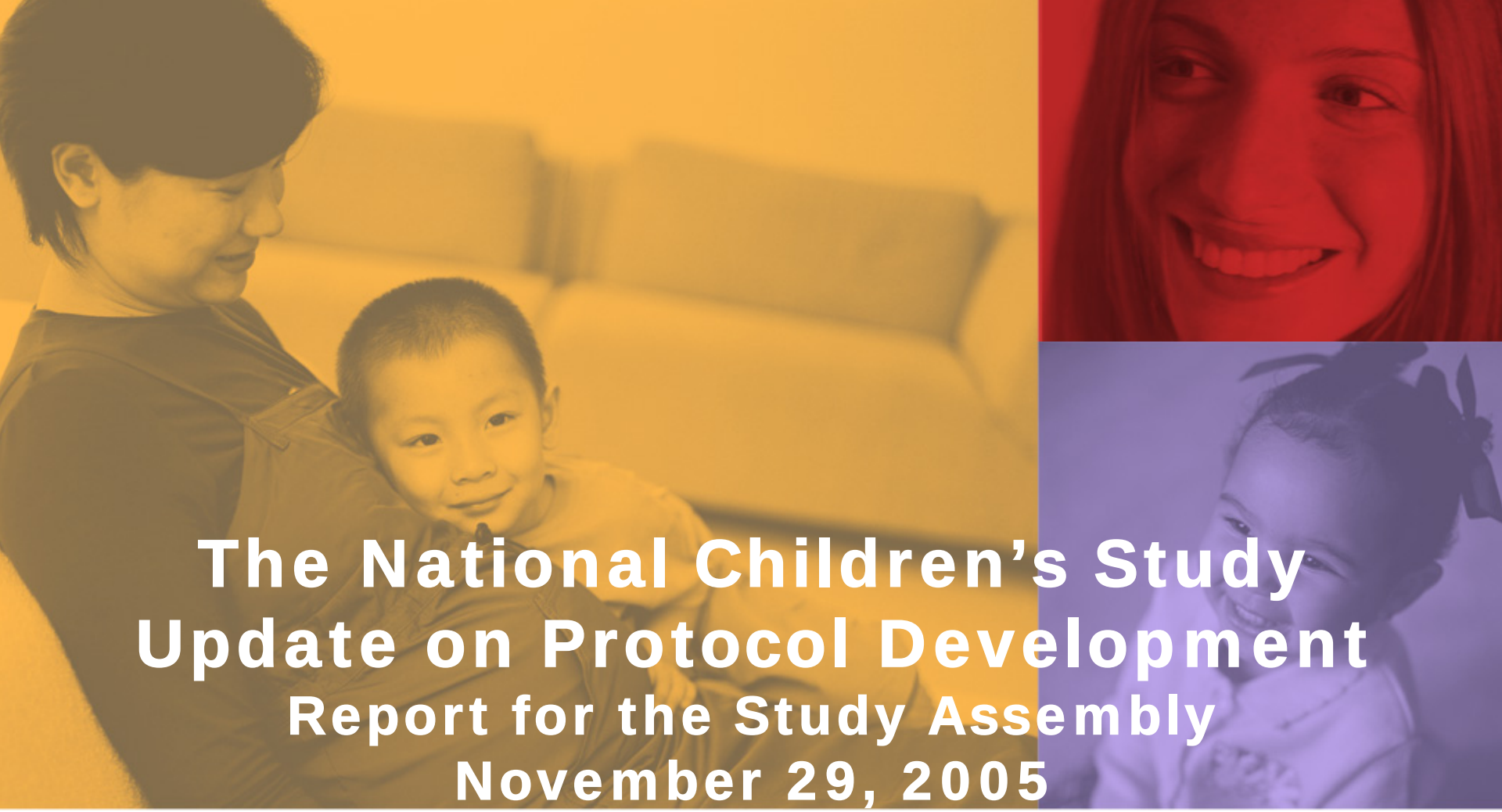

The National Children's Study
Update on Protocol Development
Report for the Study Assembly
November 29, 2005

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National Institute of Child Health and
Human Development,
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THE NATIONAL CHILDREN'S STUDY

Update on Study Protocol
Outline of Presentation

- 2000-2004

  Children's Health Act → Study Plan
- Development of the Study Plan
- Current Status

  Study Plan → Study Protocol

Initial Guidance – Children's Health Act - 2000

"... to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development."

Background 2000-2004

- Longitudinal Cohort Study Proposal (2000)
  - Interagency Coordinating Committee
- Fed. Advisory Comm. and 22 Workgroups (2001)
  - Development of focused hypotheses and suggested measurements
- Other Scientific Activities (2001-)
  - Pilot Studies
  - White Papers and Workshops
- Development of a measurements database (2003)
  - Interagency Coordinating Committee
- Decision of the sampling strategy (2004)

Decision on The Sample Design

- Commissioned analysis “Sampling Strategies for the Proposed NCS” Fall 2002
- Presented to the Advisory Committee (Spring 2003)
- “White Papers in Support of NCS Sampling Strategies” (Fall 2003)
- Expert Panel (June 2004)
- Recommendation by the Advisory Committee with endorsement by the Institute Director (June 2004)

The Study Plan

- Published as part of the Request for Proposals in November 2004
- Outlines the general study design of the National Children's Study
- Purpose was to guide offerors so that they were better able to develop their proposals
- Less detailed than a full study protocol or operational manual, yet more detail than many RFPs
- Study plan will evolve in greater detail with input from investigators from the Vanguard Centers, Coordinating Center and initial experience

Scope of the Study Plan

- Sampling strategy and Study locations (generally counties)
  - Does not specify secondary sampling units (neighborhoods)
- General approach to recruitment, household sampling approach and eligibility criteria
  - Does not specify approach to community engagement
- Target sample size, 250 births/location/year
- Schedule and location of face to face visits
- Very broad specification of the general domains and types of measurements at each visit

Study Protocol

- Study protocol – the document that will detail more specifically the data collection
- Specify both measurement and non-measurement aspects of the Study
  - Who, When, Where, What, +/-How
- Draft Protocol planned– Feb 2006

Study Plan to Study Protocol (January 2005 – November 2005)

Program Office work groups

- Exposure Assessments
  - Psychosocial and Environmental
- Developmental Outcomes

- Continued pilots and other contracts
  - Development of the information management system
  - Specific pilots, e.g. the North Carolina Cohort Study, electronic capture of medical events

- Now able to get input from the Vanguard Centers and the Coordinating Center

Current Process

- Fill in the details of the Study Protocol and finalize key aspects of the Study Plan
- Process: Formation of working teams with members from the Program Office, Vanguard Centers, Coordinating Center
- Deliberations of the Study Teams are informed by previous work and by information in the Submitted Proposals
- Recommendations of the teams are brought to the full Steering Committee

Teams

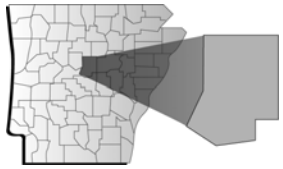
- Sampling
- Recruitment and retention
- Topic Specific Assessments (questionnaire and observational)
  - Neurocognitive and Social-emotional outcomes
  - Nutrition
- Environmental Specimens
- Biological Specimens
- Physical Examinations
- Human Subjects
- Study Operations
- IMS Development

Two Examples

- Sampling Plan
- Schedule of face-to-face contacts

National Children's Study Sample

National probability sample



All Births in the Nation

↓

Sample of Study Locations

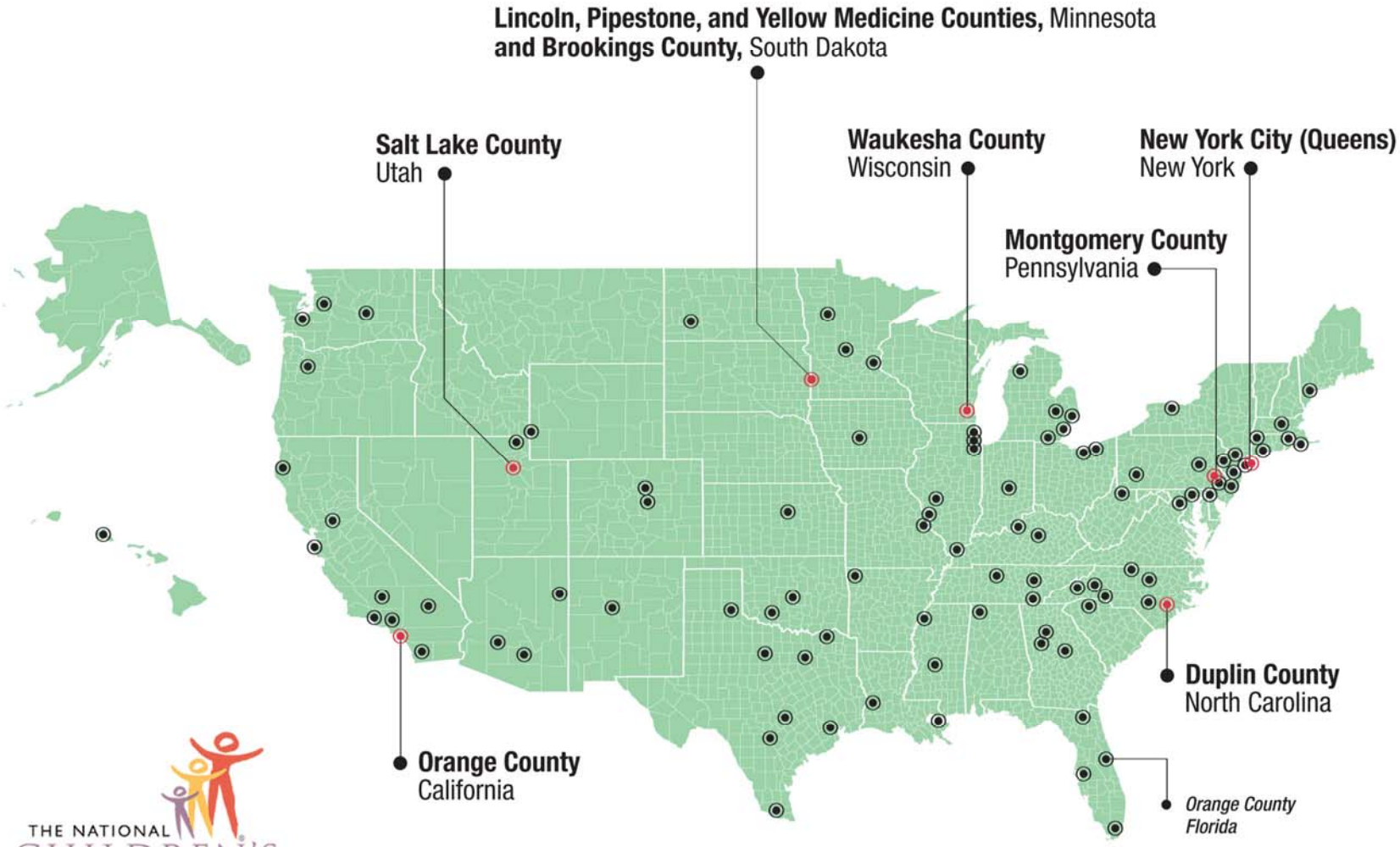
↓

~4 million births in 3,141 counties

105 Locations

National Children's Study Locations

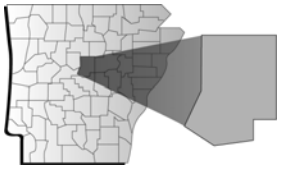
Vanguard locations: Study Centers awarded (bold)
Vanguard locations: Study Centers pending award (italic)



THE NATIONAL CHILDREN'S STUDY
HEALTH GROWTH ENVIRONMENT

November 2005

National Children's Study Sample



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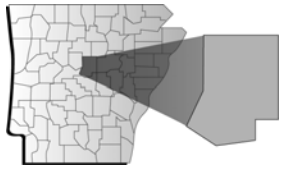
National Children's Study Sample



All Births in the Nation

↓

Sample of Study Locations

↓

Sample of Study Segments

↓

~4 million births in 3,141 counties

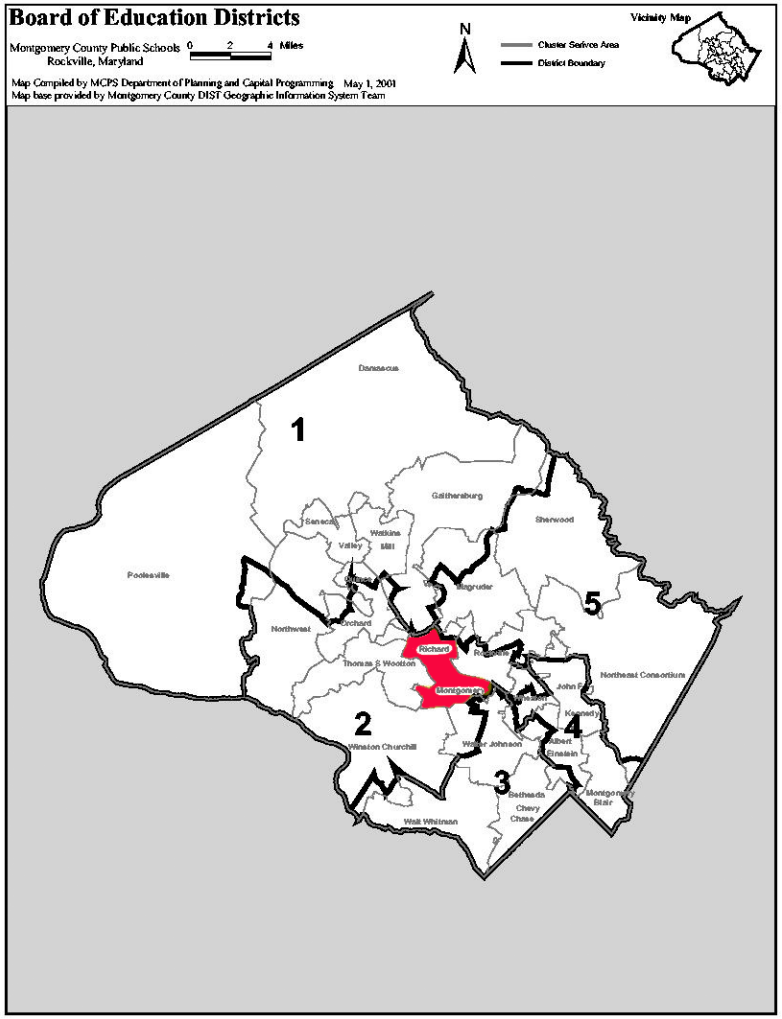
105 Locations

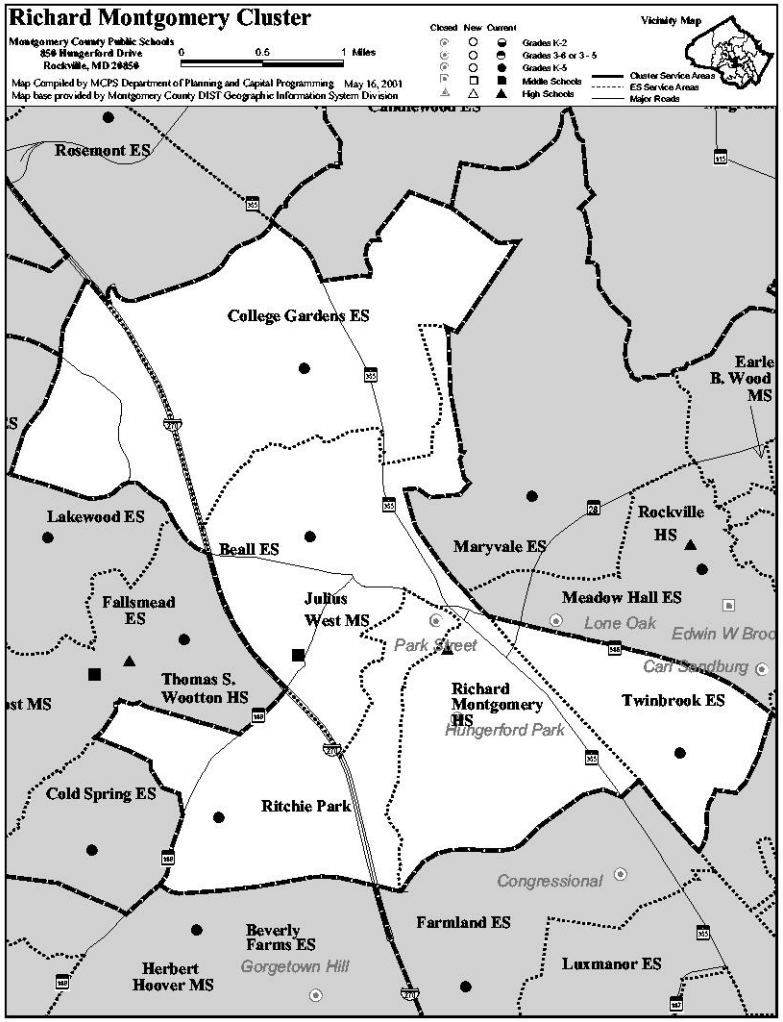
Selection of neighborhoods

Second Stage of Sampling

- Define the sampling units (segments)
  - Vanguard Centers
- Select the segment that will be targeted for recruitment of women
  - Program Office/Coordinating Center
- Challenges
  - Diverse set of locations. Number of births per year range from ~700 to ~45,000

Example: Clusters defined by School Catchment Areas

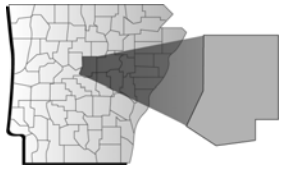




Sampling Team

- Leaders: Lester Curtin (NCHS); Michael Brick (Westat)
- Members: Scientific experts from three Vanguard Centers
- Activities:
  - Expert meeting on optimal cluster size
  - Developing document for collection of uniform information from all Vanguard Centers to guide the next steps
- Short-term goal: Select Segments by March, 2006

National Children's Study Sample



All Births in the Nation

Sample of Study Locations

Sample of Study Segments

Sample of Study Households

Sample of Study Women

~4 million births in 3,141 counties

105 Locations

Selection of neighborhoods

All or a sample of households within neighborhoods

All eligible women in the household

Schedule of Face to Face Contacts

- Women with low probability of pregnancy – initial screening visit
- Women with moderate probability of pregnancy – initial screening visit and one additional data collection visit
- Women with high probability of pregnancy – screening visit plus 4 additional visits

Schedule of Face to Face Contacts

- 16 face-to-face contacts over the 21 year study period
- Contacts most frequent early in the study

1st Trimester	18 months
OGTT	3 years
2nd Trimester	5 years
3rd Trimester	7 years
Delivery	9 years
1 month	12 years
6 months	16 years
12 months	20 years

Clinical Setting

Home

Short term working teams

- Goal: Finalize the schedule of face to face visits by the end of November
- Process: Two working teams
  - Preconception visits: high probability of pregnancy
  - Obstetric visits:
    - Number and timing, fetal ultrasounds;
    - OGTT; feasibility and burden, alternate measurements

Projected Timeline for Protocol Development and Review

Nov 2004	Initial posting of Request for Proposals and the Study Plan
Sep 2005	Award initial contracts (coordinating center and vanguard centers)
Nov 2005	First Steering Committee Meeting
Dec 2005	Working Teams Established
Jan 2006	Recommendations for measurements and key non-measurement aspects of the protocol
Feb 2006	Integration into a unified Study Protocol
Mar 2006	Submission for Internal Governmental Reviews
Apr 2006	Submission for Peer Review
May 2006	Period of public comment

Contact Information

- Web site: http://NationalChildrensStudy.gov
- Listserv for news and communication
- E-mail: ncs@mail.nih.gov