Clinical Trial Networks: The Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT)

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The University of Iowa

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Objectives

NeuroNEXT was designed to conduct studies in neurological diseases through partnerships with academia, private foundations, and industry in order to expand NINDS capabilities to:

- Test promising new therapies
- Increase efficiency of clinical trials
- Respond quickly as new opportunities arise to test promising treatments for people with neurological diseases

Network Infrastructure

- NIH/NINDS
  - Janice Cordell, PhD
    Robin Conwit, MD
    Codrin Lungu, MD
- Clinical Coordinating Center
  - Massachusetts General Hospital
    (Merit Cudkowicz, MD, MSc)
- Data Coordinating Center
  - University of Iowa
    (Christopher S. Coffey, PhD)

National Institute of Neurological Disorders and Stroke

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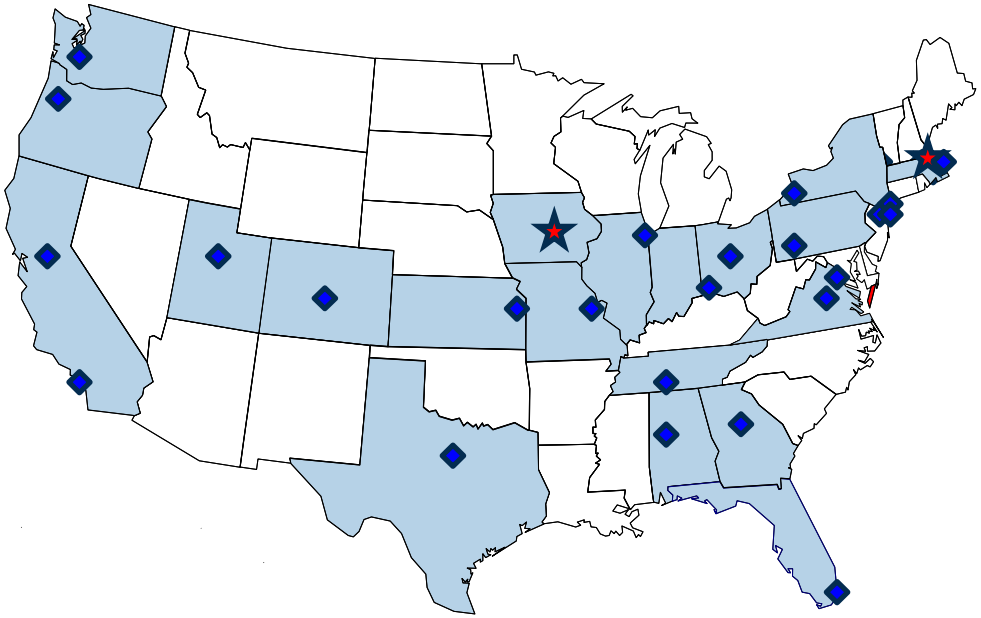
NeuroNEXT

Network Infrastructure



For additional information, visit our website:

www.neuronext.org

Why Apply to Use NeuroNEXT

- Allows access to NeuroNEXT infrastructure
- Novel initiatives to increase efficiency of conducting clinical trials in the network:
  - Utilization of a Central IRB (CIRB) of record
  - Pre-existing Master Clinical Trial Agreements (MCTA) between the CCC and all clinical study sites
  - Availability of experienced trial design staff to assist with protocol and grant development
  - Experienced sites with full time funded coordinator and record of high enrollment and quality study conduct

Submitting Proposals to NeuroNEXT

- Contact Robin Conwit, MD at NINDS
  - conwitr@ninds.nih.gov / 301-496-9135
- Complete Concept Form, submit to NINDS
- NINDS initial review to determine if proposal meets goals and missions of NeuroNEXT
  - If yes, proposal sent to:
    - NeuroNEXT Executive Committee (NEC) for feasibility review
    - NINDS Extramural Science Committee (ESC) for scientific merit & budget review
  - If no, NINDS informs Protocol PI and discusses other funding options

Determining Study Feasibility

- How many patients were seen in the last consecutive 12-month period at your institution who meet the above criteria?
- How many patients that fit the criteria above, do you anticipate your site would be able to enroll in 1 year?
- Does your site have any comments/concerns about the inclusion/exclusion criteria listed above?
- Does your site have any ongoing/planned trials that would compete with this patient population?

Determining Site Interest

- Does your center have preliminary interest in conducting this trial?
- Please rate the following on a scale of 1 to 5 with 1= lowest and 5= highest
  - The positive impact of the proposed study on the field of study _____
  - The ability of the study to meet an unmet need in the field of study _____
  - The overall enthusiasm for the proposed study by disease experts in the field at your site _____

Why does NEC Decline a Proposal?

- Lack of adequate patient population or resources within the Network – Rare
- No definitive phase 2 question proposed (appeared to be under powered Phase 3 study)
- Lack of overall enthusiasm from disease experts at Network sites