



National Children's Study Update January 26, 2011

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Outline



- Description and time line
- Alternate Recruitment Substudy launch status
- Formative research
- FISMA compliance
- Federated IRB
- Next steps

National Children's Study (NCS)



- The National Children's Study will examine the effects of the environment, as broadly defined to include factors such as air, water, diet, sound, family dynamics, community and cultural influences, and genetics on the growth, development and health of children across the United States, following them from before birth until age 21 years.
- The goal of the Study is to improve the health and well-being of children and contribute to understanding the role various factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible.

National Children's Study Leadership



- NIH: National Institutes of Health
 - NIH Office of the Director: Oversight and scientific direction
 - NICHD: *Eunice Kennedy Shriver* National Institute of Child Health and Human Development – *Lead operational agency*
 - NIEHS: National Institute of Environmental Health Sciences
- EPA: Environmental Protection Agency
- CDC: Centers for Disease Control and Prevention

NCS Structure



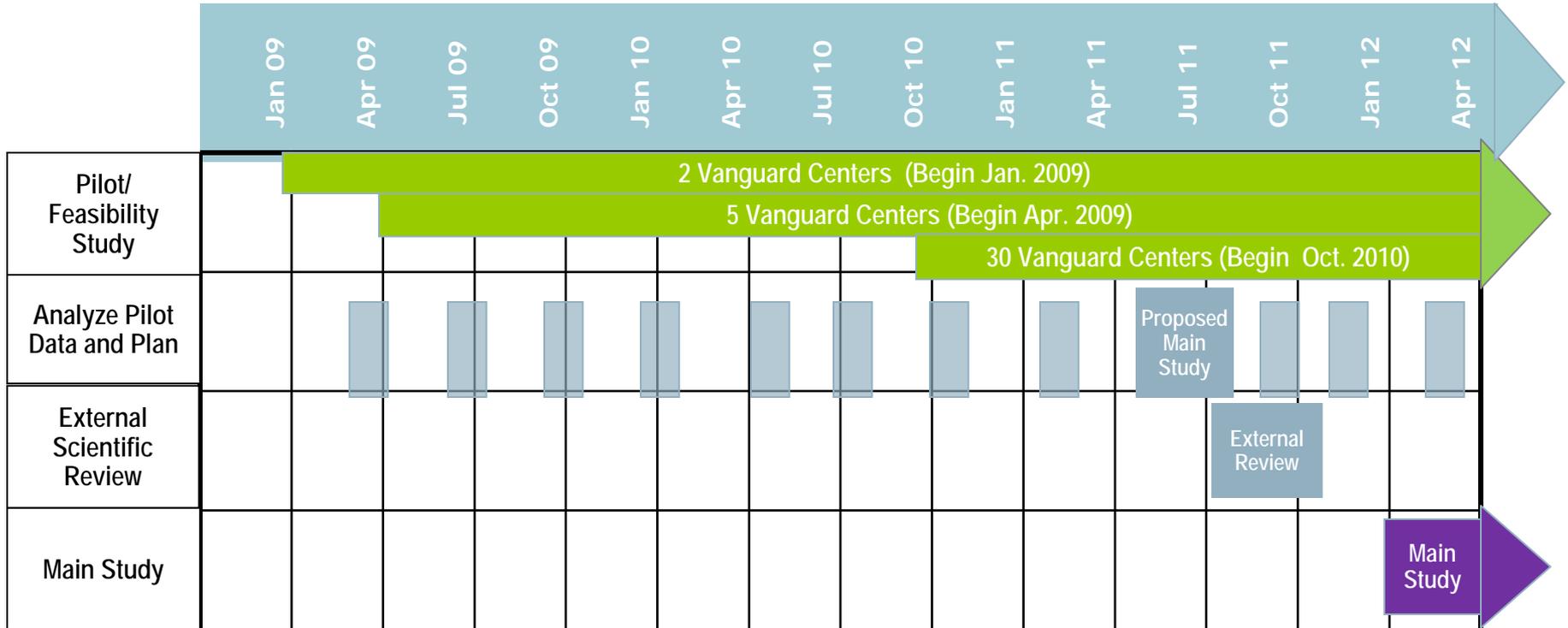
- The NCS is being implemented in several phases
- All components and phases together form the NCS
- Current major components are the
 - NCS Vanguard Study
 - NCS Main Study
 - NCS Substudies

NCS Vanguard Study Goals



- Vanguard Study designed to evaluate:
 - Feasibility (technical performance)
 - Acceptability (impact on participants, study personnel, and infrastructure)
 - Cost (personnel, time, effort, money)
- of
 - Study recruitment
 - Logistics and operations
 - Study visits and study visit assessments

NCS Projected Timeline



Alternate Recruitment Substudy Status



- Alternate Recruitment Substudy
 - Provider based
 - Two tier High intensity Low intensity
 - Enhanced household
- Infrastructure
- Communications and outreach
- Initial data collection effort focused on questionnaires
- Specimen and sample collection will be phased in over the coming months
- Cooperative learning and process improvement

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

Informatics Development and Data Standards



- NCS Operational data elements (the concepts and data fields that describe study operations) may serve as model for potential general data standards for operational data elements
- Alignment of NCS architecture and standards with the Data Document Initiative and the Clinical Data Interchange Standards Consortium
- Development of standardized terminology

Communications and Outreach



- Communications and outreach activities following distributed model with study locations initiating activities guided by general NCS policies and messages
- Each active study location has a web site linked to the NCS public web site
- Targeted outreach to various populations
- Incorporation of additional community representatives to Steering Committee

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
- Two rounds of formative research requests initiated based on gap analysis
- Additional formative research opportunities in coming year

Formative Research Goals



- The National Children's Study (NCS) has initiated several formative research projects that are limited in scope and duration and are intended to augment the NCS Vanguard Study to address specific technical questions and provide information on the acceptability, feasibility, and cost of the research.
- These formative research projects will provide data to explore new and potentially cost effective approaches in many areas, including genetic, cognitive, and environmental assessments, that have not previously been evaluated from an operational perspective.
- Based on the results of these formative research projects, the NCS can evaluate the types of research questions that would be feasible for the Main Study.

Formative Research Topic Areas



- Real-Time Analysis of Study Samples, Specimens and Measurements
- Study Logistical Analysis and Improvements
- Biospecimen Collection and Processing
- Environmental Sample Collection and Processing
- Physical Measures
- Questionnaire Development and Validation
- Study Infrastructure Development

FISMA Compliance



- The Federal Information Security Management Act of 2002 (FISMA) requires a secure informatics environment for federal projects and activities
- The NCS contractors are collecting data on behalf of the federal government and must be FISMA compliant
- NCS implemented a program to achieve FISMA compliance at all study locations
- FISMA compliance has been challenging but achievable

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
- Other NIH programs and studies have expressed interest in adapting the Federated IRB model
- Presentation to Secretary's Advisory Committee for Human Research Protections on October 19, 2010

Federated IRB Participation in the National Children's Study



- In NCS are 36 Study Centers
 - 17 have reliance on lead IRB = NICHD Intramural IRB (47%)
 - 6 share responsibility with lead IRB (14%)
 - 13 independent review with information sharing (36%)
- Implementation process in NCS and other contexts systematically studied for process improvement

Office of Management and Budget Interactions



- 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
- Next phase of Vanguard Study under review
- Formative research clearance pending

A Learning Community



- Except for the focus of the Study remaining on the health of children, all other aspects of the NCS are potentially subject to re-evaluation and change.
- The concurrent deployment of three different recruitment strategies plus a formative research program provides an exceptional opportunity for launching a learning community with structured and systematic training, feedback, process maps, process improvement, modeling, and simulations.
- The NCS has adapted these approaches both centrally and in the field, particularly in the two-tier high intensity/low intensity recruitment cohort, to build an effective learning community.

Next Steps



- Alternate Recruitment Substudy enrollment and data analysis
- Continued analysis of data from initial 7 Vanguard locations including biospecimens and environmental samples
- Gap analysis for formative research opportunities
- New models for visit schedule
- New models for visit assessments
- Introduction of specimen and sample collection across the Vanguard Study locations
- Begin construction of framework and architecture for Main Study protocol and infrastructure

Near Term Transitions



- Departing NCSAC Members
 - Dr. Michael Lebowitz
 - Dr. Thomas Ten Have
 - Dr. Melissa Tassinari
 - Dr. Michael Greene
 - Dr. Elena Gates