



# National Children's Study Current Status April 27, 2010

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# Outline



- Vanguard Study goals
- Focus on recruitment
  - Resource intensive
  - Critical for meeting study goals
  - Testing 3 strategies with 3 communications plans
- Methodology is business model termed facilitated decentralization
- Informatics
- Data acquisition
- Study visit assessments
- Communications
- Timelines
- Formative Research

# Vanguard Study Goals



To assess the:

- Feasibility (technical performance and reliability)
- Acceptability (impact on study participants and study infrastructure)
- Cost (level of effort, personnel, resources and money)

of

Recruitment, study logistics and operations and study visit assessments

# Vanguard Study Data Acquisition



- Operational and performance data are of primary interest
- Analytic data acquisition for exposure response relationships is the goal of the Main Study

# Alternate Recruitment Strategies



1. Provider based
  2. Enhanced household enumeration
  3. Two tier high low intensity
- Each strategy will
    - occur in 10 locations that are geographically and demographically diverse
      - No attempt to have a population that can be generalized to the U.S. for any of the strategies
      - Specific interest in examining potential bias
    - be approximately equally resourced
    - Have a specific communications theme associated with each one

# Recruitment Parameters



The primary outcome measure is a description of recruitment rates and retention among three proposed recruitment strategies.

Key rates associated with recruitment include:

- The number of women identified for contact by the study, per month
- The number of women successfully contacted by the study, per month

The number of women determined to be eligible for the study, per month

- The number of eligible women consented into the study, per month

# Retention Parameters



Key proportions associated with retention include:

- The proportion of age- and geographically-eligible women initially contacted when not pregnant who join the Study when subsequently becoming pregnant.
- The proportion of consented women who participate in at least one data collection study visit
- The proportion of women consented during pregnancy, who participate in all data collection visits through the birth of a child.
- The proportion of women who receive an antepartum data collection visit who also receive a birth visit.

# Secondary Outcomes



The distribution of key characteristics of recruited women among the three recruitment schema, will be analyzed, which will include:

- Distribution of women enrolled prior to pregnancy (preconception), during pregnancy, or perinatally
- For pregnant women, distribution of gestational age at enrollment and at the first study visit
- The monthly enrollment rate of infants among consented women with due date within that month
- Distribution of the primary source of entry into the study for the women, such as self-referral, provider referral, household enumeration, community outreach events, and many other possibilities.
- Distribution of the ways and number of ways women heard about the study, such as friends, mailings, community members, and other possibilities

# Demographic Evaluation



Individual level characteristics:

- Race
- Ethnicity
- Age
- Marital status
- Primary Language
- Employment
- Education

Center or community level characteristics:

- Urbanicity
- Study center organizational structure and types of partners
- Community engagement strategies employed

# Cost Evaluations



- The costs of the recruitment strategies will be determined empirically. Examples of the type of data to be collected include:
- The cost of recruiting and enrolling a woman into the study, by timing of entry (for example preconception, early pregnancy). Costs will be determined by tracking staff time, supplies, travel and equipment.
- The cost of media and community outreach per recruited and enrolled woman by outreach methods employed particular to each of the three recruitment strategies. Cost will be determined by media invoices, staff time and materials.

# Facilitated Decentralization



- Centralized development of specifications, quality controls and policies
- Local implementation allows for integrating skills, talent and resources; and flexibility to adapt to local factors

# NCS Informatics- New Model



NCS Program Office develops

- Specific questions to address in the Study through Data Analysis Team
- Data fields, data tables and data table relationships
- Data transmission standards
- SQL Server data archive to receive data
- Specifications and guidelines for data security and regulatory compliance

# NCS Informatics-New Model



Study Centers select

- Case management system
- Data acquisition platform
- Data collection tools

Flexibility allows adaptation of tools and resources that best fit local needs

All data is collected and transmitted based on specifications

Analogous to collecting information in multiple languages or currencies but converting all to English or the dollar for harmonization, consolidation and analysis

# Data Platforms



- NCS Specifications encourage use of open source platforms and collaboration
- Original 7 Vanguard study locations will be phased over to new system with similar options for local implementation
- All Study Centers will develop local implementation of data security procedures including background checks and accreditation

# Phased Approach to Data Collection



- A phased approach is planned
  - Initially infrastructure and logistics testing
  - Study visits will at first consist only of minimal questionnaires designed to characterize system logistics and not to produce analytic datasets for other types of analysis
  - After study logistics are established, study visits will become more complex and more robust with phased introduction of biospecimens and environmental samples

# Minimal Study Visits



- Questionnaires use items excerpted directly or adapted from instruments already approved and in use for Vanguard Study
- Questionnaires developed for:
  - Enumeration (as applicable)
  - Pre-conception
  - Pregnancy screening
  - Early pregnancy
  - Late pregnancy
  - Birth visit

# Study Visit Assessments



- Current experience undergoing systematic evaluation
- Catalog of study visit assessments will receive structured analyses
- Inventory of about 122 000 samples and specimens undergoing stability, storage conditions, and analyte evaluation

# Communications



- Facilitated decentralization model also applies to communications
- Three armed approach to implementation
  - National campaign for study goals of general applicability, health, development and antecedents of conditions
  - Local implementation of population specific and targeted messaging including events
  - Federal partners for leveraging existing programs, resources and contacts for awareness and potential participant identification

# Regulatory Timelines



- Office of Management and Budget Review
  - 60 day notice published
  - Ongoing exchanges between OMB, NICHD and NCS
  - Submission will be in mid May
  - Approval expected mid June
- Institutional Review Boards (IRBs)
  - Revised Vanguard Protocol approved by NICHD IRB
  - Recruitment schema submitted as protocol amendment
  - IRB approval at 30 locations expected prior to July
  - Federated IRB preparations continue

# Formative Research



- Additional projects to address specific technical questions related to NCS implementation
- Study Centers volunteer to perform additional tasks based on interest and expertise
- Broad scope of topics including environmental assays, models, behavioral assessments, fetal cell and placental genetic assessments, dietary intake and operations research

# Summary



- Vanguard Study goals
- Focus on recruitment
  - Resource intensive
  - Critical for meeting study goals
  - Testing 3 strategies with 3 communications plans
- Methodology is business model termed facilitated decentralization
- New paradigms for data collection and storage