



# Advancing The National Children's Study

*Pre-proposal conference*  
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# Pre-proposal Conference



- Welcome
- Very brief overview and history
- Structure of the NCS
- Organization & components
- Milestones and timeline
- Questions and clarifications to follow



# Background and Rationale



- President's Task Force on Environment and Health Risks to Children
  - Co-chairs Sec. HHS & Adm. EPA + 7 other cabinet member
  - Charge: National strategies to control environ. risks
  - Finds
    - Existing studies limited in size and scope
    - Longitudinal design to infer causality with multiple exposures and multiple outcomes
    - **Bold study** needed to identify effects or ensure safety
- Children's Health Act of 2000: " ..authorize NICHD to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development"



# Study Concepts



- Aims
  - Identify potential environmental effects: harmful, harmless, helpful
  - For conditions and diseases of children, identify potential preventable causes
  - National resource for future studies
- Hypothesis driven
- Exposure begins with pregnancy
- Has power to study uncommon high priority conditions ( $n \sim 100,000$ )
- Gene environment interaction
- National resource for future studies



# Planning Process for the NCS



- Interagency Coordinating Committee: NICHD, NIEHS, CDC, EPA
- Federally Chartered Advisory Committee\*
- Expert Working Groups
  - Hypotheses
  - Measures/methods
- Workshops\*
- Literature reviews/white papers\*
- Pilot Studies\*
- Program Office Staff
- Study investigators (CC and Study Centers)

\* Findings on website: [nationalchildrensstudy.gov](http://nationalchildrensstudy.gov)



# Hypothesis Based Priority Health Outcomes/Exposures



Priority Exposures	Examples
Physical Environment	Housing quality, neighborhood
Chemical Exposures	Pesticides, phthalates, heavy metals
Biologic Environment	Infectious agents, endotoxins, diet
Genetics	Interaction between genes and environment
Psychosocial milieu	Family structure, socio-economic status, parenting style, social networks, exposure to media and violence



Priority Health Outcomes	Examples
Pregnancy Outcomes	Preterm, Birth defects
Neurodevelopment & Behavior	Autism, learning disabilities, schizophrenia, conduct and behavior problems
Injury	Head trauma, Injuries requiring hospitalizations
Asthma	Asthma incidence and exacerbation
Obesity & Physical Development	Obesity, diabetes, altered puberty



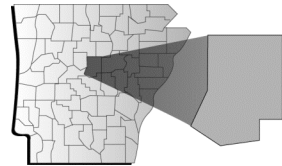
# Sampling and Center strategies



- National probability sample important
  - Exposure-outcome relationship representative of the U.S. population
  - Important exposures with varied and unknown distributions are not missed
  - Clustered for community attributes & logistics
- Centers of excellence important
  - Broad scientific input
  - Measures require center based expertise and facilities
- Probability sample by Centers
  - Unique combination
  - Requires flexibility and adaptation of center to the scientific design
  - Requires support and guidance by coordinating center



# 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

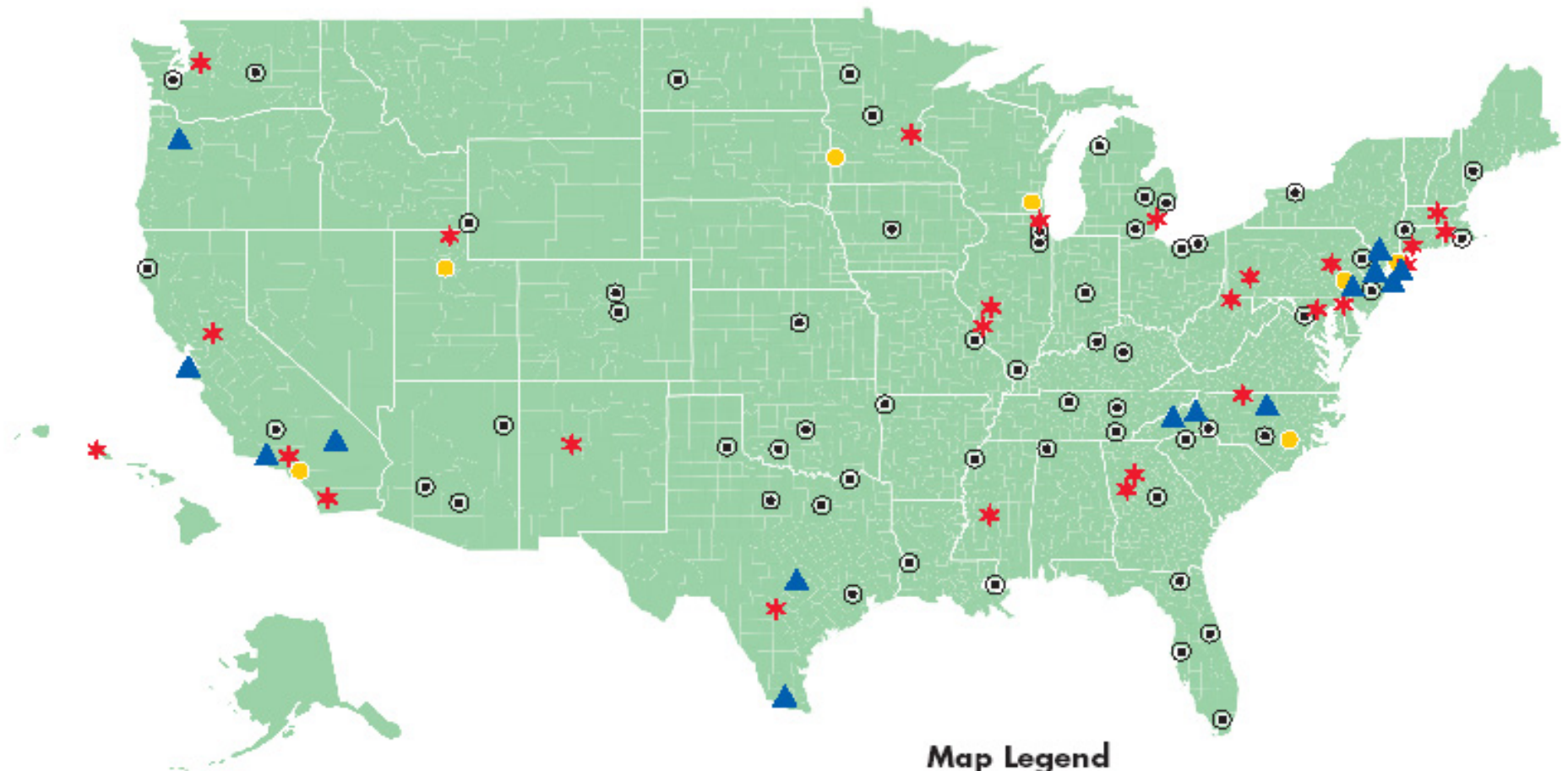
All or a sample of  
households within  
neighborhoods

All eligible women in  
the household





# National Children's Study Locations



## Map Legend

- Vanguard Locations (active)
- ★ 2007 Locations (active)
- ▲ Awarded Locations (not active)
- ⊙ 2008-2010 Locations

# Locations vs. Centers



- Sites—geographic locations (counties) from which participants will be recruited
  - Selected by stratified probability sample of primary sampling units
  - 105 Locations
- Centers—entities or institutions that will carry out Study at the Locations
  - Selected by a competitive process
  - Each will cover more than one site
  - 30-50 Centers





# Study Organization: Key Entities



- Interagency Coordinating Committee (ICC) – Senior staff and scientists of supporting Federal Agencies: – **Federal oversight**
- Federal Consortium – Representatives of Federal Agencies – **Broad Federal input**
- National Children’s Study Advisory Committee (NCSAC) – **Review and advice**
- Program Office (PO) at NICHD – **Day-to-day scientific and operational management**
- Steering Committee – Center PI’s and Federal scientists – **Primary scientific deliberations**
- Coordinating Center – **Data management and clinical coordination**
- Data safety monitoring committee – **monitor data and advise on interventions based on findings**



# Steering Committee

## Roles and responsibilities



- Identifying problems and best practices that arise in the conduct of the study
- Scientific input/expertise to support decision-making
- Making recommendations regarding scientific content of a study component
- Review and approval (not the only) regarding adjunct/add-on studies
- Decision-making about non-direction changing (and budget neutral) issues related to the protocol and MOP
- Proposing changes to the protocol



# Study Components



- In place
  - Scientific support reviews, analyses, surveys
  - Information technology development Contractor (BAH, CC/Westat)
  - Clinical/data Coordinating Center (CC)
  - Initial/Vanguard Study Centers (7)
  - Wave I Study Locations (33) and Study Centers (24)
- Over this year - 2008
  - Wave II Study Locations (30+/-) and assoc. Centers
- Following – 2009+
  - Specimen Repository
  - Laboratory services (NCEH, EPA, contracts)
  - Remaining Study Locations and Center



# Access to Data and Publication



- Maximum use and publication will be a guiding principle.
- Primary hypotheses and analyses - Data access and analyses through Center PI's and other participating investigators (including Federal Agency Scientists)
- Publication Sub-committees of the Steering Committee for policies and oversight regarding publications.
- Data Use and Confidentiality Protections Committee for access to data, public use and disclosure review
- Specimen Oversight Committee as guardian for use of valuable biospecimens
- Public use datasets to be available with each phase as per NIH guidelines, by confidentiality requirements.
- Federal statutes and contractual agreements will prevail.



# 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
- Adjunct study proposals are **NOT** a requirement for this solicitation









# Thank You

Next  
**Ruth Brenner**  
Director for Study Centers