



## National Children's Study Update

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# National Children's Study



- Congressionally mandated by Children's Health Act of 2000
- An integrated system of activities to examine the relationships between environmental exposures and genetics on growth, development and health
- Environment is broadly defined to include factors such as air, water, soil, dust, noise, diet, social and cultural setting, access to health care, socio-economic status and learning.

# NCS Principles



- Data driven
- Evidence based
- Community and participant informed

# Examples of Exposure Areas of Interest



- Exposure to industrial chemicals and byproducts in the air, water, soil and commercial products
- Exposure to natural products in the air, water, soil and commercial products
- Exposure to pharmaceuticals used for therapy and in the environment
- Radiation exposure
- Effects of proximity to manufacturing, transportation and processing facilities

# Examples of Exposure Areas of Interest



- Living with animals, insects and plants
- Media and electronic device exposure, noise
- Access to routine and specialty healthcare
- Learning opportunities that are structured and unstructured
- Diet and exercise
- Family and social network dynamics in cultural and geographic context

# Examples of Outcome Areas of Interest



- Interpersonal relationships and bonding
- Inflammatory processes including allergies, asthma and infections
- Genetic and epigenetic status
- Epilepsy and other neurologic disorders
- Cardiovascular screening and function
- Childhood cancer
- Multidisciplinary multidimensional aspects of sensory input, learning and behavior
- Precursors and early signs of chronic diseases such as obesity, asthma, hypertension and diabetes

# NCS Structure



- The NCS is an integrated system of activities
- All components and phases together form the NCS
- Current major components are the
  - NCS Vanguard Study- pilot phase for methods-runs for 21 years-started in 2009 with 7 centers- expanded in 2010 with 30 additional centers
  - NCS Main Study-exposure response phase- runs for 21 years about 3 years time shifted from Vanguard Study-planned start in 2012
  - NCS Substudies- studies within studies
  - Formative Research-short term limited studies, often methods development, to support and inform the Vanguard and Main Studies

# 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 Vanguard Protocol Development



- The protocol development process follows a hierarchy of
  - selection of topic areas and items within a topic area
  - assembly of items into questionnaires known as study instruments
  - assembly of instruments and other types of data collection into a visit
  - assignment of Operational Data Elements to each logistical component and operation of the visit
- The Operational Data Elements form the basis for the primary Vanguard Study analyses

# Additional NCS Vanguard Activities



- The NCS Program Office and Study Centers launched an initiative to define child health in positive objective terms across developmental stage
- The NCS Program Office, Study Centers, support contractors and multiple domestic and international partners launched a neonatal terminology harmonization effort as part of a larger effort to harmonize terminology across developmental stages

# NCS Vanguard Study Methods Development



- Systematic testing of all study components prior to scale up
- Distributed operations to leverage local and collaborative expertise within a framework of centrally developed specifications
- Vanguard Study focus on Operational Data Elements to quantitatively describe study operations and costs
- Integrating data standards into an “end to end” process across the data life cycle (design, planning, implementation, analysis, archiving, dissemination)
- Harmonizing terminology across subspecialties and developmental stages

# Alternate Recruitment Substudy



- NCS Vanguard is now at 37 locations across the country with 30 engaged in new recruitment using one of three different strategies
  - Household based- participants learn about the study through field workers walking through neighborhoods
  - Provider based- participants learn about the study through trusted health care providers with a broad definition of provider including physicians, public health nurses, midwives, etc.
  - Direct to the public- participants learn about the study directly through media and community outreach
- The goal is compare strategies to assemble a toolkit for cost effective directed recruitment for the Main Study launch
- Both direct data analysis and predictive modeling employed

# NCS Recruitment as of April 2011



	Provider	Enhanced Household	Direct	<i>All Alt. Recruitment</i>	Initial Household
Locations	<b>10</b>	<b>10</b>	<b>10</b>	<b>30</b>	<b>7</b>
Locations currently in the field	9	10	10	29	7
Recruitment Duration, months	5	5	5	5	18
Women Identified for contact	3650	14850	3050	21550	33000
Women contacted	1150	11200	1450	13800	30000
Women Eligible	300	1150	650*	2100	2450
Women consented	250	600	500*	1350	1400
Babies	50	50	^	100	600

Person and participant numbers above have been rounded to the nearest 50, following the NCS rounding policy.

^ - Caret symbol indicates that the number rounds to zero

\*- Asterisk symbol indicates that the number is a count of low-intensity participants.

# A Learning Community



- Except for the focus of the Study remaining on the health and exposures 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 direct to participant recruitment cohort, to build an effective learning community.