Title: Biospecimen Submission Requirements

Document ID:	CP-CTNet SOP 02-06
Version:	2.0
Version Date:	September 10, 2020
Document Distribution:	Distribution of this document to persons or organizations outside of CP-CTNet without consent is strictly prohibited.

REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
2.0	SEP-10-2020	Added that shipments to FNLCR are confirmed upon receipt.
1.0	AUG-17-2020	Original version of document

1. INTRODUCTION AND PURPOSE

As described in each protocol, the Lead Academic Organization (LAO) and Affiliated Organizations (AOs) are responsible for collecting, processing, storing, and shipping CP-CTNet study biospecimens to the appropriate laboratories for biomarker and/or other analyses. Any remaining biospecimens after analyses and other study-related activities are completed are required to be shared with the research community. These biospecimens may be submitted to the Frederick National Laboratory for Cancer Research (FNLCR) for storage and distribution to the community for investigational use.

2. SCOPE

This document details the responsibilities of the LAOs regarding biospecimen data collection and shipment to FNLCR. These responsibilities may be delegated to the AOs as described in the protocol.

3. PROCEDURES

1. Requirements for study-specific biospecimen management, including collection, storage, banking and shipping, are defined in Section 12 of each study protocol.
2. Storage and distribution of biospecimens required at the end of a study may be managed by FNLCR.
    2.1. Biospecimens designated for centralized storage and distribution must be confirmed as consented for future use ***prior*** to forwarding these specimens to FNLCR. Any biospecimens that are lacking this consent should ***not*** be shipped to FNLCR and should be managed per institutional requirements.
    2.2. An electronic item-level Material Transfer Manifest is to be submitted prior to shipment of any biospecimens to FNLCR. DMACC will assist the LAOs in preparing the Manifest.
    2.3. The ***minimum data items required*** for each biospecimen submitted are listed below. Definitions of the data items can be found in Appendix 1. Additional data may be required and/or requested depending on the specialized needs of the project and/or protocol requirements.
        - Verification of consent for future use
        - Item Number
        - DCP Protocol Number
        - Current Label
        - Center
        - Hemolyzed
        - Subject ID
        - Date Drawn
        - Material Type
        - Material Modifiers
        - Date Processed
        - Label Status
        - Volume
        - Volume Unit
        - Box
        - Row

2.4. The Manifest should be submitted to FNLCR at diazmayoraln@mail.nih.gov and to DCP at NCIDCP-CTNetBiospecimens@mail.nih.gov at least 48 hours prior to shipping the listed biospecimens.

2.5. When the site is ready to ship the biospecimens, they will contact FNLCR. A webinar will be held by FNLCR with the institution responsible for shipment, to discuss the specifics of the study's biospecimen collection, review supply and shipment instructions, and develop a timeline for related tasks and activities. Supplies and related materials will be provided by FNLRC to ensure the proper packaging and transportation of biospecimens to the FNLCR repository.

3. Supplies are provided by FNLCR for frozen, chilled and room temperature shipments, as required. The supplies will include packaging, instructions, points of contact, shipping address, and prepaid courier documents.

3.1. Biospecimens should be shipped with a copy of the Manifest and a packing slip in each package. The shipping address for these materials is noted on the Manifest. Details regarding completion of the Manifest and packing slip will be reviewed during the pre-shipment webinar with the responsible institution.

3.2. All shipments to FNLCR are confirmed when they arrive (box, condition, temp, # of boxes, # of vials).

4. The FNLCR Head of Bioprocessing and Trial Logistics is responsible for general oversight of this process, laboratory administration, shipping supplies, and biospecimen database inquiries:

Norma A. Diaz-Mayoral, MS, MBA
Head, Bio Processing and Trial Logistics
Frederick National Laboratory for Cancer Research
Leidos Biomedical Research, Inc.
Office: 301-228-4208
Cell: 240-409-6846
Fax: 301-846-6222
diazmayoraln@mail.nih.gov

4. ADDITIONAL INFORMATION:

Refer to the **CP-CTNet Acronym List** to see the description of commonly used acronyms in this SOP.

Please send questions and comments regarding this SOP to DataManagement_CP-CTNet@frontierscience.org

5. REFERENCES

- None

6. APPENDICES

- Appendix 1: Manifest Data Item Definitions

Appendix I
Manifest Data Item Definitions

Data Item	Definition
Verification	Verification or confirmation that all biospecimens listed on the Manifest have been reviewed for the appropriate consent for future specimen use
Current Label	Unique biospecimen ID that is on the vial
Center	Institute where the specimen was collected
Hemolyzed	Degree to which a specimen is hemolyzed (e.g. slight, moderate, severe, not applicable, not hemolyzed)
Subject ID	Protocol-specific, de-identified participant ID
Date Drawn	Date and time biospecimen/material was obtained or created (mm/dd/yyyy 00:00)
Material Type	Type of material/specimen (e.g. Plasma, serum, FBS, DNA, slide)
Material Modifiers	Additional information to define material/specimen type/additives (e.g. EDTA, Control, Adipose, fasting, pre-menopausal)
Label Status	Identify the label by one of the following statuses: * handwritten * printed but not barcoded * barcoded
Volume	Quantity of the Material Type per label or unique biospecimen ID
Volume Unit	Unit of measure for each Volume (e.g. mL, ul, unit, mcg, slides)
Box	Box name and/or box number recorded on each box; box and box lid should have the same number
Row	Position of the biospecimen(s) by the box row number
Column	Cross-position of the biospecimen(s) by the box column number