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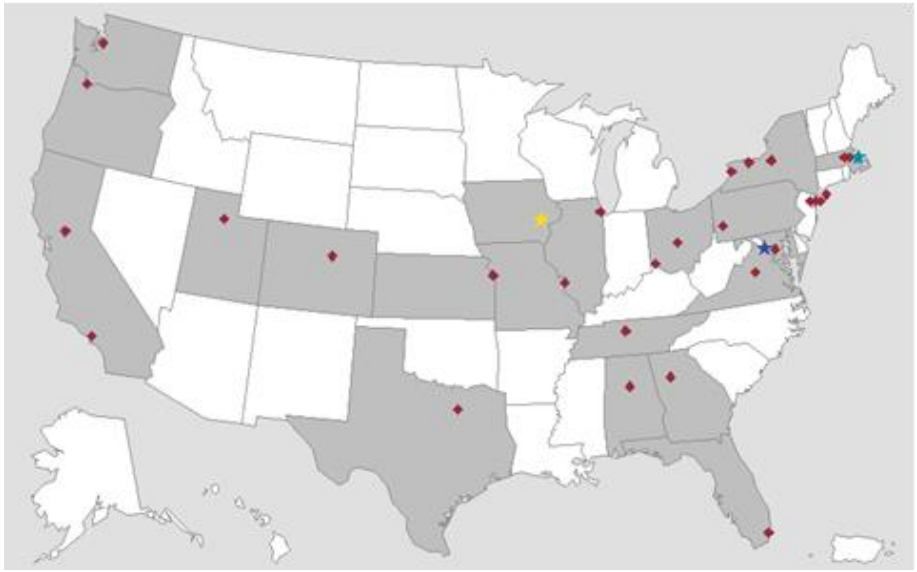
NeuroNEXT Experiences During the Pre-Grant Process

What is NeuroNEXT?



- The Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT)
- Created by NINDS
- Comprised of 25 clinical sites
  - Master clinical trials agreements
  - Central IRB (Harvard Partners)
- The CCC is at Harvard Partners
- The DCC is at Iowa
- Central Pharmacy at University of Rochester Medical Center

Entering NeuroNEXT: NEC

- Proposals that NINDS finds to be suitable for NeuroNEXT are reviewed by the NeuroNEXT Executive Committee (NEC)
- NEC is charged with determining whether a proposal is feasible within the network
- Feasibility is largely determined by the NeuroNEXT sites' responses to the feasibility questionnaire
  - About the sites' ability to recruit eligible subjects
  - Whether the sites have any specific concerns about the proposed study
  - **Lesson Learned:** How enthusiastic each site is about participating in the proposed study
- **Lesson Soon-to-be Learned:** What to do when two very similar proposals enter NEC at the same time?

Entering NeuroNEXT: Working Groups

- When a proposal is found to be feasible within the network by NEC, it heads to the working group phases:
  - Introduction Call Working Group
  - Pre-design Budget Working Group
  - Design Working Group
  - Grant Development Working Group
  - Webinar
- These working groups used to be combined into one, large protocol working group (PWG)

Introduction Call Working Group

- For every proposal, an introduction call is the first step after NEC approval
- For investigators, this call:
  - Allows them to become acquainted with the NeuroNEXT personnel that will be aiding them throughout the pre-grant process
  - Provides an outlet for any questions
- For the NeuroNEXT CCC and DCC, this call:
  - Allows the coordinating centers to 'set the pace' of the proposal
  - Allows for the passing of guidance documents and templates
  - **Lesson Learned**: This call is among the best times to head off common misconceptions!

Common Misconceptions (CM)

- CM#1: Once a proposal has been accepted into the NeuroNEXT network by NEC, it is guaranteed to be funded
- CM#2: The NeuroNEXT coordinating centers prepare, write, and submit the grant application
- CM#3: The investigators' budget is the only factor for deciding whether a proposal must go to ESC review
- CM#4: Site selection includes both NeuroNEXT and non-NeuroNEXT sites

Pre-Design Budget Working Group

- NINDS, as is NIH policy, requires those studies which have any budget year direct cost total greater than $500,000 submit for NINDS review
- This review is known as the NINDS Extramural Science Committee (ESC)
- Investigators need to build their schedule of activities, per subject fee, and their own investigator budget
- **Lesson Learned:** Request that the investigators find themselves a local grants administrator that can join the pre-design budget working group calls

Design Working Group

- Each proposal receives a CCC lead and a DCC lead
  - The CCC lead is a clinician with relevant clinical trials experience in the disease area and subject population
  - The DCC lead is a statistician, also with relevant clinical trials experience in the proposed statistical design and analysis
- The basic goal of this working group is to bring enough clinical trials experience together in order to ensure that the proposed study will be able to successfully answer the question(s) of interest

Design Working Group

- The number and frequency of design working group meetings varies for each proposal
- They continue until both the CCC and DCC leads feel that the proposal can adequately answer its question(s) of interest
  - Technically, it is up to the investigators whether or not they incorporate the CCC and DCC leads' advice
  - The CCC and DCC leads, however, play an important part in the letter of support that the network sends in with every proposal
- **Lesson Learned:** Like the grants administrator in the pre-design budget working group, having access to local experienced clinical trialists can be very beneficial
- **Lesson Learned:** Make sure you know whether the investigators have a local clinical trialist they are leaning on – and invite them to the meetings!

Grant Development Working Group & Webinar

- This working group helps investigators progress to their webinar and grant submission
- During this phase, the protocol, requirements for study drug supply, budget, budget justification, IND/IDE submission, vendor agreements, and grant application are finalized
- A webinar is then delivered to the network's clinical sites
  - This is an opportunity for the investigators to present their rationale and an overview of their study to the sites that will (hopefully) carry out the study
  - After the webinar, the CCC solicits site interest in participating in the study

Other Specific Experiences of Interest

- Working with junior investigators
- Working in private-public collaborations
- Working pro bono
- What is a Phase 2 Study?
- Drug supply and laboratory considerations
- Catch-22