

*Request for Information (RFI): Inviting Comments and Suggestions on the Environmental influences on Child Health Outcomes (ECHO) Program (the National Children's Study Alternative)*

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**Submitted on behalf of the Society of Behavioral Medicine; August 2015**

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***The Core Elements:***

*Potential benefits, drawbacks, and areas of consideration for leveraging existing cohorts to collect standardized data elements*

**RESPONSE:**

The ideal cohort for consideration would be one beginning near or before conception with available data on socio-demographic, psychosocial, physiological and/or environmental factors on both mother and father and similar data on the child during gestation, infancy, childhood, adolescence, and adulthood. Data on characteristics of the micro environment - (ecological momentary assessment, data collected from activity and diet trackers) or macro-environment (geospatial data from home, school or neighborhood) would also be ideal.

The ideal cohort will also have biobanked specimens from multiple biological matrices from the pregnant or nursing mother (e.g., blood from prenatal period, hair, urine, saliva, and/or breast milk), the infant/child (e.g., meconium, cord blood, urine, fecal sample) or placental tissue. At a later stage of childhood, banked naturally shed deciduous teeth would also be ideal.

Consideration will need to be given to data harmonization efforts; incomplete, insufficient or non-viable biological data; and inconsistencies or variability in measurement of core data elements.

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*Additional core elements to be considered*

- Linkage to electronic medical/health record
- Data on common exposure during pregnancy, such as, smoking, alcohol use, prepregnancy BMI, gestational weight gain, gestational diabetes, etc.
- Intergenerational data on biological mother/father, grandparents
- Gold standard measurements of perceived environment and objective measurements of school/home/neighborhood physical environment
- Measurement of perceived stress or adverse events
- Ability to geocoding of home, school, neighborhood

- Micro/social environment (e.g. ecological momentary assessment, data collected from activity and diet trackers)
- Changes in adiposity including depot-specific (e.g. visceral, deep subcutaneous, superficial subcutaneous)
- MR elastography to track non-alcoholic fatty liver disease
- Functional MRI
- Energy expenditure and intake and body composition (e.g. 24-hour metabolic chamber for calorimetry, mass spectrometry, hepatic lipid and intramyocellular lipid spectroscopy, internal organ volumes)
- Fitness testing
- Measurement of infant temperament, child social-behavioral functioning, or measured cognitive functioning of mother and child
- Measurement of epigenetic biomarkers from Humanmethylation450 (450K) BeadChip
- Measurement of maternal cortisol
- Measurement of postnatal parenting style of food-specific parenting

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*Considerations for harmonizing data across cohorts*

The PCORNet sponsored by the Patient-Centered Outcomes Research Institute created a Common Data Model that could provide infrastructure for this project to harmonize data collection.

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*High impact areas of opportunity in addition to those listed*

- Comparison of offspring of mothers with and without gestational diabetes
- Trajectories of growth (weight and height) from birth through childhood and adolescence
- Racial/ethnic disparities in focus area outcomes
- Variation in prenatal maternal stress and child health outcomes

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*Anticipated advances and/or considerations for implementing state-of-the-art data collection and analytic methodologies throughout the duration of the study*

- Assays of naturally shed deciduous teeth to determine timing and level of exposures from prenatal and postnatal periods.

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***The four Focus Areas:***

*Suggestions of existing research studies or resources that might address one or more of these areas, including a description of the study or resource (e.g., sample size, demographic information, major health or behavioral outcomes, environmental exposures, success with or potential for follow-up through childhood, available biologic or environmental specimens)*

- The Green and Health Homes Initiative (GHHI) is a national public-private partnership designed to coordinate efforts of public and private agencies that focus on creating healthy and energy efficient homes for low and moderate income populations. Outcomes: asthma episodes, ED visits, and hospitalizations.
  - Norton RA, Brown BW. Green & Healthy Homes Initiative: Improving Health, Economic, and Social Outcomes Through Integrated Housing Intervention. Environmental Justice. 2014; 7.
- Anthropometric Assessment of Abdominal Obesity and Health Risk in Children and Adolescents (Waist) - <https://clinicaltrials.gov/ct2/show/NCT01595100?term=katzmarzyk&rank=3>
  - n = 423 5-18 year olds with baseline assessment in 2010-11
  - Strengths: balanced for obesity status, sex, and race; anthropometry, adiposity by DXA and abdominal MRI, lifestyle habits, blood biomarkers
- International Study of Childhood Obesity, Lifestyle and the Environment (ISCOLE) - <https://clinicaltrials.gov/ct2/show/NCT01722500?term=katzmarzyk&rank=5>
  - n = 6000 9-11 year olds with baseline assessment 2011-13 (> 500 in U.S.)
  - Strengths: Gold standard measurements of perceived environment, objective school/home/neighborhood environment; policy environment; balance of low and high socioeconomic status schools
- Tianjin Gestational Diabetes Prevention Program (TGDPP) (GDM) - <https://clinicaltrials.gov/ct2/show/NCT01554358?term=hu+tianjin&rank=4>
  - n = offspring of 1200 mothers with gestational diabetes and 600 mothers without
  - Strengths: genetic profiling, glucose, insulin resistance, incidence of type 2 diabetes in mothers
- Newborn Epigenetic Birth Cohort Study (NEST) and child follow-up studies. 1R01DK085173, 1R01ES016772, 1R01HD084487, 5P01ES022831
  - N ~ 2000 women from community cohort enrolled close to their first trimester.
  - Strengths: prenatal blood samples, cord blood, ongoing collection of child saliva and blood; epigenetic data, electronic health records data, measured weight for infants and children, and ongoing data being collected on neurodevelopment.
- Avon Longitudinal Study of Parents and Children, University of Bristol, UK <http://www.bristol.ac.uk/alspac/>
  - n ~ 14,500 since early 1990s
  - strengths: comprehensive biogenetic and sociocultural measurement and tracking of birth cohort starting at 12 weeks gestation; follow-up ongoing