



The National Children's Study
Update 2006
Public Policy Forum
Pediatric Academic Societies

Peter Scheidt, MD, MPH
National Institute of Child Health
and Human Development,
Department of Health and Human Services



Nothing to disclose

- No disclosures of conflict of interest
- No discussion of use of drugs, products, or devices



The National Children's Study

- Recommended by a President's Task Force and authorized by Congress in the Children's Health Act of 2000
- A longitudinal study of 100,000 children, their families, and their environments (before birth through age 21)
- Hypothesis-driven and a national resource for future studies
- Exposure data beginning with pregnancy and before (physical, chemical, biological and psychosocial)
- Genetic and genomic data to study interaction with environment
- To yield evidence-based data to guide child health care and health policy



National Children's Study Locations

Vanguard locations: Study Centers awarded (bold)

**Lincoln, Pipestone, and Yellow Medicine Counties, Minnesota
and Brookings County, South Dakota**

Salt Lake County
Utah

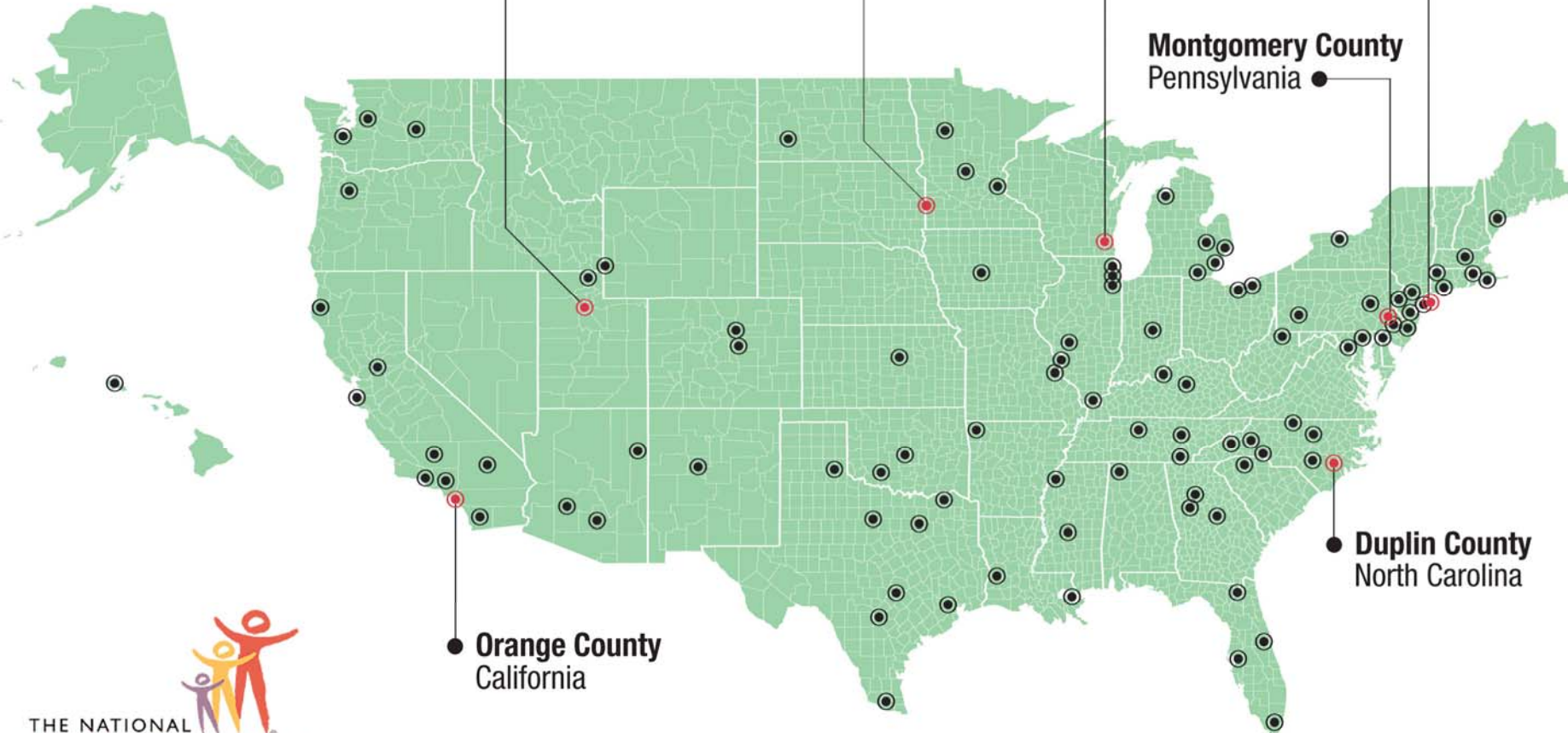
Waukesha County
Wisconsin

New York City (Queens)
New York

Montgomery County
Pennsylvania

Duplin County
North Carolina

Orange County
California



Challenges for the National Children's Study



- The President's Task Force on Environmental Health and Safety Risks to children, January 2000 – "BE BOLD"
- One major challenge
 - How can centers be constituted to implement a core protocol with a given probability sample?
 - How will the research community responded to this challenge?



Vanguard and Coordinating Centers established for the NCS

- Coordinating Center:
WESTAT with Harvard Medical School, Univ. of Penn, and Daston Communications
- Vanguard Centers:
 - **Orange County, CA:** University of CA—Irvine and Children's Hospital of Orange County
 - **Queens, New York City:** Mount Sinai School of Medicine, Columbia Mailman School of Public Health, U. Medicine and Dentistry of NJ and NYC Dept of Health and Mental Hygiene
 - **Duplin County, NC:** Univ. of North Carolina, Batelle Memorial Institute, and Duke University
 - **Montgomery County, PA:** Children's Hosp of Pennsylvania, Univ. of Pennsylvania, and Drexel University School of Public Health
 - **Salt Lake County, Utah:** University of Utah
 - **Waukesha County, WI:** University of Wisconsin, Medical College of Wisconsin, NORC and a Consortium
 - **Brookings, SD; Lincoln, Yellow Medicine, Pipestone MN:** South Dakota State U., U. Cincinnati



Study Plan to Full Protocol in 2006



- Study plan: The document that outlines the general study design to guide offerors to develop their proposals
- Study protocol: The document that specifies both measurement and non-measurement aspects of the Study
 - Who, When, Where, What, +/-How
 - Starting with working group and workshop findings
 - With federal staff, Center investigators, consultants, and **a big dose of reality**
 - For requisite reviews: peer, OMB, IRBs, public comment



Funding Status as of April 2006

- FY 00-06: ~\$50m from existing budgets of NICHD/EPA/CDC/NIEHS
 - Scientific development: federal staff, Federal Advisory Committee, workshops (28), scientific reviews (20), pilot studies (16); hypotheses (30 at www.nationalchildrensstudy.gov); protocol
 - Infrastructure: IMS, Coordinating Center and seven Vanguard Study Centers
- FY 07: \$69m required to implement on the current timeline as per Congress
 - No NCS funding in the President's FY 2007 budget
- To conduct the full Study: FY 08-34
 - ~ \$100m/year for 26 years



2007 Plans

If Funding Provided for the NCS

- RFP for additional centers anticipating:
 - More than one location per center
 - Some level of regionalization
- RFP for specimen repository
- Establish laboratory capacity - led by National Center for Environmental Health (CDC)
- Ready to enroll first participants at Vanguard Centers



How does or would NCS fit with pediatric research enterprise?

- Platform for adjunct studies
- Training for clinical and epidemiological research
- Consortia for combined research
- Public use and secondary data analysis
- Expands investigator initiated (R-01) research



Adjunct studies

- Involve a portion of the sample using some NCS infrastructure and data to address additional or in-depth question
- Funding: R-01 or other grant, Public-private partnerships (foundation, industry, other), NCS
- Process for review and approvals established at NCS Program Office
- Examples
 - Genomic analysis of subgroup specimens for targeted gene-environment interactions
 - Functional neuro-imaging of exposed subgroup for mechanism of effect on child development
- However, adjunct studies require full study to be in place



Training opportunities Related to NCS

- Extensive data base for theses and other trainee projects
- Leverage for training grants
- Broad network for collaborative experiences
- As with other large multi-center projects would produce a generation of clinical and epidemiological researchers



Consortia of Networks

- Coordinated planning efforts: Canada, France, New Zealand, Mexico, Japan
- International Childhood Cancer Cohort Consortium (ICCCC) established for study of cancer, birth defects etc.:
 - China – Collab. Birth Defects 247,831
 - Denmark – National Birth Cohort 101,042
 - Norway – Mother & Child Cohort 100,000
 - Israel – Jerusalem Perinatal Cohort 91,408
 - France – ELFE 20,000
 - UK – ALSPAC 14,062
 - Australia – Tasmanian Inf. H. Survey 10,627
 - Spain – NIMA 4,500



Public use and secondary data analysis

- Important to maximize use and productivity of this extensive program
- Public use data to be available by level of identifiability
- Data sets to be released for each phase as soon as possible (maximum within one year of first publication).
- Funding projections have included RFA's for investigator initiated analyses



Complimentary, not competitive, with investigator initiated research (R-01's)

- Funds for planning and initiation from sources not available for R-01's (contracts line and other agencies)
- NCS seeks to expand pediatric research enterprise and does not assume a "zero sum game".
- Small investigator initiated projects cannot study issues requiring large sample, multiple measures and long term F/U
- R-01 opportunities would increase with projects leveraged on NCS as adjunct studies



Contact Information

- Join the 'Study Assembly' Listserv for news and communication

www.NationalChildrensStudy.gov

- E-mail: ncs@mail.nih.gov

