National Institutes of Health
Environmental influences on Child Health Outcomes (ECHO)

Environmental influences on Child Health Outcomes (ECHO)-wide Cohort Data Collection Protocol Overview

ECHO Program Director	Matthew W. Gillman, MD, SM Director, Environmental influences on Child Health Outcomes (ECHO) Office of the Director, National Institutes of Health Phone: (301) 402-3388 Email: matthew.gillman@nih.gov
ECHO-wide Cohort Data Collection Protocol Working Group Co-Chair	David Cella, PhD Principal Investigator, PRO Core Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, 633 N St. Clair St, Chicago, IL 60612 Phone: (312) 503-1086 Email: d-cella@northwestern.edu
ECHO-wide Cohort Data Collection Protocol Working Group Co-Chair	Emily Oken MD, MPH Cohort Principal Investigator Department of Population Medicine Harvard Medical School and Harvard Pilgrim Health Care Institute Phone: (617) 867-4879 Email: emily_oken@hms.harvard.edu

The purpose of this document is to provide stakeholders in the ECHO Program with a high-level overview of the ECHO-wide Cohort Data Collection Protocol so that they can respond to the Request for Information (RFI). This overview contains information regarding the background of the ECHO Program, the objectives of the ECHO-wide Cohort Data Collection Protocol, the history of the protocol development process to date, the ECHO participant population, and a brief summary of the current protocol design. This overview concludes with an active link to the data elements currently included in the ECHO-wide Cohort Data Collection Protocol.

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Abbreviations

CC	ECHO Coordinating Center
CHEAR	Children's Health and Exposure Analysis Resource
DAC	Data Analysis Center
ECHO	Environmental influences on Child Health Outcomes
ISPCTN	IDeA States Pediatric Clinical Trials Network
LMP	Last Menstrual Period
NIH	National Institutes of Health
PRO	Person-Reported Outcome
RFI	Request for Information

ECHO-wide Cohort Data Collection Protocol Overview Glossary

The following table contains a glossary of specialized terminology used within the ECHO-wide Cohort Data Collection Protocol Overview.

Term	Definition
Adolescence Life Stage	11 through 21 years
Airways	The outcome domain focused on upper and/or lower airway-related outcomes (e.g., asthma, allergies, sleep-disordered breathing).
Biospecimens Working Group	The working group charged with developing policies and procedures for biospecimen utilization, collection, processing, and storage and with exploring novel methodologies.
Chemical Exposures Working Group	The working group charged with developing and implementing a set of recommendations for the analysis of chemical exposures across multiple ECHO cohorts.
Children's Health and Exposure Analysis Resource (CHEAR)	The component of ECHO that provides a focused infrastructure for comprehensive exposure analysis of biological samples to provide: 1. Rigorous assessment of a range of environmental exposures, xenobiotics, physiological measurements, and other biological indicators of environmental exposure and response. 2. Statistical tools and data science approaches to manage and analyze newly generated datasets in a cohesive and integrated manner.
Cohorts	Longitudinal studies consisting of existing participant populations; there are currently 35 ECHO Pediatric Cohort Awards comprising 84 constituent cohorts.
Common Data Element	Per the Request for Applications OD16-004, common data elements include: a. Demographics (e.g., race, ethnicity, gender, socioeconomic status, geographic location) b. Typical early development (e.g., growth, milestones, physical activity, sleep, and optional sub element—microbiome) c. Environmental exposures (e.g., physical, chemical, in-utero, microbial, psychosocial, natural and built environment) d. Genetics (genotyping to be provided by an ECHO Genetics Core and optional sub element—epigenetics) e. Person-reported outcomes.
Coordinating Center	The ECHO component that provides the organizational framework for the management, direction, and overall coordination of all common ECHO activities.
Data Analysis Center	The ECHO component that provides the data repository and the data analysis functions for all common ECHO activities.

Term	Definition
Early Childhood Life Stage	12 months through 6 years of age, with gestational age adjustments through 36 months for preterm infants
ECHO-wide Cohort	A data platform that will consist of essential data elements from all 35 ECHO Pediatric Cohort Awardees and their 84 constituent cohorts, plus more specialized data from a subset of Cohort Awards.
ECHO-wide Cohort Data Collection Protocol	The protocol that will specify what data cohorts should collect (new data) and share (both existing and new data) across the life course from preconception through adolescence. This protocol will facilitate the creation of the ECHO-wide Cohort data platform.
ECHO-wide Cohort Data Collection Protocol Development Working Group	Led by 2 Co-chairs, includes members from the CC, PRO Core, and Pediatric Cohort Awards, and also 6 Life Stage Subcommittees. Each Life Stage subcommittee is co-led by a representative from the PRO Core and a Cohort PI, and includes representatives from the DAC, from the Biospecimens and Chemical Exposures Working Groups, and from each of the 5 Outcome Working Groups.
ECHO Program Office	The NIH ECHO Program Office consists of the ECHO Director, a Senior Program Official, 4 additional Program Officials, a Chief of Staff, a Communications Specialist, and an Executive Assistant.
Essential Data Elements	Apply to all 84 pediatric cohorts; collection and sharing of essential data elements will be required for participation in ECHO.
Executive Committee	Represents the interests of all ECHO components, provides overall direction for the ECHO Program within the vision and rules stipulated by NIH. The Executive Committee proposes strategic decisions regarding overarching program issues, which the Steering Committee considers for ratification.
Existing Data	Cohort data that existed prior to a cohort becoming ECHO-funded; these existing data will contribute to ECHO analyses.
Exposure	A determinant, risk or resilience factor, predictor, or independent variable to be associated with child health. Exposures could be physical, chemical, social, behavioral, or biological. ECHO Pediatric Cohorts define the exposure period from preconception to age 5 years.
Extant Cohort	A cohort that already exists and has enrolled participants.
Gestational Age	Best estimate of number of weeks post-LMP. Date of conception can also be used to measure gestational age if the child was conceived with assisted reproductive technology. Gestational age adjustments for preterm infants will be used through 36 postnatal months.

Term	Definition
IDeA States Pediatric Clinical Trials Network	Component of ECHO that is separate from the Pediatric Cohorts. Network enables access to state-of-the art clinical trials among children from underserved and rural areas. Consists of 17 clinical sites and a Data Coordination and Operations Center. The ECHO-wide Cohort Data Collection Protocol does not apply to this Network.
Infancy Life Stage	46 weeks post-LMP through 24 months (with gestational age adjustments through 36 months for preterm infants)
Life Stage Subcommittees	Group of experts representing the 6 developmental life stages investigated across ECHO. Committees also include representation from each outcome domain as well as the Biospecimens and Chemical Exposures Working Groups. Charged with identifying relevant outcomes, exposures and covariates within each life stage and further identifying valid measurements for inclusion in the ECHO-wide Cohort Data Collection Protocol.
Middle Childhood Life Stage	5 through 12 years of age
Minimally Acceptable Measures	Basic measures in terms of participant and researcher burden and data collection feasibility that still maintain sufficient scientific rigor. May include short form versions and subscales of longer instruments and assessments with remote administration.
Neurodevelopment	The outcome domain focused on neurodevelopmental outcomes (e.g., attention, cognition, emotion, social/language/behavioral development).
New Data	Cohort data collected using ECHO or other funding after 21 September 2016; these new data will contribute to ECHO-wide Cohort analyses.
Obesity	The outcome domain focused on obesity and obesity-related outcomes (e.g., nutrition, metabolic risk factors, activity level).
Outcome Domains	ECHO studies will focus on 5 key pediatric outcome domains that have a high public health impact: 1. Pre, peri, postnatal outcomes 2. Neurodevelopment 3. Upper and lower airways 4. Obesity and related conditions 5. Positive health.
Outcome-Focused Measures	Measures that ECHO will encourage cohorts to collect, especially for data elements related to their ECHO outcome area(s) of focus. These measures will provide an opportunity for in-depth and innovative data collection.

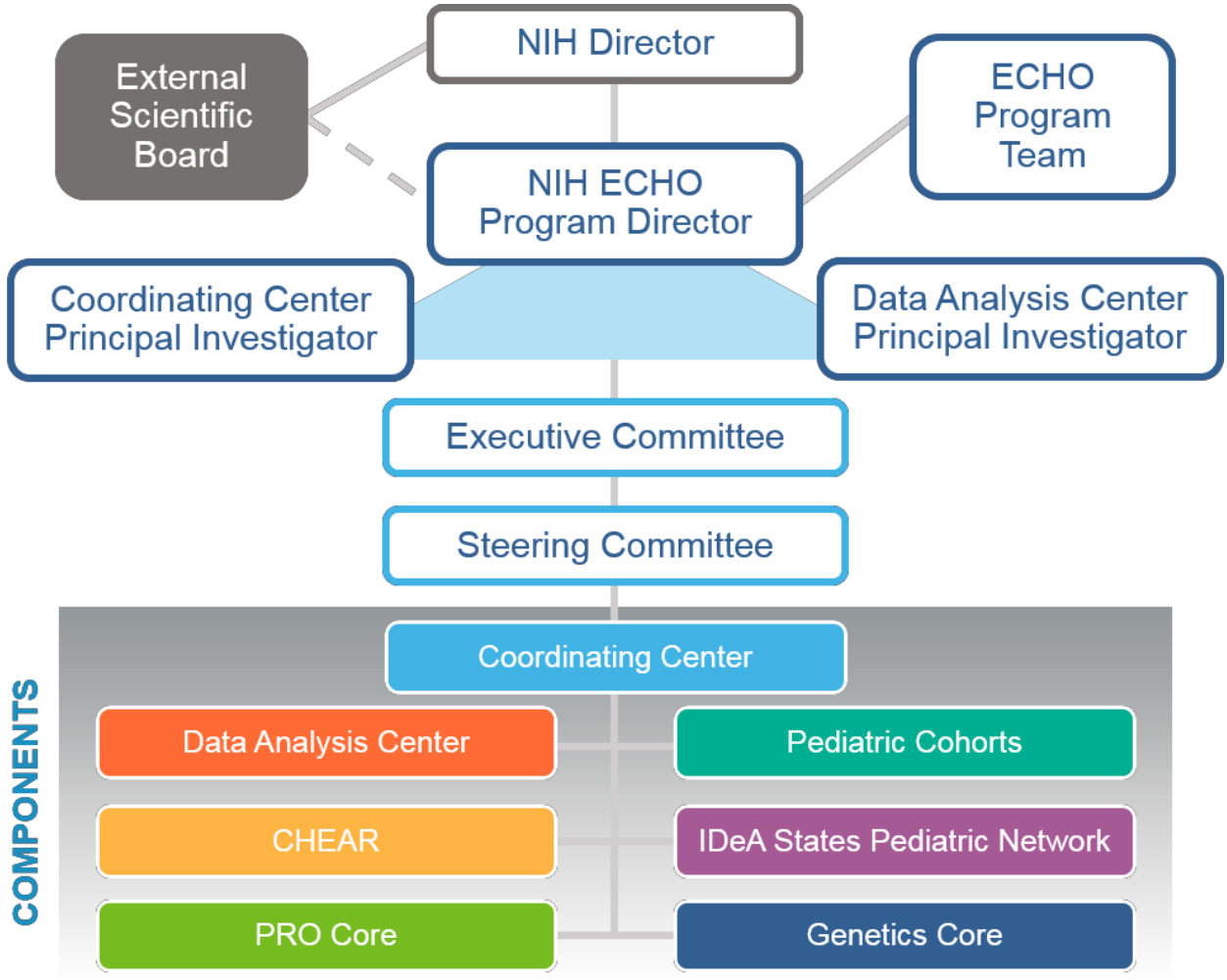
Term	Definition
Outcome Working Groups	Core group of experts representing the 5 ECHO outcome domains; charged with developing outcome-focused research questions and identifying data elements and appropriate measurements to inform the development of the ECHO-wide Cohort Data Collection Protocol.
Participants	ECHO cohorts are composed of participants, typically children and their parents, including at least one index child who is the primary focus of the study.
Perinatal Life Stage	Birth through 45 weeks post-LMP (with gestational age adjustments through 36 months for preterm infants)
Person-Reported Outcomes Core (PRO Core)	The component of ECHO that provides measurement expertise in the development, selection, validation and of self-reported and performance-related outcomes as assessed from children and proxy participants in the ECHO cohorts.
Positive Health	Outcome domain focused on healthy functioning, including well-being, global health, and sleep.
Preconception Life Stage	Prior to conception (parental measures)
Preferred Measures	Measures that balance innovation with feasibility, burden with efficiency, and breadth with depth. May require special resources or novel technologies, additional time to administer, and/or a higher level of participant or researcher burden. More detailed than minimally acceptable, less detailed than outcome-focused.
Prenatal Life Stage	Post-conception to pre-birth (parental and fetal measures)
Pre, Peri, Postnatal	The outcome domain focused on pre, peri, and postnatal outcomes (e.g., birth defects, prematurity, neonatal/infant mortality).
Recommended Data Element	Data elements that ECHO encourages, but does not require, cohorts to collect.
Steering Committee	Represents the interests of all ECHO components, provides overarching strategic direction for the ECHO Program within the vision and rules stipulated by NIH. Guides the scientific work of the ECHO Program by ratifying key decisions presented by the Executive Committee.
Team Science	Team Science engages stakeholders in expansive studies that address a broad array of complex and interacting variables; Team Science advances a whole that is greater than the sum of its parts by facilitating transdisciplinary research.
Transdisciplinary Research	Researchers from different disciplines work jointly to develop and apply an innovative, shared conceptual framework that synthesizes and extends discipline-specific theories, concepts, and methods to create new approaches to address a common problem.

1. Background and Rationale

In 2016, the NIH established the Environmental influences on Child Health Outcomes (ECHO) Program, an innovative and collaborative research initiative. The overarching scientific goal of ECHO is to advance understanding of the effects of a broad array of early environmental exposures on children's development and health outcomes with high public health impact. To achieve this goal, the ECHO Program will leverage and expand existing research participant populations (cohorts) that represent various environmental exposures (e.g., physical, chemical, social, behavioral, and biological) to support multiple synergistic, longitudinal studies. The studies supported by ECHO will share standardized data collection methods and focus on 5 key pediatric outcome domains: pre, peri, and postnatal outcomes; neurodevelopment; upper and/or lower airways; obesity and obesity-related outcomes; and positive health. All cohorts will collect the following standardized, targeted common data elements: demographics, typical early health and development, genetic influences on child health and development, environmental factors, and person-reported outcomes (PROs).

The ECHO Program has 7 components: the Pediatric cohorts, the Coordinating Center (CC), the Data Analysis Center (DAC), the Person-Reported Outcomes (PRO) Core, Children's Health and Exposure Analysis Resource (CHEAR), the IDeA States Pediatric Clinical Trials Network (ISPCTN), and (to be established) a Genetics Core. The organizational structure of the ECHO Program, including the ECHO governance structure and the 7 ECHO components, is depicted in Figure 1.

Figure 1 ECHO Program Organizational Structure



There are currently 35 ECHO Pediatric Cohort Awardees, comprising 84 constituent cohorts. Over the course of the ECHO Program, these cohorts will include approximately 50,000 children and 40,000 parents and guardians. These existing cohorts are drawn from diverse study populations with varying research goals, data collection procedures, measurements, and follow-up schedules, and include preconception, prenatal (over half of the ECHO cohorts are prenatal cohorts), birth, infancy, and early childhood inception cohorts.

Enrollment in these cohorts spans multiple decades, with some recruitment beginning in the early 1980s, while many other ECHO cohorts have ongoing recruitment efforts. ECHO is a nationwide program with approximately 248 engaged ECHO cohort sites distributed across the United States, with diversity of participants in race/ethnicity (including indigenous populations) and socio-economic status. The 5 key pediatric outcome domains described above are represented broadly across the ECHO cohorts.

This large network of 35 Pediatric Cohort Awardees, each with diverse inception cohorts, represents promising potential to achieve ECHO's primary scientific goal via the formation of a dynamic ECHO-wide Cohort. The purpose of the ECHO-wide Cohort Data Collection Protocol is to standardize data collection and sharing across these ECHO cohorts, which is key to the success of the ECHO Program.

2. Objective and Development of the ECHO-wide Cohort Data Collection Protocol

2.1 Primary Objective of the ECHO-wide Cohort Data Collection Protocol

The primary objective of the ECHO-wide Cohort is to address the impact of a broad array of early environmental influences on child development and health. The ECHO-wide Cohort Data Collection Protocol will serve as a starting point for standardized data collection across the ECHO Program and will specify what data elements cohorts should collect (new data) and share (both existing data and new data) across the life course, from preconception through adolescence.

The ECHO-wide Cohort Data Collection Protocol will facilitate the generation of a single data platform, called the ECHO-wide Cohort, which ECHO investigators and the wider scientific community can use to address innovative, high-impact research questions that require multiple cohorts and relate a broad range of early environmental influences to child health outcomes. Given the dynamic nature of scientific discovery and methodology development, the ECHO-wide Cohort Data Collection Protocol will evolve over the course of the ECHO Program.

2.2 Development of the ECHO-wide Cohort Data Collection Protocol

The ECHO-wide Cohort Data Collection Protocol is not intended to address one specific research question, but rather to facilitate the development of a novel data platform (the ECHO-wide Cohort) that investigators can use to explore numerous innovative, hypothesis-driven research questions across the 5 ECHO outcome domains.

The development of the ECHO-wide Cohort Data Collection Protocol has been an iterative process guided by Team Science that includes stakeholders across ECHO, as evidenced by the close collaboration between the ECHO-wide Cohort Data Collection Protocol Development Working Group and its Life Stage Subcommittees, the Outcome, Chemical Exposures, and Biospecimens Working Groups, the ECHO Executive Committee and Steering Committee, and the NIH ECHO Program Office.

This transdisciplinary, Team Science approach to protocol development has now resulted the issue of an RFI, a formal mechanism for the NIH to solicit valuable input on the ECHO-wide Cohort Data Collection Protocol from a variety of stakeholders, including non-ECHO Investigators, advocacy groups, and the general public.

2.2.1 Brief History of ECHO-wide Cohort Data Collection Protocol Development

Following the November 2016 ECHO Program Kickoff Meeting, ECHO charged its Outcome Working Groups to develop broad research topics and questions to inform the development of the ECHO-wide Cohort Data Collection Protocol (Table 1). These overarching research questions are intentionally broad to stimulate discussion and are not intended to be specifically addressed by the protocol. However, these questions are vital to the protocol development process, and ultimately, to the generation of the ECHO-wide Cohort.

For future ECHO analyses using the ECHO-wide Cohort, writing groups will develop concept proposals that contain more refined research questions in conjunction with the Data Analysis Center and will be approved by the ECHO Steering Committee.

Table 1 Outcome Working Group-Generated Overarching Research Topics and Questions

Outcome Area	Overarching Research Topics and Questions
Airways	Natural History of Asthma – longitudinal analysis
	Air pollution on respiratory health
	Role of airway and gut microbiota on respiratory health
	Integrative -omics and asthma: Regions of the epigenome at birth will be differentially methylated in relation to prenatal and postnatal exposures that show a relation with childhood asthma
	Effect of viral illness on lung function: What hosts genomic factors influence the long-term effects of early life respiratory viral illness on later life lung function trajectory and respiratory morbidity?
Neurodevelopment	Which chemical and non-chemical exposures are independently and/or jointly associated with neurodevelopmental outcomes? Are there specific exposure windows of susceptibility? Do any of these exposures play a causal role? Can these exposures explain ethnic/racial and socioeconomic disparities in neurodevelopment and if so, which exposures can be modified to reduce the risk?
	What is the relationship between preconception, prenatal, and perinatal environmental exposures and autism spectrum disorder-related phenotypes?
	Which environmental exposures during the preconception, prenatal and perinatal period are associated with externalizing and internalizing traits, disorders, and their neurocognitive components?
	Are there high-dimensional biomarkers (e.g., metabolomics, epigenomics, microbiome and other -omics; gene expression) measured in biosamples taken during pregnancy and/or postnatally that predict the neurodevelopmental outcomes and trajectories in the child?

Table 1 Outcome Working Group-Generated Overarching Research Topics and Questions

Outcome Area	Overarching Research Topics and Questions
Obesity	To examine the independent and joint associations between pre-birth and early life exposures and markers/trajectories of childhood obesity childhood vascular function, and childhood metabolism.
	To explore potential mediators of the prior associations.
	Can we use epigenetic data (e.g., DNA methylation, chromatic remodeling, others) to develop an individual fingerprinting that can be used to reconstruct exposures during sensitive time windows that predict?
Pre-, Peri-, and Postnatal Outcomes	What are the exposures both environmental and maternal that either individually or combined occur during the prenatal and neonatal period that if modified would improve pregnancy outcomes leading to healthier children?
	What are the paternal-maternal-fetal molecular pathways that mediate either positively or negatively the environmental impact on pregnancy outcomes and newborn health?
Positive Health	How does positive health develop during childhood, overall and across the ECHO focus areas?
	How do social environments (family, peers, school) influence the development of wellbeing/global health, overall and by socio-demographic sub-groups?
	How do environmental exposures influence sleep function, overall and by socio-demographic subgroups?

Using these overarching questions to guide their discussions, the Life Stage Subcommittees then identified the most relevant exposures, outcomes and covariates for cohorts to measure in their respective life stages. For the purposes of protocol development, the childhood life course is organized across distinct developmental life stage categories as summarized in Table 2. For heuristic purposes, ECHO assigned specific age bands to each life stage based on consensus of pediatric developmental experts. Several of these life stages intentionally overlap across age bands as there is age-variability in normal maturation and development.

Table 2 ECHO-wide Cohort Data Collection Protocol Development: Life Stages

Life Stage	Age Span
Preconception	Prior to conception (parental measures collected)
Prenatal	Post-conception to pre-birth (parental and fetal measures)
Perinatal	Birth through 45 weeks post-last menstrual period (LMP), with gestational age adjustments through 36 months for preterm infants
Infancy	46 weeks post-LMP through 24 months, with gestational age adjustments through 36 months
Early Childhood	12 months to 6 years, with gestational age adjustments through 36 months
Middle Childhood	5 to 12 years
Adolescence	11 to 21 years

3. ECHO Program Participant Population

3.1 Inclusion Criteria

The ECHO-wide Cohort Data Collection Protocol will apply to all ECHO Pediatric Cohort Awardees, their constituent cohorts, and their participants who have provided informed consent.

At the participant level, the inclusion criteria will be:

1. Participants enrolled in an ECHO cohort from whom investigators have collected (or plan to collect) exposure data before age 5 years.

2. Participants who have provided informed consent, and as appropriate child assent, that will allow participation in the ECHO-wide Cohort Data Collection Protocol.

3.2 Exclusion Criteria

Participants will be excluded if they, or their parent/guardian, as appropriate, are unable or unwilling to provide informed consent or assent that will allow for participation in the ECHO-wide Cohort Data Collection Protocol.

3.3 Number of Participants

The ECHO Program currently consists of 35 Pediatric Cohort Awardees that comprise 84 cohorts and their associated engaged sites (approximately 248 sites). The number of participants will likely reach approximately 50,000 children and 40,000 parents and guardians over the course of the ECHO Program.

3.4 Duration of Participation

The initial funding period for the ECHO Program is seven years.

4. ECHO-wide Cohort Data Collection Protocol Design Summary

The ECHO-wide Cohort Data Collection Protocol will support numerous future longitudinal studies through the creation of the ECHO-wide Cohort data platform. This data platform will leverage existing participant populations (i.e., cohorts) that will share standardized data collection methods.

4.1 ECHO-wide Cohort Data Collection Protocol Design: Data Elements

The ECHO-wide Cohort Data Collection Protocol will feature 2 types of data elements, essential (Section 4.1.1) and recommended (Section 4.1.2).

These 2 data element types differentiate and therefore ensure the robust collection of data elements that are essential to power analyses using the ECHO-wide Cohort data platform, while they also identify important, recommended data elements that will further enrich the depth and breadth of the ECHO-wide Cohort data platform.

An active link to the current list of all data element concepts currently included in the ECHO-wide Cohort Data Collection Protocol is provided in Section 5.

4.1.1 Essential Data Elements

Essential data elements apply to all 84 pediatric cohorts. ECHO requires that cohorts collect and share essential data elements[1]. The essential data elements featured in the ECHO-wide Cohort Data Collection Protocol encompass, but are not limited to, the targeted common data elements specified in the Request for Applications OD16-004, including demographics, typical early development, environmental exposures, genetics, and person-reported outcomes.

4.1.2 Recommended Data Elements

The ECHO-wide Cohort Data Collection Protocol will contain a diverse array of recommended data elements. ECHO encourages, but does not require, cohorts to collect recommended data elements.

[1] The NIH will approve exemptions from data collection requirements if data collection is not possible due to extenuating circumstances. Examples of extenuating circumstances could include (but will not be limited to) adoption cohorts where data/biospecimen collection from the biological parents may not be possible, or cultural norms that prohibit collection of certain data/biospecimens; or the participant has passed the life stage specified for the collection of required data/biospecimens and the requirement cannot be fulfilled by administrative data or valid recall measures.

4.1.3 Sharing of Existing Data

For all data elements and biospecimens in the ECHO-wide Cohort Data Collection Protocol (both essential and recommended), if a cohort has already collected them, ECHO expects the cohort to share them with the ECHO-wide Cohort, as specified by the ECHO Data Sharing and Biospecimen Policies (in development).

If an ECHO cohort did not collect an essential data element during the relevant life stage window, and cannot collect it via valid/reliable recall or existing administrative data (e.g., electronic medical records, administrative claims), then the NIH may exempt the cohort from this requirement.

4.2 ECHO-wide Cohort Data Collection Protocol Design: Measures

The ECHO-wide Cohort Data Collection Protocol RFI focuses upon the review of the data element concepts (see Sections 4.1.1 and 4.1.2 above) and not the associated measurements—the "what" rather than the "how." The ECHO-wide Cohort Data Collection Protocol Development Working Group will subsequently identify and define measurement of each element as either outcome-focused (Section 4.2.1), preferred (Section 4.2.2), or minimally acceptable (Section 4.2.3), as described below.

4.2.1 Outcome-Focused Measures

The ECHO-wide Cohort Data Collection Protocol may assign essential data elements an outcome-focused measure. ECHO will encourage cohorts to collect outcome-focused measures, especially for the data elements related to their ECHO outcome area(s) of focus. These measures will provide an opportunity for in-depth and innovative data collection. If there is no outcome-focused measure assigned to a given data element, ECHO will expect cohorts to collect the preferred measure (see Section 4.2.2).

4.2.2 Preferred Measures

The ECHO-wide Cohort Data Collection Protocol will assign all data elements (both essential and recommended) a preferred measure. If there is no outcome-focused measure assigned, or it is not feasible to collect an outcome-focused measure, ECHO will expect cohorts to collect preferred measures to the extent possible.

Preferred measures will be those that sufficiently balance innovation with feasibility, burden with efficiency, and breadth with depth. These measures may require special resources or novel technologies, additional time to administer, and/or a higher level of participant or researcher burden; however, the rigor of such measures and the resulting data outweigh these potential measurement challenges.

4.2.3 Minimally Acceptable Measures

If the collection of the outcome-focused or preferred measure is not feasible, cohorts may instead substitute the minimally acceptable measure. Minimally acceptable measures will tend to be more basic measures in terms of participant and researcher burden and data collection feasibility that still maintain sufficient scientific rigor. These measures may include short form versions and subscales of longer instruments and assessments with remote administration (e.g., online questionnaires, phone interviews, or pencil and paper questionnaires that can be mailed or returned during an in-person visit).

The ECHO-wide Cohort Data Collection Protocol will assign all essential data elements a minimally acceptable measure, however, for many data elements this may be the same measure as the preferred measure. Recommended data elements will not have a minimally acceptable measure assigned as ECHO will not require their collection.

5. Tabular Display of ECHO-wide Cohort Data Collection Protocol Data Elements

A tabular display of the current list of all data element concepts (both essential and recommended) currently included in the ECHO-wide Cohort Data Collection Protocol can be found in the following pages.

Data Element Concept	Collect once	Preconception	Prenatal	Perinatal	Infancy	Early Childhood	Middle Childhood	Adolescence
Essential Data Elements - Demographics								
Child biologically related to parents? y/n	X							
Child Date of Birth	X							
Child Ethnicity	X							
Child Race	X							
Child Sex	X							
Language of assessment		X	X	X	X	X	X	X
Child Grade in school/educational level						X	X	X
Child Individual Education Plan (IEP)? y/n						X	X	X
Child grade retention? y/n						X	X	X
Date of assessment/Child exact age at assessment				X	X	X	X	X
Maternal age - month and year of birth	X							
Maternal Education at birth	X							
Maternal Ethnicity	X							
Maternal Race	X							
Maternal US born y/n	X							
Maternal Occupation Maternal Occupation	X							
Maternal Primary Language Spoken	X							
Maternal Primary Language Read	X							
Maternal Marital Status		X	X	X	X	X	X	X
Paternal age - month and year of birth	X							
Paternal Education at birth	X							
Paternal Ethnicity	X							
Paternal Race	X							
Paternal US born y/n	X							
Paternal Occupation	X							
Family Household Composition		X	X	X	X	X	X	X
Any federal assistance (e.g., WIC, foodstamps, housing assistance)	X							
Lifetime/updated Residential address (GIS)		X	X	X	X	X	X	X
Access to healthcare (GIS)		X	X	X	X	X	X	X
Lifetime/updated school address (GIS)						X	X	X
Essential Data Elements - Child & Family Health History								
Lifetime/updated child medical history (including immunizations + major congenital anomolies)				X	X	X	X	X
Child Medications				X	X	X	X	X
Child health insurance status				X	X	X	X	X
Index Child Death y/n + circumstances				X	X	X	X	X
Index Child Death Certificate	X			X	X	X	X	X
Lifetime/updated First degree relative family medical conditions		X	X	X	X	X	X	X
Paternal height	X							
Paternal weight	X							
Essential Data Elements - Built/Physical Environment								
Outdoor air pollution		X	X	X	X	X	X	X
Pets - indoor and outdoor		X	X	X	X	X	X	X
Farm animal exposure		X	X	X	X	X	X	X
Household dust		X	X	X	X	X	X	X
Housing characteristics - general		X	X	X	X	X	X	X
Housing characteristics - child safety/hazards					X	X	X	X
GIS-based Neighborhood Conditions (crime/violence, stressors, income)		X	X	X	X	X	X	X
Child exposure to second hand smoke (i.e., cigarette, e-cigarette, marijuana)				X	X	X	X	X
Maternal exposure to second hand smoke during pregnancy (i.e., cigarette, e-cigarette, marijuana)			X	X				
Maternal + Paternal Work Exposures					X			
Essential Data Elements - Home Environment								
Parenting Behavior + Quality of home environment					X	X	X	X
Maternal-Fetal Attachment			X					
Maternal-Infant Attachment					X			
Family Relationships						X	X	X
Household conflict					X	X	X	X
Home activity environment						X	X	X
Home Food environment						X	X	X
Essential Data Elements - Pregnancy-Related								
Maternal alcohol in pregnancy	X							
Maternal smoking in pregnancy (i.e., cigarette, e-cigarette, marijuana)	X							
Maternal other substance use in pregnancy	X							
Maternal Diet in Pregnancy			X					
Maternal Physical Activity in pregnancy			X					
Maternal preconception or early prenatal weight	X							
Maternal gestational weight gain	X							
Maternal Waist Circumference			X					
Maternal Body Composition				X				
Maternal height	X							
Maternal reproductive history (including index pregnancy)	X							
Maternal pregnancy intentions and time to index pregnancy				X				
Maternal early pregnancy routine lab results (from EMR)	X							
Maternal receipt of prenatal care (e.g., when care began, number of prenatal visits)	X							
Maternal Immunizations		X	X	X				
Need for assisted reproduction		X	X	X				
Paternal/partner engagement		X	X					

Data Element Concept	Collect once	Preconception	Prenatal	Perinatal	Infancy	Early Childhood	Middle Childhood	Adolescence
Maternal pre-pregnancy disease	X							
Maternal diseases in pregnancy	X							
Maternal Infection in pregnancy	X							
Maternal prenatal medication and antibiotic use during pregnancy	X							
Maternal supplements during pregnancy	X							
Sharing placenta				X				
Multiple gestation				X				
Labor and delivery (including complications)	X							
Location of delivery (e.g., hostpital, home)				X				
Photo therapy				X				
Date of first feed				X				
Date of full PO feed				X				
Date of full volume feed				X				
Child Antibiotic use				X				
Child blood culture results				X				
Child NICU admission y/n			X					
Essential Data Elements - NICU (only applicable if infant admitted to the NICU)								
Length of stay in NICU (days)			X					
Infant resuscitation y/n				X				
NICU antibiotics				X				
NICU NNNS				X				
NICU post natal steriods				X				
Infant CSF culture results				X				
Infant meningitis				X				
Infant NEC				X				
Infant rate of growth				X				
Infant treatment for NAS y/n; if y, days of treatment				X				
Infant urine culture results				X				
Discharge on oxygen				X				
Infant cooling				X				
Infant surgery y/n + type				X				
Intrapartum - antenatal steriods				X				
Intrapartum - chorio				X				
Neonatal ROP				X				
NICU BPD				X				
NICU IVH				X				
NICU PDA surgery				X				
NICU PVL				X				
NICU - ventilator days				X				
NICU admission temp				X				
NICU days of pain/withdrawal				X				
NICU pressor use for BP support				X				
NICU psychosocial interventions				X				
NICU respiratory support				X				
NICU/Hospital - # of nicu beds				X				
NICU/Hospital - family centered care				X				
NICU/Hospital - NICU level				X				
NICU/Hospital - NICU volume				X				
NICU/Hospital - private room for infant				X				
NICU/Nursery antibiotics				X				
NICU/Nursery type (parental visitation, nursery level,)				X				
Nursery (assisted ventilation, transfusions, parental visitation, nursery level, surgery)				X				
Kangaroo care				X				
Essential Data Elements - Maternal Neuro-psychosocial								
Lifetime/updated maternal stressful life events		X	X	X	X	X	X	X
Maternal discrimination		X	X	X				
Maternal depression		X	X	X	X	X	X	X
Maternal stress			X	X	X	X	X	X
Maternal Social Support			X	X	X	X	X	X
Financial strain		X	X	X	X	X	X	X
Maternal Perceived Neighborhood Conditions (crime/violence, stressors, income)		X	X	X	X	X	X	X
Neighborhood Capital		X	X	X	X	X	X	X
Maternal global health		X	X	X	X	X	X	X
Maternal Wellbeing - Life Satisfaction		X	X	X	X	X	X	X
Maternal Wellbeing - Meaning & Purpose		X	X	X	X	X	X	X
Maternal IQ	X							
Essential Data Elements - Child Physical Health & Functioning								
Child length at birth				X				
Child birth weight				X				
Child gestational age at birth				X				
Child discharge diagnoses at birth				X				
Child head circumference (birth through age 3)				X	X	X		
Child height/stature					X	X	X	X
Child weight					X	X	X	X
Child Waist Circumference						X	X	X
Child Body Composition				X	X	X	X	X
Child pubertal development (includes age at menarche)								X
Child Blood pressure						X	X	X
Child Healthcare Utilization				X	X	X	X	X
Child Asthma Phenotype						X	X	X
Child respiratory support				X				
Child Asthma exacerbations					X	X	X	X
Child Asthma Severity						X	X	X
Child Lung function				X	X	X	X	X
Child Acute Respiratory Infection (ARI)				X	X	X	X	X
Child Allergens (pets, dust mites, pollens, molds)				X	X	X	X	X
Essential Data Elements - Child Health Behaviors/Lifestyle								
Duration of any breastmilk feeding, exclusive breastfeeding, intro to solids, milk source/route					X			
Infant Feeding Behavior					X			
Child Diet (Energy)						X	X	X
Child Physical activity /sedentary behavior (includes media exposure items)					X	X	X	X
Child Substance Use - cigarette, e-cigarette, tobacco, alcohol, marjuana, other drugs								X
Child Sexual Behavior								X
Teen reproductive history								X
Essential Data Elements - Child Neurodevelopmental Health & Functioning								
Child Apgar score 1 min				X				
Child Apgar score 5 min				X				
Child Developmental Milestones					X	X		
Child IQ					X	X	X	X
Child Executive Function					X	X	X	X
Child Disruptive Behavior					X	X	X	X
Child Attention/Impulsivity					X	X	X	X
Child Anxiety/behavioral inhibition					X	X	X	X
Child Depression/sad-withdrawn affect					X	X	X	X
Child Perceived Stress							X	X
Child Negative Life Events					X	X	X	X
Child Social Cognition						X	X	X
Essential Data Elements - Child Social Role Performance & Functioning								
Child Relationships, Bullying, Discipline						X	X	X
Child Peer Relationships						X	X	X
Child-Teacher Connectedness - 3rd-12th grade							X	X
Child Engagement in School - 3rd-12th grade							X	X
Child academic performance						X	X	X
Child school Attendance						X	X	X
Child Gender identity / Sexual Orientation								X
Essential Data Elements - Child & Parent Sleep Health & Ecology								
Child Sleep Health (e.g., timing, chronotype, duration, quality, satisfaction)					X	X	X	X
Child Sleep Ecology (e.g., sleep routines and practices)					X	X	X	X

Data Element Concept	Collect once	Preconception	Prenatal	Perinatal	Infancy	Early Childhood	Middle Childhood	Adolescence
Parent Sleep Health (e.g., timing, chronotype, duration, quality, satisfaction, shift work)		X	X	X	X	X	X	X
Parent Sleep Ecology (e.g., sleep routines and practices)		X	X	X	X	X	X	X
Essential Data Elements - Child Wellbeing								
Child global health (overall physical, mental, and social health and wellbeing)						X	X	X
Child wellbeing - life satisfaction							X	X
Child wellbeing - meaning and purpose							X	X
Child Positive affect					X	X	X	X
Child Positive Health Index (includes 4-6 life stage/developmental stage specific indicators that are risks to be avoided or indicators of positive health (e.g., QoL, HrQoL, wellbeing/life satisfaction, + general health)					X	X	X	X
Recommended Data Elements								
Child Ear infection				X				
Child Healthcare interventions								X
Infant Anal Genital Distance (AGD)				X				
Infant temperature at delivery				X				
Infant total number of days - Total Parenteral Nutrition (TPN)				X				
Infant Blood culture Med record				X				
Infant EKG				X				
Infant hearing screen				X				
Infant neuro imaging and/or EEG				X				
Infant Delivery hospitalization record w/ new born exam				X				
Child Exposure to corticosteroids					X			
Fetal growth trajectory			X					
Fetal movement				X				
Ultrasounds - fetal size parameters - femur length, biparietal diameter, abdominal circumference			X					
Child Locomotion							X	X
Child Endurance							X	X
Child Balance							X	X
Child Strength							X	X
Child dental Health						X	X	X
Child Resting heart rate				X				
Child Vascular Stiffness							X	X
Child Ectopic Fat				X				
Child academic achievement						X	X	X
Child Social Emotional Competencies						X	X	X
Child Information Processing Speed						X	X	X
Child Emotion knowledge						X		
Child Reward processing						X	X	X
Child Threat sensitivity/Attention bias						X	X	X
Child Activity Level/Energy						X	X	
Child Adaptive Behavior						X		
Child Attentional Shifting						X	X	
Child Loneliness								X
Child Physiologic Regulation - Cortisol						X	X	X
Child Sensory Sensitivity					X	X	X	X
Child Early language exposure					X	X		
Child Home Sceen Media Access & Use					X	X	X	X
Child Acculturation						X		
Child Peer Victimization							X	X
Child Social Support							X	X
Child Airway hyperresponsiveness							X	
Child Asthma Predictive Index (API)					X	X	X	X
Child Surfactant				X				
Child reactions to food, soap, household products, environment/plants, medications, animals					X	X	X	X
Indoor air pollution		X	X	X	X	X	X	X
Child time spent outdoors				X				
Outside Temperature (heat/cold), daylight/darkness						X	X	X
Child product use - e.g., soap, shampoo, diapers, sunscreen, insect repellant						X	X	X
Child Caffeine use								X
Caregiver transition								X
Maternal Healthcare interventions (e.g., MRI, Imaging, Xray)		X	X	X	X			
Maternal Nausea vomiting in pregnancy, other pregnancy symptoms			X					
Maternal Pregnancy awareness/intendedness			X					
Intrapartum - blood transfusion				X				
Intrapartum - length of ROM				X				
Intrapartum - Magnesium				X				
Intrapartum - timing of cord clamp				X				
Intrapartum - Tocolytics				X				
Intrapartum -induction of labor - date, method, reason				X				
Intrapartum -rupture of membranes, method, date				X				
Maternal age at menarche				X				
Maternal cardiac and vascular structure + function				X				
Maternal fever in pregnancy				X				
Maternal Glucose challenge results			X					
Maternal dental health							X	
Maternal Sexually Transmitted Infections (STIs)		X	X	X				
Family Income		X	X	X	X	X	X	X
Parent incarceration		X	X	X	X	X	X	X
Maternal Personal and household product use		X	X	X				
Maternal Sexual Behavior		X	X					
Parent-Partner Relations		X	X	X	X	X	X	X
Parenting sense of competency					X			
Parent ASD-related Phenotype						X		
Parent Positive Health Index (includes 4-6 specific indicators that are risks to be avoided or indicators of positive health (e.g., QoL, HrQoL, wellbeing/life satisfaction, + general health)		X	X	X	X	X	X	X
Maternal Religion		X	X	X	X	X	X	X
Maternal Religious Activities		X	X	X	X	X	X	X
Parent commuting exposures					X	X	X	X
Maternal Travel/Infections (e.g., Zika)		X	X	X	X	X	X	
Water pollution - via drinking water samples		X	X	X				
Paternal inflammation		X	X					
Paternal mental health								X
Paternal stress				X				
Paternal wellbeing - Life Satisfaction		X	X	X	X			
Paternal wellbeing - Meaning & Purpose		X	X	X	X			

Data Element Concept	Collect once	Preconception	Prenatal	Perinatal	Infancy	Early Childhood	Middle Childhood	Adolescence
Essential Biospecimens								
Child Sample for DNA [a]	X							
Child Whole Blood [b]							X	X
Child Plasma [b]							X	X
Child Serum [b]							X	X
Child Blood spot				X	X	X	X	X
Child urine						X	X	X
Child stool					X			
Chlid hair						X	X	X
Child Cord Blood [c]				X				
Child Toenails					X	X	X	X
Child Shed Teeth [d]							X	X
Maternal Sample for DNA [a]	X							
Maternal Whole Blood [b]		X	X					
Maternal Plasma [b]		X	X					
Maternal Serum [b]		X	X					
Maternal Urine [e]		X	X					
Maternal stool			X					
Maternal Hair [f]			X	X				
Placenta				X				
Maternal Toenails [g]			X					
Recommended Biospecimens								
Maternal Breastmilk [h]					X			
Maternal Vaginal Swab			X	X				
Child stool						X	X	X
Chlid hair				X	X			
Child Nasal/pharyngeal sampling [i]				X	X	X	X	X
Child Meconium				X				
Paternal Stool		X						
Paternal Semen [j]		X						

[a]Buffy coat from plasma preferred; saliva acceptable if not collecting blood; [b] 1 mL miminum; [c] Dried blood spot is acceptable though cord blood is preferred; [d] Stored teeth (teeth shed from 5 to 13 years of age) can be collected from middle childhood through adolescence; [e] Collect prenatal urine at least once, prefer at first visit and every visit thereafter if possible; [f] Perinatal hair (at delivery) is preferred; prenatal second and third trimester hair is acceptable; [g] Should be collected as late in pregnancy as possible; [h] collect once at first post-partum visit, collect sample of formula after mixed if not exclusively breastfeeding; [i] Infancy is highest priority; [j] collect once in preconception.