Pathology Review

The primary purpose of pathology review is to verify patient eligibility for a protocol. The SWOG pathology committee reviews each protocol to determine whether pathology review is required. Pathology materials are also used to study questions of scientific interest to the pathology committee.

For protocols where pathology review is used to verify eligibility, materials from tissue obtained prior to patient registration are reviewed to establish that the pathologic features match protocol eligibility requirements. This review process occurs after a patient is registered. Treatment decisions and/or protocol registration are not based on SWOG pathology review results. Eligibility is partly determined by this process; a patient who is pathologically ineligible will be rendered ineligible for the study.

In some protocols, additional pathology materials from a biopsy or surgical procedure done after registration are required. These materials frequently are used to document presence or absence of microscopic disease after treatment or to document disease characteristics after response. This review is not used to establish eligibility; rather, it provides a detailed pathologic assessment of tumor response.

Material Submission
The following procedures and guidelines should be followed when preparing pathology materials for submission.

1. Prior to patient registration, consult the Discipline Review section of the protocol to identify whether pathology review is required, and if so, what materials and paperwork need to be submitted.

2. When pre-registration materials are required, verify that the materials and requested paperwork are available to send to the address given in the Discipline Review section of the protocol. A patient is deemed ineligible if these pre-registration materials are not submitted for review.

3. Most SWOG studies require the entry and tracking of pathology specimens using the SWOG online Specimen Tracking System (STS). A link to this system can be found on the CRA Workbench. A copy of the Shipment Packing List produced by the Specimen Tracking system must be printed and submitted with the pathology materials. Detailed instructions for using this system are available on the STS welcome page.
4. The designated pathologist at the registering/submitting institution should screen all materials to make sure the appropriate materials are sent. In some cases, only one diagnostic slide is necessary. In other cases, additional materials such as unstained slides and/or blocks and special forms may be required. A Packing List must always accompany pathology materials unless otherwise specified in the protocol. For intergroup studies conducted by other groups, follow the instructions in the protocol for reporting of submission (e.g. submission form provided by the protocol or entry into an online specimen tracking system).

5. Use appropriate packing materials for shipping slides. Do not use the large cardboard slide display cases; rather, use plastic slide cases which generally are available in the pathology department. Label each slide case with patient initials, SWOG patient number and study number. Protect the plastic cases by surrounding them with packaging materials such as Styrofoam peanuts, plastic air bubble sheets, or foam rubber. Tape the containers so they do not open in shipment. Blocks should be wrapped (with packing material such as gauze pads) to prevent breakage. Pack all materials and paperwork together in canisters, padded envelopes, or boxes for shipping. Be sure to package materials so that the carton can withstand 100 pounds of pressure and a three-foot drop, in order to comply with U.S. Postal Service regulations. More than one pathology case may be packed together in the same shipping container, but each case must be individually labeled and paperwork for all specimens provided. When pathology slides and blocks arrive broken or damaged, pathology expectations cannot be resolved and materials cannot be reviewed.

6. Incomplete submissions do not resolve the pathology materials expectations. In the event of an incomplete submission, a note is added to the patient’s pathology submission expectation and a request for the missing information is sent to the institution. Requests are also sent to institutions whose materials are not properly identified by patient and/or study number. In the event that the wrong type of material arrives, pathology expectations cannot be resolved.

Review Process
Receipt of adequate materials is used to resolve the pathology expectation generated at the time of patient registration. Subsequently, reviewing pathologists determine acceptability of cases for SWOG protocols based on received materials. Following review, pathology materials are generally held by the pathologist until the study is closed and results are published.

If the submitting pathologist requires the return of materials for his or her patient care responsibilities, contact the lab or individual designated in the Discipline Review section of the protocol and materials should be returned in a timely fashion. Copies of completed SWOG pathology review forms are not routinely mailed to the submitting institution. Instead, institutions may obtain the information on a case-by-case basis by contacting the assigned study Data Coordinator at (206) 652-2267.
Radiation Therapy Review
All RT discipline review for radiotherapy regimens on SWOG studies are now being done by the Quality Assurance Review Center (QARC) in Providence, RI. To determine if your study has RT review, refer to Section 12.0 of the protocol. This section will document the following:

- Specifically what data is to be sent for rapid review with respect to treatment planning,
- What needs to be submitted for the final review once the patient has completed radiation therapy,
- The URL for the QARC website documenting which forms are to be submitted along with the RT films,
- Contact information for RT related questions.

Questions regarding submission of materials and/or treatment should be directed either to the RT study coordinator listed in the table of contents or to QARC.

References: Section 7.0 (Treatment), Section 8.0 (Adverse Events), Section 12.0 (Discipline Review), Section 9.0 (Study Calendar) and Section 14.0 (Data Submission).