ECHO Cohort Ancillary Studies Policy

I. Introduction and Purpose

The scientific impact of the ECHO Cohort relies upon its data and biospecimen resources, which ECHO makes available in two ways: 1) with limited personally identifiable information (PII) on the ECHO Cohort Data Platform (Data Platform)—a highly secure, FISMA compliant cloud environment, along with the biospecimens in the ECHO Biorepository; and 2) de-identified, controlled-access, public-use datasets—currently located on the NICHD Data and Specimen Hub (DASH)—available to the broader scientific community.

Another way the scientific community may take advantage of ECHO resources is to propose ancillary studies. **The ECHO Cohort Consortium defines an ancillary study as one that derives funding from a non-ECHO source and accesses non-publicly available, limited identifiable data on the Data Platform, or biospecimens in the Biorepository**.

The purpose of this policy is to govern the process for proposing ancillary studies (see diagram of the *ECHO Cohort Ancillary Studies Process from Applicant Perspective* in the attachment section of page 6 below).

II. Scope

This policy applies to any individual or institution proposing an ancillary study supported by non-ECHO funding that seeks access to:

A. ECHO Cohort data (with limited PII) *only*

B. ECHO Cohort biospecimens and associated data

Note: This policy does *not* currently allow requests for access to ECHO Cohort participants, including for piloting new methods or data or biospecimen collection in addition to the *ECHO Cohort Data and Biospecimen Collection Protocol*.

III. Definitions

Refer to the ECHO Glossary for full list of ECHO terminology.

IV. Policy

NIH and the ECHO Cohort Steering Committee (Steering Committee), or a sub-group they appoint, must review all ancillary study proposals promptly and, if they approve it, provide a letter of support to the ancillary study investigator.

A. Criteria

The first criterion for ECHO ancillary studies is whether studies require support from non-ECHO funding. If so, the second criterion is whether studies require use of ECHO Cohort biospecimens or limited data including PII on the ECHO Cohort Data Platform. If the study meets both criteria, (1) requiring non-ECHO funding and (2) requiring access to ECHO Cohort

data or biospecimens, then the study may be ancillary and can proceed only in accordance with the policy below, beginning with requesting a letter of support from the Steering Committee.

If the proposed study does not require use of ECHO Cohort biospecimens nor use of data with PII on the ECHO Cohort Data Platform, then the controlled-access, public-use data from the ECHO Cohort located on the NICHD Data and Specimen Hub (DASH) may be appropriate. If so, the investigators can submit a request to access the requisite data using the DASH resource request system.

B. Letters of support from the ECHO Cohort Steering Committee

Prior to applying for non-ECHO funding or an NIH ECHO X01 (see Section IV part D. below), every ancillary study proposer must request a letter of support from the Steering Committee, or from a sub-group they appoint. The applications for non-ECHO funding and the ECHO X01 for the ancillary study must each include this letter of support.

To begin the Letter of Support Request process, proposers must first submit their study summary to the NIH ECHO Program Office during an open period. Learn more at https://echochildren.org/-echo-ancillary-studies/. Once the NIH ECHO Program Office approves, the proposer can submit the full request form to the ECHO Cohort Consortium according to the instructions on https://echochildren.org/request-a-letter-of-support/.

C. Non-ECHO funding

ECHO ancillary studies require support from non-ECHO funding sources. In addition to funding to cover ancillary study site staff time, resources, and training, the funding must provide adequate support for the ECHO Cohort Consortium cores and centers (e.g., Coordinating Center, Data Analysis Center, Laboratory Core) for the duration of the ancillary study period. Learn more about budgets at https://echochildren.org/request-a-letter-of-support/.

D. Application for access to ECHO Cohort data and biospecimens

ECHO requires investigators to apply for an NIH ECHO X01 award in two scenarios.

1) Investigators who are not currently funded as part of the ECHO Cohort Consortium must apply for an NIH ECHO X01 award.
2) ECHO-funded investigators who seek to use ECHO biospecimens for an ancillary study must apply for an NIH ECHO X01 award.

   Note: ECHO investigators do not need an X01 award for data-only ancillary studies.

The ECHO X01 is a resource access mechanism that allows NIH oversight of the ancillary study (see Section IV part G below). The ECHO X01 does not provide funding.

Access to the ECHO Cohort's limited identifiable data on the Data Platform or biospecimens for an ancillary study are contingent upon the investigators obtaining the following:

a) Non-ECHO funding
b) An ECHO X01 award for resource access, if needed

c) Proper training and certification from the ECHO Cohort Consortium cores and centers

d) Adherence to the *ECHO Cohort Data Sharing and Use Policy*, *ECHO Cohort Biospecimens Policy*, *ECHO Cohort Publications Policy*

All ECHO resource access applications must include the letter of support from the Steering Committee obtained according to Section IV part B of this policy. If applying for non-ECHO funding to support their ECHO ancillary study, investigators must simultaneously (or as close to simultaneously as possible) apply for an ECHO X01. If investigators already have funding in hand, they must still apply successfully for an X01 before beginning their ancillary study.

E. Restriction of access to ECHO Cohort participants

This policy excludes study proposals seeking access to ECHO Cohort participants. ECHO investigators seeking access to ECHO Cohort participants for the purposes of piloting new methods or potential changes to the *ECHO Cohort Data and Biospecimen Collection Protocol* can apply to the ECHO Opportunities and Innovation Fund.

F. Exemptions

If ECHO Cohort Study Sites, Cores, or Centers sponsor training award applicants (e.g., to F or K awards), the investigators in training can propose their training projects as *data only* ECHO Cohort ancillary studies. Principal investigators of such training projects should request Letters of Support for their ancillary studies *prior* to their training award application submissions, so that they can attach their Letter of Support to their applications.

Given the limited budget for most training awards, ECHO Cohort Consortium sponsors should identify a project analyst who will undergo, or who has previously completed, training and certification required for ancillary studies by the Data Analysis Center. Alternatively, training award principal investigators may serve as project analysts and undergo the training and certification by the Data Analysis Center.

If so, training award applicants requesting letters of support for ancillary studies are exempt from both

- Proposing ancillary study budgets to support ECHO cores or centers
- Applying for an ECHO X01

Note: The exemptions above may not apply to K99/R00 awards. Applicants to K99/R00 awards should check with the NIH ECHO Program Office about possible exemptions.

G. NIH Oversight

The NIH ECHO Program Office provides oversight to all ECHO ancillary studies through the X01. All X01 awardees must abide by all NIH policies as well as the ECHO policies mentioned in section IV part D above.

To help NIH ensure the responsible conduct of ECHO's research—including ancillary studies—the X01 requires ancillary study investigators

a. Assure proper training and certification of their site staff to access and use ECHO Cohort resources.
b. Provide reports to NIH ECHO Program staff, the ECHO Coordinating Center, the ECHO Data Analysis Center, and the ECHO Laboratory Core, as needed or when requested, regarding X01 award site activities, including but not limited to, staff training and certification, and summaries of ancillary study progress.
c. Protect the confidentiality of participants, promote ethical and beneficial use of data among data users, and minimize potential harms to people groups or individuals.

H. Disputes and Appeals

Investigators may dispute Consortium decisions about ECHO ancillary studies. The Steering Committee or ECHO Cohort Operations Committee hears such appeals.

If an appeal remains unresolved after Steering Committee or Operations Committee hearings, consortium members may ask the ECHO Program Office to convene a Dispute Resolution Committee.

V. Review and Revision

Review of ECHO Program Manual documents occurs every three years; however, as processes change, or major edits identified, this may warrant additional review of documents.

VI. Supporting Documents

None

VII. References

- NICHD Data and Specimen Hub (DASH)
- NIH Guide
- ECHO Opportunities and Innovation Fund

VIII. Attachments

ECHO Cohort Ancillary Studies Process from Applicant Perspective

IX. History of Change

Version Number	Effective Date	Section Affected	Summary of Changes
2.0	02/Jul/2025	Entire Policy	Revised policy to support ECHO Cycle 2.
1.0	01/Oct/2021	N/A	New Policy

Approval Page

Name/Title	Approval Date
NIH ECHO Program Office	02Jul2025

Attachments

Attachment A: ECHO Cohort Ancillary Studies Process