

The HOME Study: A Cincinnati Cohort Examining Health Outcomes & Measures of the Environment



Kimberly Yolton, PhD

Associate Professor

Division of General & Community Pediatrics
Cincinnati Children's Hospital Medical Center
University of Cincinnati College of Medicine

University of Cincinnati

Data and Biospecimen Sharing in Environmental Health

October 16, 2015

Overview

Current Principal Investigators:

- Bruce Lanphear, MD, MPH Simon Fraser U
- Kimberly Yolton, PhD CCHMC
- Aimin Chen, MD, PhD UC
- Joseph Braun, PhD Brown U

Pregnancy and birth cohort study examining the impact of a wide range of environmental exposures on child outcomes

HOME Study History

- Established through a Children's Environmental Health Center grant awarded in 2001 by the NIEHS and US EPA (PIs: Lanphear & Dietrich)
- 5 integrated research projects focused on exposures to environmental toxicants and child health
- 2 of these projects created the **HOME Study**
- Study of this cohort has continued for over 14 years through multiple grant mechanisms



National Institute of
Environmental Health Sciences



Primary Objective

To improve our understanding of the impact of exposures to ***common environmental toxicants*** on infant and child ***health, development, and behaviors.***

Focus on Common Environmental Toxicants

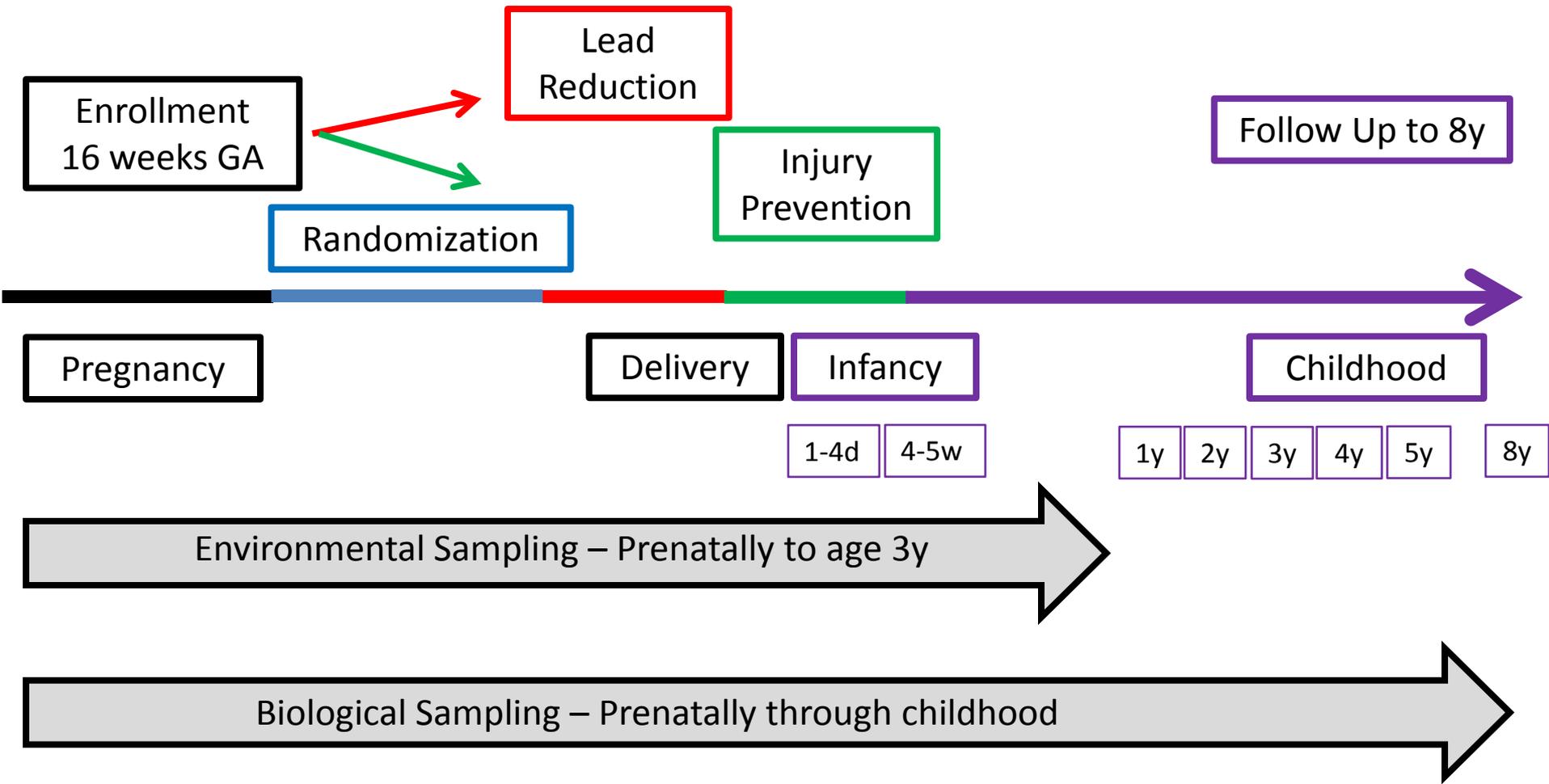
Original Toxicant List

- Lead
- Tobacco (cotinine)
- Pesticides (OP, OC)
- Methyl mercury
- PCBs

Toxicants Added

- Phthalates
- Bisphenol-A
- Flame retardants
- Perfluorinated chemicals
- Air pollution
- Other metals (As, Cd)

Study Design: Randomized Trial and Longitudinal Observation



Study Design: Randomized Trial

Lead Hazard Reduction

- Primary Prevention
 - Before delivery = before exposure
- Lead-Safe Contractors
 - Stabilize paint
 - Replace windows
 - Dust control
 - Cover soil
 - Install water filter

Average Renovation Cost:
\$5585

Injury Prevention

- Primary Prevention
 - Before mobility = before injury
- Reduce falls, cuts, burns
 - Smoke detectors
 - Stair gates
 - Safety latches
 - Outlet covers
 - Window guards

Average Renovation Cost:
\$321

Study Design: Phases

PHASE 1:

Enrollment at OB office
Maternal Measures

16 & 26w Home/Office visits
Maternal Measures

Birth and Infant Measures
Early Infant Neurobehavior

1, 2, 3y Home visits

1, 2, 3y Clinic visits

Cognitive and Motor Development
Behavior
Growth

PHASE 2:

4 and 5y Clinic Visits
Language Development
Cognition (IQ)
Reading Readiness
Executive Function
Behavior
Growth

PHASE 3:

8 Year Clinic Visit
Cognition (IQ)
Reading and Math Achievement
Executive Function
Spatial Reasoning
Gender Identity
Behavior
Growth

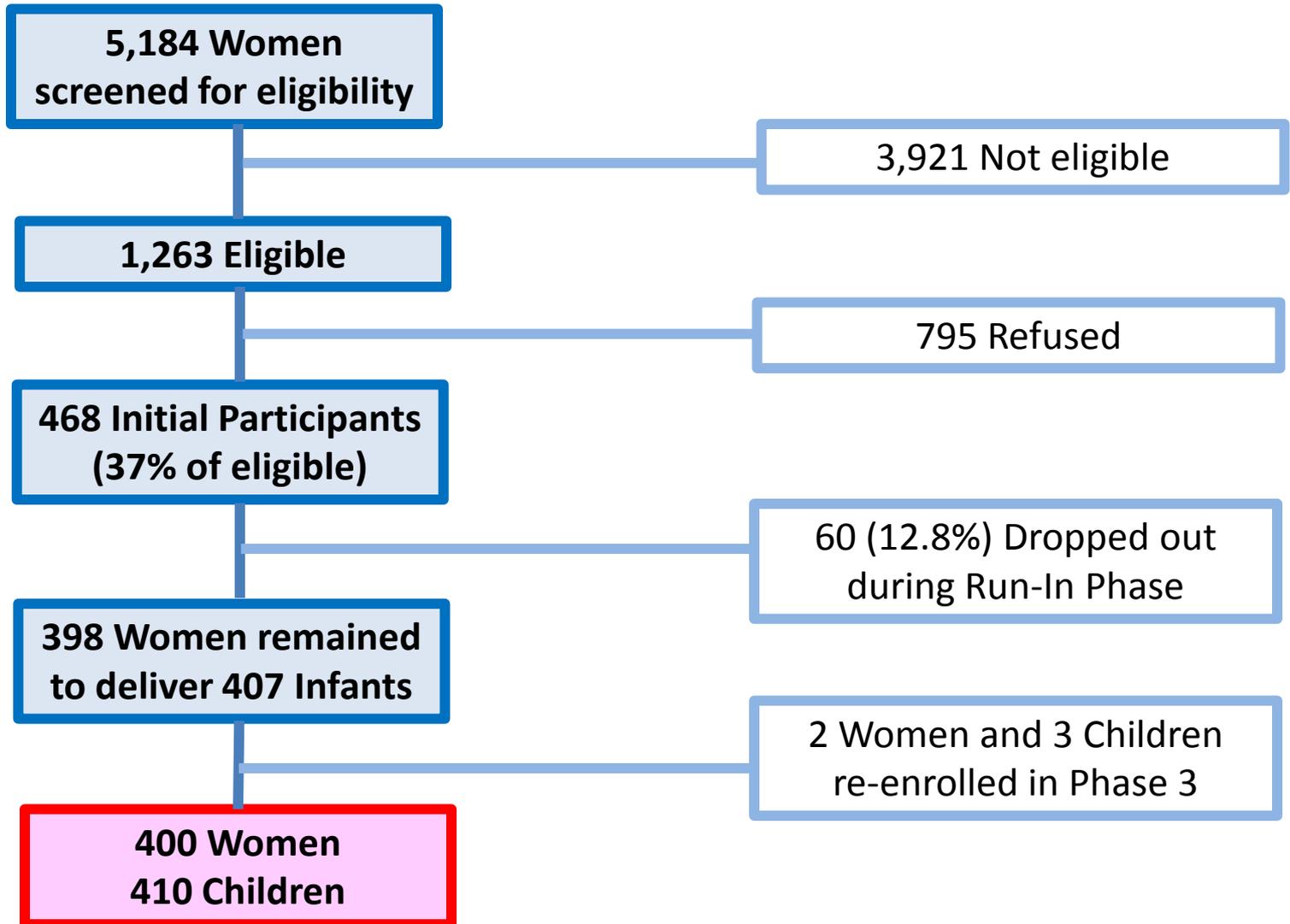
Neurobehavioral Assessment:

Parent report
Direct assessment of skills
Child report

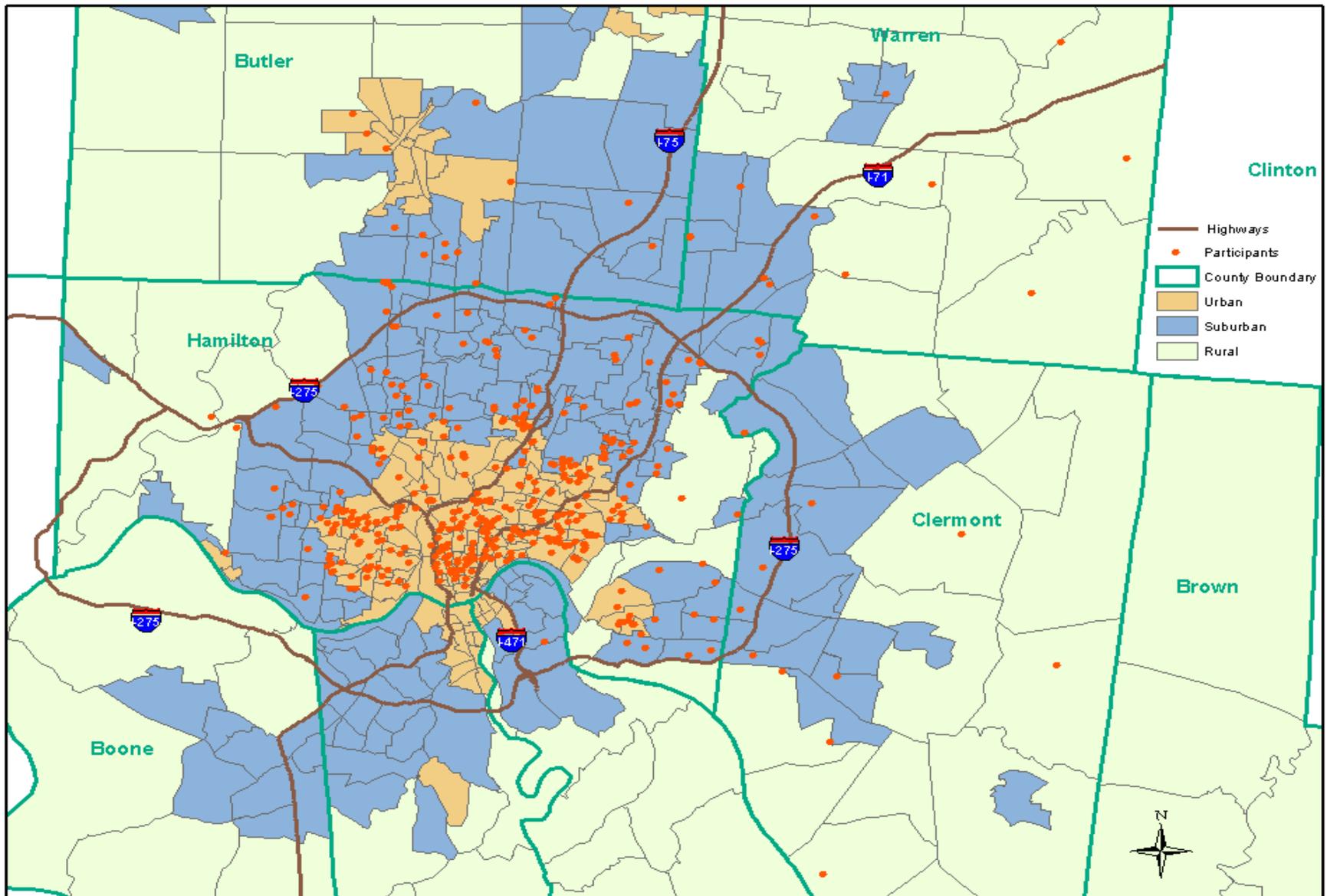
Planned Future PHASE 4:

11 to 13 Year Outcomes
Anxiety
Depression
Social Impairment
Behavior
Growth
Neuroimaging
Adiposity

Study Enrollment



Study Participants



Characteristics of the Cohort (Phase 1)

Maternal Characteristics	
Black	32%
Age at delivery	29y
Married	64%
Household income	\$55,000
Employed	81%
>HS or GED	75%
Urban	61%
Child Characteristics	
Male	46%
Birth weight	3360 g
Gestational age	39.0 weeks

Mean Exposure Characteristics (Phase 1)

Toxicant Measured	Original Cohort (n=398)	% Detectable	NHANES Females 2003-2004
Child Blood Lead (ug/dL)	1.68	100	1.7
Maternal Blood Lead (ug/dL)	0.67	99.7	1.19
Blood Mercury (ug/L)	0.58	92	0.78
Serum Cotinine (ng/mL)	0.073	64	0.05
Serum PBDE47 (ng/mL)	20.7	100	19.6
Serum PFOA (ng/mL)	5.5	100	3.5
Total PCB (ng/g lipid)	61.6	100	79.2
OP pesticides DAP (nmol/L)	63	100	n/a
Phthalates DEHP (nmol/L)	365	100	n/a
Phthalates DBP (nmol/L)	152	100	n/a
BPA (ng/mL)	2.2	99	2.4

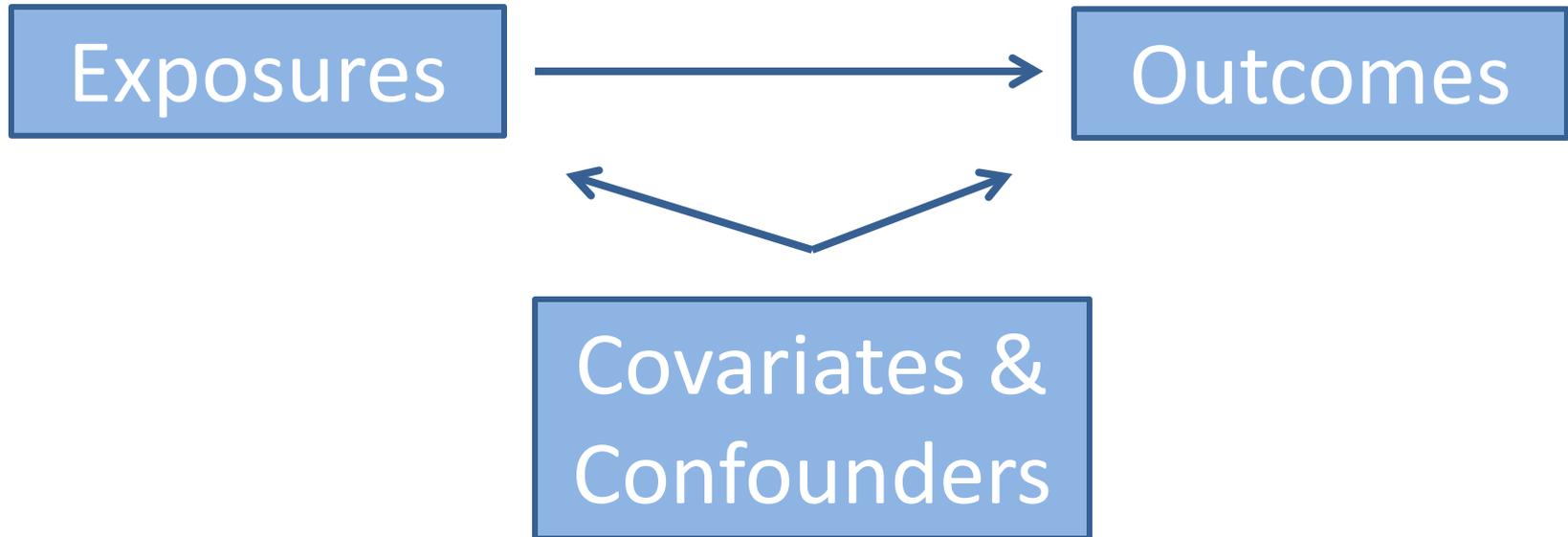
Enrolled Children are Typically Developing

	Number completed	Mean	SD
Cognitive Development/IQ *			
Bayley II MDI – 1y	337	93	10
WPPSI FSIQ – 5y	210	102	15
WISC-IV – 8y	231	102	16
Behavior Problems (BASC2) **			
Externalizing	239	50	9
Internalizing	239	48	9
Behavior Symptoms	239	50	9

* Standardized Mean = 100, SD = 15

** Standardized Mean = 50, SD = 10

Variables Collected



Variables Collected

~32,000 survey questions:

- Exposure surveys
- Demographics
- Maternal and child health

Growth (child and parent)

Derived Variables such as:

- Reported tobacco smoke exposure
- Breast feeding duration
- Maternal supervision

• Comprehensive Neurobehavioral Battery:

- Infant neurobehavior
- Child development
- Intelligence and Achievement
- Behavior (multiple dimensions)
- Executive function
- Visual-spatial learning
- Parent traits

**> 1 million
variables collected,
>10GB of data storage**

Biospecimens Collected

16w 26w Delivery 4w

Maternal Samples

- Urine
- Whole blood & serum
- Hair
- Saliva
- Extracted DNA
- Breast milk and/or formula

Child Samples

- Umbilical cord blood & serum
- Vernix
- Meconium
- Urine
- Whole blood & serum
- Hair
- Shed deciduous teeth
- Exhaled NO
- Extracted DNA

Delivery 1y 2y 3y 4y 5y 8y

37,555 biological samples collected

Environmental Specimens Collected

- Soil
- Vacuum dust
- Dust wipes
- Water

**15,000 environmental samples
collected from the homes of
410 participants**

Pregnancy	1y	2y	3y	Renovation	Move
-----------	----	----	----	------------	------

Data Sharing

- We welcome secondary projects that can benefit from the richness of the HOME Study data
- 2012 – Implemented a protocol for applying for use of data
- Ensures there is no overlap with ongoing or planned projects
- Ensures proper acknowledgement of key investigators
- Acknowledges key funding sources and investigators

Data Sharing

- Data use form must be completed indicating all variables requested, available funding for data management support, publication intent
- Approval by committee of 5 investigators including 1 biostatistician/epidemiologist
- Evaluation by data manager regarding feasibility and time line for delivery of data set(s)
- Per CCHRF, the protocol mandates that 1 investigator from CCHMC be included on all manuscripts
- Have approved >30 projects through this mechanism

Challenges

- Keeping track of the multiple projects and analyses
 - Ensuring adequate progress
 - Status of publications
- Ensuring all data users comply with protocol
- Ensuring destruction of data following analysis
- Data management is not FREE

Collaboration Makes Us Stronger



Simon Fraser
University



BROWN

W
UNIVERSITY of
WASHINGTON



STATE UNIVERSITY OF NEW JERSEY
RUTGERS



MOUNT SINAI
SCHOOL OF
MEDICINE



Dartmouth

The HOME Study Team

Investigators

Cincinnati

Mekibib Altaye
Aimin Chen
Kim Dietrich
Tanya Froehlich
Richard Hornung
Jane Khoury
Kieren Phelan
Paul Succop
Heidi Sucharew
Kim Yolton

External

Joseph Braun
Amy Kalkbrenner
Bruce Lanphear
Adam Spanier
Heather Stapleton

Dedicated Staff

Sam Morgan

Yingying Xu

Stacey Liddy
Ann Popelar
Leah Tyzinski
W Mim Larkin
Sarah Stewart
Sharon Penko
Suzette Baez
Hadley Sauers
Will Bell
Jason Meyer
Diana Henderson

Jessica Cruey
Hafiz Mohamed
Keith Payne
Rick Hutchinson
Donna Strauss
Robert Tamer

**Summer Students
and Interns**

HOME Study Participants