

<b>ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY</b>	<b>CORRELATIVE SCIENCE PROCEDURE MANUAL</b> Biospecimen Collection for Randomized Phase II Trial of Lutetium Lu 177 Dotatate Versus Everolimus in Somatostatin Receptor Positive Bronchial Neuroendocrine Tumors  Short Title- A021901	Version No: 2.2	Effective Date: 03/15/2024
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## CORRELATIVE SCIENCE PROCEDURE MANUAL

### 1. Purpose

This document describes the procedures required for the collection, shipping, and processing of biospecimens from patients enrolled or registered who have consented to participate in A021901. This document also describes the procedures that will be followed subsequent to the receipt of biospecimens by the Alliance Biorepository (i.e. Siteman Cancer Center Tissue Procurement Core at Washington University) or by Duke University, prior to their use for protocol-specified and future, unspecified correlative science research studies. This document should be used by staff involved with any aspect of the A021901 biospecimen collection, processing, and submission, including staff at satellite institutions.

### 2. Scope

This document applies to all biospecimens collected specifically for A021901 only. Please refer to the trial protocol-specific language for additional details regarding eligibility, participant enrollment, data submission, and specific procurement procedures. **Please ensure that you are reading the most updated version of this document. This document may experience minor updates, revisions, and clarifications independent of a formal protocol amendment. The most recent version of this document may be found on the Alliance and CTSU websites.**

### 3. Definitions

Term	Definition
ABWUSTL	Alliance Biorepository at Washington University in St. Louis
FFPE	Formalin Fixed, Paraffin Embedded

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#### 4. Contact Information

<b>Protocol-related questions may be directed as follows:</b>	
<b>Questions</b>	<b>Contact (via email)</b>
Questions regarding patient eligibility, treatment, and dose modification:	Study Chair: Thomas A. Hope, MD <a href="mailto:thomas.hope@ucsf.edu">thomas.hope@ucsf.edu</a>  Nursing Contact: Lisa Kottschade, APRN, MSN, CNP, FAPO <a href="mailto:kottschade.lisa@mayo.edu">kottschade.lisa@mayo.edu</a>  Protocol Coordinator: Jamie Crawley <a href="mailto:jcrawley@bsd.uchicago.edu">jcrawley@bsd.uchicago.edu</a>  (where applicable) Data Manager: Brandon Bright <a href="mailto:bright.brandon@mayo.edu">bright.brandon@mayo.edu</a>
Questions related to data submission, RAVE or patient follow-up:	Data Manager: Brandon Bright <a href="mailto:bright.brandon@mayo.edu">bright.brandon@mayo.edu</a>
Questions regarding the protocol document and model informed consent:	Protocol Coordinator: Jamie Crawley <a href="mailto:jcrawley@bsd.uchicago.edu">jcrawley@bsd.uchicago.edu</a>
Questions related to IRB review:	Alliance Regulatory Inbox <a href="mailto:regulatory@allianceNCTN.org">regulatory@allianceNCTN.org</a>
Questions regarding CTEP-AERS reporting:	Alliance Pharmacovigilance Inbox <a href="mailto:pharmacovigilance@allianceNCTN.org">pharmacovigilance@allianceNCTN.org</a>
Questions regarding specimens/specimen submissions:	Alliance Biorepository at Washington University: <a href="mailto:alliance@email.wustl.edu">alliance@email.wustl.edu</a>
Questions regarding drug supply:	Drug Distribution Contact: Advanced Accelerator Applications <a href="mailto:Customerservice-us@adacap.com">Customerservice-us@adacap.com</a>
Questions regarding drug administration:	Pharmacy Liaison: Maria Andrea Monckeberg, MS, RPh, BCOP <a href="mailto:mamonckeberg@lifespan.org">mamonckeberg@lifespan.org</a>

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**4.1** For information on using the BioMS system, please refer to the ‘Help’ links on the BioMS webpage to access the online user manual, FAQs, and training videos. To report technical problems, such as login issues or application errors, please contact: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org). For assistance in using the application or questions or problems related to specific specimen logging, please contact: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org).

**4.2** For all other questions regarding biospecimen procurement and shipping procedures, please contact the Alliance Biorepository Program Manager: 1-314-747-4402 or [alliance@email.wustl.edu](mailto:alliance@email.wustl.edu)

## 5. Site Preparation

**5.1** Please refer to A021901 protocol document for any specific requirements related to patient enrollment, registration, and regulatory compliance.

**5.2** Please ensure that you have appropriate log on credentials and can successfully access the BioMS application. The BioMS application is used for logging the collection and shipment of biospecimens to the Alliance Biorepository at Washington University and to Duke University. For training and assistance in using the application or questions or problems related to specific specimen logging, please contact: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org).

## 6. Collection Schema

The following biospecimens are to be collected at each of the time points. Please refer to individual biospecimen collection and processing methods and specific shipping procedures below.

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Time Point	Kit (Y/N)	Biospecimen	Quantity	Collection / Processing Method	Shipping	Recipient Lab	Notes
<b>Mandatory for all patients registered to A021901</b>							
Prior to initiation of treatment	N	H&E stained slide  <b>OR</b> Scanned slide images	1 slide	H&E stained slide for central pathology review (9.2)  <b>OR</b> Scanned slide images (9.5)	Ambient	ABWUSTL (11.2)	1
<b>For patients registered to A021901 Biobanking</b>							
Prior to initiation of treatment	Y	Whole blood (ACD tubes)	3 x 8.5 mL	Whole blood- ACD (10.1)	Ambient	Duke (11.3)	2
Prior to initiation of treatment	Y	Whole blood (Streck BCT tubes)	2 x 10 mL	Whole blood- Streck BCT (10.2)	Ambient	ABWUSTL (11.2)	2
Prior to initiation of treatment	Y	Whole blood for plasma	8 x 1 mL aliquots	Frozen Plasma (10.3)	Dry Ice	ABWUSTL (11.2)	2, 3
Prior to initiation of treatment	N	Tumor tissue block  <b>OR</b> H&E stained slide  <b>AND</b> Tumor tissue scrolls	1 block  <b>OR</b> 1 H&E stained slide  <b>AND</b> 10 x 10 micron scrolls	Fixed tissue block (9.3)  <b>OR</b> H&E Stained Slide  <b>AND</b> Fixed tissue scrolls (9.4)	Ambient	ABWUSTL (11.2)	2, 4
4 wks (+/- 1 wk) after initiation of treatment	Y	Whole blood (ACD tubes)	3 x 8.5 mL	Whole blood- ACD (10.1)	Ambient	Duke (11.3)	2
4 wks (+/- 1 wk) after initiation of treatment	Y	Whole blood (Streck BCT tubes)	2 x 10 mL	Whole blood- Streck BCT (10.2)	Ambient	ABWUSTL (11.2)	2

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4 wks (+/- 1 wk) after initiation of treatment	Y	Whole blood for plasma	8 x 1 mL aliquots	Frozen Plasma (10.3)	Dry Ice	ABWUSTL (11.2)	2, 3
At progression	Y	Whole blood (ACD tubes)	3 x 8.5 ml	Whole blood- ACD (10.1)	Ambient	Duke (11.3)	2
At progression	Y	Whole blood (Streck BCT tubes)	2 x 10 ml	Whole blood- Streck BCT (10.2)	Ambient	ABWUSTL (11.2)	2
At progression	Y	Whole blood for plasma	8 x 1 ml aliquots	Frozen Plasma (10.3)	Dry Ice	ABWUSTL (11.2)	2, 3
At progression	N	Tumor tissue block <b>OR</b> H&E stained slide <b>AND</b> Tumor tissue scrolls	1 block  <b>OR</b> 1 H&E stained slide <b>AND</b> 10 x 10 micron scrolls	Fixed tissue block (9.3)  <b>OR</b> H&E Stained Slide <b>AND</b> Fixed tissue scrolls (9.4)	Ambient	ABWUSTL (11.2)	2, 4

**Notes:**

1. Retrospective central pathology review will be conducted using the bronchial neuroendocrine tumor tissues from the diagnostic specimen (i.e. biopsy/surgery). The submission of this sample for pathology review is required for all patients registered to this study. See **section 9.2** for additional details. Sample must be submitted prior to OR within 3 months after initiation of treatment. If unable to submit glass diagnostic H&E for retrospective central histopathology review, scanned slide image files of the H&E slide in .SVS file format may be uploaded digitally to the Biorepository, see **section 9.5** for additional details.
2. Collection is optional for patients, but all sites are required to offer to patients to consent. Please see protocol-specific consent document.
3. Aliquots are derived from 2 x 10mL EDTA tubes.
4. A representative diagnostic fixed tissue block from a primary and progressive tumor should be submitted, if available. If entire tissue block cannot be submitted, 1 H&E stained slide **AND** ten (10um) serial tissue scrolls will be accepted as an alternative. If tissue is limited, please submit H&E and as many tissue scrolls as possible. **BLOCK SUBMISSION IS STRONGLY PREFERRED.**

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## 7. Biospecimen Collection Kits

- 7.1** To facilitate the proper collection and shipping of all biospecimens, biospecimen collection kits and materials will be provided. The cost of the kit and shipping the kit to the site will be paid for. The institution is expected to pay for shipping the kit with the biospecimens back to ABWUSTL or to Duke University via priority overnight shipping.
- 7.2 NOTE: Kits will be sent via FedEx at no additional cost to the participating institutions. Kits will not be sent via rush delivery service unless the participating institution provides their own FedEx® account number for express service. The study will not cover the cost for rush delivery of kits.**
- 7.3** Kits should be requested at least 10 working days in advance of the anticipated collection date. As many as 2 kits can be requested at one time. Since the collection materials (vacutainer tubes) have expiration dates, do not request kits more than 90 days prior to their anticipated use. **All kits must be requested by using the BioMS system; do not request kits via CTSU.**
- 7.4** Distributed kits will have a minimum shelf life of 90 days; unless precluded by the stability of a particular component.
- 7.5** Kit contents and specific instructions for use of the kit are provided in the kit box. During warm weather months (i.e. June—August), a refrigerated pack (not frozen) should be included in the shipment to maintain ambient temperature. When shipping during other months of the year, a room temperature pack should be included in the shipment.
- 7.6** Once a kit is received, do not discard the outer cardboard overwrap. The kit, containing biospecimens, is to be shipped back in the same box.
- 7.7** Please return all components of the kit, regardless of whether they have been used or not. Kits and kit components are recycled when possible, minimizing the kit cost.

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- 7.8** Well in advance of collecting biospecimens, inspect the biospecimen collection kit to ensure that all components are present and not expired, particularly if the kit has been onsite for longer than 30 days.
- 7.9** Note that individual kit components that are expired, damaged, or missing cannot be replaced. The remedy is to order a complete, new kit (please note in your request that you are replacing an expired or damaged kit).
- 7.10** Please return all kits that have expired or missing components. Return the ENTIRE kit using the cheapest possible shipping method at your expense. DO NOT DISCARD kits that have missing or expired components. Recycling kits keeps the cost of kit materials to a minimum. Please note that all outgoing and incoming kits are tracked, and sites that have requested many more kits than they have returned will be charged for non-returned kits.
- 7.11** If a biospecimen collection component (e.g. vacutainer collection tube) is missing, damaged, or expired, the institution may substitute a like-kind collection tube from their own supply. However, note that while some kit components are generic (i.e. EDTA tubes), others are highly specialized (e.g. Streck BCT) and probably are not available at the institution.
- 7.12** Note that protocol requirements are based on blood volumes, not tube sizes. If the protocol requires the collection of 8 ml of whole blood, generally a 10 ml tube is provided in the kit for convenience. If desirable or necessary to collect 8 ml in 3 x 3 ml tubes (for example), that is permissible.
- 7.13** Because paraffin blocks, scrolls, or slides cut from such blocks may be requisitioned and received from the surgical pathology department at a different time than the day of procurement for other biospecimens, paraffin blocks or cut slides may be sent independently of other biospecimens using the following guidelines:
- 7.13.1** There is no independent “kit” for submission of paraffin blocks, scrolls, or slides.



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**7.13.2** Blocks, scrolls, and slides should be packaged to avoid breakage using a padded envelope or, preferably, a small Styrofoam container.

**7.13.3** During warm weather months, paraffin blocks, scrolls, and slides should be shipped in an insulated container that contains a refrigerant pack, to avoid heat > 25 degrees C (77 degrees F) that may melt paraffin and damage the tissue specimens.

**7.13.4** Blocks, scrolls, and slides may be shipped for standard overnight delivery according to institutional policies and using the preferred vendor.

**7.14** Please see **Section 11 – Biospecimen Shipping** for specific instructions on shipping to ABWUSTL and Duke University.

## 8. Biospecimen Labeling and Tracking

**8.1** All research biospecimens (vacutainer tubes, tissue bags) **MUST** be labeled with the Alliance patient ID number, patient initials (Last, First, Middle), the date and time (if applicable) of collection, and specimen type (i.e. “plasma”).

**8.2** Surgical pathology tissue blocks should not be labeled in any manner. The institutional surgical pathology number (e.g. “S16-1234”) and the individual block identifier (e.g. “A3”) should be readable on the block. The H&E stained slide and fixed tissue scrolls should be labeled with the Alliance study number (A021901), Alliance patient ID number, institutional surgical pathology number, and the block identifier. Provide **a de-identified copy of the surgical pathology report**, labeled with the Alliance patient ID number, corresponding to the blocks or slide submitted to ABWUSTL. Please ensure the institutional surgical pathology number and block ID are maintained on the surgical pathology report. See **section 9** for additional details.

**8.3** Label all containers and vials with an indelible, solvent-resistant marker when they are at ambient temperature.

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- 8.4** Do not affix any labels to vials, slides or tubes. Label the collection containers directly with the marking pen.
- 8.5** All biospecimens that are collected and sent to the Alliance Biorepository and to Duke University **must be logged and tracked in BioMS**. The BioMS system is a web-based application that tracks the collection and shipping of biospecimens. Once individual biospecimens are logged and ‘shipped’ in the BioMS system, a packing manifest will be created by the system. This manifest must be printed out and must accompany all biospecimen shipments. To become familiar with the BioMS system and for further information about training, access, and use, please contact the BioMS Help Desk at: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org).
- 8.6** In the event that BioMS cannot be accessed, please complete a BioMS Specimen Log and Shipping Manifest form which can be found here: <http://tinyurl.com/alliance-biomscontingency>.

## 9. Tissue Collection

### 9.1 Overview

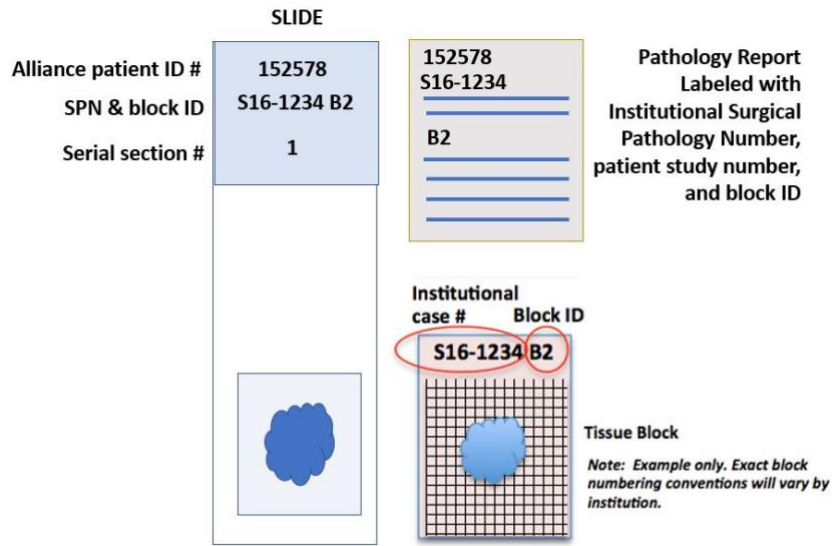
- 9.1.1** The method for research tissue procurement (needle core biopsy, sampling of surgically resected tumor) is dependent upon the disease site and the individual patient.
- 9.1.2** When procuring tissue biospecimens by any method, when possible, avoid tissue that is grossly necrotic, hemorrhagic, fatty, or fibrous. If in doubt, briefly (1 min or less) place the tissue segment in a sterile specimen cup containing physiologic (normal) saline to rinse the tissue. Necrotic, hemorrhagic, and fatty tissue will generally dissolve or float on the surface while tumor and parenchymal tissue will remain intact and sink to the bottom of the cup.
- 9.1.3** Include a copy of the **de-identified pathology report with all tissue submissions**.

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**9.2 Diagnostic H&E-Stained Slide for Central Pathology Review**

**9.2.1** Retrospective central pathology review requires submission of one (1) H&E stained slide containing bronchial neuroendocrine tumor tissues from biopsy or surgery.

**9.2.2** See figure below for proper mounting and labeling.



**9.2.3** Include a copy of a de-identified pathology report with all slide submissions.

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### 9.3 Fixed Tissue Blocks for Biobanking

- 9.3.1** For patients who consent to A021901 Biobanking for future use, one representative diagnostic block from primary and progressive disease should be submitted.
- 9.3.2** Any clinical surgical pathology block that is submitted for research studies will not be exhausted or rendered unsuitable for future diagnostic use. Any clinical surgical pathology block that is submitted will be returned within ten working days of written request, when needed for clinical management or clinical trial enrollment for a specific patient. Otherwise, all blocks will be returned to the submitting institution when the trial and correlative science study end points have been met.
- 9.3.3** In the event that an institution will not release a tissue block from primary and progressive disease, the institution may instead submit 1 H&E stained slide **AND** tissue scrolls as an alternative (see **section 9.4**). **BLOCK SUBMISSION IS STRONGLY PREFERRED.**
- 9.3.4** **During warm weather months, paraffin blocks and slides should be shipped in an insulated container that contains a refrigerant pack, to avoid heat > 25 degrees C (77degrees F) that may melt paraffin and damage the tissue specimens.**

### 9.4 H&E Stained Slide and Fixed Tissue Scrolls for Biobanking

- 9.4.1** In cases where an institution is unwilling or unable to submit a tissue block for biobanking, a single H/E stained slide for references and serial tissue sections (scrolls, ribbons, curls) from the same block may be submitted.
- 9.4.2** Cut and perform a routine H/E stain on a single section from the tumor tissue block. Be certain to label the stained slide using all of the conventions and guidelines outlined in **section 9.2**.

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**9.4.3** Cut a “ribbon” (scroll) of 10 paraffin tissue sections at 10 microns. Place the ribbon of tissue directly into a single microcentrifuge tube or any other suitable container. Do not float the tissue ribbon or sections in a water bath. Label the tube of tissue following the guidelines outlined in **section 9.2**.

**9.4.4** During warm weather months, paraffin blocks and slides should be shipped in an insulated container that contains a refrigerant pack, to avoid heat > 25 degrees C (77degrees F) that may melt paraffin and damage the tissue specimens.

## 9.5 Scanned Slide Images

**9.5.1** In cases where institutions are unwilling or unable to submit the requested fixed tissue block or fixed tissue slides, scanned slide images of an H&E-stained slide and/or any other stained slides produced for histopathologic diagnosis required by the protocol may be submitted.

**9.5.2** Scanned slide images will be uploaded via the Digital Pathology Image Portal (DPIP) in BioMS. Please see Appendix 1 for instructions on how to upload scanned slide images.

**9.5.3** Unless otherwise specified in the protocol correlative science manual (CSM), scanned slide images must be created using an Aperio / Leica scanner at 40X magnification in an .SVS file format.

**9.5.4** Scanned slide images should not contain PHI (patient name, date of birth, institutional surgical pathology number). The slide scanner should be configured to crop or exclude any image of the slide label. Alternatively, post-processing of the slide image file should remove the slide label image from the SVS file. **Images submitted with PHI or with the labels intact will not be accepted.**

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- 9.5.5** A digital de-identified pathology report (i.e. PDF file) must be included with all scanned slide image submissions, uploaded to BioMS. The surgical pathology number / accession number should be retained in order to correlate the report to the digital image specimen. The pathology report **must** also retain reference to individual block identifiers and must include the Alliance patient ID number and study ID so that each slide image can be correlated with the corresponding pathology report narrative. Please see **Appendix 1** for instructions on how to upload the de-identified pathology report to BioMS.
- 9.5.6** The file name of the de-identified pathology report should correspond to the *Study ID, Alliance patient ID number, and last two digits of the institutional surgical pathology number* corresponding to the file name(s) assigned by DPIP.
- 9.5.7** Once the images have been uploaded, site staff should send an electronic copy of the manifest to [alliance@email.wustl.edu](mailto:alliance@email.wustl.edu).
- 9.5.8** Questions regarding appropriate image labeling, file naming conventions, and how to submit scanned slide images should be addressed to the Alliance Biorepository Protocol Management team ([alliance@email.wustl.edu](mailto:alliance@email.wustl.edu)). Questions related to BioMS should be addressed to the BioMS help desk ([bioms@alliancencn.org](mailto:bioms@alliancencn.org)).

## 10. Blood Collection Methods

### 10.1 Whole blood (ACD Tube – no processing)

- 10.1.1** Collect 8.5 ml of blood into each of the three (3) ACD tubes using standard venous phlebotomy. Invert tubes 10 times.

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**10.1.2** Store ACD tubes with whole blood at ambient temperature until shipping. Do not freeze or refrigerate the tubes. Blood should be collected Monday-Thursday only. **The tubes must be shipped on the same day they are collected and must be received by Duke University within 24 hours of collection (e.g. Friday-Saturday collections or holiday collections are not allowed).** Ensure that the ACD tubes are shipped at ambient temperature to avoid freezing. **During warm weather months (i.e. June—August), a refrigerated pack (not frozen) should be included in the shipment to maintain ambient temperature. When shipping during other months of the year, a room temperature pack should be included in the shipment.**

## **10.2 Plasma Nucleic Acid ( Streck BCT) Tube Processing**

**10.2.1** Collect 10 ml of blood into each of the two (2) Streck BCT tubes using standard venous phlebotomy. Invert tubes 10 times.

**10.2.2** Store Streck BCT tubes with whole blood at room temperature. Do not freeze or refrigerate the tubes. The tubes may be stored for up to 72 hours at ambient temperature before shipment. Ensure that the Streck BCT tubes are shipped at ambient temperature to avoid freezing. **During warm weather months (i.e. June—August), a refrigerated pack (not frozen) should be included in the shipment to maintain ambient temperature. When shipping during other months of the year, a room temperature pack should be included in the shipment.**

## **10.3 Plasma Processing**

**10.3.1** Collect 10 ml whole blood by standard venous phlebotomy technique into each of the two (2) purple top (EDTA) tubes. Invert tubes 10 times.

**10.3.2** Within 2 hours of collection, spin the vacutainer tubes at room temperature in a clinical centrifuge at 2500 x G for 15 minutes.

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**10.3.3** Carefully remove the plasma layer from each tube (~4 ml), without touching the white, buffy coat layer, and transfer to new, 15 ml conical centrifuge tubes.

**10.3.4** Spin the centrifuge tubes containing plasma at room temperature in a clinical centrifuge at 2500 x G for 15 minutes.

**10.3.5** Label eight (8) cryovials as instructed in **section 8**. Make certain each vial is labeled completely and identically.

**10.3.6** Carefully remove 8 ml of plasma (without touching the pellet) and divide into eight (8), 1 ml labeled cryovials.

**10.3.7** Freeze plasma containing cryovials on dry ice or a -70 to -90 degree Celsius ultralow freezer. Store at -70 to -90 degrees C until ready for shipment on dry ice.

## 11. Biospecimen Shipping

### 11.1 Overview

**11.1.1** Please see the Directions for Use (DFU) document that is included in each kit for specific directions on how to package and ship biospecimens.

**11.1.2** Place the original, completed copy of the BioMS packing manifest in the shipment. If sending tissue, include a copy of the de-identified surgical pathology report. Do not send specimens without a completed BioMS Packing Manifest or substitute "BioMS Downtime Form." Biospecimens cannot be accepted without this completed form.

**11.1.3** All biospecimens should be shipped within the time frame specified in **sections 9-10** above. If collected biospecimens cannot be shipped within the specified time frame (e.g. Friday – Saturday or Holiday collections), please contact the Alliance Biorepository Program Manager: 1-314-747-4402 or [alliance@email.wustl.edu](mailto:alliance@email.wustl.edu) for further instructions, at least 24 hours prior to anticipated collection.



<b>ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY</b>	<b>CORRELATIVE SCIENCE PROCEDURE MANUAL</b> Biospecimen Collection for Randomized Phase II Trial of Lutetium Lu 177 Dotatate Versus Everolimus in Somatostatin Receptor Positive Bronchial Neuroendocrine Tumors  Short Title- A021901	Version No: 2.2	Effective Date: 03/15/2024
		Replaces: 2.1	Page 17 of 20

**11.1.4 Do not ship on Friday, Saturday, Sunday or the day before a nationally recognized holiday.**

**11.2 Shipping to ABWUSTL**

**11.2.1** Ship container for PRIORITY OVERNIGHT DELIVERY according to IATA guidelines and standard institutional policies and using the preferred vendor.

Ship to:

**Alliance Biorepository  
c/o Siteman Cancer Center Tissue Procurement Core  
Washington University School of Medicine  
425 S. Euclid Ave  
Room 5120  
St. Louis, MO 63110-1005  
Phone: (314) 454-7615**

**11.3 Shipping to Duke University**

**11.3.1** Ship container for PRIORITY OVERNIGHT DELIVERY according to IATA guidelines and standard institutional policies and using the preferred vendor. **Notice of shipment and FedEx tracking information should be emailed to Substrate Services**

**Core: [surgerysubstrate@dm.duke.edu](mailto:surgerysubstrate@dm.duke.edu)**

Ship to:

**Attn: Substrate Services Core and Research Support  
Duke University Medical Center  
203 Research Drive  
MSRB I, Room 459  
Durham, NC 27710  
Phone: (919) 684-2294**

<b>ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY</b>	<b>CORRELATIVE SCIENCE PROCEDURE MANUAL</b> Biospecimen Collection for Randomized Phase II Trial of Lutetium Lu 177 Dotatate Versus Everolimus in Somatostatin Receptor Positive Bronchial Neuroendocrine Tumors  Short Title- A021901	Version No: 2.2	Effective Date: 03/15/2024
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## 12. ABWUSTL Biospecimen Receipt and Quality Assurance Measures

- 12.1** Upon receipt, all biospecimens will be accessioned into the TPC informatics system, OpenSpecimen.
- 12.2** All biospecimens will be logged, associated, and tracked by the unique patient biopsy control number.
- 12.3** Each individual biospecimen will receive and be physically labeled with a unique biospecimen identifier, associated with the biopsy control number in the TPC informatics system.
- 12.4** Upon receipt, all physical biospecimens received will be reconciled with what is recorded on the BioMS packing manifest. Any discrepancies noted will be communicated to the Program Manager who will contact the submitting site for reconciliation.
- 12.5** Upon receipt, any biospecimen received that is not in appropriate physical condition (e.g. broken vials, frozen samples that are thawed, ambient samples that are frozen) will be reported to the Program Manager, who will contact the submitting site for reconciliation.
- 12.6** Frozen aliquoted biofluids will be stored under liquid nitrogen vapor.
- 12.7** All biospecimens will remain in storage until additional processing or review is requested in writing by the appropriate protocol PI.

<b>ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY</b>	<b>CORRELATIVE SCIENCE PROCEDURE MANUAL</b> Biospecimen Collection for Randomized Phase II Trial of Lutetium Lu 177 Dotatate Versus Everolimus in Somatostatin Receptor Positive Bronchial Neuroendocrine Tumors  Short Title- A021901	Version No: 2.2	Effective Date: 03/15/2024
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### 13. Document History

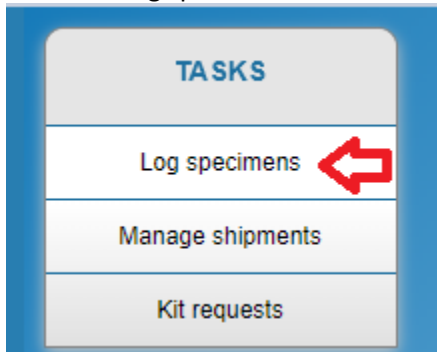
Version	Description and Justification of Change	Author	Effective Date
2.2	Added contact table. Changed 'tissue sections' to 'tissue scrolls' throughout for clarity. Added option to submit digital image of diagnostic H&E at "Prior to Initiation of Treatment" timepoint.	KL	03/15/2024
2.1	Added tumor tissue submission for biobanking at the "Prior to Initiation of Treatment" timepoint	AAW	08/15/2022
2.0	Added block alternative, removed mandatory block submission.	AAW	05/27/2022
1.3	Included provisions for shipping during warm weather months	PAA	09/01/2021
1.2	Fixed minor typos and grammatical errors	PAA	04/02/2021
1.1	Corrected shipping for frozen plasma	PAA	08/10/2020
1.0	New	GLS, PAA	06/22/2020

<b>ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY</b>	<b>CORRELATIVE SCIENCE PROCEDURE MANUAL</b> Biospecimen Collection for Randomized Phase II Trial of Lutetium Lu 177 Dotatate Versus Everolimus in Somatostatin Receptor Positive Bronchial Neuroendocrine Tumors  Short Title- A021901	Version No: 2.2	Effective Date: 03/15/2024
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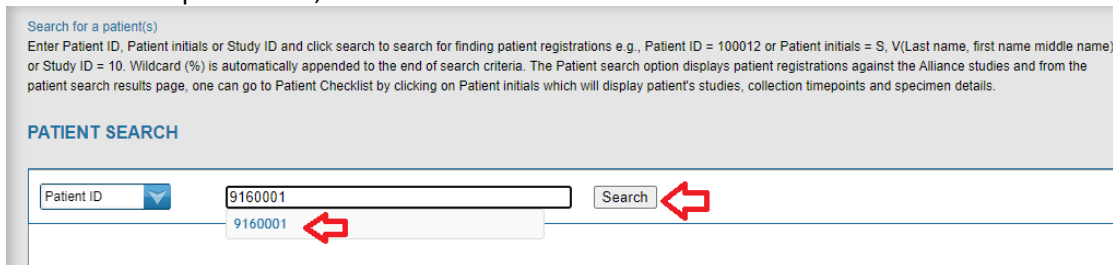
Appendix 1: Digital Pathology Image Portal Instructions

Please note that while the Study ID and specimen requirement title might be different than your study, the concept is still the same.

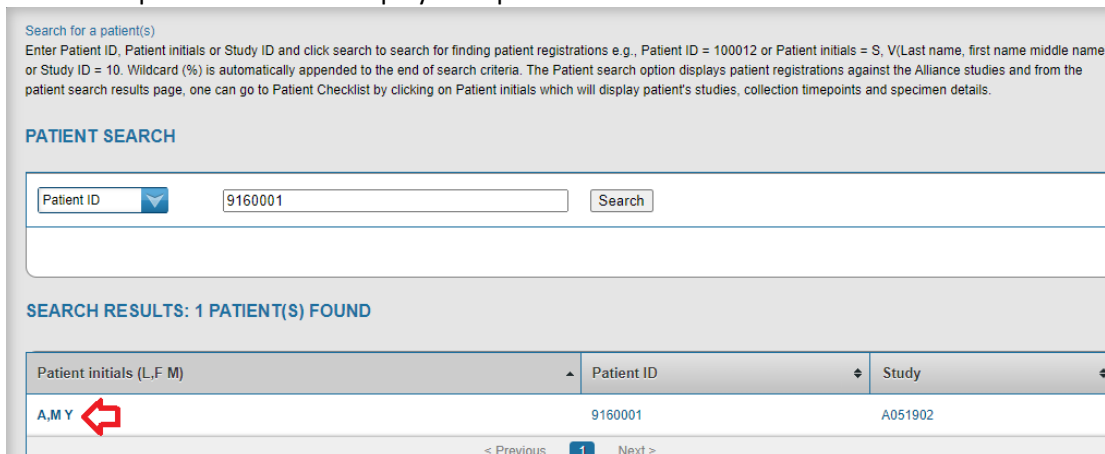
1. Login BioMS <https://bioms.wustl.edu/bioms/login>
2. Select "Log specimens" from the Task menu.



3. Enter the patient ID (obtained when registering the patient in OPEN), in the search field, select the matching ID from the drop-down list, click "Search."



4. Click the patient initials to display the Specimen Checklist view.



5. Click on the Alliance Digital Pathology Image (DPI) Portal Icon. Do not enter the slide count or collection date as only specimens in a "Pending" status can have images uploaded.

Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<b>Consented to Biobanking : Registration</b>						
<input type="checkbox"/>	A051902	FFPE Block- Tumor	1.0 count	<input type="text"/>	14 Not Collected	
<input type="checkbox"/>	A051902	Unstained Slides (4-5um)	0.0 count	<input type="text"/>	14 Pending	
<input type="checkbox"/>	A051902	5 Unstained Slides (10um)- Tumor	5.0 count	<input type="text"/>	14 Pending	
<input type="checkbox"/>	A051902	Stained Slides (4-5um)	0.0 count	<input type="text"/>	14 Pending	
<input type="checkbox"/>	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm	<input type="text"/>	14 Pending	
<input type="checkbox"/>	A051902	Scanned Slide Images	1.0 count	<input type="text"/>	14 Pending	

6. A new browser tab will open displaying the DPI Portal. This tab must remain open during the entire loading process. Closing the new browser will terminate the loading process.

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*) and click on 'Choose File' to select a file. To add more files, click on the 'Add' button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902    Patient ID: 9160001    Collection Arm: Consented to Biobanking    Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *	Upload File name	Upload progress
<input type="text"/>	<input type="text"/>	<input type="text" value="Please select"/>	<input type="button" value="Choose File"/> No file chosen		

7. Please note the instructions at the top of the page. All files must be in .SVS format and cannot exceed 5GB  
 8. Enter the last 2 digits of the Surgical Pathology Number. (Example if the SPN is 24-12345, then enter 45)

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*) and click on 'Choose File' to select a file. To add more files, click on the 'Add' button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902    Patient ID: 9160001    Collection Arm: Consented to Biobanking    Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
<input type="text" value="45"/>	<input type="text"/>	<input type="text" value="Please select"/>	<input type="button" value="Choose File"/> No file chosen

9. Enter the block ID (Example: if the slide was cut from block A2 then scanned, enter A2)

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*). Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. You can continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the naming convention in the window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
<input type="text" value="45"/>	<input type="text" value="A2"/>	Please select	<input type="button" value="Choose File"/> No file chosen

10. Select the "Stain Type" from the drop-down list.

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*). Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. You can continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the naming convention in the window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
<input type="text" value="45"/>	<input type="text" value="A2"/>	Please select	<input type="button" value="Choose File"/> No file chosen

11. Click Choose File, then select the file from your computer directory.

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*). Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. You can continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the naming convention in the window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
<input type="text" value="45"/>	<input type="text" value="A2"/>	Hematoxylin and Eosin (H&E)	<input type="button" value="Choose File"/> No file chosen

12. BioMS will then rename the file to the DPI format (StudyID\_PatientID\_Last2Digitsof SPN\_BlockID\_Stain Type\_.svs

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*) and click on 'Choose File' to select a file. To add more files, click on the 'Add' button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *	Upload File name	Upload progress
45	A2	Hematoxylin and Eosin (H&E)	Choose File patient_1_HE.svs	A051902_9160001_45_A2_HE.svs	

Add

Upload File      Cancel

13. If there are additional files to load for the patient, click Add and repeat steps 8-11

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*) and click on 'Choose File' to select a file. To add more files, click on the 'Add' button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
45	A2	Hematoxylin and Eosin (H&E)	Choose File patient_1_HE.svs
		Please select	Choose File No file chosen

Add

Upload File      Cancel

14. Once all files are selected, click "Upload File."

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*) and click on 'Choose File' to select a file. To add more files, click on the 'Add' button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
45	A2	Hematoxylin and Eosin (H&E)	Choose File patient_1_HE.svs
45	A2	Ki67 (K67)	Choose File patient_1_Ki67.svs

Add

Upload File      Cancel

15. BioMS will display a progress bar for each file. DO NOT close the DPI window as it will terminate the load process. Users can navigate to other windows during the load process.



**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*) and click on 'Choose File' to select a file. To add more files, click on the 'Add' button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902    Patient ID: 9160001    Collection Arm: Consented to Biobanking    Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *	Upload File name	Upload progress
45	A2	Hematoxylin and Eosin (H&E)	Choose File patient_1_HE.svs	A051902_9160001_45_A2_HE.svs	24%
45	A2	Ki67 (K67)	Choose File patient_1_Ki67.svs	A051902_9160001_45_A2_K67.svs	35%

Add    Upload File    Cancel

**Warning:** Please ensure that this window remains open after initiating a file transfer request. Once the file transfer is complete, you will receive a completion message on this page. At that time, you can exit and close this page. While the file transfer is in progress, feel free to continue working in BioMS or other tasks. However, please **DO NOT CLOSE THIS PAGE** until the transfer is finished.    Uploading

16. BioMS will display a successful message in the Alliance DPI portal and send an email to the user once all images are transferred.

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*) and click on 'Choose File' to select a file. To add more files, click on the 'Add' button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902    Patient ID: 9160001    Collection Arm: Consented to Biobanking    Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *	Upload File name	Upload progress
45	A2	Hematoxylin and Eosin (H&E)	Choose File patient_1_HE.svs	A051902_9160001_45_A2_HE.svs	Completed
45	A2	Ki67 (K67)	Choose File patient_1_Ki67.svs	A051902_9160001_45_A2_K67.svs	Completed

Add    Upload File    Exit

**File Upload Completed Successfully!**  
Please click on the BioMS Patient Checklist link below to mark the Digital Specimen as collected and proceed to ship it to the respective repository. If you are not currently logged into BioMS, please log in on a different tab and then click on the BioMS Patient Checklist link below to complete the Digital Specimen collection and shipment process. Thank you.  
[BioMS Patient Checklist](#)

- 17. The Alliance DPI portal window may now be closed.
- 18. Navigate back to the patient's check list view to now log the images as "collected."
- 19. Enter the number of images loaded in the "Quantity" field.
- 20. Enter the date of the procedure (biopsy, surgery) in the "Collection Date."

Registration    On Therapy

Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<b>Consented to Biobanking : Registration</b>						
<input type="checkbox"/>	A051902	FFPE Block- Tumor	1.0 count	14	Not Collected	
<input type="checkbox"/>	A051902	Unstained Slides (4-5um)	0.0 count	14	Pending	
<input type="checkbox"/>	A051902	5 Unstained Slides (10um)- Tumor	5.0 count	14	Pending	
<input type="checkbox"/>	A051902	Stained Slides (4-5um)	0.0 count	14	Pending	
<input type="checkbox"/>	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm	14	Pending	
<input checked="" type="checkbox"/>	A051902	Scanned Slide Images	2 count	10/19/2022 00:00	Pending	

21. Click the "Clip board" icon to load a digital copy of the corresponding surgical pathology report.

Registration		On Therapy				
Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<b>Consented to Biobanking : Registration</b>						
<input type="checkbox"/>	A051902	FFPE Block- Tumor	1.0 count		14 Not Collected	
<input type="checkbox"/>	A051902	Unstained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	5 Unstained Slides (10um)- Tumor	5.0 count		14 Pending	
<input type="checkbox"/>	A051902	Stained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm		14 Pending	
<input checked="" type="checkbox"/>	A051902	Scanned Slide Images	2 count	10/19/2022 00:00	14 Pending	

### SPECIMEN COMMENTS

**⚠ If you are submitting tissue from a pathology block, slides, curls, etc. PLEASE remember to include a printed, de-identified copy of the corresponding pathology report in your shipment.**

### SPECIMEN ATTACHMENTS

Title	Attachment	Action
-------	------------	--------

Path Report Patient 1 Choose File A051902

22. Click Save

Registration On Therapy

Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<b>Consented to Biobanking : Registration</b>						
<input type="checkbox"/>	A051902	FFPE Block- Tumor	1.0 count		14 Not Collected	
<input type="checkbox"/>	A051902	Unstained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	5 Unstained Slides (10um)- Tumor	5.0 count		14 Pending	
<input type="checkbox"/>	A051902	Stained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm		14 Pending	
<input checked="" type="checkbox"/>	A051902	Scanned Slide Images	2.0 count	10/19/2022 00:00	14 Collected	

Save Go to shipments

23. Click "Go To Shipments" to now create the digital shipment

Registration On Therapy

Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<b>Consented to Biobanking : Registration</b>						
<input type="checkbox"/>	A051902	FFPE Block- Tumor	1.0 count		14 Not Collected	
<input type="checkbox"/>	A051902	Unstained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	5 Unstained Slides (10um)- Tumor	5.0 count		14 Pending	
<input type="checkbox"/>	A051902	Stained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm		14 Pending	
<input checked="" type="checkbox"/>	A051902	Scanned Slide Images	2.0 count	10/19/2022 00:00	14 Collected	

Save Go to shipments

24. From the Manage Shipment page, check the box for the specimen requirement, leave the shipment default to "Auto" and click the green arrow pointing to the right.

**SPECIMENS AND SHIPMENTS**

Filter By Ship To:

**SPECIMENS FOR 9160001 (A,M Y) AND STUDY A051902**

All

<input type="checkbox"/>	Specimen ID & Title	Patient ID & Initials	Study & TimePoint
<input checked="" type="checkbox"/>	135090740 - Scanned Slide Images	9160001 (A,M,Y)	A051902 - Registration

Auto  
Manual

→

←

25. BioMS will move the specimen requirement into an appropriate shipment. The shipment ID containing the specimen requirement will be displayed at the top of the screen.

Specimen(s) added to shipment(s) [135141040]

Logged into BioMS as BRINKA Logout ? Help

Review Pending Specimens and Shipments  
Review the list of specimens and shipments pending to be shipped. To view the contents of a particular shipment, click on downward arrow icon below the box icon for the shipment. Select the shipment by clicking on the round button above the box icon for the shipment, then click on the appropriate button on the top/bottom of the shipments section to perform a particular action for the selected shipment.

**SPECIMENS AND SHIPMENTS**

Filter By Ship To:

**SPECIMENS FOR 9160001 (A,M Y) AND STUDY A051902**

All

<input type="checkbox"/>	Specimen ID & Title	Patient ID & Initials	Study & TimePoint
<input type="checkbox"/>			

Auto  
Manual

→

←

**SHIPMENTS**

Create Send Delete Print Edit

<input type="radio"/>		Shipment ID: 135141040
		Ship to: Alliance Biorepository Washington University St. Louis
		Ship method: Unspecified
		Status: Not Shipped

26. Click the radio button for the shipment, then click Send.

**SHIPMENTS**

Create Send Delete Print Edit


Shipment ID:	135141040
Ship to:	Alliance Biorepository Washington University St. Louis
Ship method:	Unspecified
Status:	Not Shipped

▼(1)


27. On the manifest page, enter your phone number, email address.
28. Select "Digital Upload" as the carrier.
29. Enter "N/A" for the tracking number.
30. Enter the date the images were transferred / uploaded as the shipment date.
31. Click Send Shipment.

Send shipment
← Back


**BioMS ShipmentID**



135141040

<b>Shipment ID</b>	135141040	<b>Status</b>	Not Shipped	<b>Carrier *</b>	Digital Upload
<b>Sender site *</b>	Washington University School of Medicine	<b>Receiver site</b>	Alliance Biorepository Washington University St. Louis	<b>Tracking number</b>	N/A
<b>From *</b>	660 South Euclid Avenue Saint Louis, Missouri 63110	<b>To</b>	425 S. Euclid Ave. RM 5120 St. Louis, Missouri 63101	<b>Shipping date *</b>	01/18/2024 
<b>Sender contact *</b>	Amy Brink	<b>Receiving site email</b>	tbank@wudosis.wustl.edu	<b>Received date</b>	
<b>Phone *</b>	999-999-9999	<b>Receiving site phone</b>	(314) 454-7615	<b>Notes</b>	
<b>Sender email *</b>	abrink@wustl.edu				

**CONTENTS**

BioMS Specimen ID	Specimen	Qty	Collection Date	Patient ID	Study ID	Epoch, Arm, CPE
 135090740	Scanned Slide Images	2.0 count	10/19/2022 00:00	9160001 (A,M Y)	A051902	Registration, Consented to Biobanking, Registration

32. Email a copy for the BioMS manifest to [alliance@email.wustl.edu](mailto:alliance@email.wustl.edu)

For additional information and screen shots please visit

<https://washu.atlassian.net/wiki/spaces/BP/pages/468844574/Alliance+Digital+Pathology+Image+Portal+DPI>