General Specimen Submission Guidelines

Specimen Collection

- Always refer to the protocol for collection and submission guidelines
 - Section 15 has the most detailed information for specimen collection, processing (when applicable), etc.
 - Section 9, Study Calendar some general information about specimen collection
 - Section 12, Discipline Review information about centralized pathology reviews
- General specimen submission information: <u>https://www.swog.org/clinical-trials/biospecimen-</u> resources/biospecimen-processing-and-submission-procedures
 - Also includes label templates

SWOG Labeling Guidelines

	Requirements pecimens)	Additional Data for FFPE Tissue (blocks, slides, scrolls/curls)	Other labeling requirements
Middle the ST • Date of spe	als nitials as "Last, First " as they appear on S Packing List. ccimen collection type (whole blood,	 From the corresponding pathology report: Surgical pathology ID (SPID, accession #) Block number 	 Bone Marrow: Laterality – right (R), or left (L) Protocol-specific requirements: If specified in the protocol, the label Collection time (e.g., PK specimens) Tissue type – primary (P), metastatic (M), or normal (N) Tissue slide thickness, in µm

Required Documents Guidelines

Specimen Type	Required Documents
Fresh or frozen stool and liquid specimens (blood, bone marrow, plasma, serum, buffy coat, urine, stool, etc.)	1. SWOG STS Packing List
FFPE tissue (blocks, slides, scrolls/curls)	 SWOG STS Packing list Pathology report <i>corresponding to the tissue removal procedure</i>

Guidelines for Requesting FFPE Tissue Block Returns

- All specimen returns must be approved by Dr. James Rae (jimmyrae@med.umich.edu).
- Contact the SWOG Biospecimen Bank (<u>BPCBank@nationwidechildrens.org</u>) to request a specimen return form
 - Include the email with Dr. Rae's approval.
- The form must be completed, including:
 - Registration number (SWOG patient ID)
 - Date of request
 - Date return needed (note: this cannot be guaranteed)
 - Requested by (name)
 - Contact phone number and email address
 - Shipping address
 - FedEx account number
 - Reason for request (this is a check box)
 - Information about the specimen requested (type, surgical pathology ID, block number, number of specimens, and collection date)

Dry Ice Shipping Guidelines

- 1. Ship frozen specimen(s) buried in dry ice.
 - Add some dry ice to the bottom 1/3 of the box. Place the specimens on top of the dry ice.
 - Add the dry ice to the sides and top of the specimens. Specimen containers should be completely covered on all sides. A minimum of about 5 lbs should be used per shipment, more dry ice is needed for larger shipments or larger boxes.
 - The shipping box must be large enough to pack sufficient dry ice around the specimens.
- 2. FedEx Priority Overnight service is preferred for all shipments, but especially shipments with dry ice. Use of other courier services may delay package receipt and compromise specimen integrity.
- 3. Frozen specimens may only be shipped Monday through Thursday to arrive Tuesday through Friday. **Do NOT ship frozen specimens on a Friday or the day before a holiday.**
- 4. For questions about shipping specimens around a holiday, please reference the Bank's holiday hours memo distributed by the Protocol Department office or call the Bank directly at 614-722-2865.

Recommended dry ice weights per size of shipping container

Dry ice will sublimate 5-10 lbs every 24 hours depending on the quality of the shipping container. If shipping longer distances or during inclement weather, increase amount of dry ice used.

Box size	Volume (Qts)	Dry ice (lbs/kgs)
10 x 10 x 10	17	10 lbs/4.5kgs
12 x 12 x 12	30	20lbs/9kgs
15 x 15 x 15	55	30lbs/14kgs
15 x 15 x 20	77	40lbs/18kgs

S2101 immunoMATCH Pilot Study Frequently Asked Questions

Q: What are the labeling requirements for iMATCH?

- Refer to Section 15.5 Specimen Labeling and Required Forms for the current labeling instructions.
- The "Label to use" example that prints out on the STS Packing List is an example label of what is generally requested for SWOG protocols. *The labeling requirements for S2101 specimen submissions may vary from this template.*
- Write Initials as "Last, First Middle" as they appear on the STS Packing List.

Q: What documents are required at the time of specimen submission?

• Refer to Section 15.5.c:

Specimen	Required Forms
Archival FFPE Tissue	SWOG STS Packing ListPathology report <i>corresponding to the archival procedure</i>
Formalin-fixed tissue biopsies	 SWOG STS Packing List Diagnostic pathology report (from the procedure of the original diagnosis) Operative and/or radiology reports corresponding to the biopsy procedure Appendix 18.8 Tissue Biopsy Verification Form
Blood	SWOG STS Packing List

Q: How should the pathology report be redacted?

- The following can be redacted: full name (keep initials), date of birth, SSN, and insurance information.
- Do not redact the following: date of procedure, SPID, block number and diagnosis.
 - Note: If these are redacted, processing cannot proceed until a report with all of this information is provided.
- Label each page of every document submitted with the SWOG registration number. Refer to Section 15.5.c.

Q: How much tissue should be submitted for testing?

- Refer to Section 15.3 Translational Medicine Samples for Screening for the current tissue size requirements.
- Submitting adequate tissue is critical to provide the best opportunity for obtaining results. When possible, we recommend submitting the "optimal" tissue surface area/volume indicated in the protocol.

Q: What is the difference between the Baseline and Cycle 1 submissions?

- Whole blood in Streck cfDNA for germline genomic analysis is mandatory for screening. This is the "Baseline, Submit within 24 hours after registration" submission. The EDTA at this timepoint is required if the participant consents. Refer to Section 15.3.a.2.
- Whole blood in EDTA and Streck cfDNA at the "Baseline, Cycle 1, Pre Tx" timepoint are for banking. Refer to Section 15.4.a.
- Note: these time point names may be better differentiated in an upcoming amendment.