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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 A032002. 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 A032002 biospecimen collection, processing, and submission; including staff at satellite institutions.

2. Scope

This document applies to all biospecimens collected specifically for A032002 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
H&E	Hematoxylin and Eosin

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4. Contact Information

Questions	Contact (via email)
	Study Chair: Himanshu Nagar, MD
	(hnagar@med.cornell.edu)
	Nursing Contact: Archana Ajmera
Questions regarding patient eligibility,	(<u>aajmera@health.ucsd.edu</u>)
treatment, and dose modification:	Protocol Coordinator: Shiva Baghaie, MPH
	(sbaghaie@bsd.uchicago.edu)
	Data Manager: Pamela Fain-Pribyl
	(fainpribyl.pamela@mayo.edu)
Questions related to data submission, RAVE or	Data Manager: Pamela Fain-Pribyl
patient follow-up:	(fainpribyl.pamela@mayo.edu)
Questions regarding the protocol document	Protocol Coordinator: Shiva Baghaie, MPH
and model informed consent:	(sbaghaie@bsd.uchicago.edu)
Overstiens related to IDD review	Alliance Regulatory Inbox
Questions related to IRB review	(regulatory@allianceNCTN.org)
Questions regarding CTEP-AERS reporting:	Alliance Pharmacovigilance Inbox
Questions regarding CTEF-AENS reporting.	(pharmacovigilance@alliancenctn.org)
Questions regarding specimens/specimen	Alliance Biorepository
submissions:	(alliance@email.wustl.edu)
Questions regarding drug administration	Pharmacy Contact: Jerline Hsin
	(jhsin@coh.org)

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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 A032002 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 biospecimen collection and processing methods and specific shipping procedures below.

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Time Point	Biospecimen	Quantity	Collection / Processing Method	Shipping	Notes
			Method		
	Mandatory	for all patients register	ed to A032002		
After registration &	Diagnostic H&E slides for	Case dependent	H&E Slides for	Ambient	1
prior to C1D1	histopathology review		Histopathology Review		
	<u>OR</u>		(9.2)		
	Scanned Slide Images				
				N/A	
			Scanned Slide Images		
			(9.5)		
	For patient	s consented to A03200	02 biobanking		
After registration &	Fixed tissue block- tumor	1	Fixed tissue blocks (9.3)	Ambient	2, 4
prior to C1D1					
After registration &	H&E stained slide	1 H&E Stained Slide	Fixed tissue slides (9.4)	Ambient	2, 4
prior to C1D1	AND	<u>And</u>			
	5 um unstained slides	3 (5 um)			
	AND	Unstained Slides			
	10 um unstained slides	AND			
		20-25 (10 um) Unstained			
		Slides			
After registration &	Whole blood (EDTA) for	6 x 1 ml aliquots	Frozen plasma (10.1)	Dry Ice	2, 3, 7
prior to C1D1	plasma				
After registration &	Whole blood (EDTA) for	2 aliquots	"Buffy Coat" (10.2)	Dry Ice	2, 3, 7
prior to C1D1	"buffy coat"				
After registration &	Urine (EDTA)	2 x 10 ml	Urine (11.0)	Cold Pack	2, 3
prior to C1D1					
6 weeks after	Whole blood (EDTA) for	6 x 1 ml aliquots	Frozen plasma (10.1)	Dry Ice	2
registration	plasma				
6 weeks after	Urine (EDTA)	2 x 10 ml	Urine (11.0)	Cold Pack	2
registration					
3 months after	Whole blood (EDTA) for	6 x 1 ml aliquots	Frozen plasma (10.1)	Dry Ice	2
registration	plasma				
3 months after	Urine (EDTA)	2 x 10 ml	Urine (11.0)	Cold Pack	2
registration					
	1	1		1	
Disease Progression	Whole blood (EDTA) for plasma	6 x 1 ml aliquots	Frozen plasma (10.1)	Dry Ice	2, 5, 6
Disease Progression	Urine (EDTA)	2 x 10 ml	Urine (11.0)	Cold Pack	2, 5

Biospecimen C	CORRELATIVE SCIENCE PROCEDURE MANUAL Biospecimen Collection for Phase II Randomized Trial of Immunotherapy versus	Version No: 4.1	Effective Date: 02/01/2024
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Notes:

- 1. Collection is mandatory for all patients registered to A032002. Please refer to **section 9.2** for additional details. Alternatively, scanned slide image files of the stained slides in .SVS file format may be uploaded digitally to the Biorepository, see section 9.5 for additional details.
- 2. All participating institutions must ask patients for their consent to participate in the banking of their specimens for future correlative studies, although patient participation is optional.
- 3. Should be collected before patient receives first dose of study drug, recommend on the same day of registration.
- 4. The study protocol requests a representative, archived tumor tissue block from either the metastatic biopsy or surgical specimen for submission, if available. If entire tissue block cannot be submitted, 1 H&E stained slide AND three (5 um) AND 20-25 (10 um) unstained slides will be accepted as an alternative. If tissue is limited, please submit H&E and as many unstained slides as possible. BLOCK SUBMISSION IS STRONGLY PREFERRED.
- 5. Progression samples may be collected and submitted up to 1 month after progression.
- 6. Whole blood (EDTA tubes) for plasma specimen submission should continue to be collected if there is early discontinuation of protocol therapy until disease progression.
- 7. Peripheral blood (EDTA) 2 x 10 ml to be processed for plasma (6 x 1 ml aliquots) and "buffy coat," frozen on site and shipped on dry ice.

7. Biospecimen Collection Kits

- 7.1 There are no "kits" provided for submission of blood, tissue, or urine specimens for this study. Sites are responsible for acquiring materials for collection and shipping of these specimens to the Biorepository.
- 7.2 Please see Section 12 Biospecimen Shipping for specific instructions on shipping to ABWUSTL.

8. Biospecimen Labeling and Tracking

8.1 All research biospecimens (vacutainer tubes, 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). Specimen labels must match BioMS records.

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- 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. If tissue slides are being submitted instead of the block, each tissue section slide should be labeled with the Alliance patient ID number, institutional surgical pathology number, the block identifier, and the serial section number (if applicable). Please do NOT use sticky labels on slides. Provide a de-identified copy of the surgical pathology report, labeled with the Alliance patient ID number, corresponding to the blocks or slides submitted. 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.
- **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 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.

In the event that BioMS cannot be accessed, please complete a BioMS Specimen Log and Shipping Manifest form which can be found herehttp://tinyurl.com/alliancebiomscontingency.

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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, or tumor 'debulking') 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 H&E Stained Slides for Central Pathology Review

- **9.2.1** Submission of diagnostic H&E stained slides from tumor tissue is required for retrospective central pathology review to confirm local diagnosis. Sites should submit H&E stained slides to the Biorepository.
- **9.2.2** Any stained slides submitted must be labeled as indicated in **section 8**.
- 9.2.3 Include a copy of a de-identified pathology report with all slide submissions.

9.3 Diagnostic Pathology Fixed Tissue Block

9.3.1 This protocol requests submission of one representative, diagnostic pathology, formalin fixed paraffin embedded block containing urothelial tissue from the metastatic biopsy or surgical specimen.

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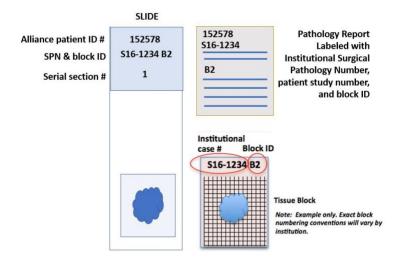
- 9.3.2 Any clinical surgical pathology block that is submitted for research studies will not be exhausted or rendered unsuitable for future diagnostic use. Any clinical surgical pathology block that is submitted will be returned within ten working days of written request, when needed for clinical management 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, the institution may instead submit unstained slides (see section 9.4). <u>BLOCK SUBMISSION IS STRONGLY</u> PREFERRED.
- 9.4 Fixed Tissue slides from Diagnostic Fixed Tissue Block
 - 9.4.1 In cases where institutions are unable or unwilling to submit the requested tissue block, a set of unstained slides may be submitted as an alternative. An H&E stained slide should be from the same block from which the unstained slides were cut. If fewer than the requested number of unstained slides can be submitted, please submit as many as possible. Please follow the procedures below for submitting unstained tissue slides. If your pathology department is unwilling or unable to follow these tissue-sectioning instructions, please consider submission of a tissue block, which can be cut at the biorepository and returned to your institution at a later date.

# of slides	Section thickness	Slide type	Purpose
3	5 micron	Positively Charged	СуТОБ
20-25	10 micron	Positively Charged	RNA, DNA

9.4.2 Serial tissue sections should be cut fresh at 5 or 10 micron onto positively charged slides.

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- **9.4.3** Ensure that each slide is labeled with the Alliance patient ID number, the institutional surgical pathology number and block identifier, and the slide serial section number (1, 2, 3, etc.).
- **9.4.4** Do not label slides with adhesive labels. Write or print information on the textured surface of the slide with indelible, solvent-resistant ink. Labels must be xylene resistant.
- **9.4.5** No adhesives or other additives should be used in the water bath.
- **9.4.6** Mount only one tissue section per slide. Make certain sections are placed on the painted / textured side of the slide.
- **9.4.7** 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.
- **9.4.8** See figure below for proper mounting and labeling.



9.4.9 Air dry slides for 12-24 hours prior to shipping. Do not oven dry slides.

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- **9.4.10** 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.
- **9.4.11** A de-identified surgical pathology report should accompany slide submission.

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 <u>Scanned slide images should not contain PHI</u> (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.
- 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 <u>must</u> 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.

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- **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.
- **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). Questions related to BioMS should be addressed to the BioMS help desk (bioms@alliancenctn.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 two purple top (EDTA) tubes (total volume, 20 ml). Invert tubes 10 times.
- **10.1.2** Within 30 minutes of collection, spin the vacutainer tubes at room temperature in a clinical centrifuge at 2500 xG for 15 minutes.
- 10.1.3 Carefully remove the plasma layer (~3—5 ml in volume) from each tube, without touching the white, buffy coat layer, and transfer to new 15 ml conical centrifuge tubes. If collected at a timepoint which requests submission of buffy coat, the vacutainer tube containing the buffy coat layer should be retained and processed following instructions in 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.

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- **10.1.6** Carefully remove 6 ml of plasma (without touching the pellet) and divide into 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.

10.2 "Buffy Coat" (White Blood Cell) Processing

- **10.2.1** Follow procedures in **section 10.1** for collecting and processing plasma from EDTA tube.
- **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.
- 10.2.4 Transfer the buffy coat layer (approximately 0.2 0.5 ml) from EDTA tube 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.

11. Urine Collection

- **11.1** Instruct patients to collect approximately 50 ml of urine into a clean specimen cup.
- **11.2** Within 60 minutes of collection, distribute 20 ml of urine into 2 x 10 ml EDTA vacutainer tubes. Remaining urine may be discarded following standard institutional procedures.
- 11.3 Urine in EDTA preservative may be held for up to 72 hours at 4 degrees Celsius (i.e. refrigerated) prior to shipping. Urine tubes should be shipped on a cold pack to maintain temperature between 2—15 degrees Celsius.

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12. Biospecimen Shipping

12.1 Overview

- 12.1.1 Place the original, completed copy of the BioMS packing manifest in the shipment. Do not send specimens without a completed BioMS Packing Manifest or substitute "BioMS Downtime Form." Biospecimens cannot be accepted without this completed form. If sending tissue, include a copy of the de-identified surgical pathology report.
- **12.1.2** Blood tubes should be packaged to avoid breakage using a padded envelope or, preferably, a small Styrofoam container.
- **12.1.3** Urine tubes should be packaged in an insulated container along with a cold pack to maintain temperature of 2—15 degrees Celsius while shipping. Urine may be held for up to 72 hours following collection.
- 12.1.4 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. If sending specimens from multiple patients within a single shipment, please ensure all specimens are properly labeled and logged in the BioMS system. Specimens from each individual patient should be placed into their own biohazard bag that is clearly labeled with the Alliance patient ID number. The accompanying BioMS manifest should be sealed within each individual bag.

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- **12.1.5** Blocks and slides should be packaged to avoid breakage using a padded envelope or, preferably, a small Styrofoam container. 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 (77 degrees F) that may melt paraffin and damage the tissue specimens.
- 12.1.6 All biospecimens should be shipped within the timeframes indicated above in sections 9, 10, and 11. If collected biospecimens cannot be shipped within the specified timeframe (e.g. Friday Saturday or Holiday collections), please contact the Alliance Biorepository Program Manager: 1-314-747-4402 or alliance@email.wustl.edu for further instructions, at least 24 hours prior to anticipated collection.
- 12.1.7 <u>Do not ship on Friday, Saturday, Sunday or the day before a nationally recognized holiday.</u>

12.2 Shipping to ABWUSTL

12.2.1 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 Univ. School of Medicine 425 S. Euclid Ave. Room 5120

St. Louis, MO 63110-1005

Phone: 314-454-7615

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13. ABWUSTL Biospecimen Receipt and Quality Assurance Measures

- **13.1** Upon receipt, all biospecimens will be accessioned into the TPC informatics system, OpenSpecimen.
- **13.2** All biospecimens will be logged, associated, and tracked by the unique patient biopsy control number.
- **13.3** 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.
- **13.4** 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.
- **13.5** 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.
- **13.6** Aliquoted biofluids will be stored under liquid nitrogen vapor.
- **13.7** All biospecimens will remain in storage until additional processing or review is requested in writing by the appropriate protocol PI.

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14. Document History

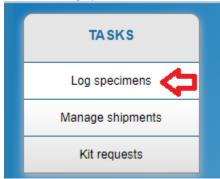
Version	Description and Justification of Change	Author	Effective Date
4.1	Updated digital image alternative	KL	02/01/2024
	instructions.	5.0.4.0	10/15/0000
4.0	Updated trial title	PAA / KL	12/15/2023
	Updated collection to remove PD-L1		
	Added protocol contacts to section 4		
	Changed Streck tubes to EDTA		
	Removed kits		
	Added collection of buffy coat at single		
	timepoint		
	Added digital image alternative for		
	diagnostic H/E submission		
3.1	Changed address of CellCarta (formerly	AAW	09/30/2022
	HistoGeneX)		
3.0	Edited block alternative footnote to be	AAW	07/25/2022
	consistent with protocol.		
2.1	Updated assay lab name from CellCarta to	PAA	11/29/2021
	CellCarta (formerly HistoGeneX)		
2.0	Updated assay lab name from HistoGeneX	PAA	11/24/2021
	to CellCarta		
	Include new version of requisition form		
1.0	New	PAA	10/04/2021

	CORRELATIVE SCIENCE PROCEDURE MANUAL Biospecimen Collection for Phase II Randomized Trial of Immunotherapy versus	Version No: 4.1	Effective Date: 02/01/2024
ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY	Immunotherapy and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (IMMORTAL) Short Title- A032002	Replaces: 4.0	Page 17 of 17

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.

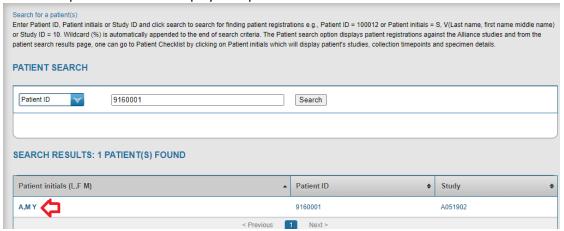
- 1. Login BioMS https://bioms.wustl.edu/bioms/login
- 2. Select "Log specimens" from the Task menu.



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."



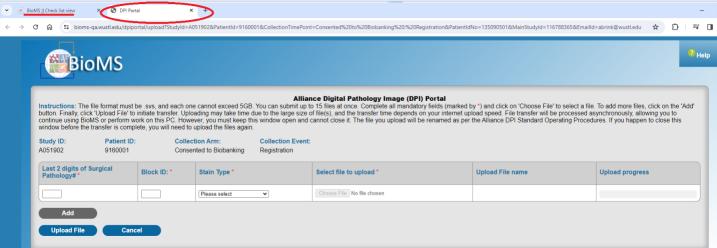
4. Click the patient initials to display the Specimen Checklist view.



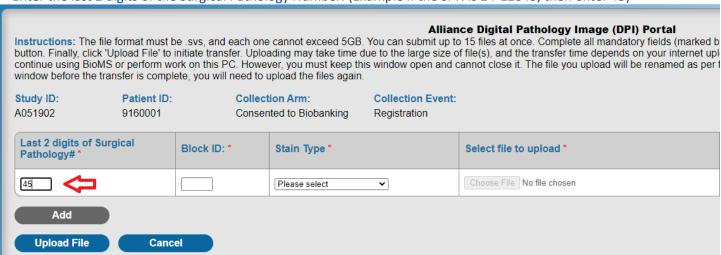
5. Click on the Alliance Digital Pathology Image (DPI) Portal Icon. Do not enter the slide count or collection date as only specimens in a "Pending" status can have images uploaded.



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.



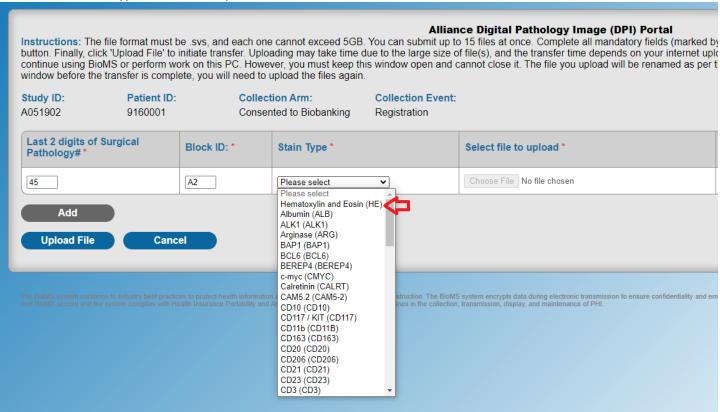
- 7. Please note the instructions at the top of the page. All files must be in .SVS format and cannot exceed 5GB
- 8. Enter the last 2 digits of the Surgical Pathology Number. (Example if the SPN is 24-12345, then enter 45)



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 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 uplo 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 window before the transfer is complete, you will need to upload the files again. Patient ID: **Collection Event:** Study ID: Collection Arm: A051902 9160001 Consented to Biobanking Registration Last 2 digits of Surgical Block ID: * Stain Type * Select file to upload * Pathology# 3 Choose File No file chosen 45 A2| < Please select Add Upload File Cancel

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



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

Alliance Digital Pathology Image (DPI) Portal bmit up to 15 files at once. Complete all mandatory fields (

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 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 up 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 window before the transfer is complete, you will need to upload the files again.

Study ID: A051902	Patient ID: 9160001		tion Arm: nted to Biobanking	Collection Event: Registration	
Last 2 digits of Surg Pathology#*	jical	Block ID: *	Stain Type *		Select file to upload *
45		A2	Hematoxylin and Eosin	(HIV)	Choose File No file chosen
Add					
Upload File	Canc	el			

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: Patient ID: Collection Arm: Collection Event: A051902 9160001 Consented to Biobanking 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 (HI ▼	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

button. Finally, click 'Upload continue using BioMS or per	File' to initiate tran	sfer. Uploading may take time due	Alliance Digital Pathology Image (DPI) Portal fou can submit up to 15 files at once. Complete all mandatory fields (marke to the large size of file(s), and the transfer time depends on your internet window open and cannot close it. The file you upload will be renamed as proceed to the control of the contr
Study ID: Pati	ient ID:	Collection Arm:	Collection Event:
	0001	Consented to Biobanking	Registration
Last 2 digits of Surgical Pathology#*	Block ID: *	Stain Type *	Select file to upload *
45	A2	Hematoxylin and Eosin (HI ✔	Choose File patient_1_HE.svs
>		Please select 🔻	Choose File No file chosen
Add	-		
Upload File	Cancel		

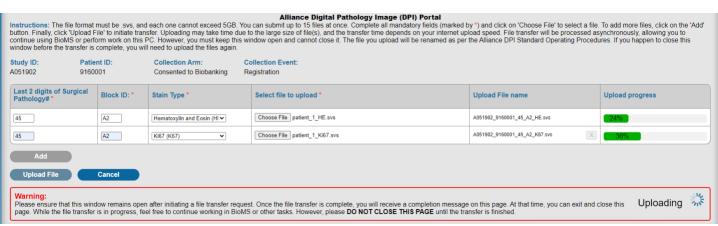
14. Once all files are selected, click "Upload File."

Alliance Digital Patho

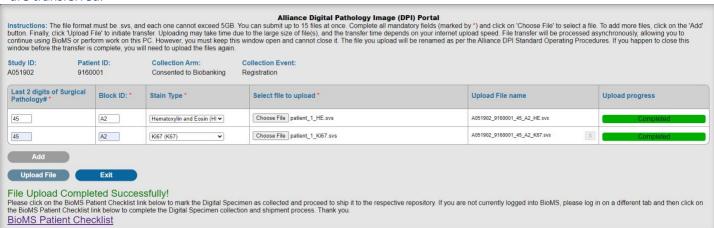
Instructions: The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. C button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the tra continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The window before the transfer is complete, you will need to upload the files again.

Study ID: A051902	Patie 91600			Collection Event: Registration
Last 2 digits of Sur Pathology#*	gical	Block ID: *	Stain Type *	Select file to upload *
45		A2	Hematoxylin and Eosin (HI 🗸	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.



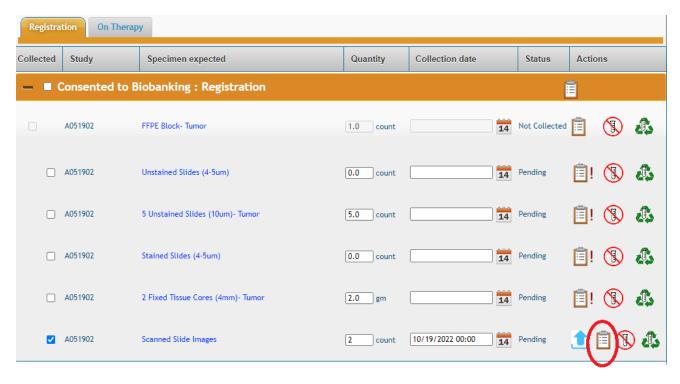
16. BioMS will display a successful message in the Alliance DPI portal and send an email to the user once all images are transferred.



- 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."

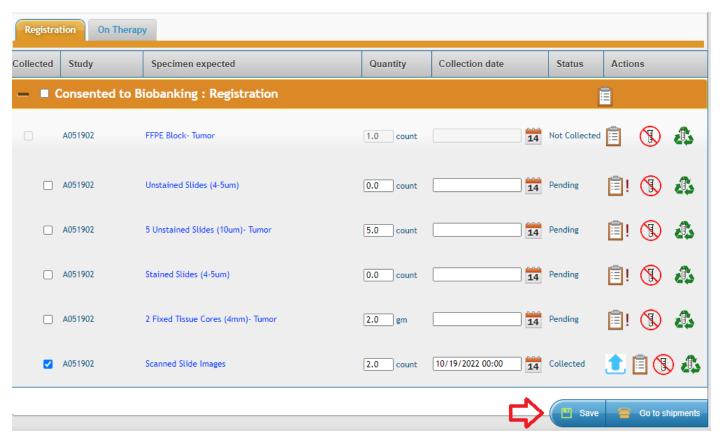


21. Click the "Clip board' icon to load a digital copy of the corresponding surgical pathology report.

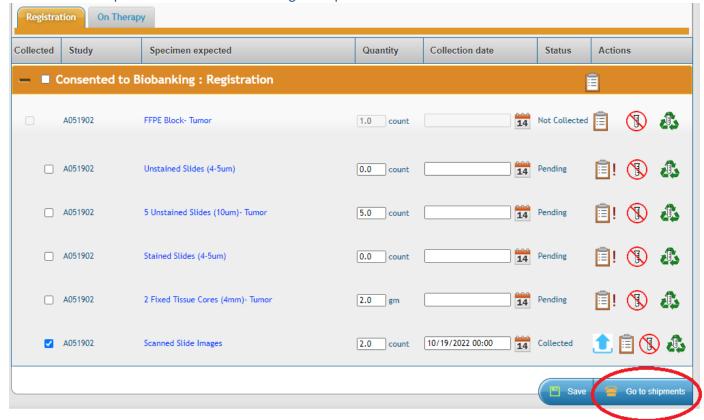


If you are submitting to	tissue from a pathology block, slides, cur	ls, etc. PLEASE
If you are submitting to remember to include report in your shipme	tissue from a pathology block, slides, cur a printed, de-identified copy of the corre nt.	ls, etc. PLEASE esponding patholog
If you are submitting to remember to include report in your shipme	tissue from a pathology block, slides, cur a printed, de-identified copy of the corre nt.	ls, etc. PLEASE esponding pathology
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SPECIMEN ATTACHMENT Title Path Report Patient 1	Attachment	
report in your shipme SPECIMEN ATTACHMENT Title	Attachment	

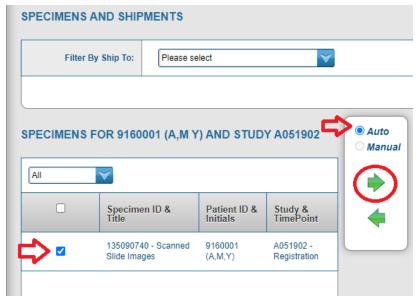
22. Click Save



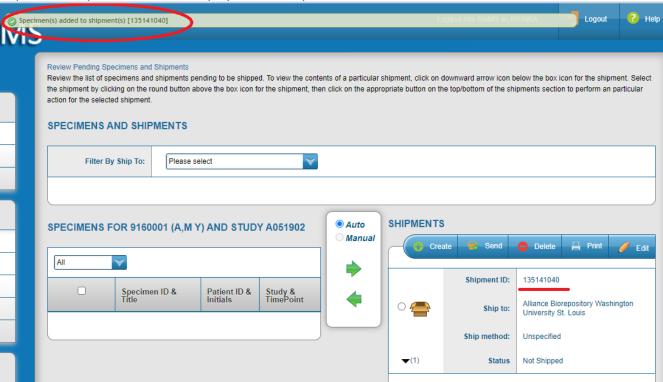
23. Click "Go To Shipments" to now create the digital shipment



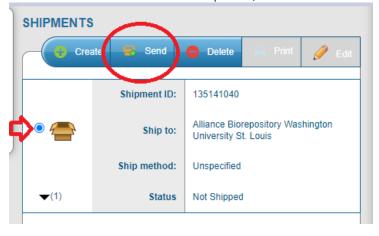
24. From the Manage Shipment page, check the box for the specimen requirement, leave the shipment default to "Auto" and click the green arrow pointing to the right.



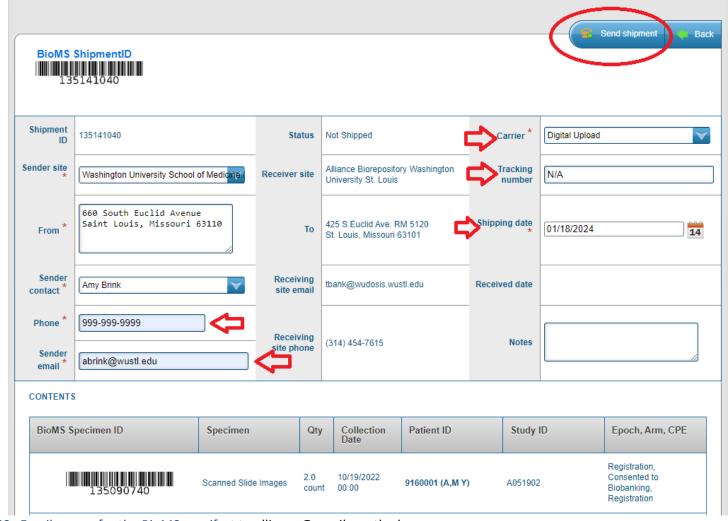
25. BioMS will move the specimen requirement into an appropriate shipment. The shipment ID containing the specimen requirement will be displayed at the top of the screen.



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



- 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.



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