ECHO-WIDE BIOSPECIMEN (TYPE C) USE and RESERVE POLICY

I. Introduction

Under direction from the Environmental Influences on Child Health Outcomes (ECHO) Steering Committee, the principles set forth in this policy direct the use and reserve of the ECHO-wide TYPE C biospecimens and establishment of processes and systems.

II. Purpose

The goal of this policy is to maximize the scientific and public health impact of ECHO by balancing commencement of TYPE C biomarker assays while ensuring availability of biospecimens for future analyses.

III. Scope

The principles of this policy apply to any Analysis Proposal that requests the use of TYPE C biospecimens.

IV. Definitions

Item	Description
Biospecimen	Material taken from the human body (e.g., blood, urine, tissue).
HHEAR	Human Health Exposure Analysis Resource
CC	Coordinating Center
CPS	Collection, Processing, and Storage
DAC	Data Analysis Center
ECHO-wide Cohort Data Collection Protocol (EWCP)	The protocol that specifies what data and biospecimens cohorts should collect (new) and submit (both existing and new) across the life course from preconception through adolescence. This protocol facilitates the creation of ECHO-wide Cohort data platform.
ECHO-wide Cohort Analysis	An analysis that uses the ECHO-wide Cohort (i.e., uses data from at least two ECHO Cohort Awardees). Referred to as Analysis Proposal in this document

Item	Description
Biorepository	Location of stored TYPE C biospecimens (defined below) available for analyses. Fisher BioServices serves as the vendor for the ECHO biorepository.
SC	Steering Committee
Type B Biospecimen	Biospecimens collected through ECHO Program funding to address ECHO cohort-specific aims or other projects, such as Opportunities and Infrastructure Fund (OIF) projects. These biospecimens are not stored in the ECHO Biorepository unless converted to TYPE C biospecimens. The metadata for converted biospecimens will be available at the ECHO DAC.
TYPE C Biospecimen	Biospecimens included in, and collected under, the EWCP. These are stored in the ECHO Biorepository. TYPE C biospecimens are designated as "Essential" or "Recommended" for a particular participant at a particular life stage. Some Type C biospecimens may have been converted from Type B and were transferred to the ECHO Biorepository for ECHO-wide Cohort use.

V. Policy

A. Type C Biospecimens

The ECHO cohorts must deposit any essential or recommended TYPE C Biospecimens collected under the EWCP in the ECHO Biorepository. The Biorepository will store and catalog all TYPE C biospecimens.

The CORE Laboratory Information Management System (LIMS) at the Biorepository is integrated with Bio-Track, the biospecimen management system hosted by the ECHO Data Analysis Center (DAC). In addition to storage of all biospecimen data, Bio-Track provides local tracking of TYPE C biospecimens from the point of collection until shipped to the biorepository.

B. Biospecimen Use Principles

The primary principles are:

1) Scientific impact of proposed analyses
    a. Analysis of TYPE C biospecimens, as with other analyses, will place a premium on solution-oriented research.

b. The Publications Committee review will serve as the principal means of reviewing Analysis Proposals for scientific impact.

2) Feasibility of proposed analyses

a. Following the processes for the Publications Program, the DAC and HHEAR (if applicable) will provide a feasibility assessment. The Analysis Proposal writing teams submit information such as biospecimen characteristic requirements, the number of biospecimens needed, the lab selected, the analysis approach, etc. to assist in the feasibility assessment and proposal review.

3) Maximization of scientific return from the biospecimens over the potential life-course of the ECHO project

a. Identify opportunities to maximally conserve biospecimen and to maximize use across concepts

b. Identify opportunities to multiplex proposed assays with related assays that may be of interest to the ECHO scientific community

Based on the information provided by the Analysis Proposal writing team in the submission, the Publications Committee will assemble the appropriate review group according to its policy and processes. The assembled reviewers will evaluate the Analysis Proposal for scientific merit, public health benefit, and opportunities to maximize biospecimen use and make recommendations about approval of the Proposal. During feasibility assessment and/or evaluation of the Proposal, the experts will also take into consideration other Analysis Proposals previously approved or in review and availability of existing data.

The National Institute of Health (NIH) ECHO Program Office will review the recommendation from the Publications Committee and have final decision-making authority to approve or not approve the Analysis Proposal.

C. Biospecimen Reserves Principles:

1) ECHO cannot allow use of reserved aliquot(s) of any biospecimen type from any participant in analysis (See Table 1 for recommended reserve volumes) without an approval from the NIH Program Office. The Biospecimens Working Group will review this aspect of the reserve policy periodically and may revise it. The Analysis Proposal writing team may adjust the proposed number of participants to avoid using last aliquots or seek an exception from the NIH Program Office.

2) The Biorepository and DAC will reserve biospecimens for use in an approved Analysis Proposal. Biospecimens that are yet to be collected cannot be reserved.

3) The Biorepository will dispense biospecimens in amounts such that there is minimal residual volume, which may be returned to the biorepository.

D. Resources Table 1. ECHO Biospecimen Reserve Volumes

Biospecimen	Biospecimen Quantity per CPS Protocols	Aliquots per CPS Protocols	Reserve Volume
Tooth	Up to 3 teeth	1 envelope	No Reserve
Toenail	Up to 10 toenails	1 envelope	100-200 mg
Hair	Up to 100 strands	1 envelope	50 strands
Urine	10 mL	1 mL in 3 mL cryovial: creatinine, 1.4 mL (3) in 2 mL cryovial: metals, 2 mL (2) in 3 mL cryovial: organics, 2 mL (2) in 3 mL cryovial: Unspecified analysis, Up to 7 mL in 10 mL cryovial: unspecified analysis	2 mL urine in 3 mL vial used for organics
Breastmilk	25-33 ml total	11 vials: 1 mL per(8) 2 mL cryovial, 8 mL per (2) 10 mL cryovial, 2-8 mL per last (1) 10 mL vial	1 aliquot of 8 mL and 4 aliquots of 1 mL
Breastmilk	2 Whatman spot cards	(5) 50 uL spots per card	1 card
Placenta	7 vials	1 gm of tissue in (5) 2 mL cryovials, 50 mg of tissue in (2) 2.0 mL RNAlater tubes	2 aliquots of 1 gm tissue and 1 aliquot of 50 mg in RNAlater
Nasal Mucous	1 UVT swab, 1 COPAN Elution Swab (Eswab)	1 UVT swab, 1 COPAN Elution Swab (Eswab)	Not applicable
Colostrum	Up to 1 mL	0.1 mL per vial (10 vials)	2 vials
Meconium and stool	1 Zymo DNA/RNA shield fecal collection tube and 2 fecal collection tubes	3 tubes:1 scoop in a Zymo DNA/RNA shield fecal collection tube1 scoop in (2) fecal collection tubes	0.25 g each of Zymo preserved and non-preserved stool

Biospecimen	Biospecimen Quantity per CPS Protocols	Aliquots per CPS Protocols	Reserve Volume
Blood kit	10-15 mL whole blood	26 vials, 1 Whatman card 50uL blood spots (5) on Whatman cards, 120 uLplasma (10) in 1 mL cryovials, 1 mL plasma (3) in 2 mL cryovials, Buffy coat (2) in 1 mL cryovials, 1.8 mL RBCs (2) in 2 mL cryovials, 120 uL serum (5) in 1 mL cryovials, 1 mL serum (2) in 2 mL cryovials	• 1 filter paper spot • 1x120-µL plasma • 1x1-mL plasma • 1x1-mL buffy coat • 1x1.8-mL RBC • 1x120-µL serum • 1x1-mL serum
Cord Blood	15 mL, 1 Whatman card	26 vials, 120 uL plasma in (10) 1 mL cryovials, 1 mL plasma in (3) 2 mL cryovials, Buffy coat (2) in 1 mL cryovials, 1.8 mL RBCs (2) in 2 mL cryovials, 120 uL serum (5) in 1 mL cryovials, 1 mL serum in (2) 2 mL cryovials	• 1x1 mL plasma cryovial • 1x1 buffy coat cryovial • 1.8 mL RBC • 1 mL serum

VI. Review and Revision

Review of all ECHO Program Manual documents occurs at least every two years; however, more frequent review may be warranted as processes change or major edits are identified.

VII. Supporting Documents

None

VIII. References

A. Publications Policy

B. Biospecimen Utilization Policy

C. ECHO Glossary

IX. Attachments

None

X. History of Change

Section Affected	Version Date	Changes Made
N/A	19Feb2021	New Document

Approval Page

Name/Title	Signature/Date
ECHO Steering Committee	19Feb2021 (v1.0)