ME/CFS Researcher and Clinician-Scientist Recruitment Workgroup

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Members & Contributors

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Outline

- Reminder of mandate and charge
- Recommendations
- Evidence for the recommendations
- Recap
- Discussion

Mandates of the Workgroup

- Identify gaps in the recruitment and retention process of researchers and clinician scientists to the field of ME/CFS
  - Increase awareness
  - Increase opportunities

- End-goal: Provide an actionable set of **evidence-based** recommendations to the Secretary

Charge

- "…increasing awareness among basic and clinical researchers about ME/CFS research and suggesting strategies to increase the number of interested researchers who will apply for current and future research funding opportunities"

Current Working Recommendations

1. CFSAC recommends that the NIH adapt the architecture of the National Database for Autism Research (NDAR) to setup a data sharing platform for ME/CFS research.

Current Working Recommendations

2. CFSAC recommends that the NIH issue a Request for Applications (RFA) for ME/CFS research that is responsive to the recommendations of the Trans-NIH ME/CFS Research Working Group following their review of the 2011 NIH State of the Knowledge Workshop and to the Pathways to Prevention Program for ME/CFS research panel report- both intended to document the gaps in ME/CFS knowledge and the research best intended to fill these gaps. If established, this RFA should also encourage investigators to use the aforementioned NIH data sharing platform.

Evidence-base for Recommendations

- Strategically aligned with past and current federal efforts/investments
  - 2011 - State-of-the-Knowledge Workshop
    - http://orwh.od.nih.gov/research/mecfs/pdfs/ORWH_SKW_Report.pdf
  - Trans-NIH ME/CFS Research Working Group
    - http://orwh.od.nih.gov/research/me-cfs/index.asp
  - Pathways to Prevention (P2P) Program for ME/CFS
    - https://prevention.nih.gov/programs-events/pathways-to-prevention
  - Institute of Medicine (IOM) initiative to evaluate current clinical diagnostic criteria for ME/CFS
    - http://www.iom.edu/Activities/Disease/DiagnosisMyalgicEncephalomyelitisChronicFatigueSyndrome.aspx
  - FDA drug development initiative
    - http://www.fda.gov/Drugs/NewsEvents/ucm319188.htm
  - CDC multi-site clinical assessment of ME/CFS study
    - http://www.cdc.gov/cfs/programs/clinical-assessment/index.html

Rationale for Recommendations

- Address major limitations to ME/CFS research
- Capitalize on current efforts
- Continue momentum
- Progress towards increasing investigator awareness and participation in ME/CFS research.

Major Limitations

- Lack of infrastructure
- Lack of robust research opportunities

Infrastructure

- Defined:
  - Data sharing platform
  - Allows for federation, aggregation, collection, storage and analysis
  - Includes – phenotype and biological data

Conflicting Data

- Small research community & heterogeneous patient population:
  - Inconsistent results
  - No validated biomarkers
  - No FDA approved treatments
  - No known etiology
  - Poorly understood pathophysiology
- Infrastructure
  - A central platform to lower the barriers to conducting ME/CFS research

Primacy of Infrastructure for ME/CFS Research

- Research infrastructure is critical for accelerating discovery, providing pathways for collaboration and attracting the best and brightest researchers to study ME/CFS
- National Database for Autism Research (NDAR) example

NDAR

- Infrastructure
    - a data sharing platform to create a large database
    - a common data dictionary and data standards that can be applied across studies
    - protection of patient privacy
    - protection of investigator intellectual property

- Success of NDAR
    - Contains data from over 87,000 patients

2010 - State-of-the-Knowledge Workshop Report

- **Moving Forward**
  - "To capture the extensive information from such studies (clinical trials), a centralized interactive database, using common data elements and accessible to everyone, is **sorely needed** to collect, aggregate, store, and analyze results."
  - "The study of ME/CFS can benefit from an interdisciplinary collaborative approach using well-connected clinical and research networks. Moreover, additional highly qualified investigators must be attracted to study ME/CFS."

http://orwh.od.nih.gov/research/mecfs/pdfs/ORWH_SKW_Report.pdf

Trans-NIH ME/CFS Research Working Group

- A partnership:
  - NIH institutes and centers
  - The Office of Research on Women's health (ORWH)

- To promote research on ME/CFS
  - Does not have grant making authority
  - **Informs NIH Centers & Offices & works to leverage resources for ME/CFS research**
  - **Considers unique ways to support ME/CFS research**

Pathways to Prevention Program for ME/CFS

- P2P evidence-based methodology workshop goals:
  - Identify research gaps and methodological and scientific weaknesses in a scientific area
  - Suggest research needs
  - Move the field forward through an unbiased, evidence-based assessment of a complex health issue

http://www.iom.edu/~/media/Files/Activity%20Files/Disease/MECFS/Maier%20IOM%20MECFS%20Presentation.pdf

Conclusion

- The first critical step:
  - Establish the infrastructure necessary to accelerate CFS research
- The second critical step:
  - Release a RFA responsive to responsive to the research gaps that have been identified by researchers, agencies and stakeholders

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A Roadmap for ME/CFS

- Development of a clear research agenda
  - Based on information and recommendations from numerous sources
  - Communicated and championed by the Trans NIH ME/CFS working group
  - Supported by strong infrastructure

- This is the path to:
  - Increase awareness among basic and clinical researchers
  - Increase collaboration
  - Increase applications for funding

- Move the field forward

Discussion