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# **THE NATIONAL CHILDREN'S STUDY: ADJUNCT STUDIES**

## **2007 Children's Environmental Health Workshop: EPA**

**October 12, 2007**



**US Department of Health  
and Human Services**



**US Environmental  
Protection Agency**

# The National Children's Study



- Authorized in 'The Children's Health Act of 2000': study effects of the environment on child health and development
- Environment broadly defined: chemical, biological, physical, psychosocial-cultural
- Gene-environment interaction and gene expression
- Largest/longest such study ever conducted in the U.S.
- Longitudinal study of 100,000 children, from before birth (even before conception) through age 21
- Representative sample of children across the U.S.
- Power to study important but uncommon outcomes
- National resource for future research



# Aims of the Study



- Identify environmental effects on children:
  - harmful, harmless, and helpful
  - in the context of gene-environment interaction
- Identify preventable causes of important health-related conditions in children
- Provide evidence-based data to guide decisions regarding children's healthcare and health policy



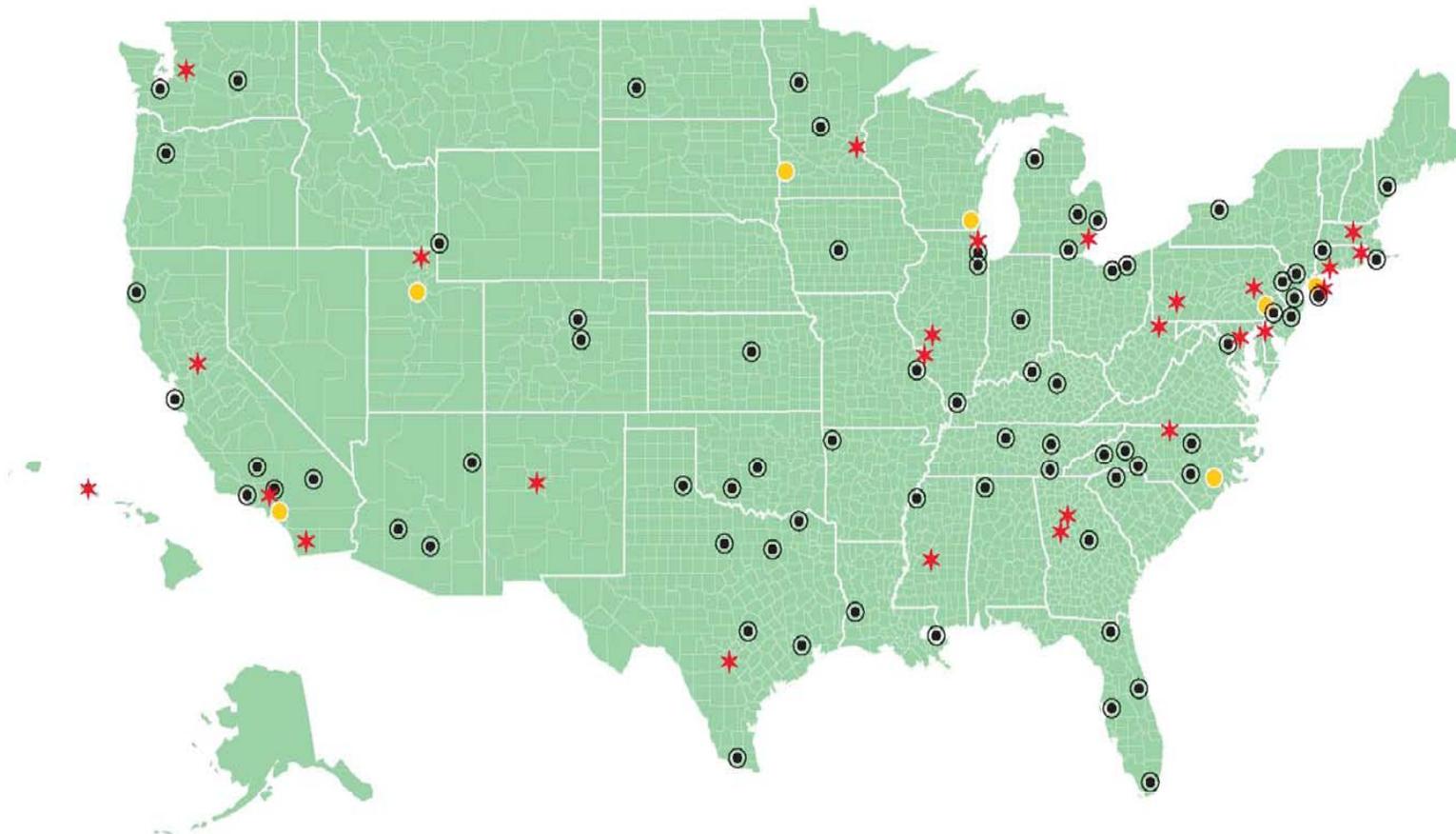
# Organizational Structure



- Program Office (PO) at NICHD – NCS Director, scientists, administrative staff
- Interagency Coordinating Committee – NICHD, CDC, EPA, NIEHS
- Chartered Advisory Committee
- Federal Consortium: key government agency reps
- Steering Committee – Study Center PIs, federal scientists and community representatives
- Coordinating Center – Data management/coordination
- Study Centers – 7 Vanguard Centers & 22 new Centers
- Study Assembly - 4500 interested scientists & others



# National Children's Study Locations



## Map Legend

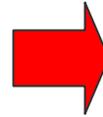
- ★ 2007 Locations
- Vanguard Locations
- ⊙ 2008-2010 Locations



# Priority Exposures and Outcomes



Priority Exposures	Examples
Physical Environment	Housing quality, neighborhood
Chemical Exposures	Pesticides, phthalates, heavy metals
Biologic Environment	Infectious agents, endotoxins, diet
Genetics	Interaction between environmental factors and genes
Psychosocial-cultural Milieu	Families, SES, institutions, social networks



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



# Leveraging the National Children's Study

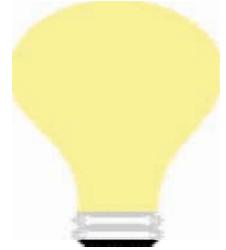


**The Research Plan or Protocol...**

**The potential links between exposure & outcome measures...**

**The ongoing research findings as the Study progresses...**

**will spark ideas for further research leveraging the core study -> adjunct study proposals**



# Adjunct Studies: Key Characteristics



- **Involve a subset of the NCS cohort**
- **Modular, focused studies utilizing NCS infrastructure: participants, and/or bio-specimens, and/or environmental samples.**
- **Initiated by: government scientists, Study Center scientists, independent investigators, research advocates, industry...**



# Adjunct Studies: Key Characteristics (cont'd)



- **Focus**
  - a unique research interest/capability  
or
  - a specific public health or community concern
- Utilize, complement, leverage the core protocol for mutual benefit
- 'Outside' (not core-NCS) funding



# Key Review Factors For NCS Quality and Integrity



- **Scientific merit**
- **Public health importance: potential contribution to health care or policy**
- **'Fit' with the NCS (priority exposure or outcome, sampling, tools, timing...)**
- **Appropriate use of bio-specimens and environmental samples**



# Key Review Factors (cont'd)



- **Burden on participants (time, discomfort...)**
- **Burden on the Study infrastructure (logistics...)**
- **Human Subjects issues: ethical & legal considerations**
- **Peer review, IRB review, funding**



# Application: Review and Approval Process



- **Brief electronic Preliminary Application**
- **The Full Application is provided after NCS approval of the Preliminary Application**
- **Iterative process to facilitate timely review of proposals: Program Office, ICC, Steering Committee, Sample Oversight Group...**



# 'Outside' Funding (not 'core-NCS' \$\$\$)



- **'Partnerships' with government agencies (e.g. intramural scientists and funding; RFAs to extramural scientists...)**
- **Government grants (e.g. R-01...)**
- **Public-private partnerships: industry, foundations, academia, research advocacy groups, etc.**



# Timing (as of 10-07)



- **July 2008 to July 2009: VC pilot year**
- **July 2009: Enrollment begins at Vanguard and new Study Centers for the 'full Study'**
- **Adjunct Study proposals for pre-conception, pregnancy, delivery, newborn and early infancy periods could be submitted soon to commence ~July '09**



# In summary: Opportunities for scientists in government and academia



- **Opportunities will continuously arise for additional research by leveraging the NCS**
- **Opportunities exist for public-public (other government agencies) and public-private partnerships**
- **Adjunct studies will broaden and enhance the NCS contribution to children's environmental health**
- **On the NCS website:**
  - **'Adjunct Study Overview'**
  - **Application for adjunct study proposals**





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