Concept Proposal:
The IDeA States Pediatric Clinical Trials Network (ISPCTN)---Network Renewal

Alan E. Simon, MD
Project Scientist-ISPCTN/ECHO
January 25, 2019
Presentation to the Council of Councils, Office of the Director, NIH
Mission Statements

• Two main components of ECHO
  • ECHO Cohorts
  • IDeA States Pediatric Clinical Trials Network (ISPCTN)

• **ECHO Mission**: To enhance the health of children for generations to come

• **ISPCTN Goals**:
  • To provide medically underserved urban and rural populations access to state-of-the-art clinical trials
  • To build pediatric research capacity within IDeA States
Institutional Development Award (IDeA) States

- Program builds research capacities in states that historically have had low levels of NIH funding
- Enhances the ability of investigators to compete successfully for additional research funding
- Serves the research needs of medically underserved communities.
What have we accomplished in 2 years?

• Clinical Trials & Development Projects
  • 2 trials ongoing—both pharmacokinetics
  • Opioid-related
    • 1 observational study (medical record abstraction) completed—analysis phase
    • 2 trials in development as part of Helping to End Addiction Long-Term (HEAL) Initiative
  • Multiple pilot projects in development

• Capacity Building
  • Structure—Data Coordination and Operations Center increased staff/knowledge; Network governance structure; Research teams, Equipment, and Space
  • Process—Governance processes, Single IRB, Professional Development (network wide and site specific), New investigators, Collaborations with other IDeA programs, and ECHO Cohorts
  • Outcomes---Trials, Analyses, Posters, Presentations, Manuscripts, Grants submitted
Rationale for ISPCTN Renewal: Trials and Capacity Building in IDeA States

• Children in rural communities in IDeA states:
  • Experience worse health outcomes
  • Are under-represented in clinical trials

• IDeA states institutions need capacity building to learn how to develop and implement clinical trials.

• IDeA states institutions still struggle to compete for NIH grant funding
  • ~ $1.9 billion to IDeA states*
  • ~ $25 billion to non-IDeA states*

*Based on ECHO analysis of data obtained from the NIH RePORTER website (10/15/2018)
Approach—Network Structure

- Remain at current size
  - 1 RFA for 17 clinical sites
  - 1 RFA for Data Coordination and Operations Center
- Both open competition among IDeA states institutions
- Cooperative agreements
- 5 years
- Start in 2020
Approach—Clinical Trials

• Continue clinical trials
  • Minimum of 3 multicenter clinical trials over 5 years

• Data Coordination and Operations Center responsibilities:
  • resource allocation for trials, data management, analysis, and data sharing
  • protocol development assistance

• Clinical sites responsibilities:
  • develop and implement trials
  • As part of application, propose a protocol for a multicenter trial
  • Propose and implement a plan to engage rural communities in trials
Approach—Capacity building

• Both Clinical Sites and Data Coordination and Operations Center would propose and implement capacity building plan for junior faculty, senior faculty, and research coordinators.

• All applicants encouraged to collaborate with:
  • In-state IDeA Program Infrastructure for Clinical and Translational Research awardee institution (IDeA-CTR)
  • Or in-state Clinical and Translational Science Award awarded institution (CTSA)
  • Or other collaborators but majority of each award must stay in IDeA states.
Questions or thoughts?