



ECHO

Environmental influences
on Child Health Outcomes

A program supported by the NIH

Version: 1.0

Effective Date: 03January2020

Title: ECHO Individual Return of Research Results Policy

ECHO Individual Return of Research Results Policy

I. Introduction and Purpose

The Environmental influences on Child Health Outcomes (ECHO) Return of Individual Research Results Policy aims to outline the principles and framework for returning individual research results to those ECHO participants who wish to receive their results. The following principles guided the development of the policy:

A. National Academies of Sciences, Engineering, and Medicine Consensus Study Report – *Returning Individual Research Results to Participants: Guidance for a New Research Paradigm*

This report, released in July 2018, suggests a process-oriented approach to returning individual research results that considers the value to the participant, along with the risks and feasibility of return.

The ECHO Return of Individual Research Results Policy attempts to balance the above-mentioned principles with feasibility and resources available within the ECHO Cohorts and within the ECHO Program.

B. ECHO Guiding Principles for Engagement of Participants, Families, and Communities in the Process of Results Return

ECHO engagement of participants, families, and communities is based on four principles:

1. ECHO recognizes the valuable contributions of participants to research design, conduct, oversight and dissemination. Engagement should occur in our work as early and often as possible.
2. ECHO recognizes participants are embedded within families and communities that must be incorporated into stakeholder engagement frameworks.
3. ECHO supports its investigators in building internal and community capacity to enhance engagement at the local level in order to create mutual value.
4. ECHO is transparent and trustworthy. We communicate Program updates and share results in formats and language understandable to participants; and we engage in dialogue with communities where the research is conducted.



ECHO

Environmental influences
on Child Health Outcomes

A program supported by the NIH

Version: 1.0

Effective Date: 03January2020

Title: ECHO Individual Return of Research Results Policy

II. Scope

This document applies to data collected by or generated from the conduct of the ECHO-wide Cohort Data Collection Protocol. The cohort Principal Investigator (PI) will be the responsible party for return of relevant individual results to the individuals in his/her cohort. ECHO and non-ECHO investigators who generate data from ECHO biospecimen analyses or ancillary data collection will be responsible for developing a mechanism to communicate individual results with the cohort PIs from whom the samples or data collection originated so that they may be returned to participants under the auspices of this policy.

This policy does not apply to summary research results, as a separate ECHO policy will address return of summary research results, or to research results produced by the ECHO Institutional Development Awards (IDeA) States Pediatric Clinical Trials Network, which governs its own results return policies.

The ECHO Executive Committee, Steering Committee, and National Institutes of Health (NIH) Program Office will review, revise, and approve this Return of Individual Research Results Policy on a regular basis (see section V).

III. Definitions

None

IV. Policy

The policy applies to individual results as they become available to the cohort. Findings deemed to present immediate risk to the participant will be handled according to guidelines outlined in the Manual of Procedures. Findings presenting significant risk to participants or others will be handled per cohort specific procedures and requirements of federal, state and local laws. Participants will retain the right to refuse the return of any specific individual results, or all return of individual results.

A. Return of Results Standards

1. Return of individual results should be framed by context, incorporating reliable, published evidence (e.g., Environmental Protection Agency (EPA) Integrated Risk Information System: <https://www.epa.gov/iris>, American Academy of Pediatrics, well normalized test data, genetic data <https://www.genome.gov/about-genomics/policy-issues/Human-Subjects-Research-in-Genomics/Return-of-Research-Results>) when available.
2. Cohorts should have an Institutional Review Board (IRB) approved process for return of individual results and responding to related queries from participants.



ECHO

Environmental influences
on Child Health Outcomes

A program supported by the NIH

Version: 1.0

Effective Date: 03January2020

Title: ECHO Individual Return of Research Results Policy

3. Cohorts should maintain a list of referral resources for potentially clinically relevant results, or results that may require follow-up.
4. Results that are available immediately (e.g., immediately scored test) with available interpretation should be returned immediately.
5. Results that require post processing such as labs or food frequency questionnaires should be returned periodically via mail, email or in person visits or other ways.
6. Results that may be highly delayed, e.g., for years, or that may be associated with a high degree of latency of effect, should be evaluated for their potential current utility before returning.
7. Results should be returned in a language appropriate for the recipient.
8. Results for a child participant who is under 18 years old should be returned to the parent. Results for participants ≥ 18 will be returned to them. If assent of older children is used, guidance on method of returning results will occur in accordance with the procedures outlined in the Manual of Procedures.

B. Tiered Approach for Return of Results

The *ECHO Individual Return of Research Results Process* Document provides specific tiers for return of results by domain, and within each domain relevant specific item results/data, using the same terminology as for collection of ECHO-wide protocol data and specimens from participants.

1. Required
2. Recommended
3. Not to be returned

V. Review and Revision

The ECHO Executive Committee, Steering Committee, and NIH Program Office will review and approve updates to all ECHO Program related documents (e.g., Manuals of Procedures, ECHO Return of Results Policy) at least every 12 months.

VI. Supporting Documents

ECHO Individual Return of Results Process Document



ECHO

Environmental influences
on Child Health Outcomes

A program supported by the NIH

Version: 1.0

Effective Date: 03 January 2020

Title: ECHO Individual Return of Research Results Policy

VII. References

1. ECHO Guiding Principles for Engagement of Participants, Families, and Communities
2. National Academies of Sciences, Engineering, and Medicine Consensus Study Report – *Returning Individual Research Results to Participants: Guidance for a New Research Paradigm*

VIII. Attachments

None

IX. History of Change

Section Affected	Effective Date	Changes Made
N/A	03 January 2020	New Policy



ECHO

Environmental influences
on Child Health Outcomes

A program supported by the NIH

Version: 1.0

Effective Date: 03 January 2020

Title: ECHO Individual Return of Research Results Policy

Approval Page

Name/Title	Signature/Date
ECHO Steering Committee	03 January 2020

FOR REFERENCE ONLY