SPARK:
A CCTS REAARCH SUPPORT PROGRAM
Scientific Partners Advancing Research Kickoff

Background

- A committee of research experts
- Formed in 2007 by the CCTS
- Originally focused on expediting implementation of protocols submitted to the Clinical Research Unit (CRU)
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AIMS

➢ The overall aim of SPARK is to expedite research start up
  o Support for research development
  o Navigation of research approval processes
Committee of experts

- Research Design and protocol development
- Biostatistics
- Bioinformatics
- Regulatory and IRB application
- Clinical trial budgeting
- Study implementation
- Funding sources
- Other research resources
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Research Design and protocol development

- Assessing feasibility
- Formulation of research testable question and/or hypothesis
- Selection of appropriate research design
- Formatting and writing protocol
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Biostatistics

- Sample size determination
- Data analysis plan
- Randomization plan
- Analysis of data
Bioinformatics
- Data collection and management
  - REDCap
- Case Report Forms
- Preliminary data
  - Data warehouse
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Regulatory and IRB Application
- IND/IDE application process
- IRB application process
- Informed consent writing
- Clinicaltrials.gov registration
- Good Clinical Practice policies
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Clinical Trial Budgeting
- Clinical Trials Resource Center
- Clinical Research Unit
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Study Implementation

- Project set up
- Industry sponsors
- Coordinator support
Other Research Resources

- Funding sources
  - NIH, foundations, other private funding agencies and industry sponsors
- Collaborators and mentors
- Patient and community groups for engagement
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Patient Stakeholder Committee for Research

- Funded by PCORI
- Committee within the Harris Health System
- Patients and other stakeholders being trained to engage with researchers
  - PCORI
  - AHRQ
  - NIH pragmatic trials
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