National Institutes of Health
Research into ME/CFS

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National Institutes of Health
Bethesda, MD, USA

IACFS/ME Conference
Ft. Lauderdale, FL
October 26-30, 2016

Trans-NIH ME/CFS Working Group
• 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

- 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
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

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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

Trans-NIH ME/CFS Working Group
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.
ME/CFS Research Funding

Dollars in Millions


Award Directs
Award Indirects

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
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

Trans-NIH ME/CFS Working Group
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
NIH ME/CFS Website: https://www.nih.gov/mecfs