Title: CP-CTNet Specimen Procedures

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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
1.0	JUL-07-2026	Original version of document.

1. INTRODUCTION AND PURPOSE

This reference guide outlines specimen procedures for the Cancer Prevention Clinical Trials Network (CP-CTNet), including the specimen request process for internal investigators and the specimen destruction process. Specifically, this document defines a process for requesting, reviewing, approving, distributing, and using specimens collected in CP-CTNet for purposes not originally defined in the protocol, ensuring ethical use, scientific merit, and compliance with participant consent and regulatory requirements. This specimen request process should be followed by investigators even in cases where the specimens are already in their possession. This document also outlines the process of requesting a certificate of destruction to document the destruction of CP-CTNet specimens.

This reference guide applies to all CP-CTNet Investigators requesting the receipt or destruction of specimens and all network entities involved in specimen governance, including the Lead Academic Organizations (LAOs), accruing LAOs, Affiliated Organizations (AOs), Data Management, Auditing, and Statistical Center (DMASC), and Division of Cancer Prevention (DCP).

2. DEFINITIONS

Term	Definition
AO	Affiliated Organization
CP-CTNet	Cancer Prevention Clinical Trials Network
DCP	Division of Cancer Prevention
DCP Study Team	DCP Medical Monitor, Nurse Consultant, and Scientific Lead assigned to the study
DM	Data Manager
DMASC	Data Management, Auditing, and Statistical Center
DSR	Destroyed
DUA	Data Use Agreement
FDAAA	Food and Drug Administration Amendments Act of 2007
GCLP	Good Clinical Laboratory Practice
ICF	Informed Consent Form
IRB	Institutional Review Board
LAO	Lead Academic Organization
LDMS	Laboratory Data Management System
MTA	Material Transfer Agreement
PI	Principal Investigator
SOP	Standard Operating Procedure

3. CP-CTNET SPECIMEN REQUEST PROCESS FOR INTERNAL INVESTIGATORS

1. Responsibility Overview

    1.1. Requesting Investigator:

    - Submits a specimen request via email.
    - Maintains local IRB approval or a waiver for the proposed study.
    - Confirms that the completed ICFs for the study where the specimens were collected cover the future use of specimens.
    - Uses specimens and data only for the approved purpose.

- Destroys leftover specimens after the approved research is complete and provides documentation to DMASC and the CP-CTNet Director.

1.2. CP-CTNet Director (in consultation with the DCP Study Team and study PI):

- Reviews the request for scientific merit, feasibility, specimen impact, and alignment with network priorities.

1.3. DMASC:

- Reviews specimen requests for completeness, specimen availability, and consent.
- Confirms which study participants have provided informed consent for future use of their specimens.
    - DMASC DMs run reports to verify which participants consented to future use of their specimens based on the responses to the future use of specimens question(s) entered in Medidata Rave. DMASC DMs provide these reports to the Requesting Investigator via email.

      Note: The LAOs are required to complete a review of all signed ICFs for the studies that they oversee, so the completion of these questions on each ICF is verified during this process. In addition, LAOs should compare the completed ICFs to the corresponding information that is entered in Medidata Rave.
- Confirms specimen availability.
- Coordinates the specimen request, including preparation of specimen request lists and letters.
- Tracks key specimen request milestones.

2. Specimen Request and Review Process

2.1. **Submission**

- The Requesting Investigator submits a specimen request (maximum of three pages) via email that includes:
    - Study objectives and scientific rationale.
    - Associated CP-CTNet study(ies).
    - Specimen type(s), number, and timepoint(s).
    - Planned analysis (if desired).
    - Local IRB approval or a waiver for the proposed study.
    - Confirmation that the completed ICFs for the study where the specimens were collected cover the future use of specimens.
    - Funding source and timeline.
    - Associated data needs (if applicable).

      Note: Requests should be emailed to Admin_CP-CTNet@frontierscience.org.

2.2. **Review**

- DMASC reviews the specimen request for completeness, specimen availability, and consent, and passes the request details to the CP-CTNet Director.
- The CP-CTNet Director reviews the request for scientific merit, feasibility, specimen impact, and alignment with network priorities.

  Note: Requests may be approved, conditionally approved, or denied by the CP-CTNet Director. The decision is communicated to the Requesting Investigator via email from the CP-CTNet Director or designee.

3. Requirements for Release

   3.1. Before specimens can be released, the Requesting Investigator must:

   - Confirm that executed MTAs are in place with each accruing LAO and AO outside the United States where specimens were collected or confirm that MTAs are not needed.
   - Confirm that local IRB approval or a waiver is on file.
   - Review and approve the specimen request materials prepared by DMASC, including the specimen request lists and letters with the shipping address and instructions.

4. Specimen and Data Distribution and Use

   4.1. After all requirements for release are met, DMASC sends specimen request lists and letters to the biorepository or laboratories where specimens are stored.

   Note: Requesting Investigators may be responsible for processing and shipping costs.

   4.2. Specimens are prepared and shipped (if needed) per biorepository or laboratory SOPs and regulatory requirements.

   4.3. DMASC works with the shipping biorepository or laboratories and Requesting Investigator to track the completion of shipments (if needed).

   4.4. DMASC or the LAO sends approved datasets to the Requesting Investigator.

   4.5. Specimens and data may only be used for the approved purpose.

   4.6. Sharing of specimens or data with third parties or changes in scope requires prior written approval.

   4.7. Re-identification of participants is prohibited.

5. Reporting, Publications, and Disposition

   5.1. DMASC tracks key specimen request milestones.

   5.2. The Requesting Investigator provides progress updates and a final specimen use report to DCP as part of the annual progress report.

   5.3. Resulting publications must acknowledge CP-CTNet and follow network publication policies.

   5.4. Remaining specimens must be destroyed or returned per the MTA, with written confirmation provided.

6. Non-Compliance

   6.1. Failure to comply with this document or agreement terms may result in suspension of access and restriction from future requests.

4. CP-CTNET SPECIMEN DESTRUCTION PROCESS

1. The Requesting Investigator sends an email to the CP-CTNet Director and DCP Study Team to request approval for destroying CP-CTNet specimens. The request should contain:
    1.1. Study number.
    1.2. Type and number of specimens to be destroyed.
    1.3. Reason for destruction.
2. Reasons for destroying specimens may include:
    2.1. Thawed shipment.
    2.2. Freezer failure.
    2.3. Specimens stored from participants who did not enroll.
    2.4. Study is FDAAA complete and the participant(s) did not consent to future use of their specimens.
    2.5. Testing remnants.
3. The request is reviewed by the CP-CTNet Director and DCP Study Team, and the decision is emailed back to the Requesting Investigator.
4. If approved, the Requesting Investigator coordinates the destruction of the specimens with the relevant laboratory. The laboratory ensures that specimens are destroyed in accordance with all local institutional policies, any applicable local or country laws, and in a GCLP-compliant manner. For specimens logged into LDMS, the laboratory or LAO staff update LDMS to accurately reflect that the specimens were destroyed, including removing the specimens from the storage module, assigning the appropriate condition (e.g., DSR), and adding comments to LDMS to document the date, responsible staff, and reason for specimen destruction.
5. The laboratory creates a certificate of destruction to document the occurrence of CP-CTNet specimen destruction and sends it to the LAO. The following information must be included in the certificate of destruction:
    5.1. Study number.
    5.2. Notifying authority from DCP.
    5.3. Type and number of specimens destroyed.
    5.4. Date and time of destruction.
    5.5. Reason for destruction.
    5.6. Laboratory staff member’s signature and date (i.e., the person responsible for specimen destruction).
    5.7. Laboratory Director or designee’s signature and date.
6. The Requesting Investigator sends a copy of the certificate to the CP-CTNet Director and DCP Study Team.
7. The laboratory is responsible for retaining a record of specimen destruction in accordance with all applicable regulations, institutional and DCP policies, and guidelines.

5. ADDITIONAL INFORMATION

Please send questions and comments to DMASC at Documentation_CP-CTNet@frontierscience.org.

6. REFERENCES

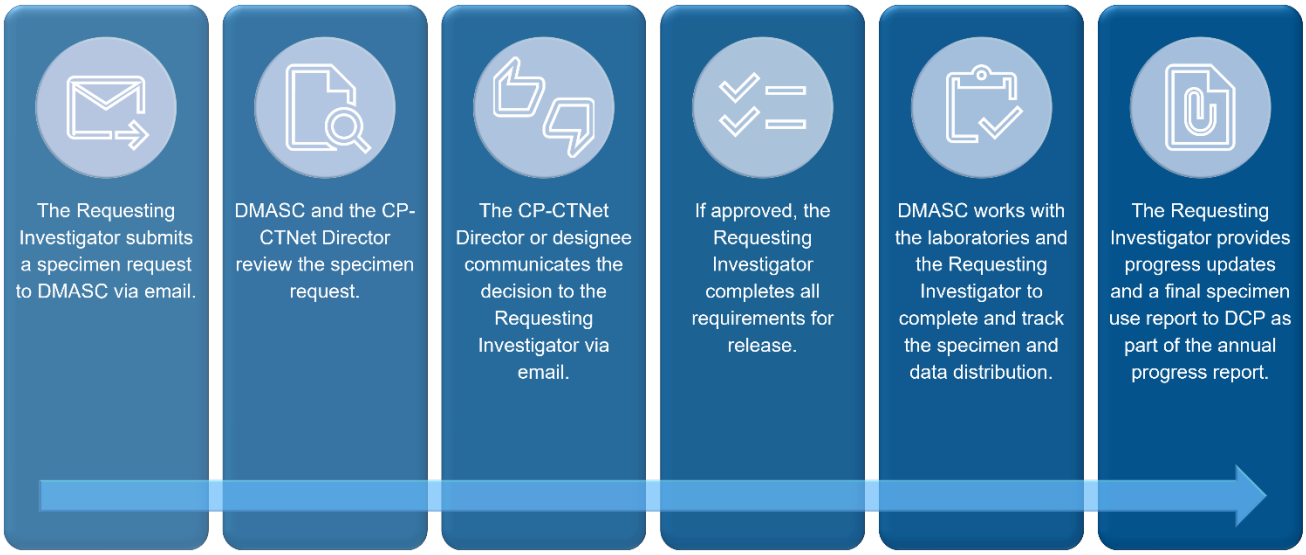
None.

7. APPENDICES

1. Appendix I *Summary of the Specimen Request Process for Internal Investigators*
2. Appendix II *Summary of the Specimen Destruction Process*

Appendix I

Summary of the Specimen Request Process for Internal Investigators



Appendix II

Summary of the Specimen Destruction Process