NIH NATIONAL CANCER INSTITUTE

SOP340567: Tumor Frozen Needle Biopsy Specimen Collection, Handling and Shipment to EET Biobank

Effective Date: 01/02/2025

Please check for revision status of the SOP at

http://dctd.cancer.gov/drug-discovery-development/assays/validated-biomarker-assays

and be sure to use the current version.

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Version History

1. Approvals

IQC Approval:	Li Li	Approval:	LI LI -S (Affiliate) Digitally signed by LI LI -S (Affiliate) Date: 2025.03.06 10:49:45 -05'00'
LHTP Approval:	Katherine V. Ferry-Galow	Approval:	Katherine V. Ferry-galow -S (Affiliate) Digitally signed by Katherine V. Ferry-galow -S (Affiliate) Date: 2025.03.06 12:08:49 -05'00'
DCTD OD Approval:	Toby Hecht	Approval:	Toby T. Hecht -S Digitally signed by Toby T. Hecht -S Date: 2025.03.06 20:23:28 -05'00'

2. Change History

Revision	Approval Date	Description	Originator	Approval
A	01/02/2025	Updated the website for ETCTN STS training video in Section 7.1, EET Biobank specimen shipment kit ordering information in Section 7.2., and document format.	LL/RA/AP/KFG	KFG
--	10/08/2021	New Document	LL/RA/KFG	KFG

1.0 PURPOSE

Standardize the method for collecting, handling, and shipping frozen needle tumor biopsies to EET Biobank to enable measurement of pharmacodynamic (PD) markers following treatment with anticancer agents.

2.0 SCOPE

This procedure applies to all personnel involved in the collection and handling of frozen needle tumor biopsies for use in PD marker assays during clinical trials that will be shipped to the EET Biobank. The goal of this SOP and associated training is to ensure consistency in tumor needle biopsy collection and handling between clinical collection sites.

3.0 ABBREVIATIONS

DCTD	=	Division of Cancer Treatment and Diagnosis
EET Biobank	=	NCI Early-Phase and Experimental Clinical Trials Biospecimen Bank, also referred to as the Nationwide Biorepository or ETCTN Biorepository
ETCTN	=	Experimental Therapeutics Clinical Trial Network
FNLCR	=	Frederick National Laboratory for Cancer Research
ID	=	Identification / Identifier
IQC	=	Internal Quality Control
LHTP	=	Laboratory of Human Toxicology and Pharmacology
PADIS	=	Pharmacodynamics Assay Development & Implementation Section
PD	=	Pharmacodynamic
SOP	=	Standard Operating Procedure
STS	=	Specimen Tracking System

4.0 INTRODUCTION

Specimen handling, shipping, and storage procedures (pre-analytical variables) can have a significant impact on the reliability of biomarker measurements in the laboratory. Following detailed steps for sample collection and handling procedures and recording any deviations from this procedure allows retrospective identification of artifactual changes in biomarker readout and increases the reliability of the data and validity of the analytical results.

5.0 ROLES AND RESPONSIBILITIES

Laboratory Director/Supervisor	The Laboratory Director/Supervisor directs laboratory operations, supervises technical personnel and reporting of findings, and is responsible for the proper performance of all laboratory procedures. Oversees the personnel who follow the SOPs in the laboratory and is responsible for ensuring the personnel are certified and have sufficient experience to handle clinical samples.
Certified Assay Operator and/or PK/PD Support Lab Personnel	An assay operator and/or PK/PD Support Lab personnel may be a Laboratory Technician/Technologist, Research Associate, or Laboratory Scientist who has been trained by DCTD personnel on this SOP. Working under the guidance of the Laboratory Director/Supervisor, this person performs laboratory procedures and examinations in accordance with the current SOP(s), as well as any other procedures conducted by a laboratory, including maintaining equipment and records and performing quality assurance activities related to performance.

5.1 It is the responsibility of the Laboratory Director/Supervisor to ensure that all personnel have documented training and qualification on this SOP prior to the actual handling and processing of samples from clinical trial patients. The Laboratory Director/Supervisor is responsible for ensuring the assay operator running the SOP has sufficient experience to handle and ship clinical samples. To become proficient with this SOP, sites are highly encouraged to reach out to NCI_PD_Support@mail.nih.gov for additional training materials.

5.2 It is the responsibility of the assay operator to obtain access and familiarize on the use of ETCTN STS prior to collection of clinical trial specimens.

5.3 It is the responsibility of the assay operator to request sample shipping kits from the EET Biobank and confirm inventory prior to initial specimen collections.

5.4 It is the responsibility of the assay operator to confirm scheduled specimen collection time points, print all labels, check documentation for accuracy and verify that the required collection tubes, supplies, and equipment are available for successful collection and handling of biopsy samples.

5.5 It is the responsibility of the assay operator to conduct the specimen collection and handling procedures following this SOP and complete the required tasks and associated documentation. The Biopsy Collection Record (Appendix 1) must be completed for each patient sample collection and maintained with the patient records.

5.6 The responsible personnel are to check the DCTD Biomarkers Web site (http://dctd.cancer.gov/drug-discovery-development/assays/validated-biomarker-assays) to verify that the latest SOP version is being followed.

6.0 MATERIALS AND EQUIPMENT REQUIRED

6.1 Stopwatch, total time in minutes and seconds required

6.2 1.5-mL Sarstedt o-ring screw cap, conical bottomed tubes (Sarstedt, Cat#: 72.703.416)

6.3 Disposable, fine-tipped tweezers (e.g., VWR, Cat#: 83009-010) (tweezer tips need to easily fit to the bottom of a 1.5-mL Sarstedt tube)

6.4 Thermal Transfer Printer (e.g., Zebra ZT411 or comparable printer)

6.5 Printable cryogenic microcentrifuge tube labels (e.g., Brady, FreezerBondz Cryogenic Matte Polyester Laboratory Labels for 3" Core Printers - 0.6" x 1.25", Cat#: THT-155-490-3)

6.6 Thermal Transfer Ribbon (e.g., Brady, Thermal Ribbon 4300, Cat#: R4302)

6.7 81-place freezer boxes (e.g., Fisher Scientific, Cat#: 12-565-182)

6.8 Stainless steel or polystyrene ice bucket (e.g., Southern Labware, Cat#: SS111)

6.9 Floating foam rack (e.g., VWR, Cat #:82017-634)

6.10 Liquid nitrogen or dry ice/ethanol bath

6.11 -80°C freezer (or colder)

6.12 Specimen shipping kit from EET Biobank

6.13 Dry ice (at least 20 pounds per shipment)

7.0 OPERATING PROCEDURES

7.1 Samples shipped to the EET Biobank require the use of the ETCTN Specimen Tracking System (STS) for sample tracking. Prepare to use the ETCTN STS as follows:

7.1.1 Contact CTSUContact@westat.com for initial access to ETCTN STS.

7.1.2 Contact sts.support@theradex.com for ETCTN STS technical assistance.

7.1.3 Review the following training videos for ETCTN STS before using the system:

- General ETCTN STS training: https://theradex.com/STS_training_18Feb2022/
- Label Printing training: https://www.youtube.com/watch?app=desktop&v=9_Q6_k-KHHs

7.2 Sample Shipping Kits

7.2.1 Kits for the collection and shipment of select specimens to the EET Biobank can be ordered at: https://kits.bpc-apps.nchri.org. Users at the clinical sites will need to set up an account in the Kit Management system and select a specific clinical trial protocol to request a kit. Please note that each protocol may include more than one type of kit. Each user may order two kits per kit type per day (daily max = 6 kits). Kits are shipped ground, so please allow 5-7 days for receipt and verify inventory prior to initial specimen collections. A complete list of kit contents for each kit type is located on the Kit Management system website.

7.3 Prepare Specimen Labels and Label Tubes

7.3.1 Prepare enough pre-printed specimen labels in ETCTN STS by following steps below:

7.3.1.1 Log into the ETCTN STS, go to the **Enrollment** folder and confirm the **Histology and Disease** form and **Specimen Consent** form are complete.

7.3.1.2 Go to the **All Specimens** folder.

7.3.1.3 Complete the **Specimen Tracking Enrollment** form for each specimen following the steps below.

7.3.1.3.1 Open the **Specimen Tracking Enrollment** form

7.3.1.3.2 Click **Add a new Log line** below the table to create each additional sample as shown below.

#	Timepoint	Specimen category	Specimen Type	Collection Tube Type	Block Number	Type of tissue	Surgical Path ID	Number of labels	Report	Report	Report	
1	Baseline	Frozen Tissue	Snap Frozen Tissue	_	_	Metastatic	_	1	_	_	_	
2	Baseline	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
3	Course 2 Day 1	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
4	Course 3 Day 1 (Pre)	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
5	Course 3 Day 1 (Pre)	Frozen Tissue	Snap Frozen Tissue	_	_	Metastatic	_	1	_	_	_	
6	Course 4 Day 1	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
7	Progression	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
8	Course 2 Day 1	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
9	Course 2 Day 1	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
10	Course 3 Day 1 (Pre)	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
11	Course 3 Day 1 (Pre)	Frozen Tissue	Snap Frozen Tissue	_	_	Metastatic	_	1	_	_	_	
12	Course 4 Day 1	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
13	_	_	_	_	_	_	_	_	_	_	_	

Add a new Log line | Inactivate

7.3.1.3.3 **Primary Diagnosis Disease Group** and **SnoMed Disease Term/Code** will be automatically populated from **Histology and Disease** form.

7.3.1.3.4 **Assessment time point**: Choose the time point from a dropdown list; the ETCTN STS will be populated with the relevant timepoints for each clinical trial.

7.3.1.3.5 **Specimen Category**: Choose "Frozen Tissue" from the dropdown list.

7.3.1.3.6 **Specimen Type**: Choose "Snap Frozen Tissue" from the dropdown list.

7.3.1.3.7 **Type of Tissue**: Choose disease type from the dropdown list.

7.3.1.3.8 **Surgical path ID (SPID)**: Enter the ID created by your institutional pathology department.

7.3.1.3.9 **How many labels are needed**: Enter "1" for 5 labels to be created.

7.3.1.3.10 An example of completed snap frozen tissue entry is circled below.

	Timepoint	Specimen category	Specimen Type	Collection Tube Type	Block Number	Type of tissue	Surgical Path ID	Number of labels	Report	Report	Report	
1	Pre-Treatment	Formalin Fixed Tissue	Formalin Fixed Core Biopsy	_	_	Metastatic	_	1	_	_	_	
2	Pre-Treatment	Blood	Blood	cfDNA Streck	_	_	_	2	_	_	_	
3	Pre-Treatment	Frozen Tissue	Snap Frozen Tissue	_	_	Metastatic	_	3	_	_	_	

7.3.1.4 Complete the **Print Labels** form following the steps below. Labels will be sent to the user's email address.

7.3.1.4.1 Open the **Print Labels** form and the click on the **Pencil** icon.

7.3.1.4.2 Select your **Label Layout** (one label per page or multiple labels per page).

7.3.1.4.3 Select the labels to be printed either by timepoint or by individual checkboxes.

7.3.1.4.4 Five labels will be created by default when you enter "1" in the "**How many labels are needed**" field in the **Specimen Tracking Enrollment** form as shown below.

	Specimen Enrollment Logline Number	Universal Participant ID	Specimen ID	Protocol TimePoint	Protocol TimePoint Coded Value	Specimen Category	Specimen Type/Tube Type	Relevant Codes	Biopsy Pass designation	How many labels?	Print (multiple selections allowed)	
1	1	CEC505K3	10566-CEC505K3-1	Baseline	BASELINE	Frozen Tissue	Snap Frozen Tissue	MI/A*	A	1*	*	
2	1	CEC505K3	10566-CEC505K3-1	Baseline	BASELINE	Frozen Tissue	Snap Frozen Tissue	MI/B*	B	1*	*	
3	1	CEC505K3	10566-CEC505K3-1	Baseline	BASELINE	Frozen Tissue	Snap Frozen Tissue	MI/C*	C	1*	*	
4	1	CEC505K3	10566-CEC505K3-1	Baseline	BASELINE	Frozen Tissue	Snap Frozen Tissue	MI/D*	D	1*	*	
5	1	CEC505K3	10566-CEC505K3-1	Baseline	BASELINE	Frozen Tissue	Snap Frozen Tissue	MI*		1	*	

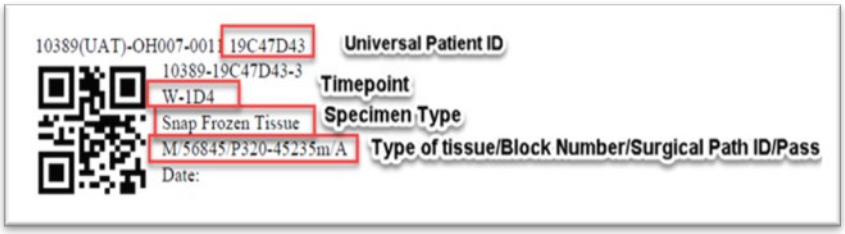
7.3.1.4.5 The first four will be designated with A, B, C and D to represent different passes of the biopsy procedure. Use the pass identifiers accurately to label the specimens: pass A should be for the first pass, B the second pass, etc. The fifth label will have no pass designation and can be used for additional biopsy passes collected. Write the letter "E or F" as pass ID on the label using a permanent marker.

7.3.1.5 Save the form.

7.3.1.6 You will receive two emails: 1) containing a PDF attachment with the labels and 2) containing the URL link to the labels.

7.3.2 Print two copies of each label received and write down the specimen collection date on the labels.

An example label is shown below:



7.3.3 Each biopsy pass will be collected into an individual 1.5-mL Sarstedt tube. These tubes are provided as part of the sample shipping kit provided by the EET Biobank.

7.3.4 Verify all sample label information and affix one to an individual 1.5-mL Sarstedt tube for each of the planned biopsy passes. One duplicate label for each biopsy can be given to the research nurse for use during the biopsy procedure to be maintained with the patient records.

7.4 Tumor Needle Biopsy Collection and Handling

7.4.1 Prior to a planned biopsy collection, the target lesion should be assessed by the clinical team as to whether the biopsy should be performed based on associated patient risk and likelihood of adequate biopsy quality. Fill out the **Pre-Biopsy Lesion Score** form in ETCTN STS using information from interventional radiologists and/or oncologists.

7.4.2 The research nurse is to notify the laboratory of scheduled PD sample collections, preferably giving at least 24 hr notice. Arrive at the biopsy collection site early enough to allow sufficient time to set up laboratory supplies, collect relevant clinical information, and ensure rapid flash freezing of specimens and transport from the procedure area to the laboratory, where they will be placed into storage at -80ºC (or colder).

7.4.3 Bring all necessary lab supplies to the biopsy collection site, including: disposable tweezers, sufficient 1.5-mL Sarstedt tubes pre-cooled on liquid nitrogen or dry ice/ethanol in an insulated bucket, the labels to give to the research nurse for the patient record, and a printout of Biopsy Collection Record (Appendix 1).

NOTE: Pre-chill additional 1.5-mL Sarstedt tubes for specimen collection in case the interventional radiologist collects additional passes, or if one of the tubes is compromised prior to collection.

NOTE: Pre-fill the top section of the Biopsy Collection Record with the Operator Name, Clinical Site Name, Protocol Number, Patient ID, Biopsy Timepoint, Collection Date, and Primary Diagnosis.

7.4.4 The total time elapsed between biopsy collection and placement into the pre-chilled tube is of **key importance** to biomarker analysis; this time should be documented in ETCTN STS for each biopsy pass. **It is important to note that all biopsies should be frozen within 2 minutes of collection.**

7.4.5 After each biopsy pass is collected, the interventional radiologist will eject the biopsy onto a sterile slide (for optimal analyte recovery the slide should be pre-chilled). Start a stopwatch at this point and note the Specimen ID and collection time in Appendix 1 and then immediately walk the slide to the sample preparation table for transfer to the pre-chilled Sarstedt tube.

7.4.6 Immediately snap freeze the biopsy by placing the tube in liquid nitrogen or a dry ice/ethanol bath (stop the stopwatch at this point). Note the time in Appendix 1.

NOTE: DO NOT let the tubes tip over in the liquid nitrogen or dry ice/ethanol bath.

7.4.7 Calculate the total time elapsed from biopsy collection to biopsy freezing and record the total number of **minutes and seconds** (Appendix 1).

7.4.8 Note the specific anatomic location of each biopsy pass collected (*e.g.*, spleen, large left upper quadrant splenic mass) (Appendix 1).

7.4.9 **IMPORTANT**: Record any deviations in the Notes section of Appendix 1.

7.4.10 Return to the sample processing laboratory and transfer the frozen biopsy specimen(s) to -80°C (or colder) for storage until shipment to the EET Biobank.

7.4.11 After biopsy collection, complete the required sample tracking documentation in ETCTN STS according to the notes recorded in Appendix 1.

7.6 Complete the **Specimen Transmittal** form in the **All Specimens** folder following instructions below:

7.6.1 **Logline Number** will be automatically populated by the system.

7.6.2 **Universal Participant ID** will be automatically populated by the system.

7.6.3 **Specimen ID** will be automatically populated by the system.

7.6.4 **Site of Disease** will be automatically populated by the system.

7.6.5 **Primary Diagnosis Disease Group** will be automatically populated by the system.

7.6.6 **Assessment Timepoint** will be automatically populated by the system.

7.6.7 **Date of Specimen Collection**: Enter date of the collection.

7.6.8 **Time of Specimen Collection**: Enter time of the specimen collection in 24 hr designation (e.g., 08:50)

7.6.9 **Hours post dose, if post treatment**: Leave blank. This will be automatically populated by the system after this form is completed.

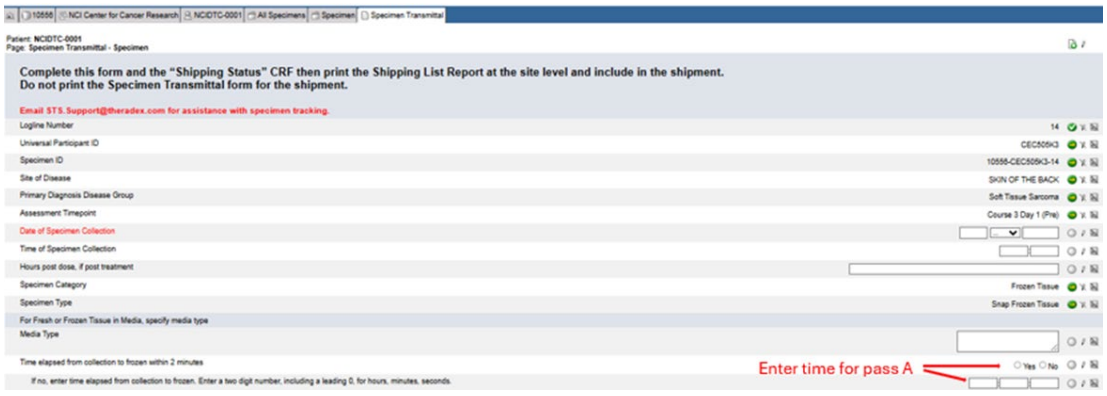
7.6.10 **Specimen Category** will be automatically populated by the system.

7.6.11 **Specimen Type** will be automatically populated by the system.

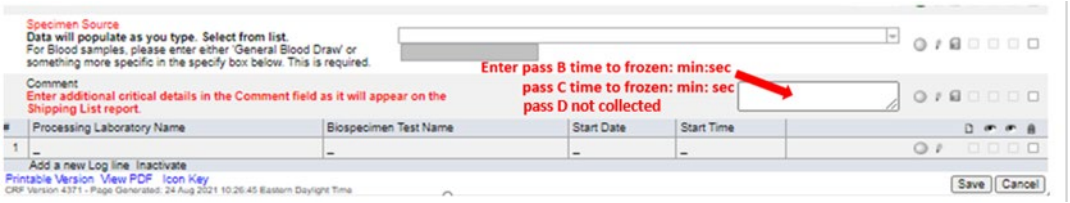
7.6.12 Enter the **elapsed time from collection to freezing** for each pass in the **Specimen Transmittal** form following the instructions below.

NOTE: It is important to fill out the time from collection to freezing for each pass with elapsed time over 2 minutes in the Specimen Transmittal form by following the instructions below.

7.6.12.1 Pass A time will be recorded in the appropriate fields as shown below.



7.6.12.2 Times elapsed for passes B, C and D will be recorded in the **Comment** field near the bottom of the Specimen Transmittal form as shown below. Biopsy passes not collected will also be recorded in the **Comment** field as shown below.



7.6.13 **Number of containers used for collection** (e.g., Total number of biopsy passes): Enter the number of biopsy passes.

7.6.14 **Number of sample containers or slides, after any processing at site, available for submission**: Enter the number of biopsy cores collected.

7.6.15 **Specimen Source**: Enter the biopsy site.

7.6.16 Save the form.

8.0 SHIP TO EET BIOBANK

8.1 When specimens are ready to be shipped, complete the **Shipping Status** form and print the **Shipping List**.

8.1.1 Click on the **Pencil icon** to fill out the fields listed below:

8.1.1.1 **Courier Name**: Enter "FedEx" as the courier.

8.1.1.2 **Shipping Tracking Number**: Enter the specific FedEx tracking number for the shipment.

8.1.1.3 **Shipping Source**: Select collection institution from the dropdown list.

8.1.1.4 **Sender's Name**: Enter sender's name.

8.1.1.5 **Sender's Email Address**: Enter sender's email address.

8.1.1.6 **Number Sent**: Enter the number of frozen biopsy cores in the shipment.

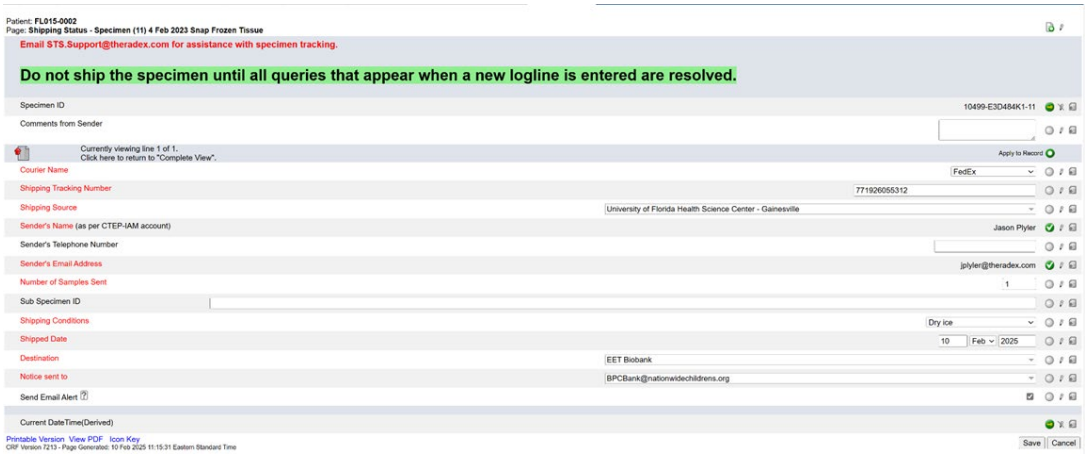
8.1.1.7 **Shipping Conditions**: Select "Dry ice" from the dropdown list for tumor frozen needle biopsy.

8.1.1.8 **Shipped Date**: Enter date of shipment.

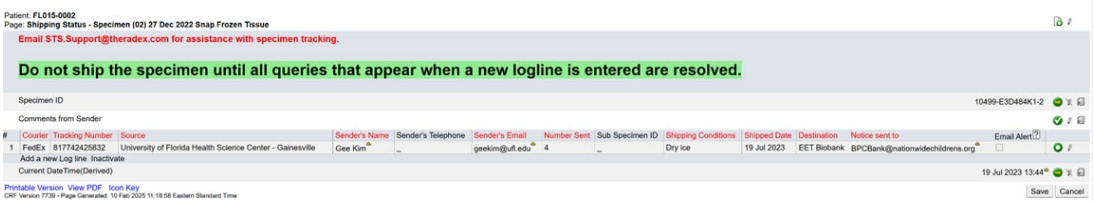
8.1.1.9 **Destination:** Select "EET Biobank" from the dropdown list for shipping to EET Biobank.

8.1.1.10 **Notice sent to**: Select BPCBank@nationwidechildrens.org from the dropdown list.

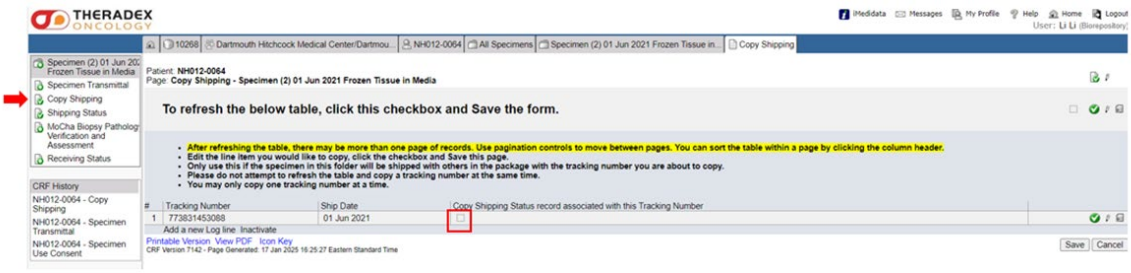
8.1.1.11 An example of completed **Shipping Status** form is shown below.



8.1.1.12 Select **Save**. After saving, verify that you see the log item populated on the **Shipping Status** page (as shown below). A notification will be sent to BPCBank@nationwidechildrens.org Only complete this step for one specimen in the shipment to avoid duplicate notifications.

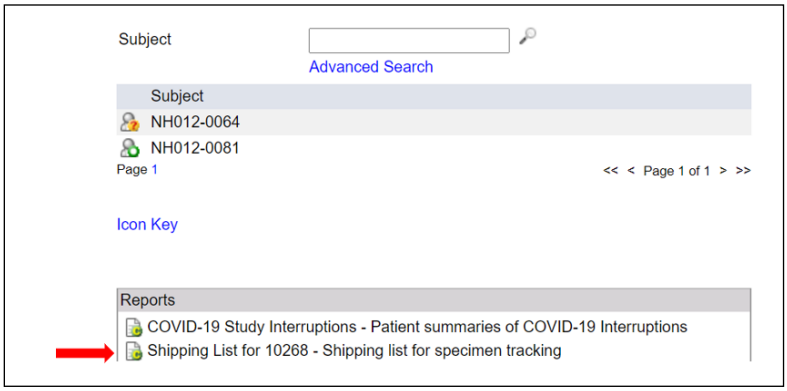


8.1.1.13 If there are other specimens to be shipped with the frozen biopsies, use the **Copy Shipping** utility form (shown below) in the other specimens' folder and select the correct tracking number associated with the shipping status record to be copied as shown below.

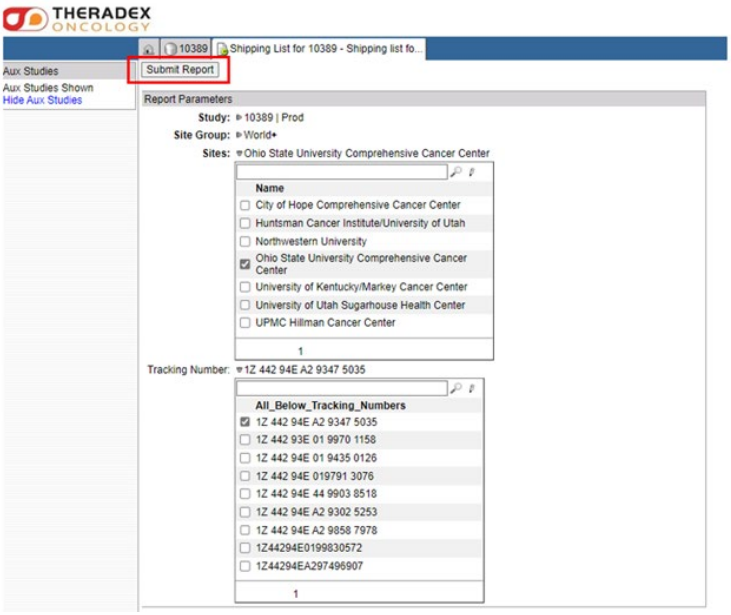


8.1.2 Print the **Shipping List** report and place it in the box with the specimens.

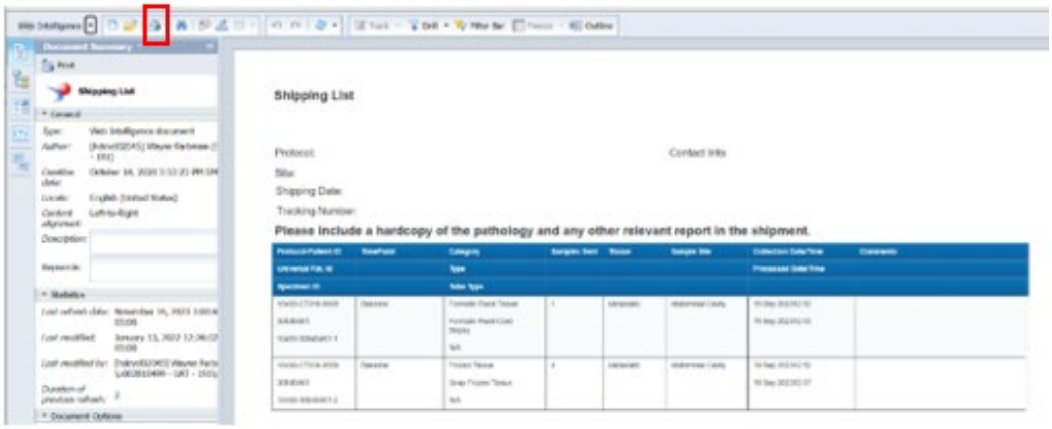
8.1.2.1 The **Shipping List** report is found in the report panel at the bottom of the window at the site level (an example is shown below) since specimens from multiple patients can be included in a single shipment.



8.1.2.2 Find your shipment's tracking number and check the box (see below). Then click **Submit Report** (see below) and **OK**.



8.1.2.3 Click the **Print icon** to export a PDF of the Shipping List (as shown below).



8.1.2.4 The shipment should include a hard copy (printed copy) of the **Shipping List**. An example is shown below.

Shipping List

Protocol: 10389 - UAT
Site: Ohio State University Comprehensive Cancer Center
Shipping Date: 10 Jul 2021
Tracking Number: 1ZF10W700199914880

Contact Info: Melissa Mineo
609-480-7366
mmineo@theradex.com

Please include a hardcopy of the pathology and any other relevant report in the shipment.

Protocol-Patient ID	TimePoint	Category	Samples Sent	Tissue	Sample Site	Collection Date/Time	Comments
Universal Pat. Id		Type				Processed Date/Time	
Specimen ID						Frozen in 2 min/Elapsed	
10389-OH007-0011 19C47D43 10389-19C47D43-1	Baseline	Blood Blood	1		General Blood Draw	21 Jun 202109:00 N/A	
10389-OH007-0011 19C47D43 10389-19C47D43-2	Archival	Formalin Fixed Paraffin Embedded Tissue FFPE Block	1	Metastatic	Esophagus	09 Jan 202115:00 N/A	
10389-OH007-0011 19C47D43 10389-19C47D43-3	Week -1 Day 4 (Expansion Cohort Only)	Frozen Tissue Snap Frozen Tissue	3	Metastatic	Esophagus	10 Jun 202111:10 N/A No/00:03:25	Pass B time to frozen: 02:20 ; Pass C time to frozen: 00:50

8.1.2.5 The shipment should also include a hard copy of the **TISSUE BIOPSY VERIFICATION** form found in the appendices of corresponding clinical protocols.

8.2 Specimen shipment to EET Biobank

8.2.1 Follow the **Shipping Specimens from Clinical Site to the EET Biobank/ETCTN Biorepository** section of the clinical protocol for general instructions of sample shipment to EET Biobank.

8.2.2 Frozen biopsies should be shipped in kits provided by the EET Biobank. The shipping container sent with kit contents should be used to ship specimens to the EET Biobank.

NOTE: Samples should be shipped with sufficient dry ice to keep the biopsies frozen for at least 96 hours (20lb minimum). Position the vials within the center of the shipping container with sufficient dry ice surrounding the specimens.

8.2.3 Follow the **Shipping Specimens from Clinic Site to the EET Biobank/ETCTN Biorepository** sections of the clinical protocols for correct address for specimen shipment to the EET Biobank.

NOTE: Specimens may be shipped on Monday through Thursday. Do not ship specimens the day before a holiday. **FedEx Priority Overnight** service is the required shipping method. The EET Biobank FedEx account will not be provided to submitting institutions. Sites are responsible for all costs for shipments to the EET Biobank, so the overnight express shipment should be billed directly to the shipping institution/site.

8.3 Useful contacts for Specimen Collection, Handling and Shipment:

8.3.1 Send all questions related to this SOP or PD assay support questions to: NCI_PD_Support@mail.nih.gov

8.3.2 Send all technical questions about the Specimen Tracking System to: STS.Support@theradex.com

8.3.3 EET Biobank queries (kit inquiries and sample shipping): BPCBank@nationwidechildrens.org

APPENDIX 1: BIOPSY COLLECTION RECORD

Instructions: This Biopsy Collection Record is to be utilized by clinical sites to record key information during the biopsy collection process for later documentation in ETCTN STS. This completed document should be filed/stored with the patient's study records at a predetermined location according to local policy for managing clinical trial information.

*Please **do not** include this document in the shipment to EET Biobank.*

A ***separate*** Biopsy Collection Record should be completed for **each patient sample set**.

Certified Operator: _____ Site Name: _____

Protocol Number: _____ Patient ID: _____

Timepoint: _____ Collection Date: _____

Diagnosis: _____

1. Biopsy Collection *Clinical sites are responsible for **entering the below information in Medidata RAVE.***

	1st Pass	2nd Pass	3rd Pass	4th Pass	5th Pass
Specimen IDs:					
Collection time: (24-hr designation)	:	:	:	:	:
Site of Biopsy: (note for each pass or write "same" for replicate cores)					
Time biopsy placed in tube:	:	:	:	:	:
Required: Time elapsed from collection to placement in tube.	**min sec**	**min sec**	**min sec**	**min sec**	**min sec**
Notes: List any collection notes or deviations from SOP.					

2. Biopsy Storage

Date/time biopsy specimen(s) placed at ≤ -80°C: _____ _____ : _____

3. Review of Batch Record by Laboratory Director/Supervisor

_____(PRINT) _____(SIGN) Date:_____