Environmental influences on Child Health Outcomes (ECHO)–wide Cohort Data Collection Protocol

Manual of Operating Procedures

INTRODUCTION

Version 01.20

Date: 30Nov2018

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INTRODUCTION

Table 1. Summary of Changes

Version	Date	Summary of Changes
01.20	30Nov2018	Original document

INTRODUCTION

1 PURPOSE OF THE MANUAL OF OPERATING PROCEDURES

The objective of the ECHO-wide Cohort Data Collection Manual of Operating Procedures (MOP) is to facilitate consistency in protocol implementation and data and specimen collection across participants and cohort sites. The use of this MOP increases the likelihood that our program will be scientifically credible and provides reassurance that we will monitor participant safety and scientific integrity.

The MOP has a threefold purpose:

1. **As a handbook** to guide ECHO-wide Cohort study conduct and operations
2. **As a reference** to follow procedures related to the ECHO-wide Cohort Data Collection Protocol
3. **As a supplement** to the study protocol by detailing the following:
    a. Regulatory requirements
    b. Operational procedures
    c. Measurement types, administration, and best practices
    d. Data capture and data management
    e. Data quality and data security procedures
    f. Biospecimen collection, processing, storage, and shipping procedures

Study personnel should have ready access to the MOP and be familiar with its contents, as applicable to their designated roles. The ECHO-wide Cohort Data Collection Protocol Materials page hosts all versions of the MOP and associated protocol materials.

2 CONTACT INFORMATION

Components	Questions
ECHO Coordinating Center (CC) **Contact:** CC Cohort Advocacy Team (CAT) Representative **Email:** ECHOCC@dm.duke.edu **Hours:** Mon-Fri, 8 AM – 5 PM ET (Response within 1 business day) **Resource:** ECHO-wide Cohort Data Collection Protocol Materials	• Operations and procedures • Protocol implementation • Consent customization • Proprietary measure access • Institutional review board submissions and regulatory requirements • Study coordinator and research administrator meetings • Trainings • Support for site issue resolution and documentation
ECHO Data Analysis Center (DAC) **Help Desk:** https://echoportal.org/Home/HelpDesk **Email**: ECHO-DAC@rti.org **Phone**: 877-225-0771 **Hours**: Mon-Fri, 8 AM – 5 PM ET (Response within 1 business day) **Resource:** ECHOPortal	• Participant registration • Data capture • Data transfer to the DAC • Mapping cohort-specific data to the ECHO-wide Cohort Common Data Model • Biospecimen tracking • Changes to visit and data collection schedules • Data collection forms • Specimen tracking and specimen information forms • Data- and specimen-related reports and queries

3 ABREVIATIONS AND ACRONYMS

Abbreviation or Acronym	Definition
CAT	Cohort Advocacy Team (ECHO CC and DAC)
CC	Coordinating Center (ECHO)
DAC	Data Analysis Center (ECHO)
DCF	data collection form
ECHO	Environmental influences on Child Health Outcomes
IRB	institutional review board
MIS	measurement information sheet
MOP	Manual of Operating Procedures (ECHO)
PI	principal investigator
PRO Core	Person-Reported Outcomes Core (ECHO)

4 MANUAL OF OPERATING PROCEDURES STRUCTURE AND CONTENT OVERVIEW

The MOP chapters describe best practices and minimum standards for participating sites to fulfill the requirements of the ECHO-wide Cohort Data Collection Protocol.

Chapter 1: Regulatory Requirements

- Institutional review board (IRB) oversight
- Protection of human subjects
- Essential regulatory documents (site regulatory file)
- IRB submissions and reporting activities

Appendix: Consenting Guidance and Best Practices

- Guidelines to assist the research administrator (data collector) during the consent process

Chapter 2: Training Requirements

- Learning Management System, types of training, use of the cohort-specific training matrix
- Training requirements for cohort trainers, research administrators (data collectors), and all other delegated study personnel

Chapter 3: Study Measurement and Procedures

- ECHO life stages, age-specific considerations
- Measurement types and modes of administration
- Best practices and guidance
- Measurement information sheets (MISs), data collection forms (DCFs), and proprietary measures

Chapter 4: Data Management

- ECHOPortal functionality:
  - Participant registration
  - Data capture
  - Data upload and download
  - Mapping of cohort-specific data models to the ECHO-wide Cohort Protocol Common Data Model
  - Tracking biospecimens
  - Viewing reports
- Data capture and management approaches
- Data quality and data security procedures

Chapter 5: Laboratory Manual

- Collecting and managing ECHO biospecimens: labeling, kitting, storing, shipping, and tracking

5 UPDATES AND VERSION CONTROL

The MOP is a dynamic document that the ECHO Coordinating Center (CC), Person-Reported Outcomes (PRO) Core, and the Data Analysis Center (DAC) will update throughout the conduct of the study to reflect any protocol amendments as well as refinement of study procedures, best practices, and guidance.

Throughout the conduct of the study, the CC will:

- Maintain all versions of the MOP on the ECHO-wide Cohort Data Collection Protocol Materials page.
- Store retired versions of the MOP separately and watermark as "retired."
- Communicate MOP revisions as numbered memos via email to cohort site principal investigators (PIs) and designated research administrators.
- Summarize content changes via memos. Change summaries will include the version and date, but will not include typographical corrections.
- Hold initial and ongoing MOP trainings according to designated roles via the Learning Management System.

The cohort site PI or designee will (in a timely manner):

- Ensure local distribution of the MOP change memos to applicable study personnel.
- Ensure study personnel complete training requirements according to designated roles.
- Implement MOP revisions at all sites immediately.
- **STORE MOP CHANGE MEMOS AND THE MOP IN THE SITE'S REGULATORY FILE.**

NOTE: For best practices on maintaining essential documents, refer to **MOP Chapter 1: Regulatory Requirements**.

NOTE: Designated study personnel should complete ongoing training requirements throughout the course of the study. Refer to **MOP Chapter 2: Training Requirements**.

6 STUDY MEASUREMENTS AND PROCEDURES: TAILOR TO YOUR COHORT

Principal investigators at the cohort site level are responsible for conducting the ECHO-wide Cohort Data Collection Protocol and for complying with the ECHO-wide Cohort Data Collection Protocol MOP.

The MOP provides detailed information and acceptable options for the conduct of the ECHO-wide Cohort Data Collection Protocol.

While there are best practices and procedures that apply to all cohorts, some site-specific choices are available throughout the MOP.

Cohorts may use established procedures if they include the minimum requirements as outlined in the ECHO MOP. The site PI (or designee) should maintain their site regulatory files to reference the location of laboratory and supplemental procedures.

- **Chapter 1 - Regulatory Requirements:** Includes 2 options for IRB oversight, either the ECHO single IRB or the local IRB. Cohorts choose an option for IRB oversight and follow associated procedures.
- **Chapter 2 - Training Requirements:** Provides training procedures that apply to all cohort sites and study personnel, according to designated roles. Cohorts should execute the chapter as written.
- **Chapter 3 - Study Measurements and Procedures:** Provides best practices and procedures for administering data measures for the ECHO-wide Cohort Data Collection Protocol. To facilitate consistent data collection across cohorts, study personnel should refer to the measure-specific MIS and DCF.
    - **MISs** are available for each essential (preferred and acceptable) and recommended measure for the ECHO-wide Cohort Data Collection Protocol and are located on the ECHO-wide Cohort Data Collection Protocol Materials page.
    - Proprietary measure MISs are located on the ECHOPortal with the associated DCFs, as applicable.
    - **DCFs,** provided by the DAC, are located on the ECHOPortal.

- **Chapter 4 - Data Management:** Provides procedures for the following:
    - Participant registration
    - Data capture
    - Data upload and download
    - Mapping of cohort-specific data models to the ECHO-wide Cohort Protocol Common Data Model
    - Tracking biospecimens
    - Viewing reports using the ECHOPortal

  Cohorts choose the platform and follow the associated procedures as defined in this chapter for:

    - DAC-hosted, centralized REDCap system
    - Locally-hosted data capture system
    - Hybrid, defined as a locally-hosted system in use before ECHO, in combination with the centralized REDCap system for capture of some or all of the data elements on the ECHO-wide Cohort Data Collection Protocol designated for collection by the cohort

NOTE: While this chapter covers the data management and tracking of biospecimens, for information about the collection, storage, or transfer of biospecimens, refer to **MOP Chapter 5: Laboratory Manual**.

- **Chapter 5 - Laboratory Manual:** Provides procedures for the management of all essential and recommended specimens collected under the ECHO-wide Cohort Data Collection Protocol. The following specimen materials are located on the ECHO-wide Cohort Data Collection Protocol Materials page:
    - Collection, processing, and storage protocols
    - Collection Instruction Sheets

  Designated study personnel may access Bio-Track via ECHOPortal. The following specimen materials are located in the resource library:

    - Bio-Track Manual
    - Specimen Information Form
    - Specimen Tracking Form
    - Specimen Tracking Form Completion Guidelines

7 COMMUNICATION PLAN

There is an ECHO Cohort Advocacy Team (CAT) assigned to each cohort. The CAT has representation from CC site management and DAC data management. The CAT provides a collaborative, efficient approach to addressing cohort- and site-specific questions.

The CAT will triage questions to the appropriate team or individual and track for timely response, review cohort-specific reports on data quality and timeliness, identify opportunities for training and quality-improvement initiatives, and oversee study closure at each cohort site when activities are completed.