



## National Children's Study Update July 19, 2010

Steven Hirschfeld, MD PhD  
Captain, U.S. Public Health Service  
Acting Director  
National Children's Study

# Outline



- Alternate recruitment launch status
- Informatics development
- Formative research
- Office of Management and Budget
- Federated IRB launch
- Transition of seven original Vanguard Centers
- Program Office reorganization

# Alternate Recruitment Launch Status



- Informatics development
- Hiring staff
- Establishing infrastructure
- Communications and outreach
- Alternate recruitment substudy kickoff meetings
  - Provider based- San Antonio- July 15<sup>th</sup>
  - Two tier High Low- Chicago- July 29<sup>th</sup>
  - Enhanced Household- St. Louis- August 6<sup>th</sup>
- Initial data collection effort focused on questionnaires
- Specimen and sample collection will be phased in over the coming months

# Informatics development



- Data fields, structure, relationships and data tables developed centrally to address specific operational questions
  - Focus is on operational data elements to study feasibility, acceptability and cost for Vanguard Study
- Data collection and transmission standards are conveyed to Study Centers (primary contractors)
- Study Centers are responsible for identifying, developing or adapting if necessary, and deploying case management and data acquisition systems
- All required data are transmitted per specifications to central data base at NICHD

# Formative Research



- Formative research is an essential component of data driven evidence based strategy for Vanguard Study
- Formative research projects are focused time limited activities for NCS contractors to address specific technical or methodological questions
- First round of formative research proposals are ready to initiate
- A second round of formative research proposals will begin in August 2010

# Transition of seven original Vanguard Centers



- Seven original Vanguard Centers have contributed important and essential data to bring Vanguard Study to current status
- With deployment of 30 additional centers and new informatics structure, 7 original centers will transition to new system and new data collection specifications to align process and instrumentation with other 30 centers
- Short term scale back in visit intensity with plans to phase in more intense visits

# Federated IRB launch



- Federated IRB model, previously discussed at NCS Advisory Committee, was approved for implementation in July 2010
- Set of 3 documents- Compact outlining Principles, Process and Performance Goals, Memorandum of Understanding, and Questions and Responses, made available to Study Centers
- NIH Deputy Director for Intramural Research is designated official and will sign bilateral agreements with participating Study Centers
- Other NIH programs and studies have expressed interest in adapting the Federated IRB model

# Office of Management and Budget



- Successful and collegial discussions have been underway with the Office of Management and Budget (OMB) and in particular with the Office for Information and Regulatory Affairs regarding the NCS Vanguard Protocol and the alternate recruitment substudy.
- OMB has provided multiple helpful suggestions and is motivated and supportive of the NCS
- Formal clearance is expected prior to the end of July 2010.

# Program Office Reorganization



- The NCS is transitioning to engage dedicated Project Managers to provide guidance and oversight for the contract Study Centers
- Currently 6 positions are available of which 4 have been filled with start dates during August 2010
- Program Office activities will be aligned in four areas- Planning, Operations, Analysis and Communications

# NCS Investigator Activities



- Steering Committee will meet on August 10<sup>th</sup>, 2010 to discuss, among other topics, Federated IRB, Vanguard Study status, Informatics and compliance with the Federal Information Security Management Act.
- Satellite meetings on topics such as Communications and Outreach, Original Vanguard Center Transitions, and alternate recruitment substudy schema.