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| ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY | CORRELATIVE SCIENCE PROCEDURE MANUAL A Randomized Phase 3 Trial of Continuous vs. Intermittent Maintenance Therapy with Zanubrutinib as Upfront Treatment in Older Patients with Mantle Cell Lymphoma Short Title- A052101 | Version No: 1.4 | Effective Date: 03/01/2024 |
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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 all patients enrolled or registered on A052101. 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), 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 A052101 biospecimen collection, processing, and submission; including staff at satellite institutions.

2. Scope

This document applies to all biospecimens collected specifically for A052101 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 website and CTSU.**

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

| Protocol-related questions may be directed as follows: | |
|--|--|
| Questions | Contact (via email) |
| Questions regarding patient eligibility, treatment, and dose modification: | Study Chair: Anne Beaven, MD anne_beaven@med.unc.edu Nursing Contact: Maribeth Hohenstein, RN mahohens@unmc.edu Protocol Coordinator: Destin Carlisle dcarlisle@bsd.uchicago.edu (where applicable) Data Manager: Kayla Benson benson.kayla@mayo.edu |
| Questions related to data submission, RAVE or patient follow-up: | Data Manager: Kayla Benson benson.kayla@mayo.edu |
| Questions regarding the protocol document and model informed consent: | Protocol Coordinator: Destin Carlisle dcarlisle@bsd.uchicago.edu |
| Questions related to IRB review | Alliance Regulatory Inbox regulatory@allianceNCTN.org |
| Questions regarding CTEP-AERS reporting: | Alliance Pharmacovigilance Inbox pharmacovigilance@alliancencn.org |
| Questions regarding specimens/specimen submissions: | Alliance Biorepository at Washington University: alliance@email.wustl.edu |
| Questions regarding drug supply | McKesson Clinical Research Services |
| Questions regarding drug administration | Pharmacy Contact: Caroline Harvey, RPh caroline_harvey@dfci.harvard.edu |

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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. 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.
- 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.

5. Site Preparation

- 5.1** Please refer to A052101 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. 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.
- 5.3** Identify a reliable source of dry ice for freezing and shipping biospecimens and a -70 to -90 degree Celsius freezer (“ultralow”) in which frozen biospecimens may be stored prior to shipment.

6. Collection Schema

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

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| Time Point | Biospecimen | Quantity | Collection / Processing Method | Shipping | Notes |
|---|---|--|---|----------|-------|
| Mandatory for all patients registered to A052101 | | | | | |
| At registration | Local diagnostic slides OR Scanned Slide Images | Case dependent | Stained local diagnostic slides (9.2) Scanned Slide Images (9.6) | Ambient | 1 |
| At registration | H&E stained slide AND Unstained slides | 1 H&E stained slide AND 5 x 5 micron unstained slides | H&E stained slide AND Unstained slides (9.3) | Ambient | 1 |
| For patients in Arms A and B who consent to Biobanking | | | | | |
| At registration | Fixed tissue block OR H&E stained slide AND tissue scrolls | 1 OR 1 H&E stained slide AND 10 x 10 micron scrolls | Fixed tissue blocks (9.4) H&E stained slide AND Fixed tissue scrolls (9.5) | Ambient | 2, 4 |
| Prior to randomization | Whole blood for plasma | 6 x 1 ml aliquots | Frozen plasma (10.1) | Dry Ice | 2, 3 |
| Prior to randomization | Whole blood for "buffy coat" | 2 aliquots | "Buffy Coat" (10.2) | Dry Ice | 2, 3 |
| 6 months after randomization | Whole blood for plasma | 6 x 1 ml aliquots | Frozen plasma (10.1) | Dry Ice | 2, 3 |
| 6 months after randomization | Whole blood for "buffy coat" | 2 aliquots | "Buffy Coat" (10.2) | Dry Ice | 2, 3 |
| 12 months after randomization | Whole blood for plasma | 6 x 1 ml aliquots | Frozen plasma (10.1) | Dry Ice | 2, 3 |
| 12 months after randomization | Whole blood for "buffy coat" | 2 aliquots | "Buffy Coat" (10.2) | Dry Ice | 2, 3 |
| 24 months after randomization | Whole blood for plasma | 6 x 1 ml aliquots | Frozen plasma (10.1) | Dry Ice | 2, 3 |
| 24 months after randomization | Whole blood for "buffy coat" | 2 aliquots | "Buffy Coat" (10.2) | Dry Ice | 2, 3 |

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Notes:

1. Submission of all local diagnostic slides is required for retrospective central pathology review to confirm local diagnosis. In addition to stained diagnostic slides, one (1) H&E stained slide **AND** five (5) unstained slides from diagnostic tumor tissue must also be submitted. All slides should be submitted within 14 days of registration. Alternatively, whole slide image scan files of the stained slides in .SVS file format may be uploaded digitally to the Biorepository, see section 9.6 for additional details.
2. Collection is optional for patients but requires all sites offer to patients during consent. Please see protocol-specific consent documents.
3. Peripheral blood (EDTA) 2 x 10 ml to be processed for plasma (6 x 1-1.5 ml aliquots) and “buffy coat,” frozen on site and shipped on dry ice. Only for patients who are randomized to Arm A or Arm B. All blood collections are +/- 30 days.
4. A representative archived diagnostic tumor tissue block should be submitted, if available. If entire tissue block cannot be submitted, one H&E stained slide **AND** ten (10 um) 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. Unstained slides will not be accepted.**

7. Biospecimen Collection Kits

7.1 Blood Specimens

7.1.1 There are no “kits” provided for submission of plasma or buffy coat specimens for this study. Sites are responsible for acquiring materials for collection and shipping of these specimens to the Biorepository.

7.2 Tissue Specimens

7.2.1 There are no “kits” provided for submission of the diagnostic stained slides, H&E slide, unstained slides, blocks, or tissue scrolls for this study.

7.2.2 Tissue should be packaged to avoid breakage using a padded envelope or, preferably, a small Styrofoam container.

7.2.3 During warm weather months, fixed tissue 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.

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7.2.4 Please see Section 11 – Biospecimen Shipping for specific instructions on shipping to ABWUSTL.

7.2.5

8. Biospecimen Labeling and Tracking

- 8.1** All research biospecimens (cryovials and 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, “buffy coat”).
- 8.2** Stained local diagnostic slides and unstained tissue slides should be labeled with the Alliance patient ID number, institutional surgical pathology number (e.g. “S16-1234”), the block identifier (e.g. “A3”), the serial section number, and stain (if applicable). Provide a **de-identified copy of the surgical pathology report**, labeled with the Alliance study ID and Alliance patient ID number, corresponding to the slides submitted. Please ensure the institutional surgical pathology number and block identifier 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.
- 8.4** Do not affix any labels to vials or tubes. Label the collection containers directly with the marking pen.
- 8.5** All biospecimens that are collected and sent to the Alliance Biorepository 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@alliancencn.org.

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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 Please refer to protocol-specific instructions for procedures related to actual tissue procurement from individual participants. 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.

9.2 Stained Local Diagnostic Slides

9.2.1 For patients who consent to A052101, submission of all local diagnostic slides from tumor tissue is required for retrospective central pathology review to confirm diagnosis. Sites should submit any stained slides produced for histopathologic diagnosis.

9.2.2 Any stained slide submitted must be labeled as indicated in **section 8.2**.

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

9.3 H&E Stained Slide and Unstained Slides

9.3.1 In addition to stained diagnostic slides, 1 H&E stained slide AND 5 (5 micron) unstained slides **from the same block** must be submitted.

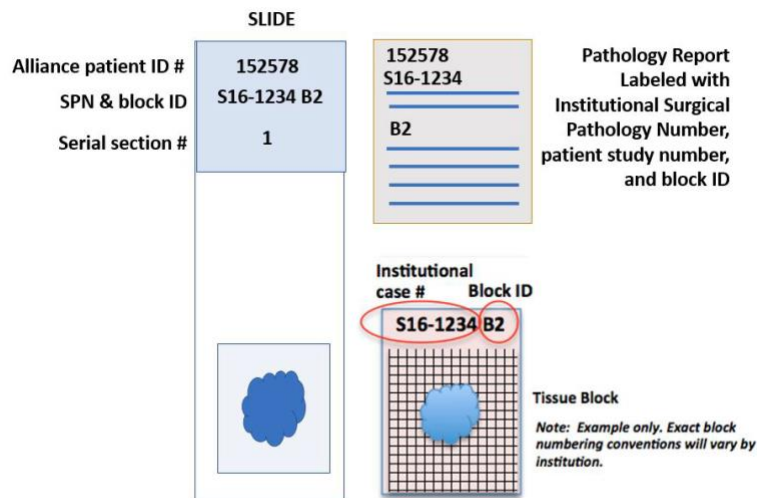
9.3.2 Cut and perform routine H&E stain on a single section from the tumor tissue block.

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- 9.3.3** Following sectioning of the slide for H&E staining, 5 additional serial tissue sections should be cut fresh from the same formalin fixed, paraffin embedded tissue block.
- 9.3.4** Cut sections at 5 micron thickness onto charged glass slides.
- 9.3.5** Ensure each slide is labeled with the Alliance patient ID number, the institutional surgical pathology number and block ID, and the slide serial section number (1, 2, 3, etc.).
- 9.3.6** Do not label slides with adhesive labels. Write or print information on the textured surface of the slide with indelible, solvent-resistant ink.
- 9.3.7** No adhesives or other additives should be used in the water bath.
- 9.3.8** Mount only one tissue section per slide. Make certain sections are placed on the painted / textured side of the slide
- 9.3.9** When placing the sections onto the slides, ensure that the tissue is placed on the bottom third of the slide. Ensure that each serial section from the block is placed in the same orientation on each slide.

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9.3.10 See figure below for proper mounting and labeling.



9.3.11 Air dry slides for 12-24 hours prior to shipping.

9.3.12 Use slide mailers or a slide box to ship slides. Slides should not be touching each other. Ensure that slides from only one patient are placed in one slide mailer.

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

9.3.14 **During warm weather months, 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 Fixed Tissue Block

9.4.1 For patients who consented to biobanking for A052101, a representative archived diagnostic block with adequate tumor should be submitted, if applicable.

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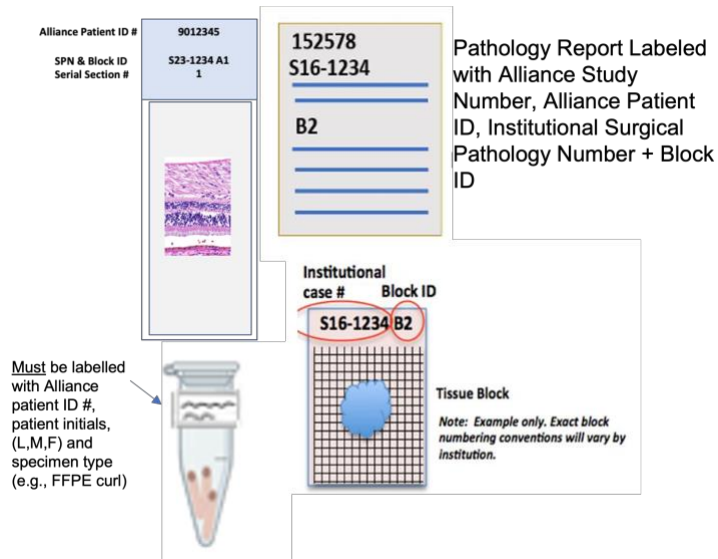
9.4.2 Any clinical surgical pathology block that is submitted for research studies will not be exhausted or rendered unsuitable for future diagnostic use. Any clinical surgical pathology block that is submitted will be returned within ten working days of written request, when needed for clinical management 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 endpoints have been met.

9.4.3 Include a copy of a de-identified pathology report with block submission.

9.5 H&E Stained Slide and Fixed Tissue Scrolls

9.5.1 In cases where an institution is unwilling or unable to submit a tissue block, a single H&E stained slide for references and serial tissue sections (scrolls, ribbons, curls) from the same block may be submitted.

9.5.2 Cut and perform routine H&E stain on a single section from the tumor tissue block. See figure below for proper mounting and labeling.



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- 9.5.3** 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 8**.
- 9.5.4** Include a **de-identified copy of the surgical pathology report** with all tissue submissions.

9.6 Scanned Slide Images

- 9.6.1** 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.
- 9.6.2** 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.
- 9.6.3** 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.
- 9.6.4** 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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- 9.6.5** 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.
- 9.6.6** 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 DPIIP.
- 9.6.7** Once the images have been uploaded, site staff should send an electronic copy of the manifest to alliance@email.wustl.edu.
- 9.6.8** 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). Questions related to BioMS should be addressed to the BioMS help desk (bioms@alliancencn.org)

10. Blood Collection Methods

10.1 Plasma Processing

- 10.1.1** Collect 10 ml of whole blood by standard venous phlebotomy technique into each of the purple top (EDTA) tubes. A total of 20 ml of whole blood should be collected into the EDTA tubes (2 x 10 ml). Following collection, invert tubes 10 times.
- 10.1.2** Within 2 hours of collection, spin the vacutainer tubes at room temperature in a clinical centrifuge at 2500 xG for 15 minutes.

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- 10.1.3** Carefully remove the plasma layer from each vacutainer tube (~3—5 ml in volume per tube), without touching the white, buffy coat layer, and transfer to new 15 ml conical centrifuge tubes. Keep the vacutainer tubes containing the white, buffy coat layers for white blood cell isolation (**section 10.2**).
- 10.1.4** Spin the centrifuge tubes containing plasma at room temperature in a clinical centrifuge at 2500 xG for 15 minutes.
- 10.1.5** Label 6 cryovials as instructed in **section 8**. Make certain each vial is labeled completely and identically.
- 10.1.6** Carefully remove 6 ml of plasma (without touching the pellet) and divide into six (6) 2 ml labeled cryovials. Each aliquot should be between 1—1.5 ml in volume.
- 10.1.7** 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. Frozen plasma should be shipped to the Biorepository within 30 days of collection. Batch shipment is allowed.

10.2 “Buffy Coat” (White Blood Cell) Processing

- 10.2.1** Follow procedures in **section 10.1** for collecting and processing plasma from EDTA tubes.
- 10.2.2** Label 2 cryovials as instructed in **section 8**.
- 10.2.3** After removing the plasma, carefully remove the white, “buffy coat” white blood cell layer, avoiding the red blood cell mass as much as possible.

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Transfer the buffy coat layer (approximately 0.2 – 0.5 ml) from EDTA tubes into the labeled cryovials. Immediately freeze the cryovials of buffy coat on dry ice or in liquid nitrogen vapor. Do NOT freeze buffy coat cells by placing a warm tube in a -70 to -90 degree Celsius ultralow freezer. Once completely frozen, the cryovials containing the buffy coat cells may be stored at -70 to -90 degrees C until ready for shipment on dry ice. Frozen buffy coat should be shipped to the Biorepository within 30 days of collection. Batch shipment is allowed.

10.2.4

11. Biospecimen Shipping

11.1 Overview

- 11.1.1 Frozen plasma and buffy coat aliquots should be placed in a biohazard bag inside of a Styrofoam cooler and covered with 3 to 4 lbs (2 kg) of commercially-prepared dry ice. Pellets or chunks are preferred. Make sure the box is filled with dry ice and the weight of the dry ice is noted on the dry ice label on the outside of the shipping container. It is the local sites’ responsibility to obtain dry ice when shipping frozen specimens. Specimens should be shipped according to IATA guidelines. **Frozen aliquots should be shipped to the Biorepository within 30 days of collection. Batch shipment of frozen aliquots is allowed.**
- 11.1.2 A completed copy of the BioMS packing manifest must accompany all shipments. 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 If sending tissue, include a copy of the de-identified surgical pathology report.
- 11.1.4 **Biospecimens should be shipped Monday—Thursday only. Do not ship on Friday, Saturday, Sunday or the day before a nationally recognized holiday.**

11.2 Shipping to ABWUSTL

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11.2.1 Ship container according to IATA guidelines and standard institutional policies via **FedEx priority overnight shipping.**

Ship to:

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

12. 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 (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** Aliquoted biofluids will be stored under liquid nitrogen vapor.

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12.7 All biospecimens will remain in storage until additional processing or review is requested in writing by the appropriate protocol PI.

13. Document History

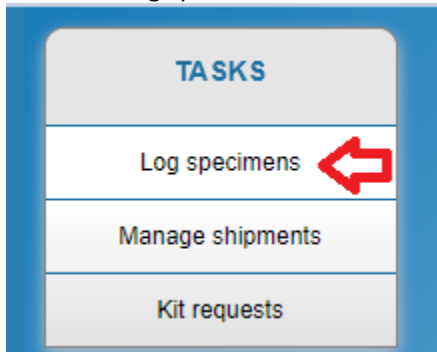
| Version | Description and Justification of Change | Author | Effective Date |
|---------|--|--------|----------------|
| 1.4 | Updated digital image submission instructions. Added fixed tissue block and alternatives to registration biobanking. | KL | 03/01/2024 |
| 1.3 | Changed buffy coats from 3 to 2 aliquots per collection. Added digital image submission as an alternative to mandatory diagnostic slide submission. Added window of submission to mandatory tissue slides at registration. | KL | 11/15/2023 |
| 1.2 | Added contact table, added warm weather shipping instructions | KL | 09/08/2023 |
| 1.1 | Clarified blood collection windows | AAW | 03/09/2023 |
| 1.0 | New | AAW | 02/13/2023 |

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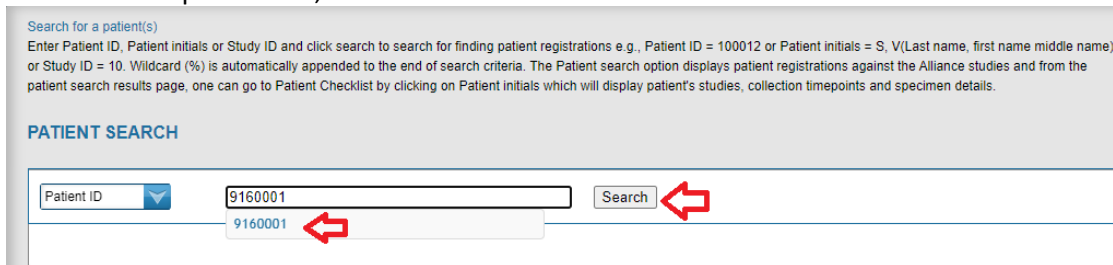
Appendix 1 – Digital Pathology Image Portal Instructions

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

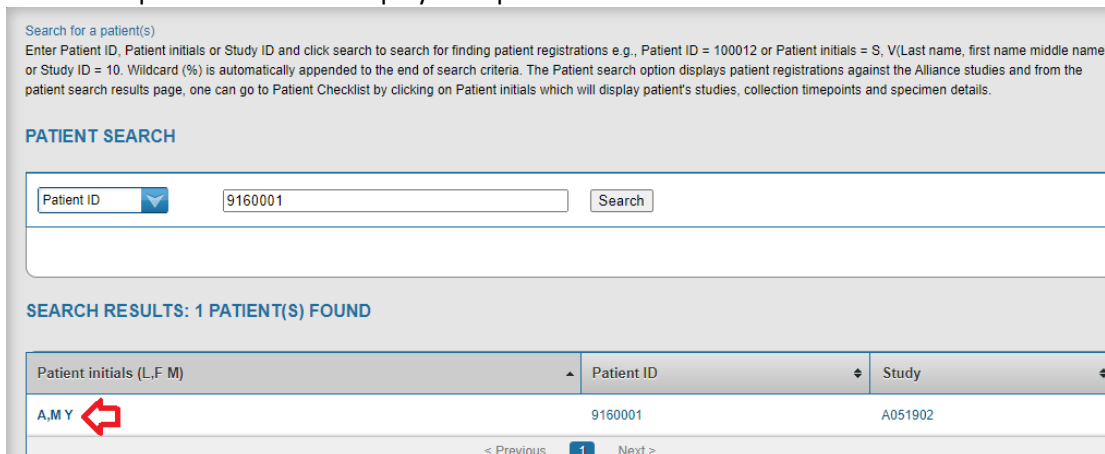
1. Login BioMS <https://bioms.wustl.edu/bioms/login>
2. Select "Log specimens" from the Task menu.



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 |
|---|---------|-----------------------------------|-----------|-----------------|---------------|---------|
| Consented to Biobanking : Registration | | | | | | |
| <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 type="checkbox"/> | A051902 | Scanned Slide Images | 1.0 count | 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 |
|--|---------------------------------|-------------------------------|---|------------------------------|-----------------|
| <input type="text" value="45"/> | <input type="text" value="A2"/> | Hematoxylin and Eosin (H&E) ▼ | <input type="button" value="Choose File"/> patient_1_HE.svs | A051902_9160001_45_A2_HE.svs | |

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 *). 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" value="A2"/> | Hematoxylin and Eosin (H&E) ▼ | <input type="button" value="Choose File"/> patient_1_HE.svs |
| <input type="text"/> | <input type="text"/> | Please select ▼ | <input type="button" value="Choose File"/> No file chosen |

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 *). 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" value="A2"/> | Hematoxylin and Eosin (H&E) ▼ | <input type="button" value="Choose File"/> patient_1_HE.svs |
| <input type="text" value="45"/> | <input type="text" value="A2"/> | Ki67 (K67) ▼ | <input type="button" value="Choose File"/> patient_1_Ki67.svs |

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 |
|---|---------|-----------------------------------|-----------|------------------|---------------|---------|
| Consented to Biobanking : Registration | | | | | | |
| <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 |
| Consented to Biobanking : Registration | | | | | | |
| <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 |
|--|--|--------|
| <input type="text" value="Path Report Patient 1"/> | <input type="button" value="Choose File"/> A051902 | |
| <input type="button" value="Add more"/> | | |

22. Click Save

Registration On Therapy

| Collected | Study | Specimen expected | Quantity | Collection date | Status | Actions |
|---|---------|-----------------------------------|-----------|------------------|------------------|---------|
| Consented to Biobanking : Registration | | | | | | |
| <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 |
|---|---------|-----------------------------------|-----------|------------------|------------------|---------|
| Consented to Biobanking : Registration | | | | | | |
| <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"/> | <p>Shipment ID: 135141040</p> <p>Ship to: Alliance Biorepository Washington University St. Louis</p> <p>Ship method: Unspecified</p> <p>Status: Not Shipped</p> |
|-----------------------|---|

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

SHIPMENTS


Create Send Delete Print Edit

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


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

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

For additional information and screen shots please visit

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