings and Presentations
- ▶ Collaboration with developers around the world

[Privacy Statement](#) | [NeuroQOL](#) | [NIH Toolbox](#) | [PROMIS](#)

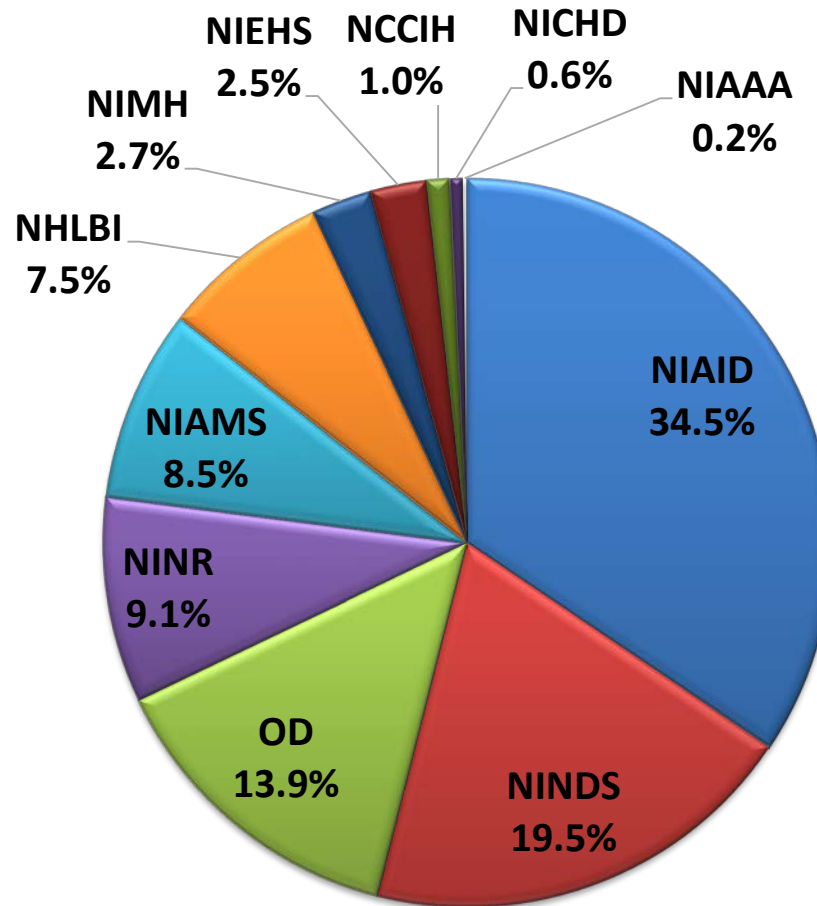


Page last updated on August 27, 2015

ME/CFS Research Funding



NIH Funding for ME/CFS Research (2007-2015)



Trans-NIH ME/CFS Working Group

NIH Request for Information

- Emerging needs and opportunities that should be considered as new ME/CFS research strategies are developed
- Analyzing responses and preparing summary of responses
- Next steps include discussion of research priorities and strategies to achieve goals of the research

Intermediate-Term Goals

- Trans-NIH CFS/ME Working Group developing an extramural research program to support studies on the cause, prevention, diagnosis, pathophysiology and treatment of ME/CFS
- Encourage Investigator-initiated grants submitted through parent grant announcements
- Encourage submission of applications from young investigators to develop pipeline of investigators

NIH Funding Opportunity Announcements

Notice of Intent to Publish RFAs released on Friday, October 22, 2016

- Multi-disciplinary, multi-site ME/CFS collaborative research centers and a data management coordinating center
- Foster use of common protocols and common data elements across sites to enable longitudinal studies of large cohorts of individuals with ME/CFS
- Enable and support research at academic centers
- Partner with Clinical Science Translational Awards (CTSAs) where possible to provide infrastructure
- Encourage involvement of young and new investigators (both basic science and clinical)
- Require community engagement and involvement to ensure success
- Discussions underway to partner with international partners to expand network of ME/CFS Collaborative Research Centers

Long-term Goals

- Support and expand ME/CFS collaborative research centers as funding allows
- Support the development of new therapies and treatments for ME/CFS
- Support clinical trials for ME/CFS
- Ultimately, to improve the quality of life for all individuals with ME/CFS

For More Information

NIH ME/CFS Website:

<https://www.nih.gov/mecfs>