	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		
		Replaces:	Page
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	2.3	1 of 17
	CD30 negative peripheral T-cell lymphomas	2.5	10117
	Short Title- A051902		

CORRELATIVE SCIENCE PROCEDURE MANUAL

1. Purpose

This document describes the procedures required for the collection, shipping, and processing of biospecimens that are being submitted for patients enrolled or registered on A051902. This document also describes the procedures that will be followed subsequent to the receipt of biospecimens by the Alliance Biorepository at Washington University in St. Louis (ABWUSTL) 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 A051902 biospecimen collection, processing, and submission, including staff at satellite institutions.

2. Scope

This document applies to all biospecimens collected specifically for the A051902 clinical trial study. Please refer to the trial protocol-specific language for additional details regarding eligibility, participant enrollment, and data submission. 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
IHC	Immunohistochemistry

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P	D 1	
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	Replaces:	Page
TRIALO IN ONCOLOGI	CD30 negative peripheral T-cell lymphomas	2.3	2 of 17
	Short Title- A051902		

4. Contact Information

Protocol-related questions may be directed as follows:			
Questions	Contact (via email)		
	Study Chair: Neha Mehta-Shah, MD, MSCI		
	mehta-n@wustl.edu		
	Nursing Contact: Maribeth Hohenstein, RN		
Questions regarding patient eligibility, treatment,	mahohens@unmc.edu		
and dose modification:	Protocol Coordinator: Destin Carlisle		
	dcarlisle@bsd.uchicago.edu		
	(where applicable) Data Manager: Andrea		
	Kordaris-Corkill kordaris-corkill.andrea@mayo.edu		
Questions related to data submission, RAVE or	Data Manager: Andrea Kordaris-Corkill <u>kordaris-</u>		
patient follow-up:	corkill.andrea@mayo.edu		
Questions regarding the protocol document and	Protocol Coordinator: Destin Carlisle		
model informed consent:	dcarlisle@bsd.uchicago.edu		
Questions related to IRB review	Alliance Regulatory Inbox		
Questions related to IRB review	regulatory@allianceNCTN.org		
Questions regarding CTED AEDS reporting	Alliance Pharmacovigilance Inbox		
Questions regarding CTEP-AERS reporting:	pharmacovigilance@alliancenctn.org		
Questions regarding specimens/specimen	Alliance Biorepository at Washington University		
submissions:	(ABWUSTL) alliance@email.wustl.edu		
Questions regarding drug supply	McKesson Clinical Research Services		
Questions regarding drug administration	Pharmacy Contact: Barbara Todaro, PharmD		
	barbara.todaro@roswellpark.org		

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		
	, , , , , , , , , , , , , , , , , , , ,	Replaces:	Page
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	2.3	3 of 17
	CD30 negative peripheral T-cell lymphomas	2.5	3 01 17
	Short Title- A051902		

- 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 the A051902 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.

6. Collection Schema

The following biospecimens are to be collected at each of the time points listed in the table below. Please refer to biospecimen collection and processing methods and specific shipping procedures that are detailed in this manual.

NOTE: NO SPECIMENS WILL BE SUBMITTED FOR PATIENTS ENROLLED TO THE SAFETY LEAD-IN COMPONENT.

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

CORRELATIVE SCIENCE PROCEDURE MANUAL Biospecimen Collection for A randomized phase II study of CHO(E)P vs. CC-486-CHO(E)P vs. duvelisib-CHO(E)P in previously untreated CD30 negative peripheral T-cell lymphomas Short Title- A051902

Version No:	Effective Date:
2.4	03/01/2024
Replaces:	Page
2.3	4 of 17

Time Point	Kit	Biospecimen	Quantity	Collection / Processing	Shipping	Notes
	(Y/N)			Method		
For all patients who consent to biobanking:						
Registration	N	Fixed tissue block OR	1 block OR	Fixed tissue block (9.2)	Ambient	1, 2
		Stained AND Unstained tissue	15 total slides	Fixed tissue slides (4-5		
		slides (4-5 um)	<u>OR</u> 15 total	um) (9.3)		
		<u>OR</u>	images			
		Unstained tissue slides (4-5 um)		Scanned slide images (9.4)		
		<u>OR</u>				
		Scanned slide images	= // 0	51 111 111 (40)		
Registration	N	Unstained tissue slides (10 um)	5 (10 um)	Fixed tissue slides (10 um)	Ambient	1, 3
		AND	unstained slides	(9.5)		
		Fixed tissue cores (4 mm)	AND	Fixed tiesus series (4 mags)		
			2 (4 mm) fixed	Fixed tissue cores (4 mm)		
			tissue cores	(9.6)		
	patien	ts registered to each arm	(Phase II Safety	*	to biobar	nking:
Cycle 1 Day 1 (+/- 3	Υ	Whole blood (Streck BCT)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	1, 4
days)						
Cycle 1 Day 8	Υ	Whole blood (Streck BCT)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	1, 4
, ,		, ,				
Up to 3 days before	Υ	Whole blood (Streck BCT)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	1, 4
Cycle 2 Day 1						
			1			
End of treatment	Υ	Whole blood (Streck BCT)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	1, 4
visit (+/- 7 days)						
Every 12 weeks (+/-	Y	Whole blood (Streck BCT)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	1, 4
14 days) for 1 year		(5.1.5.1.)				_, .
post treatment						
F	or all	patients in the Phase II Ex	pansion who co	onsent to biobanking:		
Cycle 1 Day 1 (+/- 3 days)	Y	Whole blood (Streck BCT)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	1, 4
Up to 3 days before	Υ	Whole blood (Streck BCT)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	1, 4
Cycle 2 Day 1						
		\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	12.40	DI ((5211 /40 4)		
End of treatment visit (+/- 7 days)	Y	Whole blood (Streck BCT)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	1, 4
(/ - 22/0/						
24 weeks (+/- 14	Υ	Whole blood (Streck BCT)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	1, 4
days) post						
treatment			1			

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		
	vs. duvelisib-CHO(E)P in previously untreated	Replaces:	Page
TRIALS IN ONCOLOGY	, , , ,	2.3	5 of 17
	CD30 negative peripheral T-cell lymphomas		0 0. 17
	Short Title- A051902		

Notes:

- 1. Collection is optional for patients but requires all sites offer to patients to consent. Please see protocol-specific consent documents.
- 2. A fixed tissue block <u>OR</u> submission of a total of fifteen (15) fixed tissue slides is requested. Submission of a block is strongly preferred. Slides for the markers of interest (H&E, CD3, CD4, CD20, CD21 or CD23, EBER, BCL6, PD1, CXCL13, ICOS, SAP, and CD10) plus unstained slides to a total of 15 slides are requested. For example, if submitting stained slides for 4 of the requested markers, a total of 15-4=11 unstained slides should be submitted. If stained slides are not available for submission, 15 unstained slides can be sent. See additional details in sections 9.2 and 9.3. Alternatively, scanned slide images of slides with the stains listed above may be submitted in .SVS file format. See additional instructions in section 9.4.
- 3. For patients who do not submit fixed tissue blocks, an additional set of five (5) fixed tissue slides <u>AND</u> two (2) fixed tissue cores are requested. For patients who have submitted blocks, slides and cores will be obtained at the Biorepository from the fixed tissue block submitted. See additional details in sections 9.5 and 9.6.
- 4. Peripheral blood collection for cycle 1 day 1 must be done prior to initiation of chemotherapy. It may be collected at any point following registration to the study until initiation of chemotherapy. All peripheral blood collection time points may be drawn within the window permitted for the corresponding clinic visits outlined in **section 5.0** of the study protocol.

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		
	, , , , , , , , , , , , , , , , , , , ,	Replaces:	Page
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	2.3	6 of 17
	CD30 negative peripheral T-cell lymphomas	2.0	0 01 17
	Short Title- A051902		

7. Biospecimen Collection Kits

- **7.1** To facilitate the proper collection and shipping of whole blood in Streck BCT tubes, biospecimen collection kits and materials will be provided. The cost of the kit and shipping of the kit to the site will be paid for. The institution is expected to pay for shipping of the kit with the biospecimens back to the Alliance Biorepository at Washington University in St. Louis via priority overnight shipping.
- 7.2 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.
 - **7.2.1** 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 or alternate billing number for express service. The study will not cover the cost for rush delivery of kits.
 - **7.2.2** Distributed kits will have a minimum shelf life of 90 days; unless precluded by the stability of a particular component.
- **7.3** Kit contents and specific instructions for use of the kit are provided in the kit box.
- **7.4** 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.
- **7.5** 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.
- **7.6** 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.
- **7.7** 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.

CORRELATIVE SCIENCE PROCEDURE MANUAL Version No: Effective Date: Biospecimen Collection for A randomized 2.4 03/01/2024 **ALLIANCE FOR CLINICAL** phase II study of CHO(E)P vs. CC-486-CHO(E)P Replaces: Page vs. duvelisib-CHO(E)P in previously untreated TRIALS IN ONCOLOGY 2.3 7 of 17 CD30 negative peripheral T-cell lymphomas Short Title- A051902

- 7.8 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 out-going and incoming kits are tracked, and sites that have requested many more kits than they have returned will be charged for non-returned kits.
- **7.9** 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, if available.
- **7.10** 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.
- **7.11** Because paraffin blocks 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, cores or cut slides may be sent independently of other biospecimens using the following guidelines:
 - **7.11.1** There is no independent "kit" for submission of paraffin blocks, cores, slides, or whole slide image scans.
 - **7.11.2** Blocks and slides should be packaged to avoid breakage using a padded envelope or, preferably, a small Styrofoam container.
 - **7.11.3** During warm weather months, paraffin block, cores, 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.
 - **7.11.4** Blocks and slides may be shipped for standard overnight delivery according to institutional policies and using the preferred vendor.
- **7.12** Please see **Section 11 Biospecimen Shipping** for specific instructions on shipping to ABWUSTL.

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		
	, , , , , , , , , , , , , , , , , , , ,	Replaces:	Page
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	2.3	8 of 17
	CD30 negative peripheral T-cell lymphomas	2.5	80117
	Short Title- A051902		

8. Biospecimen Labeling and Tracking

- **8.1** All research biospecimens, with exception of surgical pathology blocks and tissue slides, MUST be labeled with the Alliance study number (A051902), Alliance patient ID number, patient initials (Last, First, Middle), the date and time (if applicable) of collection and specimen type. Specimen labels must match BioMS records.
- 8.2 Surgical pathology tissue blocks should be labeled according to institutional standards, including the surgical pathology number (e.g. "S16-1234") and the individual block identifier (e.g. "A3"). Adhesive labels should not be used to cover the institutional label. If tissue section slides are being submitted instead of the block, each tissue section slide should be labeled with the procurement date, Alliance study number (A051902), Alliance patient ID number, patient initials (Last, First, Middle), surgical pathology number (SPN) and institutional block ID, slide serial section number (1, 2, 3, etc.), and section thickness. Stained slides should additionally be labeled to indicate stain type (i.e. H&E, BCL6, CD10, BCER, etc.). See section 9.4 for specific labeling instrutions for WSI.
- **8.3** A de-identified copy of the surgical pathology report, labeled with the Alliance patient ID number, is required to accompany <u>all</u> tissue submissions, including submission of WSI. Usually, this is generated by obscuring all PHI (names and dates) with white-out or a black magic marker, labeling each page of the report with the Alliance patient ID number, and photocopying the report. However, please make sure to **maintain the pathology accession numbers** so the submitted slides can be matched directly to the pathology report.
- **8.4** Label all containers and vials with an indelible, solvent-resistant marker when they are at ambient temperature.
- **8.5** Do not affix any labels to vials, slides or tubes. Label the collection containers directly with the marking pen.

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		
	, , , , , , , , , , , , , , , , , , , ,	Replaces:	Page
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	2.3	9 of 17
	CD30 negative peripheral T-cell lymphomas	2.0	3 01 17
	Short Title- A051902		

- 8.6 All biospecimens that are collected and sent to ABWUSTL must be logged and tracked in BioMS under A051902. Do not send samples to the Biorepository in which the patient has not been registered onto the study. 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.
- **8.7** 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 Fixed Tissue Block

9.2.1 For patients who consent to biobanking, a paraffin block from primary disease should be submitted.

CORRELATIVE SCIENCE PROCEDURE MANUAL Version No: Effective Date: Biospecimen Collection for A randomized 2.4 03/01/2024 **ALLIANCE FOR CLINICAL** phase II study of CHO(E)P vs. CC-486-CHO(E)P Replaces: Page vs. duvelisib-CHO(E)P in previously untreated TRIALS IN ONCOLOGY 2.3 10 of 17 CD30 negative peripheral T-cell lymphomas Short Title- A051902

- 9.2.2 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.
- **9.2.3** In the event that an institution will not release a tissue block, the institution may instead submit stained and unstained tissue slides (up to a total of 15).
- 9.2.4 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.
- 9.3 Fixed Tissue Slides, Stained and Unstained (4-5 um)
 - **9.3.1** In cases where institutions are unable or unwilling to submit the requested tissue block, a set of 15 slides may be sent as an alternative.
 - 9.3.2 Stained slides for the markers of interest (H&E, CD3, CD4, CD20, CD21 or CD23, EBER, BCL6, PD1, CXCL13, ICOS, SAP and CD10) plus unstained slides to a total of 15 slides are requested. For example, if submitting stained slides for 4 of the requested markers, a total of 15-4=11 unstained slides should be submitted.
 - **9.3.3** If stained slides are not available for submission, a set of 15 unstained slides can be sent. 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.
 - **9.3.4** Unstained slides should be prepared following instructions below.

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

CORRELATIVE SCIENCE PROCEDURE MANUAL
Biospecimen Collection for A randomized
phase II study of CHO(E)P vs. CC-486-CHO(E)P
vs. duvelisib-CHO(E)P in previously untreated
CD30 negative peripheral T-cell lymphomas
Short Title- A051902

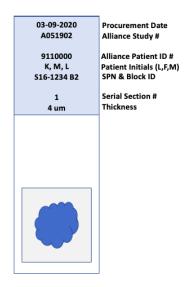
Version No:
2.4
03/01/2024

Replaces:
2.3
11 of 17

# of slides	Section thickness	Slide type	Sample Types	Purpose
	4-5	Positively	Primary tumor	Central Pathology Review
15	microns	Charged		

- **9.3.5** Serial, tissue sections should be <u>cut fresh</u> from the appropriate formalin fixed, paraffin embedded tissue block.
- **9.3.6** Cut sections at 4-5 micron thickness as indicated onto positively-charged slides.
- 9.3.7 Ensure that each slide is labeled with the procurement date, Alliance study number (A051902), Alliance patient ID number, patient initials (Last, First, Middle), surgical pathology number (SPN) and institutional block ID, slide serial section number (1, 2, 3, etc.), and thickness (4-5 microns). Please make sure to maintain the pathology accession numbers so the submitted slides can be matched directly to the pathology report.
- **9.3.8** Do not label slides with adhesive labels. Write or print information on the textured surface of the slide with indelible, solvent-resistant ink.
- **9.3.9** No adhesives or other additives should be used in the water bath.
- **9.3.10** Mount only one tissue section per slide. Make certain sections are placed on the painted / textured side of the slide.
- **9.3.11** 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.
- **9.3.12** See figure below for proper mounting and labeling.

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		
	, , , , , , , , , , , , , , , , , , , ,	Replaces:	Page
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	'	O
	CD30 negative peripheral T-cell lymphomas	2.3	12 of 17
	Short Title- A051902		



- **9.3.13** Air dry slides for 12-24 hours prior to shipping. Do not oven dry slides.
- 9.3.14 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 Scanned Slide Images

- **9.4.1** 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.
- **9.4.2** 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.
- **9.4.3** 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.
- 9.4.4 <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.

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		
	, , , , , , , , , , , , , , , , , , , ,	Replaces:	Page
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	2.3	13 of 17
	CD30 negative peripheral T-cell lymphomas	2.5	13 01 17
	Short Title- A051902		

- 9.4.5 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.
- **9.4.6** 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.
- **9.4.7** Once the images have been uploaded, site staff should send an electronic copy of the manifest to alliance@email.wustl.edu.
- 9.4.8 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)

9.5 Fixed Tissue Slides, Unstained (10 um)

- 9.5.1 In cases where institutions have NOT submitted fixed tissue blocks, a set of five (5) unstained slides cut at 10 um are requested in additional to the 15 unstained/stained slides cut at 4-5 um (section 9.3). Two fixed tissue cores should also be submitted with the unstained slides (see section 9.6).
- **9.5.2** 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.
- **9.5.3** Unstained slides should be prepared following instructions below.

# of	Section	Slide type	Sample Types	Purpose
slides	thickness			
5	10 micron	Non-charged	Primary tumor	DNA/RNA

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	Replaces:	Page
		2.3	14 of 17
	CD30 negative peripheral T-cell lymphomas		
	Short Title- A051902		

- **9.5.3.1** Tissue should be mounted and slides should be labeled following instructions in **section 9.3.**
- 9.5.3.2 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.

9.6 Fixed Tissue Cores

- 9.6.1 In cases where institutions have NOT submitted fixed tissue blocks, two fixed tissue cores are requested in addition to the 15 stained/unstained slides cut at 4-5 um and the 5 unstained slides cut at 10 um. Two (2) 4mm cores should be submitted from the primary tissue block.
- **9.6.2** Place the tissue cores directly into microcentrifuge tubes (one core per tube) or any other suitable container. Label the tubes of tissue following the guidelines outlined in **section 8**.

10. Blood Collection Methods

10.1 Plasma Nucleic Acid (Streck) Tube Processing

- **10.1.1** Collect 10 ml of blood into each of the Streck BCT tubes using standard venous phlebotomy. Invert tubes 10 times.
- **10.1.2** Store Streck 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 tubes are shipped at ambient temperature to avoid freezing.
- 10.1.3 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.

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		
		Replaces:	Page
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	2.3	15 of 17
	CD30 negative peripheral T-cell lymphomas	2.5	13 01 17
	Short Title- A051902		

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 or scanned slide images, include a copy of the deidentified 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 on Monday Thursday only. If physician or patient schedules mandate a Friday, weekend, or holiday collection, 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.
- **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 specimens to ABWUSTL on Monday through Thursday only. Do not ship on Fridays, Saturdays or on the day before a national holiday.

Ship to:

Alliance Biorepository at Washington University in St. Louis 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

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P	D 1	
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	Replaces:	Page
11(1) (20 11) 01(002001	CD30 negative peripheral T-cell lymphomas	2.3	16 of 17
	Short Title- A051902		

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 (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.
- **12.7** Fixed tissue blocks will be vacuum packed to prevent oxidation and stored at 4 degrees Celsius (refrigerated) to minimize degradation of cellular antigens.
- **12.8** All biospecimens will remain in storage until additional processing or review is requested in writing by the appropriate protocol PI.

13. Document History

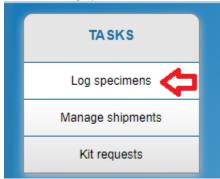
Version	Description and Justification of Change	Author	Effective Date
2.4	Added additional stain to send if sending slides for registration tissue.	KL	03/01/2024
2.3	Changed instructions for scanned slide image submission	KL	02/01/2024
2.2	Added new instructions for WSI submission	KL	10/01/2023
2.1	Changed instructions for WSI submissions, added warm weather shipping instructions, added contact table	KL	06/13/2023
2.0	Add instructions for WSI scan submissions	AAW	03/21/2023
1.1	Clarify collection for Phase II safety check	PAA	05/12/2021
1.0	New	PAA	03/30/2021

	CORRELATIVE SCIENCE PROCEDURE MANUAL	Version No:	Effective Date:
	Biospecimen Collection for A randomized	2.4	03/01/2024
ALLIANCE FOR CLINICAL	phase II study of CHO(E)P vs. CC-486-CHO(E)P		_
TRIALS IN ONCOLOGY	vs. duvelisib-CHO(E)P in previously untreated	Replaces:	Page
TRIALS IN ONCOLOGI	CD30 negative peripheral T-cell lymphomas	2.3	17 of 17
	Short Title- A051902		

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.

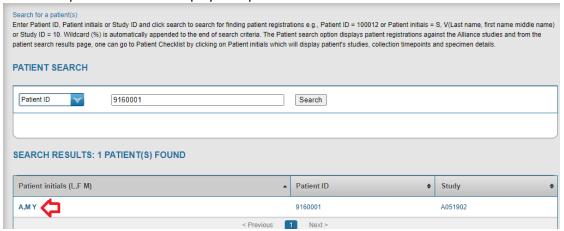
- 1. Login BioMS https://bioms.wustl.edu/bioms/login
- 2. Select "Log specimens" from the Task menu.



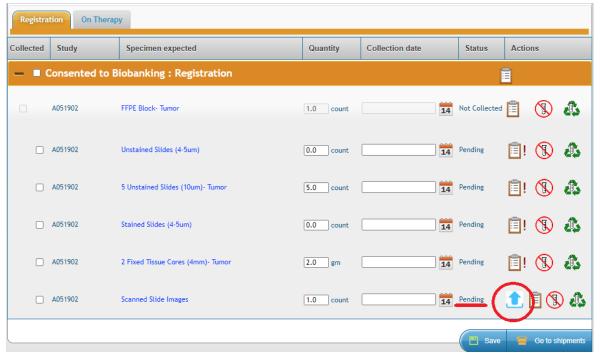
3. Enter the patient ID (obtained when registering the patient in OPEN), in the search field, select the matching ID from the drop-down list, click "Search."



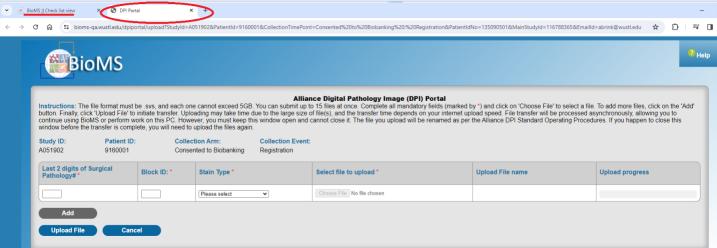
4. Click the patient initials to display the Specimen Checklist view.



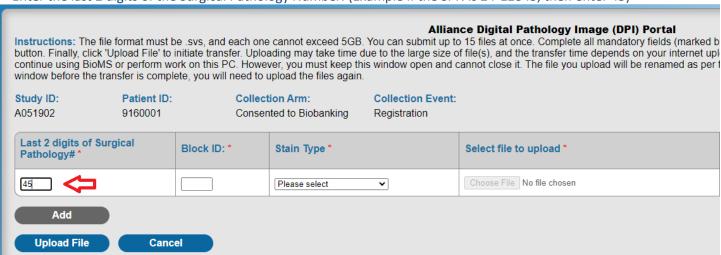
5. Click on the Alliance Digital Pathology Image (DPI) Portal Icon. Do not enter the slide count or collection date as only specimens in a "Pending" status can have images uploaded.



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.



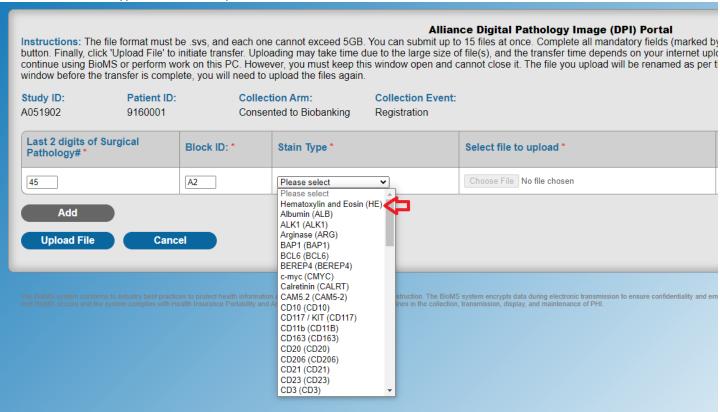
- 7. Please note the instructions at the top of the page. All files must be in .SVS format and cannot exceed 5GB
- 8. Enter the last 2 digits of the Surgical Pathology Number. (Example if the SPN is 24-12345, then enter 45)



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 * Up				Upload File name	Upload progress		
45	[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 ou can submit up to 15 files at once. Complete all mandatory fields (market 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	ent 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		

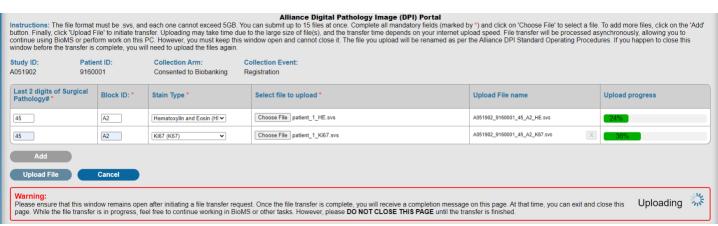
14. Once all files are selected, click "Upload File."

Alliance Digital Patho

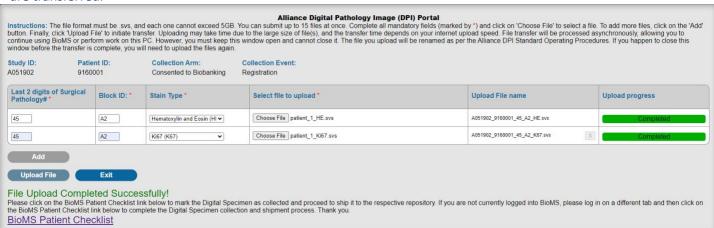
Instructions: The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. C button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the tra continue using BioMS or perform work on this PC. However,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



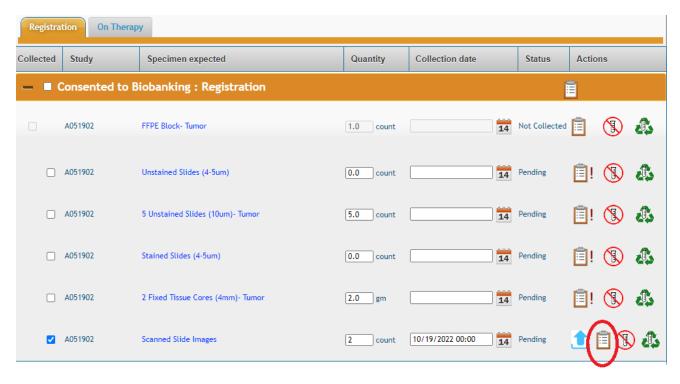
16. BioMS will display a successful message in the Alliance DPI portal and send an email to the user once all images are transferred.



- 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."

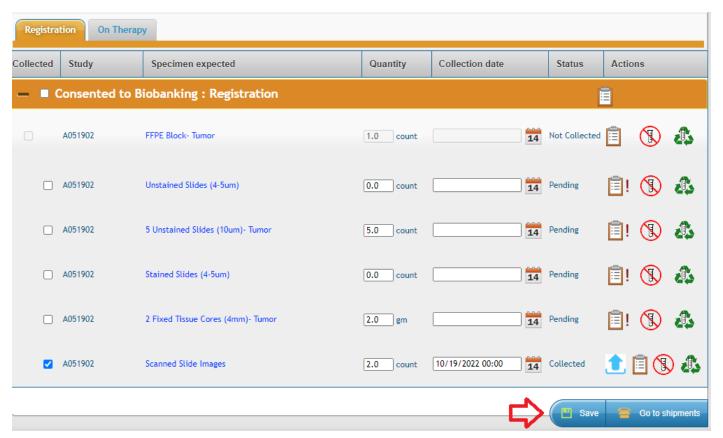


21. Click the "Clip board' icon to load a digital copy of the corresponding surgical pathology report.

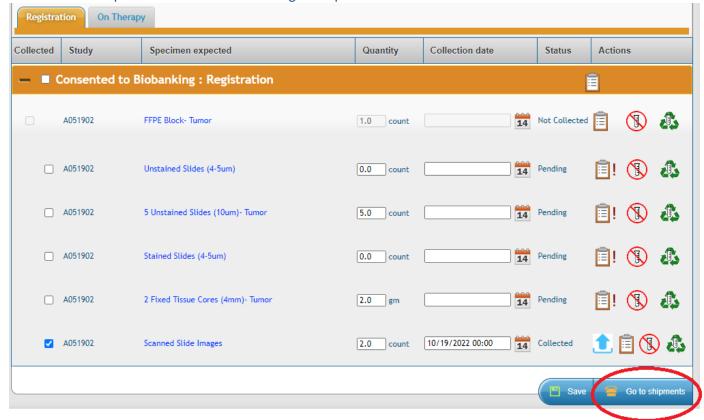


If you are submitting	tissue from a pathology block, slides, cur	rls, etc. PLEASE
If you are submitting remember to include report in your shipme	tissue from a pathology block, slides, cur a printed, de-identified copy of the corr ent.	ls, etc. PLEASE esponding patholog
If you are submitting remember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

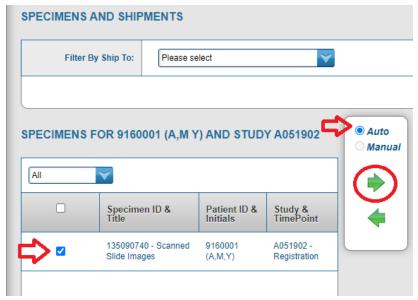
22. Click Save



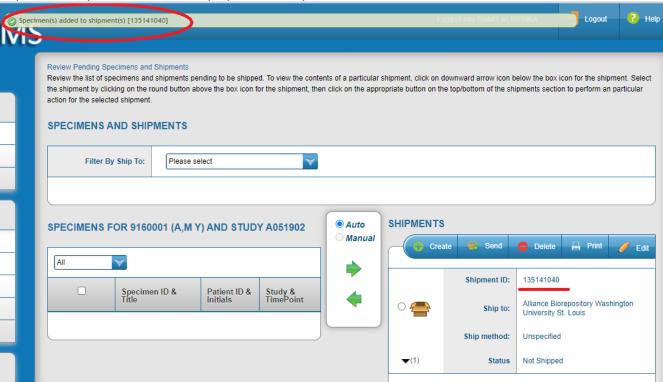
23. Click "Go To Shipments" to now create the digital shipment



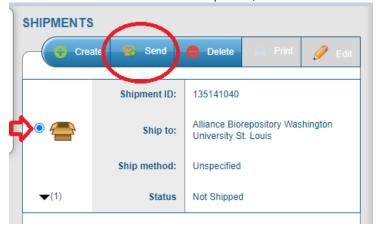
24. From the Manage Shipment page, check the box for the specimen requirement, leave the shipment default to "Auto" and click the green arrow pointing to the right.



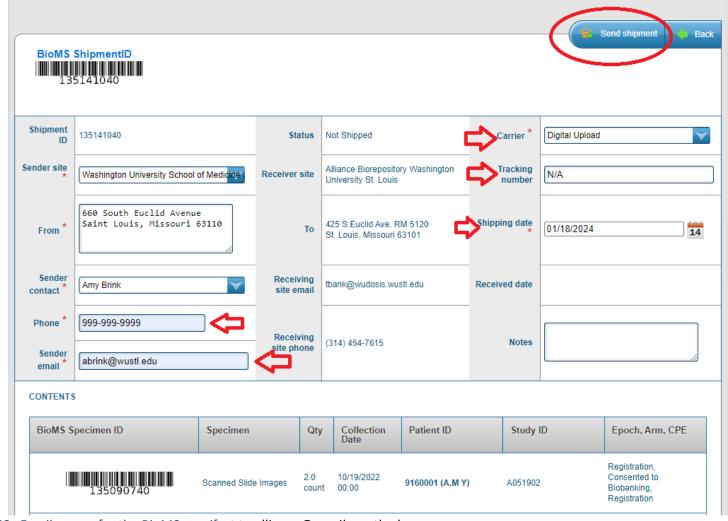
25. BioMS will move the specimen requirement into an appropriate shipment. The shipment ID containing the specimen requirement will be displayed at the top of the screen.



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