Biospecimen Collection, Processing, Documentation and Submission Procedures

This document provides specimen labeling, collection, processing, documentation, tracking, packaging, and shipment instructions for specimens that will be submitted to the SWOG Cancer Research Network Biospecimen Bank (Lab #200 or Lab #201) in Columbus, OH. If indicated in the protocol, these instructions may also be utilized for specimen submissions to other laboratories.

- **For specimen instructions: First, refer to the protocol.**
  - **Always follow protocol-specific instructions provided in the protocol document or through a linked resource.** Those instructions supersede the general instructions outlined here.
  - For SWOG-led protocols: Specimen instructions are usually outlined in Protocol Section 15 or through a linked resource.
- Many SWOG-led protocols will involve specimen submissions to both the SWOG Biospecimen Bank and/or another laboratory.
  - **Unless otherwise specified in the protocol or via a linked resource, utilize the instructions provided here.**

Important Notes

1. Participant consent and the participant ID must be obtained prior to collecting specimens.
2. Excess diagnostic specimens will be retained by the SWOG Cancer Research Network Biospecimen Bank (Biobank) and used according to the participant's designation for "future use", as indicated on the participant's consent form.
3. See also: SWOG Frequently Asked Questions for Specimen Processing and Submission *(coming soon)*.

General Specimen Requirements and Instructions:

When the protocol does not provide specimen instructions (or refers to the SWOG website for instructions), follow the instructions below for the relevant specimen type(s).

- **Specimen Labeling**
- **Specimen Collection and Processing Instructions**
- **Specimen Tracking and Documentation Requirements**
- **Specimen Packaging and Shipping Guidelines**

Common Specimen Submission Errors:

Specimen submission errors may result in queries and extra effort for the site staff. Prior to submitting specimens, please ensure designated staff have **carefully** reviewed the protocol instructions (usually in Section 15 of SWOG-led protocols) and/or the general requirements and instructions accessible from the links above.

The most common specimen submission errors received by the SWOG Biospecimen Bank are:

- Incomplete specimen labeling.
- When the information on/in the specimen label, the Specimen Tracking System and/or the printed Specimen Tracking System (STS) Packing List does not precisely align, the mismatched information is considered a discrepancy. The order and format of participant initials must be L, FM. A difference in comma placement will result in a query.
  - Note: If your institution is NOT able to include a comma on the specimen label, then the SWOG Biospecimen Bank will accept specimen labels with participant initials in format FML without a comma, however, data entry into the STS must still be entered in format L, FM.
- Missing supporting documentation (such as STS Packing List or Pathology Report).

Questions?

For questions pertaining to specimen collection, processing or submission that are not addressed in the protocol or below, contact the SWOG Data Operations Center via the appropriate disease-specific e-mail distribution lists found on the Contact us page or at (206) 652-2267.

Version Date: 03/27/2024

Specimen Labeling – Common Errors and Label Templates

Unless otherwise indicated in the protocol, specimens must be labeled as outlined in the Specimen Labeling Requirements on the next page.

Important notes / Common labeling errors:

- Dates must be in MM/DD/YYYY format.
- Participant initials must be in the following order: Last, First Middle.
  - The format of participant initials included on the specimen label must exactly match the format of the participant initials as entered into the SWOG Specimen Tracking System (STS), (i.e., L, FM). A difference in comma placement will result in a query.
  - Note: If your institution is not able to include a comma on the specimen label, then the SWOG Biospecimen Bank will accept specimen labels with participant initials in format FML without a comma, however, data entry into the STS must still be entered in format L, FM.
- See also: Required Documents for Specimen Submission.

Standard Label Templates:

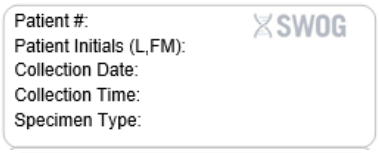
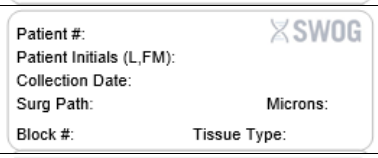
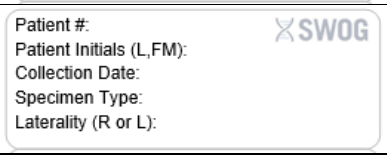
Label templates are available for download via the links below.
If label paper is not available, the label may be printed on regular paper and then taped to the specimen container.

- Basic Label Template (Information required for all specimens)
  - Use for fresh or frozen liquid, stool, or frozen specimens (unless additional requirements are indicated in the protocol).
  - A Basic Label Template in MS Word format is also accessible for download here.
- Time-based Label Template
  - Use for studies that require multiple sample collections in the same day where the lab will require collection time to differentiate the samples for processing (e.g., PK studies).
  - A Time-based Label Template in MS Word format is also accessible for download here.
- Basic Tissue Label Template
  - Use for FFPE or snap-frozen tissue specimens (unless additional requirements, such as microns/thickness or tissue type are indicated in the protocol).
  - A Basic Tissue Label Template in MS Word format is also accessible for download here.
- Tissue with Microns Label Template
  - Use for tissue specimens that include a tissue requirement per protocol.
  - A Tissue with Microns Label Template in MS Word format is also accessible for download here.
- Basic Label Template with Laterality (for Bone Marrow)
  - Use for bone marrow biopsy or bone marrow aspirate specimens that include requirement for indication of laterality per protocol.
  - A Basic Label Template with Laterality in MS Word format is also accessible for download here.

Specimen Labeling Requirements

If labeling requirements are not otherwise specified in the protocol or through a linked resource (usually in Section 15 in SWOG-led protocols), then specimens must be labeled in accordance with the standard requirements below.

Minimum Labeling Requirements	Additional Labeling Requirements for FFPE Tissue	Other Labeling Requirements
• SWOG Participant ID • Participant Initials • Date of specimen collection (MM/DD/YYYY) • Specimen Type (whole blood, serum, bone marrow, urine, stool, etc.)	From the corresponding pathology report: • Surgical Pathology ID (SPID, accession #) • Block number (e.g., A2, 3E, 2-1, B, etc.)	**Bone Marrow:** • Laterality – right (R), or left (L) **Protocol-specific requirements:** • Collection time (e.g., PK specimens) • Tissue type – primary (P), metastatic (M), or normal (N) • Tissue slide thickness, in µm (microns)

Label	Example Label	Specimen type(s)
Basic labels *or MS Word Version for Download*		• Blood/blood products (e.g., plasma, serum, buffy coat) • Bone Marrow Aspirate and Bone Marrow Biopsy • Urine • Stool • Other biofluids
Time-based labels *or MS Word Version for Download*		• Specimens collected for studies where multiple samples are collected during the same day and the lab requires collection time to differentiate them for processing
Tissue Label *or MS Word Version for Download*		• FFPE tissue (blocks, slides, scrolls/curls) • Frozen tissue
Tissue label (with microns) *or MS Word Version for Download*		• FFPE tissue slides or scrolls
Basic with Laterality *or MS Word Version for Download*		When the protocol requires indication of laterality, for: • Bone Marrow Aspirate • Bone marrow Biopsy

Additional Guidelines for Specimen Labeling

- For **vials and tubes**:
  - Place a label on each vial submitted.
  - Do not cover expiration date of collection tubes. Trim labels as needed to fit.
- For **FFPE tissue blocks**:
  - Place the specimen in a small bag and apply the label on the outside of the bag. Do not place the label directly on the tissue block.
  - The block must be labeled with the Surgical Pathology ID# (Accession#) *and* SWOG Participant ID.
- For **FFPE tissue slides**:
  - Place labels directly on the slide container or on each individual slide.
  - If placing labels on the slide container, then the SWOG Participant ID, surgical pathology ID (accession #) and block number must be included on each individual slide.
- For **frozen specimens**, cold storage can make the labels come off easily. Consider these tips:
  - Label specimens prior to freezing.
  - Wrap the label tightly all the way around the tube so the overlap is on top of the label (without covering the labeling data). Wrap the label with a bit of a tail so that the label can stick to itself instead of the tube.
  - Handwrite required information on the tubes in case the label comes off.
  - Use labels that are designed to adhere to frozen surfaces. Labtag.com sells labels that can be printed using standard inkjet or laser printers.

Version Date: 03/27/2024

Specimen Collection and Processing – General Notes

Unless otherwise indicated in the protocol, collect, handle, and process specimens as outlined in the instructions on the following six pages.

Important Notes:

1. Prior to specimen collection: Verify that the collection tube/container (e.g., for blood, bone marrow, etc.) will not expire prior to receipt by the SWOG Biospecimen Bank (or protocol-designated laboratory).
2. Always refer to the protocol for specimen collection and processing instructions.
    - When the protocol does not provide instructions (or refers to the SWOG website for specimen instructions), follow the specimen collection, handling, and processing instructions below for the respective specimen type.
3. The pathology report(s) corresponding to the tissue removal surgery must be included with each shipment of tissue. Pathology reports must be redacted as indicated here.

Specimen Handling Guidelines for Formalin-Fixed Paraffin-Embedded (FFPE) Tissue

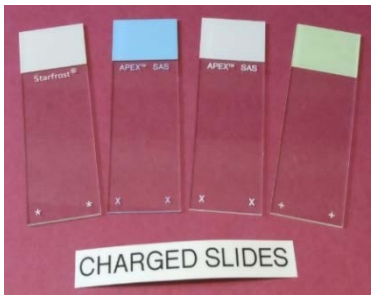
If protocol-specific tissue handling instructions for FFPE tissue are not provided in the protocol or through a linked resource (usually in Section 15 in SWOG-led protocols), then follow the instructions outlined below.

Fixing Tissue in Formalin

1. Place the fresh tissue in formalin. **Do not exceed 24 hours fixation time.**
2. Fixed tissue must be processed and embedded in paraffin within 24 hours. Follow institutional procedures for tissue processing and embedding.

FFPE Tissue Slides

- FFPE tissue slides are tissue sliced from an FFPE tissue block and mounted to a glass slide.
  - These vary in thickness and are typically 4-7 µm (microns)
- Slides often may be submitted if the institution cannot release an FFPE tissue block, but this is dependent on the protocol.
- To submit FFPE tissue slides, cut sequential sections from the representative FFPE tissue block as indicated in the protocol.
  - If these instructions are not in the protocol, then cut slides at 4-5 µm ("micron") thickness on positively charged slides.
- Slides may be stained or unstained. Unstained slides can be positively-charged (often indicated with a + or X – see figure) or uncharged.
  - If not specified in the protocol, then charged slides are preferred.



FFPE Tissue Scrolls (or curls)

1. Scrolls (also called curls) are FFPE tissue sections that are not mounted to glass slides. These are often thicker sections of tissue (e.g., 10 – 20 micron thickness).
2. Add scrolls to a small flat-bottom or conical tube.

Storage of FFPE tissue

1. Store FFPE tissue blocks and slides at room temperature until shipment.

Required Documents for Shipping FFPE Tissue Blocks and Slides:

2. Corresponding **pathology report** indicating the morphological diagnosis. The report must be labeled with the SWOG Participant ID # and surgical pathology identification number.
3. SWOG Online Specimen Tracking System Packing List.
   a. Note: for quantity of specimens, list the quantities of stained and unstained slides separately.

Biospecimen Bank Retention of FFPE Tissue Blocks and Slides:

FFPE tissue blocks and slides submitted for translational medicine or biobanking will not be returned. If the tissue is needed for participant care, approval for release of the FFPE tissue block or slides must be obtained from Dr. Jimmy Rae before the block can be returned.

Version Date: 03/27/2024

Specimen Collection and Handling Guidelines for Snap-Frozen Tissue or Bone Marrow Biopsy Cores

If protocol-specific tissue collection and handling instructions for frozen tissue are not provided in the protocol or through a linked resource (usually in Section 15 in SWOG-led protocols), then follow the instructions outlined below.

Collecting Tissue

1. If the amount of frozen tissue requested is not specified in the protocol:
    a. For bone marrow biopsy core, the core should be 1-2 cm in length. Remove peripheral blood from the biopsy by touching the biopsy with a sterile swab.
    b. For other frozen tissues, then collect > 5 mm3 (approximately "pea to almond size").
2. Tissue should be free of tissue capsules (e.g., kidney capsule or membrane) and/or hair (e.g., scalp or skin lesions).
3. Tissue should be small enough to place in a cryovial without force.

Snap Freezing Tissue

1. Snap freeze tissue immediately after the biopsy for optimal antigen preservation. If tissue cannot be frozen within 15 minutes, then store at 4°C for no longer than 2 hours.
2. Pre-label a cryovial according to specimen labeling requirements and chill by placing on dry ice.
3. Place pre-sectioned tissue on a piece of foil or in a pre-labeled, pre-chilled cryovial and snap freeze tissue on dry ice or in the vapor phase liquid nitrogen (do not submerge the tissue in liquid nitrogen). If dry ice or liquid nitrogen are not available, then freeze tissue in a -70°C to -80°C freezer.
4. If frozen correctly, tissue should be able to move freely in the cryovial (i.e., not adhered to the wall of the vial).

Storing Frozen Tissue

- Store snap frozen tissue in a liquid nitrogen freezer (at vapor phase) or a -70°C to -80°C freezer until ready to ship.

Required Documents for Shipping Frozen Tissue:

- Corresponding **pathology report** indicating the morphological diagnosis. The report must be labeled with the SWOG Participant ID # and surgical pathology identification number.
- SWOG Online Specimen Tracking System Packing List.

Specimen Collection and Handling Guidelines for Whole Blood

If protocol-specific collection and handling instructions for whole blood are not provided in the protocol or through a linked resource (usually in Section 15 in SWOG-led protocols), then follow the instructions outlined below.

Collecting Whole Blood

1. Use the protocol-specified Vacutainer tube type.
    a. If the recommended size of vacutainer tube specified in the clinical trial protocol is not available, then other sized tubes may be used to collect the total volume of blood (e.g., if 10 mL of blood is requested, then two (2) 5-mL tubes may be used).
    b. Pre-label vacutainer tube(s) according to specimen labeling requirements.
2. Use aseptic techniques and draw blood from the participant into the vacutainer tube(s). The amount of blood required will vary per protocol; refer to section 15 for required/requested collection volumes.
3. Immediately after the blood is drawn, gently invert the tube 5-10 times to thoroughly mix the blood with the anticoagulant.

Collecting Whole Blood in Streck cfDNA tubes

1. Label Streck cfDNA tube(s) according to specimen labeling requirements.
2. Collect 10 mL of blood into each pre-labeled tube and gently invert to mix. Note: blood must be thoroughly mixed to ensure preservation of specimen.
    a. Note: if patients may have an indwelling catheter: heparin should be avoided in pre-collection flush procedures. If therapeutic heparin dosing contamination is a possibility, then venipuncture is recommended as a first choice collection method. If a Streck cfDNA tube immediately follows a heparin tube in the draw order, then collecting an EDTA tube as a waste tube prior to collection in the Streck Cell-Free DNA BCT is recommended.
3. After collection, **blood in Streck cfDNA tubes should never be refrigerated**, as this will compromise the specimen. Blood collected in Streck cfDNA tubes is stable at room temperature.

Storing Whole Blood

1. After collection, keep blood at room temperature until shipment. Whenever possible, blood should be shipped on the same day of collection.
2. If blood cannot be shipped on the same day of collection, store at 4°C (40°F) until shipment the next business day. **Do not freeze whole blood.** If whole blood is stored longer than 24 hours, then note the storage time on the specimen shipping form.
    - Note: Some tubes (e.g., Streck cfDNA) must be kept at room temperature.

Specimen Collection and Processing Guidelines for Buffy Coat and Plasma

If protocol-specific collection instructions for peripheral blood and processing instructions for buffy coat and plasma are not provided in the protocol or through a linked resource (usually in Section 15 in SWOG-led protocols), then follow the instructions outlined below.

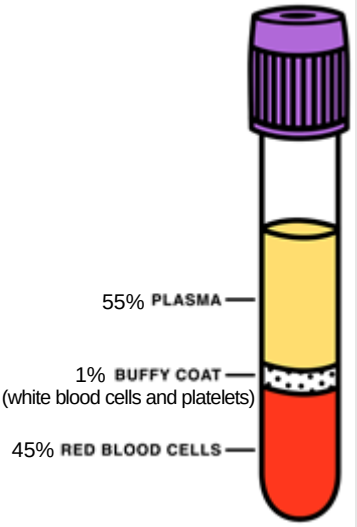
Plasma is processed from blood collected with anticoagulant (e.g. EDTA, sodium heparin, etc.). Inverting the tube immediately after collection is essential to ensure blood does not clot. Plasma and buffy coat are processed by centrifuging and removing the yellowish-clear layer (plasma) and/or the very thin white or gray-ish layer (buffy coat) – see figure. Note: after processing, plasma looks very similar to serum. If a protocol includes both plasma and serum specimens, it's *imperative* that each tube is labeled with the specimen type (e.g., plasma or serum).

Collecting Peripheral Blood

1. Use the protocol-specified Vacutainer tube type.
   - If the recommended size of vacutainer tube specified in the clinical trial protocol is not available, then other sized tubes may be used to collect the total volume of blood (e.g., if 10 mL of blood is requested, then two (2) 5-mL tubes may be used).
   - Pre-label vacutainer tube(s) according to specimen labeling requirements.
2. Draw blood from the participant into the vacutainer tube(s). The amount of blood required will vary per protocol; refer to section 15 for the collection volume.
3. Immediately after collection, gently invert the tube 5-10 times to thoroughly mix the blood with the anticoagulant and prevent clotting.
4. Blood must be processed within 2 hours after venipuncture unless otherwise noted in the protocol. Document on the specimen shipping form if the blood was not processed within 2 hours following venipuncture.

Plasma Processing

1. Centrifuge the vacutainer tube(s) at 1200 x g for 10 minutes at room temperature.
2. Pre-label cryovials according to specimen labeling requirements.
3. Using a clean disposable pipette, remove the plasma (yellow-clear liquid above the buffy coat and red blood cell layers). See Figure. No cells or debris should be present in the plasma.
4. Dispense 1 mL aliquots of plasma into the pre-labeled 2 mL-capacity cryovials and cap the tubes securely. If the aliquot volume is not specified in the protocol, use as many cryovials as needed to evenly dispense plasma into 1 mL aliquots.
   - The number of vials needed will vary based on the volume of plasma obtained but can be estimated as roughly half of the blood volume collected.
5. Immediately freeze plasma vials in an upright position, buried in dry ice or in a -70°C to -80°C freezer until ready to ship.



6. If buffy coat is also required, follow instructions below to remove buffy layer. If buffy coat is not requested, then discard remnant cells.

Buffy Coat Processing

1. Centrifuge vacutainer tube(s) at 1200 x g for 10 minutes at room temperature. *Note: if processing plasma and buffy coat, only one centrifugation is needed.*
2. Pre-label cryovials according to specimen labeling requirements.
3. Using a clean pipette, slowly remove the buffy coat (the thin, cloudy pin or gray-white layer located in between the red blood cells and the plasma; refer to figure below). Avoid aspirating the red blood cells while collecting the buffy coat.
4. Split the buffy coat equally into two 2 mL cryovials.
5. Immediately freeze vials in an upright position, buried in dry ice or in a -70°C to -80°C freezer until ready to ship.

Version Date: 03/27/2024

Specimen Collection and Processing Guidelines for Serum

If protocol-specific collection instructions for peripheral blood and processing instructions for serum are not provided in the protocol or through a linked resource (usually in Section 15 in SWOG-led protocols), then follow the instructions outlined below.

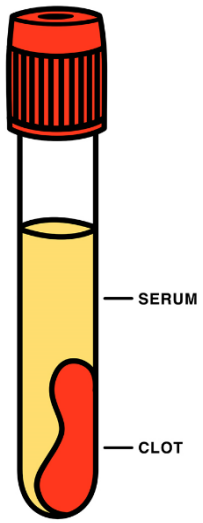
Serum is processed from blood collected without anticoagulant (e.g., plain red top tube or serum separator tube with gel). After blood has clotted, serum is processed by centrifuging and removing the yellowish-clear layer (serum). Note: after processing, serum looks very similar to plasma. If a protocol includes both serum and plasma specimens, it's *imperative* that each tube is labeled with the specimen type (e.g., serum or plasma)

Collecting Peripheral Blood

1. Use the collection tube type specified in the protocol. Note: for serum processing, it's essential to use collection tubes with no anticoagulant to collect whole blood for serum processing.
   - One or more tubes can be used to collect the required volume (e.g., if the protocol indicates to collect 10 mL of blood, then one 10-mL tube or two 5-mL tubes can be used to collect the specified volume).
2. Before collection, label all tubes according to the protocol. If not specified in the protocol, then follow the specimen labeling requirements indicated in the General Specimen Submission Instructions.
3. Use aseptic techniques and draw blood from the participant.
4. Follow the instructions below for serum collection:
   - When a red/black marble top (SST) vacutainer tube is used it must be gently inverted 5-10 times immediately after collection to activate the gel.

Serum Processing

1. Allow blood to clot for at least 30-60 minutes at room temperature.
2. Centrifuge vacutainer tube(s) at 1200 x g for 10 minutes at room temperature.
3. Pre-label cryovials according the specimen labeling requirements.
4. Using a clean pipette, remove serum (yellow-clear liquid above clot). No debris should be present in the plasma.
5. Dispense 1 mL aliquots of serum into the pre-labeled 2 mL cryovials and cap the tubes securely. If not specified in the protocol, use as many cryovials as needed to evenly dispense serum into 1 mL aliquots. The number of vials needed will vary based on the volume of serum obtained.
6. Immediately freeze vials in an upright position in a -70°C to -80°C freezer until ready to ship.



Specimen Collection and Handling Guidelines for Bone Marrow Aspirate

If protocol-specific collection and handling instructions for bone marrow aspirate are not provided in the protocol or through a linked resource (usually in Section 15 in SWOG-led protocols), then follow the instructions outlined below.

Collecting Bone Marrow Aspirate

1. Use the protocol-specified collection tube type(s) to collect bone marrow aspirate.
    a. One or more tubes can be used to collect the required volume of bone marrow (e.g., if 10 mL of bone marrow aspirate is requested, then one 10-mL or two 5-mL tubes may be used to collect 10 mL).
    b. Pre-label vacutainer tube(s) according the specimen labeling requirements.
        - Note: laterality (right or left) is a labeling requirement for bone marrow.
2. Use anticoagulated syringes to collect bone marrow aspirate. Then, place the marrow into the vacutainer tube(s).

Storage of Bone Marrow Aspirate

- Bone marrow aspirate should be shipped as soon as possible to optimize cell viability.
- If bone marrow aspirate cannot be shipped immediately after collection, then store at 4°C (40°F) until shipment. **Do not freeze the bone marrow aspirate**.
- Storage time longer than 24 hours can greatly impact specimen quality and should avoided whenever possible.

Additional Considerations for Bone Marrow Aspirate Collections for Leukemia:

- For leukemia protocols, if participants have a high white blood cell count (e.g., greater than 100,000 cells/µL), then the bone marrow aspirate may be a “dry tap” (meaning that the collection is unsuccessful). In these cases, peripheral blood is often a potential substitute. Refer to the protocol for the volume of peripheral blood that should be collected instead, as it can be a larger volume than the bone marrow requested.

Specimen Tracking and Documentation Requirements

Unless otherwise indicated in the protocol, follow the documentation and tracking instructions outlined on the following three pages.

Important Notes:

1. EACH page of supporting documents must be labeled with the SWOG Participant ID number and participant initials, which must be in L, FM format.
2. For specimens being shipped to the SWOG Biospecimen Bank: All dates must be in MM/DD/YYYY format, if written numerically.
3. Document missing or partial specimen submission in the Specimen Tracking System (STS).
    - If a specimen was not collected / is not available for submission, this must be documented via the Notify Specimen Cannot be Submitted link in the STS.
    - If only a partial submission is submitted (e.g., limited slides available), this must be documented in the STS, as indicated in the instructions provided here.
4. Unless otherwise indicated in the protocol, the STS Packing List must be included (packaged) with all specimen submissions.
5. The pathology report(s) corresponding to the tissue removal surgery must be included with each shipment of tissue. Pathology reports must be redacted as indicated here.

Specimen Tracking System (STS) Overview

1. Log into STS via the CRA Workbench (or at: https://spectrack.crab.org/Logon.aspx) using your CTEP credentials.

2. STS laboratory IDs are used to identify the laboratories to which specimens will be shipped.
   a. Each SWOG-led protocol will refer to this Lab ID # for each Specimen Type.
      - The SWOG Biospecimen Bank will either be Lab #201 for the Solid Tissue, Myeloma and Lymphoma Division or Lab #200 for the Leukemia Division.
   b. Shipping addresses are included in Specimen Tracking under the relevant Laboratory ID#.

3. STS use is required for SWOG protocols.
   a. Unless otherwise indicated in the protocol, all specimens must be logged in STS. Doing so will resolve specimen expectations.
   b. Partial submissions (e.g., only partial slides available or vials could be collected) for an expected specimen submission must also be logged in.
   c. Specimens that cannot be collected must be noted in STS using the "Notify that a Specimen Cannot be Submitted" function.

4. Each specimen type (e.g., blood or blood products, tissue blocks or slide) at each time point (e.g., baseline, Cycle 3 Day 1, progression) must be logged separately in Specimen Tracking.

5. The **SWOG Specimen Tracking Packing List** must be printed from Specimen Tracking and included in every shipment.
   a. Prior to sealing the package, confirm that the information on the STS Packing List exactly matches the specimens in the shipment. **Double-check the specimen labels versus packing list**.
   b. Collection dates must be in MM/DD/YYYY format.
   c. Participant initials must be in the following order: Last Name, First Name, Middle Name. The format of participant initials included on the specimen label must exactly match the format of the participant initials as entered into the SWOG Specimen Tracking System (STS), (i.e., **L, FM**). A difference in comma placement will result in a query.
      - Note: If your institution is not able to include a comma on the specimen label, then the SWOG Biospecimen Bank will accept specimen labels with participant initials in format FML without a comma, however, data entry into the STS must still be entered in format L, FM.
   d. If errors or differences are noted and the slide label contains the correct information, then correct the information that was entered into the STS and re-print the STS Packing List.
   e. A pathology report from the procedure MUST be included in shipment of tissue.

6. **Additional Materials and Contact Information:**
   a. For procedural help with logging and shipping specimens: Refer to the written Specimen Tracking instructions or Specimen Tracking introductory training presentation (which is also available in Spanish).
   b. How to document missing or partial specimen submission in the Specimen Tracking System (STS).
      - If a specimen was not collected / is not available for submission, this must be documented via the Notify Specimen Cannot be Submitted link in the STS.
      - If only a partial submission (e.g., limited slides available) is submitted, this must be documented in the STS, as indicated here.
   c. For answers to Frequently Asked Questions: Refer to FAQs: Data Submission | Specimen Submission Queries and FAQs: Protocol Conduct | Specimen Collection
   d. For further assistance (e.g., editing or deleting shipments in Specimen Tracking): Contact the Data Operations Center via the appropriate disease-specific e-mail distribution list found on the Contact Us page or by Phone: 206-652-2267.
   e. To report technical problems with STS, such as database errors or connectivity issues Contact technicalquestion@crab.org.

Version Date: 03/27/2024

Specimen Submission Guidelines – Required Documents

– If documentation requirements are not otherwise outlined in the protocol or through a linked resource (usually in Section 15 in SWOG-led protocols), then submit documents as indicated below, in accordance with the standard requirements.

Specimen Type	Required Documents
Fresh or frozen stool and liquid specimens (blood, serum, plasma, buffy coat, urine, and stool specimens)	**All specimen submissions must include:** 1. SWOG Specimen Tracking System (STS) Packing List *(Printed after entry of specimen information into the STS at: https://spectrack.crab.org. Note: The information entered into the STS must match the information contained on each corresponding specimen label.)* **Protocol Specific Requirements:** 2. Other required report. *(See partial redaction instructions in bone marrow/tissue section below.)*
Bone Marrow or Tissue (FFPE, core biopsy, snap frozen) (blocks, slides, scrolls/curls)	1. SWOG STS Packing List **- AND -** 2. Partially redacted pathology report *corresponding to the bone marrow or tissue removal procedure.* **Protocol Specific Requirements:** 3. Other required report.

Pathology (or Other Required) Report Redaction and Labeling Requirements

Unless otherwise outlined in the protocol (usually in Section 15 in SWOG-led protocols):

1. Reports must be in English or include a translation of all information listed below.
2. **Pathology reports MUST include:**
   - Date of procedure,
   - Surgical pathology ID (SPID) or accession number,
   - Block number(s) with description of each block,
   - Anatomic site,
   - Diagnosis, and
   - Gross description.
3. It is acceptable to print a .PDF from the EMR so that the entire *redacted* report is included with the specimens.
4. **Remove participant identifiers such as name, date of birth, medical record number, and insurance information form the pathology or other required report.**
   - Pathology reports:
     - **Do not redact** the date of procedure (collection date), surgical pathology identification (SPID) number, block number, or diagnosis.
     - Do not cut and paste from the electronic medical record (EMR).
     - If any of the required data (in #2 above) is missing, then processing may be delayed until an updated report is submitted.
   - Other required reports: Do not redact the date of procedure (collection date) or diagnosis.
5. **Label each page of the pathology or other required report with the SWOG Participant ID#.**
6. **The information contained in** the partially redacted pathology or other required **report must match the information printed on each specimen label affixed to the specimen(s) included in the package.**
7. **If the protocol requires indication of tissue type, refer to Pathology Reports for tissue type definitions.**

Pathology Reports

The pathology report corresponding to the tissue removal surgery must be included with each shipment of tissue. Do not cut and paste from the electronic medical record (EMR). It is acceptable to print a PDF so that the entire report is included with the specimens. If any of the required data is missing, then processing may be delayed until an updated report is submitted.

1. **Pathology reports must include the following:**
    a. Date of procedure,
    b. Surgical pathology ID (SPID) or accession number,
    c. Block number(s) with description of each block,
    d. Anatomic site,
    e. Diagnosis, and
    f. Gross description.
2. Reports must be in English or include a translation of all information listed above.
3. Write the SWOG Participant ID on each page of the report, and redact information that is not required (see redaction guidelines below).

Redaction Guidelines

- The SWOG Biospecimen Bank should receive only the minimum necessary personally identifiable information (PII) for translational medicine and biobanking.
- Remove participant identifiers, such as name, date of birth, medical record number, social security number, and insurance information from the pathology report.
- Do not redact the date of procedure, surgical pathology ID (SPID) number, block number, or diagnosis.

SWOG Biospecimen Bank Definitions of Tissue Type:

- **Primary**: the initial source of tumor tissue, including residual tumor from the primary site. Must make biological sense for tumor type (e.g., colon cancer in colon tissue).
- **Metastatic**: tumor tissue collected at sites separate from the primary lesion, including local and distant metastatic tumor and residual tumor from the metastatic site (e.g., lung tumor biopsy for prostate cancer)
- **Normal**: tissue that does not contain tumor, including lymph nodes negative for tumor.

Specimen Packaging and Submission – General Notes

Unless otherwise indicated in the protocol, package and ship specimens as outlined in the instructions below.

Important Notes:

1. **Specimens must be packaged to comply with IATA standards** (www.iata.org).
2. **When a participant has a *known* infection**, such as Hepatitis, a Category B label must be used in place of an Exempt Human Specimen label and Category B. Category B labels are not provided by the SWOG Biospecimen Bank.
3. For leukemia protocols: **Do NOT send cytogenetic specimens to the SWOG Biospecimen Bank.**
4. Unless otherwise indicated in the protocol, the STS Packing List must be included (packaged) with all specimen submissions.
5. The partially redacted pathology report(s) corresponding to the tissue removal surgery must be included with each shipment of tissue.
6. For questions about shipping specimens around a holiday, please reference the Bank's holiday hours memo distributed by the SWOG Protocol Development office or contact the Bank directly (Lab #201: Solid Tissue, Myeloma & Lymphoma Division or Lab #200: Leukemia Division).

Packaging and Shipping Guidelines for Ambient Specimens

Note: When a participant has a known infection, such as Hepatitis, a Category B label must be used in place of an Exempt Human Specimen label and Category B. Category B labels are not provided by the SWOG Biospecimen Bank.

Packaging guidelines for ambient specimens:

1. **Specimens must be packaged to comply with IATA standards.**
2. First, place the specimen in a leak proof biohazard envelope. Include an absorbent material if the specimen is liquid. Next, place the biohazard envelope in a puncture and pressure resistant envelope (e.g., Tyvek envelope).
3. Place the packaged specimen in an appropriate shipping container (ex. FedEx box or clinical pack).
4. Include required paperwork (e.g., STS-generated packing list(s)) in the shipment.
5. Attach an "Exempt Human Specimen" label and a shipping label to the outside of the shipping container.

Shipping guidelines for ambient specimens:

- Ambient specimens should be shipped. FedEx Priority Overnight service is preferred. Use of other courier services may delay package receipt.
- On Saturday, the Bank is only staffed to process fresh blood, bone marrow, and urine. No other specimen types should be submitted for Saturday delivery.
    - All other specimen types must be shipped Monday through Thursday for delivery Tuesday through Friday.
    - If specimens are shipped for Saturday delivery, then the airbill must be marked “For Saturday delivery.”
- Whenever possible, avoid shipping ambient specimens the day before a holiday.
- For questions about shipping specimens around a holiday, please reference the Bank’s holiday hours memo distributed by the Protocol Development office or contact the Bank directly using contact information below..
- During the months of April-September (or times of warm weather), ship fresh specimens on a refrigerated (not frozen) cold pack.
- During the months of October-March (or times of unusually cold weather), insulate fresh specimens to keep from freezing due to weather (i.e., wrap specimen in bubble wrap).
- For packaging instructions, refer to the ambient specimen packaging and shipping guidelines for ambient specimens.

Contact the SWOG Biospecimen Bank with any questions regarding specimen and shipping instructions. The laboratory ID number, shipping address, and contact information for specimen submissions are:

Lab #201 Address and Contact information:	**Lab #200 Address and Contact information:**
SWOG Biospecimen Bank Solid Tissue, Myeloma & Lymphoma Division Nationwide Children’s Hospital 700 Children’s Drive, WA1340 Columbus, Ohio 43205 Phone: 614-722-2865 FAX: 614-722-2897 Email: bpcbank@nationwidechildrens.org	SWOG Biospecimen Bank Leukemia Division Nationwide Children’s Hospital 700 Children's Drive, C0825 Columbus, Ohio 43205 Phone: 614-722-3720 FAX: 614-722-2856 Email: bpcmglab@nationwidechildrens.org

Packaging and Shipping Guidelines for Frozen Specimens

Note: When a participant has a known infection, such as Hepatitis, a Category B label must be used in place of an Exempt Human Specimen label and Category B. Category B labels are not provided by the SWOG Biospecimen Bank.

Packaging guidelines for frozen specimens:

1. When batch shipping, only submit a maximum of five participants or five time points from one participant in each shipment. Each participant and time point must be packaged separately (e.g., separate plastic bag).
2. **Specimens must be packaged to comply with IATA standards (www.iata.org).**
3. First, place the specimen in a leak-proof biohazard envelope. Include an absorbent material. Next, place the biohazard envelope containing the specimen in a puncture and pressure resistant envelope (e.g., Tyvek envelope).
4. Place the packaged specimen(s) in an appropriate shipping container (composed of an inner Styrofoam and outer cardboard layer). Place a layer of dry ice in the bottom of the shipping container, then set the specimen on top of the dry ice. Cover the specimen with dry ice until the shipping container is full.
5. Include required paperwork (e.g., STS-generated packing list(s)) in the shipment.
6. Close the shipping container and tape shut. Do not completely seal the container. Complete a dry ice label. Attach an "Exempt Human Specimen" label and the dry ice label to the side of the shipping container.
7. Attach a shipping label to the top of the shipping container.

Shipping guidelines for frozen specimens:

- Ship frozen specimen(s) buried in dry ice. FedEx Priority Overnight service is preferred. Use of other courier services may delay package receipt and compromise specimen integrity.
    - Note: a minimum of 5-10 lbs. of dry ice should be used per shipment, and specimens should be completely buried with dry ice (i.e., fill the container 1/3 full, add the specimens, and then add dry ice to the top of the container).
- 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.
- For questions about shipping specimens around a holiday, please reference the Bank's holiday hours memo distributed by the Protocol Department office or contact the Bank directly using the contact information provided below.
- For packaging instructions, refer to the packaging and shipping guidelines for frozen specimens.

Contact the SWOG Biospecimen Bank with any questions regarding specimen and shipping instructions. The laboratory ID number, shipping address, and contact information for specimen submissions are:

Lab #201 Address and Contact information:	**Lab #200 Address and Contact information:**
SWOG Biospecimen Bank Solid Tissue, Myeloma & Lymphoma Division Nationwide Children's Hospital 700 Children's Drive, WA1340 Columbus, Ohio 43205 Phone: 614-722-2865 FAX: 614-722-2897 Email: bpcbank@nationwidechildrens.org	SWOG Biospecimen Bank Leukemia Division Nationwide Children's Hospital 700 Children's Drive, C0825 Columbus, Ohio 43205 Phone: 614-722-3720 FAX: 614-722-2856 Email: bpcmglab@nationwidechildrens.org