ECHO Cohort Data Sharing and Use Policy

I. Introduction and Purpose

The scientific impact of the ECHO Cohort relies upon data and biospecimen availability, which ECHO makes available in two ways:

1) On the ECHO Cohort Data Platform (Data Platform)—a highly secure, FISMA compliant cloud environment—and the ECHO Biorepository. These resources are both available to the ECHO Cohort Consortium (Consortium) and for ancillary studies by investigators from inside and outside of the Consortium
2) As de-identified, controlled-access, public-use datasets located in NIH data repositories available to the broader scientific community

The ECHO Cohort Data Sharing and Use Policy (Data Sharing and Use Policy) balances two important goals: to maximize the value of the study data for timely and widest possible scientific discovery and to respect and protect the confidentiality of ECHO Cohort participants contributing data. The following principles guided the development of the policy:

- Accelerating research through broad and immediate data sharing
- Maximizing data availability by making data Findable, Accessible, Interoperable, and Reusable
- Protecting the confidentiality of participants and managing sensitive data according to participant consent
- Promoting ethical and beneficial use of data among data users and minimizing potential harm to individual participants or subgroups

This Data Sharing and Use policy works in alignment with 45 CFR 46 for the protection of human research subjects and HIPAA (45 CFR 160 and 164) for the protection of individually identifiable health information. To access ECHO Cohort data, investigators and their institutions must agree to, and abide by, this Data Sharing and Use policy.

II. Scope

This Data Sharing and Use policy applies to all members of ECHO Cohort Consortium (Consortium) and all ECHO Cohort ancillary study investigators and covers all projects that are 1) funded as part of the ECHO Cohort; 2) contribute data to the ECHO Cohort; or 3) request the use of data on the Data Platform.

This policy covers all data generated under Consortium and data generated by ancillary studies from assays of ECHO Cohort biospecimens, both of which must also follow the NIH Genomic Data Sharing Policy (including genomics, epigenomics, and microbiome data) and the NIH Data Management and Sharing Policy.

The NIH ECHO Program Office recognizes that policies of sovereign Tribal Nations on research and data ownership may differ from this policy. As such, specific additional stipulations may apply for access and use of ECHO Cohort data from Tribal Nations (see Section IV.F.).

III. Definitions

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

IV. Policy

A. Types of Data

The Consortium expects ECHO Cohort Study Sites (Study Sites) to share various types of data with the ECHO Data Analysis Center (Data Analysis Center). The categories below describe the categories of data that Study Sites and other ECHO-funded projects data to collect and generate.

1. Metadata

Metadata can include:

- Information about Study Sites and other ECHO-funded projects
- Documentation associated with the data including data collection forms, documentations on harmonized and derived variables, and data dictionaries
- Information regarding biospecimen collection, processing, shipping, storage, use, and assay methods

Consortium members and their collaborators or external users registered with the Data Analysis Center have access to metadata from the Data Platform.

2. Participant Data collected under the ECHO Cohort Data and Biospecimen Collection Protocol

The ECHO Cohort Data and Biospecimen Collection Protocol (Protocol) specifies data elements Study Sites collect from participants. Study Sites must use the Data Analysis Center's centralized data capture system to collect data from consented participants. These data automatically populate the Data Platform. The Data Platform also contains other participant data collected under the Protocol that are captured and processed using other ECHO-approved systems, e.g., NIH Toolbox, accelerometry, spirometry, genetics, and other biospecimen assay data. Section B describes policies regarding access to and use of data in the Data Platform.

3. Data from other ECHO-funded projects

All ECHO Cohort project awardees, including Opportunities and Innovation Fund recipients and ancillary study investigators, must ensure that they make data or technology generated from their projects available to the Consortium. Accordingly, these awardees must develop data sharing plans, which outline plans for sharing data or technology generated by their project. In consultation with the Data Analysis Center, these awardees must determine the

best mechanism for sharing data resulting from their project, whether through the Data Platform or other repository. Regardless of the sharing mechanism specified in the data sharing plan, these awardees must make their data or technology available for sharing by the end of their funded project period. The Consortium considers data resulting from these projects ECHO Cohort data.

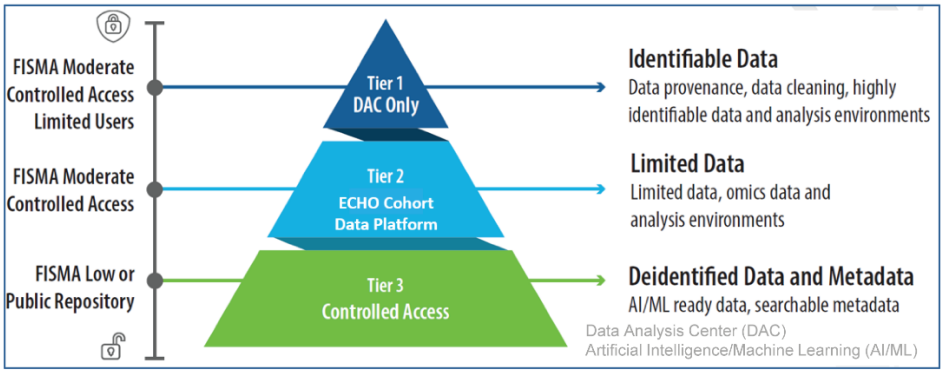
4. Participant Contact Information

The Data Analysis Center must keep participant contact information in a secure space separate from participant scientific data. The Data Analysis Center must use the contact information only to distribute online Protocol surveys to participants.

B. Data Access, Approval Requirements, and Terms of Access

1. ECHO Cohort Data Access within ECHO Data Enclave

ECHOPortal is a web portal to the secure Data Platform - FISMA Low and Moderate environments that the Data Analysis Center developed and maintains in a tiered data access system as shown in the diagram below.



2. Data Access Approval Requirements

Following the tiered approach, two types of users outside of the Data Analysis Center may access individual-level participant data. Certified users are analysts who receive extensive training from the Data Analysis Center and become certified for broader access to ECHO Cohort data with less restrictions to data specific to their approved analysis proposals. Each Study Site can have at least one certified user. Ancillary study teams must include an analyst to undergo user certification.

Non-certified users are analysts designated by Writing Team Leaders upon (1) the ECHO Cohort Publications Committee's approval of associated analysis proposals, and (2) the Data Analysis Center's approval of associated ECHOPortal data-access requests (see Section V. Supporting Documents).

Analysts have access to data for conducting approved analysis proposals. Writing Team Leaders can delegate the responsibility for conducting analyses to Data Analysis Center analysts, certified analysts, or non-certified analysts based on their need for accessing

personally identifiable information such as geographic identifiers and dates, as shown in the table below.

Analyst Type	Accessible Data
Data Analysis Center analysts	All data including addresses and real dates
Analysts certified by Data Analysis Center	Limited data, i.e., real dates but no addresses
Analysts without certification	De-identified data with no addresses, no real dates

This policy, and the ECHO Cohort Publications Policy (Publications Policy), address investigators from outside the Consortium who want to use data contained on the Data Platform. To use data on the Platform, the policies require outside investigators to either 1) collaborate with ECHO investigators serving as a Writing Team Leaders with Consortium-approved analysis proposals or 2) apply through the ECHO Cohort Ancillary Studies Process.

3. Terms of Data Use

Certified analysts have access to data, according to the certification terms, which may be specific to, or not specific to, their approved analysis proposals.

- Analysts without certification should only use data required to conduct the analyses specified in their approved analysis proposals. The Data Analysis Center must provide consultation to determine the data needed for analysis.
- Analysts may remove only summary-level results from the ECHOPortal after review by the Data Analysis Center to ensure participant confidentiality.
- In alignment with the Publications Policy, time limitations on data access may apply.
- For all analysis proposals that require access to data from Tribal Nations, a future addendum to this policy will provide the necessary guidance.

C. Controlled-access Public Use De-identified Data

The Data Analysis Center must make a public-use version of the ECHO Cohort data available to the general scientific community through an NIH-designated controlled-access data repository. Investigators wishing to use the ECHO Cohort data via the NIH data repository—currently the *All of Us* Researcher Workbench—should abide by its policies and procedures for accessibility and terms of access.

The Data Analysis Center de-identifies the ECHO Cohort data for the NIH-designated repository in compliance with the standards outlined in the HIPPA Privacy Rule/Safe Harbor Method, ensuring the identities of study participants cannot be readily ascertained by secondary data users. The Data Analysis Center implements further measures to minimize risk of participant re-identification including masking of Study Sites and removal of data from Tribal Nations. Other restrictions are detailed in the De-identification Documentation for the ECHO Cohort Public Data Release, available on the *All of Us* Researcher Workbench.

The Data Analysis Center must release accumulating public access data at yearly intervals. This release must occur as soon as possible and not more than 12 months after the availability of

data on the Data Platform, to allow time for the Data Analysis Center to apply de-identification procedures.

D. Data Privacy Breach and Abuse and Penalties for Non-Compliance with Data Sharing and Use Policy

The Data Analysis Center may monitor users' activities in the ECHOPortal to facilitate protection against unauthorized access, and to verify security procedures, survivability, and operational security. During monitoring, the Data Analysis Center may examine, record, copy, and use information for authorized purposes.

For any breach or perceived breach, the Consortium must follow the steps outlined in the *ECHO Cohort Manual of Procedures on Data Management*. Individuals who become aware of such incidents must report them to the Data Analysis Center immediately.

The Data Analysis Center must work with the ECHO Cohort Steering Committee (Steering Committee) and the NIH Program Office to remedy any ongoing concerns or revise processes to reduce the risk of a similar event recurring.

E. Other Applicable Policies

The Consortium aims to maximize scientific value while minimizing risks across the full range of data generation, research publication, and dissemination. To that end, Consortium investigators, ancillary study investigators, and all writing team members must follow all applicable ECHO and NIH policies including, but not limited to, the ECHO Cohort Data Sharing and Use Policy, ECHO Cohort Biospecimens Policy, ECHO Cohort Publications Policy, ECHO Cohort Ancillary Studies Policy, NIH Data Management and Sharing Policy, NIH Genomic Data Sharing Policy, NIH Grants Policy Statement, and the NIH Public Access Policy, as well as the requirements specified in the Cooperative Agreement Terms and Conditions of Award of each ECHO-funded investigator.

F. Acknowledgement of Agreements with Tribal Nations for Access and Use of Their Participant Data

The ECHO Data Analysis Center and other members of the ECHO Cohort Consortium have entered into data sharing and use agreements with the following Tribal Nations.

- Navajo Nation
- Cheyenne River Sioux Tribe

All ECHO Cohort Consortium members who access the ECHO Cohort Data Platform agree to abide by the terms and conditions of use outlined in these data sharing and use agreements, each of which may cover aspects of data collection, transfer, management, analysis, and ownership.

Limitations of Tribal Data Use: In accordance with these agreements, the ECHO Cohort Consortium may limit the use of participant data from Tribal Nations in ECHO Cohort analyses and restricts their use in ancillary studies.

V. Review and Revision

Review of ECHO Cohort Consortium policies occurs at least every three years; however, as processes change or circumstances evolve, this may warrant additional review and revision of this policy and associated documents.

VI. Supporting Documents

A. *ECHOPortal Data Access Request Form* (Request from Data Analysis Center)
B. *Delegation of Authority* (Request from Data Analysis Center)
C. *ECHO Cohort Manual of Procedures on Data Management* (Request from the ECHO Coordinating Center)

VII. References

A. *All of Us* Researcher Workbench
B. ECHO Cohort Ancillary Studies
C. ECHO Cohort Biospecimens Policy
D. ECHO Cohort Publications Policy
E. ECHO Cohort Ancillary Studies Policy
F. NIH Data Management and Sharing Policy
G. NIH Genomic Data Sharing Policy
H. NIH Grants Policy Statement
I. NIH Public Access Policy

VIII. Attachments

None

IX. History of Change

Version Number	Effective Date	Section Affected	Summary of Changes
5.1	01Sep2026	Section IV.C.	Updated language about the current location of ECHO's public-use dataset, which moved from NICHD DASH to *All of Us* Researcher Workbench
5.0	11Jul2025	Sections I, II, IV.A.1., IV.A.3., IV.B.2., IV.E., IV.F., VII	Section I: Made edits to include ancillary studies, added web links and line breaks to ease reading Section II: Made edits to include application to ancillary studies, and data generated by ancillary studies, and clarification around data sharing and use agreements with Tribal Nations Section IV.A.1: Made edits to clarify changes to metadata accessibility during ancillary study process development Section IV.A.3: Made edits to include ancillary studies Section IV.B.2: Added requirements for ancillary studies analysts and access via ancillary studies process Section IV.E: Added applicable policies, including Ancillary Studies Policy Section IV.F: Added language about data sharing and use agreements with Tribal Nations and limits of data access and use Section VII: Added link to ancillary studies webpage
4.0	01Sep2023	Entire policy	Revised policy to support ECHO Cycle 2.
3.0	25Feb2023	Scope Definitions Section C #2 Section C #4	Revised use of data from Native American nations. Definitions revised. Addition of processes for producing and accessing de-identified data. Revision of *Terms of Data Access*.

2.0	10Jan2020	Introduction, Scope, Definitions, and Sections A, B, and C under Part IV	Revised Policy to include reference to OIF Awardees and applicability of Data Sharing Policy to OIF projects and OIF-generated data. Also included ECHO Affiliate Investigator definition and applicability of the Policy to this investigator type. Added requirement that DAC analyst must conduct all analyses requiring access to PII, and DAC analyst or NBCS analyst must conduct all analyses when data from the NBCS is involved. Other minor editorial changes throughout the document for consistency in wording and refinement of description of DAC processes.
1.0	08Nov2017	N/A	New Policy

Approval Page

Name/Title	Approval Date
NIH ECHO Program Office	11Jul2025