# **Publications Program: Analysis Proposal Form**

**Submission Instructions**

* Writing Team Leader MUST complete an Analysis Concept (STEP 1) before submitting an Analysis Proposal (STEP 2).
* **Complete all sections** **below.** If no information, enter “n/a” or “none”.
* If this Analysis Proposal requires biosamples, submit the completed HHEAR lab forms along with completed Analysis Proposal as described in the [STEP 1B](https://flow.dcri.org/sites/echo/ProgramManual/ECHO%20Publication%20Process%20%20CHEAR%20STEP%201B_RETIRED_v1.0.PDF) process document. The HHEAR lab documents are required for Publications Committee review.
* If you have an IRB-approved conflict of interest form, or an IRB letter of exemption, please submit along with the completed Analysis Proposal form.
* Analyses that include data from the Navajo Birth Cohort Study (NBCS) require: (1) an ECHO PI as one of the Writing Team Leaders and (2) analyses must be conducted by DAC or NBCS analyst. NCBS data will not be included in any genetic studies.

## GENERAL INFORMATION

1. **Date of submission**: Click here to enter a date.
2. **Related** **Analysis Concept** (STEP 1) **Title**: Click here to enter text.
3. **Analysis Proposal** (STEP 2) **Title**: Click here to enter text.

## 

## WRITING TEAM LEADER CONTACT INFORMATION

**Writing Team Leader Name:** Click here to enter text.

**Institution:** Click here to enter text.

**Address:** Click here to enter text.

**Telephone Number:** Click here to enter text.

**Email:** Click here to enter text.

**Are you, the Writing Team Leader, affiliated with the ECHO program?**

☐ Yes

*If Yes:* Select the Writing Team Leader’s ECHO affiliation(s):

Cohort, specify: Click here to enter text.

Non-Cohort Component, specify: Click here to enter text.

Sponsored by an ECHO PI, specify: Click here to enter text.

☐ No

*If No*: Complete “Funding and IRB” questions in section C.

*If No*: Describe the affiliation(s) of the Writing Team Leader: Click here to enter text.

**Is the Writing Team Leader an ECHO PI?**

☐ Yes

☐ No

*If No:* Will this analysis include data from the Navajo Birth Cohort Study?

Yes

*If Yes:* Name of ECHO PI serving as co-writing team leader: Click here to enter text.

No

1. **Contact Person** (if different from Writing Team Leader): Click here to enter text.
2. **Writing Team Members** (include names and institutions; use semi-colon to separate member information (e.g., Jane Doe, University of Wyoming; John Smith, New York University; …): Click here to enter text.

**Do you plan on using the Data Analysis Center (DAC) for this proposal?**

Yes

*If Yes*: Provide DAC investigator and analyst (if known): Click here to enter text.

No

*If No*: Provide your analyst name and institution Click here to enter text.

*If No:* Check here to show that the Writing Team Leader is submitting a signed [Data Use Agreement Conditions of Use](https://echoportal.org/identity/login?signin=9bb25117c316e7430c3228f5b6df71a5).

## CONFLICT OF INTEREST, FUNDING, IRB

**Have you, the Writing Team Leader, completed your ECHO Conflict of Interest Form?**

***It is the responsibility of the Writing Team Leader to ensure all Writing Team members have completed the ECHO COI.***

* 1. Yes or No

Yes

No *If No:* You must complete [the form](https://flow.dcri.org/sites/echo/conflict-of-interest/SitePages/Home.aspx). Once you complete the form, check Yes to continue.

1. **Is this proposal funded by ECHO parent grant only?**

Yes

No

* 1. *If No:* Other source of funding, specify: Click here to enter text.

***COMPLETE QUESTIONS C.2 and C.3 ONLY IF THIS IS AN ECHO ANCILLARY STUDY OR THE WRITING TEAM LEADER IS NOT AFFILIATED WITH ECHO. FOR ALL OTHERS, GO TO C.4.***

1. **Have you, the Writing Team Leader, received IRB approval for this proposal?**

Yes

Pending approval

* 1. *If Yes/Pending approval:* 
     1. IRB protocol number (if not applicable, enter “n/a”): Click here to enter text.
     2. What is the IRB approval date (anticipated if “pending”)? Click here to enter text.
     3. What type of IRB did you use?

ECHO single / central  Yes  No

Local, specify IRB name and federal-wide assurance (FWA) number: Click here to enter text.

No

1. *If No:* Prior to accessing data, you will need to provide an IRB protocol number, approval date, type of IRB used, IRB name, and FWA.

Exempt research—not human subjects

1. *If Exempt research—not human subjects:* Please submit your IRB exemption notice along with the completed Analysis Proposal.
2. **Will this collaboration involve an institution or company that is not located in the United States?**  Yes
   1. *If Yes:* Name of non-US institution: Click here to enter text.

**NOTE:** *If Yes*: Please keep in mind that collaborations with non-US investigators proposing to use specimens and/or data from NIH-funded awards cannot be initiated without prior NIH approval. Should this proposal form receive Steering Committee approval, the lead investigator at each awardee institution involved with the collaboration should immediately contact the NIH Program Official to receive further details for obtaining such approval.

No

**After approval by the Steering Committee, the Writing Team Leader must submit the findings as described in this proposal to peer-reviewed journals with stated conflict of interest policies. Do you, the Writing Team Leader, agree to these terms?**

Yes  No

**Do you, the Writing Team Leader, anticipate publishing by any means other than peer-reviewed journals?**

Yes

* 1. *If Yes*: Explain: Click here to enter text.

No

1. **Would you like to provide the names and email addresses of three experts (internal or external to ECHO) that the Associate Chairs may contact as needed during the Publications Committee Reviews?**

Yes

* 1. *If Yes*: List names and emails here: Click here to enter text.

No

1. **Signature**

By submitting this Analysis Proposal, you, the Writing Team Leader, have read and agree to abide by the [ECHO Publications Policy](https://flow.dcri.org/sites/echo/cross_cutting/Publications/ECHO%20Policy_Publications_Draft_040717.docx). The policy requires that the authors submit manuscripts accepted for publication to NIHMS for PMCID number assignment ([listing of journals](http://publicaccess.nih.gov/submit_process_journals.htm) that submit to PubMed Central on the authors' behalf).

When using data and/or biospecimens from multiple cohorts, the Writing Team Leader and Data Analyst must ensure that at least one investigator from each cohort award that contributed data is invited to participate on the writing team, and that all writing team members who meet [ICMJE criteria for authorship](https://urldefense.proofpoint.com/v2/url?u=http-3A__www.icmje.org_recommendations_browse_roles-2Dand-2Dresponsibilities_defining-2Dthe-2Drole-2Dof-2Dauthors-2Dand-2Dcontributors.html&d=DwMFAg&c=imBPVzF25OnBgGmVOlcsiEgHoG1i6YHLR0Sj_gZ4adc&r=YPUssFF1f9WzFLxclV7qjNFnfqdusXWgbhifHXcIw9g&m=obFz4T86NMvFBuQQj2_sFkD_klZ2JZE32tU_PahNxsw&s=bh3L2SKfGr0VfPG9VHziKKr6UAFrHoSwsn13juFWrvU&e=) are listed as co-authors on the manuscript.

The ECHO Publications Committee expects the Writing Team Leader to submit a final manuscript for review within 12 months of approval (or of all data being available and harmonized). If lack of progress is indicated, the topic may be reassigned to another Writing Team Leader.

**Writing Team Leader Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## TYPE OF PROPOSAL and DATA

1. **Proposal includes the following ECHO awardees** (*check all that apply*)

>1 ECHO cohort awardee

HHEAR Laboratory

DAC

Genetics Core

PRO Core

1. **Outcome Focus Areas (*check all that apply*):**

**Upper and Lower Airways:**

Asthma

Allergy

Lung function

Sleep disordered breathing

Other, specify Click here to enter text.

**Obesity:**

Cardio-Metabolic outcomes

Diabetes

Physical growth

Obesity

Other, specify Click here to enter text.

**Pre-, Peri-, and Postnatal Outcomes:**

Prematurity

Placental function

Birth defects

Other pregnancy outcomes, specifiy

Neonatal/infant mortality or other peri- or postnatal outcomes

Other, specify Click here to enter text.

**Neonatal Opioid Withdrawal Syndrome**

**Neurodevelopment**

Autism Spectrum Disorder (ASD)

Behavior including Attention Deficit Hyperactivity Disorder (ADHD)

Cognition

Other neurodevelopmental outcome, specify Click here to enter text.

**Positive health**

Sleep health

Well-being

Other, specify Click here to enter text.

**Other, specify** Click here to enter text.

1. **Type of Proposal and Data**
   1. **Is this a proposal for a review paper, editorial, or commentary?**

Yes

* + 1. *If Yes*: Was this an invited review?  Yes  No
    2. *If Yes*: Does it require metadata?  Yes  No

No

* 1. **Does this proposal require analysis of individual-level data via ECHO-wide Cohort data platform?**

Yes

No

* + 1. *If No:* Specifiy where the analysis will be conducted: Click here to enter text.
  1. **Are all data as described in this proposal (including primary exposures, outcomes, confounders, and modifiers) listed in the** [**protocol**](https://flow.dcri.org/sites/echo/protocol/Site%20Pages/Protocol.aspx)**?** (*check all that apply*)

Yes

No, this analysis will require new ECHO-wide data collection (e.g., questionnaire, study visit, new specimen collection). Please complete the Protocol Amendment Proposal form and submit to PIE.

No, this analysis will use existing data other than assay results.

* + 1. Are you planning on using (*check all that apply and specifiy source of data where applicable*):

Cohort individual-level data external to the ECHO-wide Data Collection Protocol Click here to enter text.

Individual-level data external to ECHO *(e.g. NHANES, other cohort study):* Click here to enter text.

Area-level data (e.g., EPA, Census): Click here to enter text.

Other, please list data source and explain use:Click here to enter text.

* + 1. What is the process to access data? Click here to enter text.
    2. Are you linking these outside data to ECHO-wide Cohort data?  Yes  No
       1. *If Yes*: What is the linking variable to the ECHO dataset? Click here to enter text.
       2. *If Yes:* Describe linkage method between data sources: Click here to enter text.
    3. Is permission required for use of data?  Yes  No

1. *If Yes:* Has permission been granted?  Yes  No
2. *If Yes:* Have you accessed the data already?  Yes  No
3. *If Yes:* Is the use of these data limited to this Analysis Proposal?  Yes  No
   * 1. Is there a cost associated with acquiring and/or using these data?  Yes  No
   1. **Does this proposal include data from any proprietary measures licensed through the CC? Refer to the** [**ECHO Proprietary Measure Use Requirements document**](https://flow.dcri.org/sites/echo/protocol/Miscellaneous%20Documents/ECHO_Proprietary%20Measure%20Use%20Requirements.pdf?Web=1)**.**

Yes, You are required to follow the specified use requirements. Please specify which measure(s): Click here to enter text.

No

* 1. **Does this proposal require extant data from assay(s)?**

Yes, please specify: Click here to enter text.

No

* 1. **Does this proposal include genetic data?**

Yes, please specify: Click here to enter text.

No

* 1. **Does this proposal require use of biospecimens?**

Yes, please complete the biospecimen specification questions below.

* + 1. *If Yes:* What assay(s) will be performed? Please specify: Click here to enter text.
    2. *If Yes:* Please specifiy the QA and QC measures that will be taken: Click here to enter text.
    3. *If Yes:* Will the assay be performed by an HHEAR Laboratory?

No

Yes

No

*ECHO Biospecimens.* Following Steering Committee approval of this analysis proposal, per investigator’s institutional policy, a Materials Transfer Agreement may be required. For more information on biospecimen usage, refer to the [*ECHO Biospecimens Utilization Policy*](https://flow.dcri.org/sites/echo/ProgramManual/ECHO%20Biospecimens%20Utilization%20Policy.pdf)and Process documents and forms.

## BIG WIN IMPACT

1. **Do you want this Analysis Proposal to be considered as a potential Big Win**?

Yes

No, Skip to section F. Study Design

1. **Solution orientation.** Describe the specific intervention trial, other program, improvement of clinical or public health practice, guideline, or change in policy that the main result of your study will inform. (Enter text or enter Not Applicable) Click here to enter text.
2. **End-user Stakeholder Needs.** Identify the end-user stakeholder need that informs your answer to #1. Who is/are the end-user stakeholder(s)? How did you obtain information about their needs? Click here to enter text.
3. **Innovation**. Explain any novel concepts, approaches, or methodologies that you propose. Click here to enter text.

## STUDY DESIGN

1. **Lay Language Abstract** *(less than 150 words)* Click here to enter text.
2. **Background** *(maximum 400 words, not including references—include motivation, brief literature review, and any research gaps you will fill)* Click here to enter text.
3. **Specific Aims and Hypotheses** Click here to enter text.
4. **Overlap with existing ECHO publications or proposals** (Discuss the similarities and differences in this proposal compared to existing ECHO publications and/or approved Analysis Proposals.) Click here to enter text.
5. **Study design** *(e.g., cohort, case-control, cross-sectional)* Click here to enter text.
6. **Conceptual model (directed acyclic graph) showing hypothesized causal relationships including potential confounders, moderators, and mediators.** Click here to enter text.
7. **Study population** *(Describe the study population and the criteria for inclusion/exclusion of cohorts and/or participants.* Click here to enter text.
8. **Measurements**
9. Exposures (*Specify the primary exposures needed for each specific aim).* Click here to enter text.
10. Outcomes *(Specify the outcomes needed for each specific aim).* Click here to enter text.
11. Confounders and modifiers *(Specify the confounders and modifiers that need to be considered for each specific aim).* Click here to enter text.
12. Mediators *(Specify the mediators that need to be considered for each specific aim).* Click here to enter text.
13. **Approach to Data Analysis** 
    1. Descriptive. Click here to enter text.
    2. Bivariate. Click here to enter text.
    3. Multivariable, including how you intend to build statistical models that reflect your conceptual causal model. Click here to enter text.
    4. Specifiy relevant available preliminary data. Click here to enter text.
    5. Include table shells if appropriate. Click here to enter text.
14. **Sample size and statistical power** *(Specify the sample size and estimate the statistical power for each specific aim.)* Click here to enter text.
15. **Strengths and Limitations** *(Discuss strengths of the study such as conceptual advances; and the limitations of the data, the study design, and the data analysis--include discussion of how you will address potential selection and information biases.)* Click here to enter text.
16. **Impact** *(Brief paragraph summarizing the potential impact of the new knowledge gained from this research product on programs, policies, or practices to improve the health of children and adolescents. Include comments on the generalizability of the results.)* Click here to enter text.