DISCIPLINE REVIEW

Discipline review is an important part of the SWOG patient data evaluation system and is included with the patient evaluations for the study chair’s review. Discipline coordinators review cases for protocol eligibility or compliance in regards to pathology, radiation therapy or surgery. They also determine pretreatment status (pathology), review procedures performed (surgery and radiation therapy), or outcome (pathology and surgery).

The discipline review results are entered into the data base at the SWOG Data Operations Center by the Data Coordinator for the particular study. Entering the data automatically updates overall eligibility (when applicable) and creates notification of changes in eligibility status.

Pathology Review

The primary purpose of pathology review (by a physician or pathologist, not a lab) is to verify patient eligibility for a protocol. Pathology materials are also used to study questions of scientific interest to the pathology committee. The SWOG pathology committee reviews each protocol to determine whether pathology review is required.

For protocols where pathology review is used to verify eligibility, materials from tissue obtained prior to patient registration are reviewed to determine if the pathologic features match protocol eligibility requirements. This review process occurs after a patient is registered. Eligibility is determined by this review process. A patient who is pathologically ineligible will be rendered overall ineligible for the study.

Some protocols require additional pathology materials from a biopsy or surgical procedure which was done after registration. 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.

The Confirmation of Registration (see Chapter 4) contains a list of expectations for data submission and will list pathology requirements. The amount of time allowed for pathology submission is based on the registration date and treatment plan. Complete pathology materials generally must be submitted within 30 days.
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 usually Sec. 12.0 of the protocol to identify whether pathology review is required and if so, what materials and reports need to be submitted.

2. As of January 1, 2007, all specimen submissions for all active SWOG studies must be entered and tracked using the SWOG online Specimen Tracking System (STS). This system can be accessed via the CRA Workbench on the SWOG website. Be sure to read the instructions. For questions regarding STS, call the Data Coordinator for the specific SWOG study @ 206-652-2267.

3. When pre-registration materials are required, verify that the materials are available to send to the SWOG reviewer designated in the protocol. Questions about specific submissions can be directed to the reviewing pathologist. A patient is deemed ineligible if these pre-registration materials are not available for review.

4. The designated institutional pathologist 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 may be required. Also consult the protocol to determine paperwork required for submission, such as pathology reports, operative reports or onstudy forms. Clearly label all paperwork with patient number, initials and study identification and registration step.

5. Use appropriate packing materials for shipping slides. Do not use the large cardboard slide display cases; rather, use plastic slide containers which generally are available in the pathology department. Label slides and cases using labels available at Specimen Tracking Home page link for Specimen Labels or on the CRA Workbench under Tools of the Trade. Complete the patient number, initials, specimen type and collection date, tissue type, surg path number (if available) and block number (if applicable). 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. Pack all materials and paperwork together in canisters, padded envelopes or boxes for shipping. Affix a neon magenta “SWOG Pathology Materials” sticker. The template is available on the CRA Workbench under the “Tools of the Trade” link and on the Specimen Tracking Home page. SWOG recommends using Avery neon magenta high visibility labels (see product number 5970 at www.avery.com). 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.

6. More than one pathology case for the same protocol may be packed together in the same shipping container but each case must be individually identified. When institutions submit pathology slides and blocks that have been broken and/or might have been broken due to poor packaging, a notification is sent to the member institution.
7. Incomplete submissions do not resolve the pathology materials expectations. In this event, a note is added to the patient's pathology submission expectation and a request for the missing information is sent to the institution. Requests also are sent to institutions whose materials are not properly identified by patient and/or study number.

Review Process

In most cases, submissions are sent directly to the specific SWOG study pathologist reviewing the materials and may be forwarded to additional reviewers if necessary.

Following review, results are sent (usually via a Path Review Form) to the SWOG Data Coordinator for that study. Reviewing pathologists determine acceptability/eligibility of cases for SWOG protocols based on the received materials.

Completed review results are entered into the database by the Data Coordinator.

Following review, pathology materials are held in repositories coordinated by the reviewing pathologist. Materials are generally returned to the institution after publication of the study. However, upon request to the repository they can be returned sooner. Materials will be used for additional reference and review or for preparation of educational materials to benefit the entire pathology group.

If the submitting pathologist/institution requires the return of materials for his or her patient care responsibilities, contact the reviewing pathologist or the SWOG Repository (Nationwide Childrens in Ohio) and the materials will be returned as soon as is possible.

Radiation Therapy Review

Review of radiation therapy (RT) is not done for all SWOG studies that have radiation therapy. RT review is done only on those studies which have radiation therapy research questions or complicated radiation therapy procedures.

The purpose of RT review of SWOG protocols is to ensure that the RT is given safely and according to protocol instructions. Some SWOG RT protocols go through more than one review. The Discipline Review section of each protocol describes what is required for each review that is done.

- Some protocols require a rapid review of RT. Rapid review is performed by the Quality Assurance Review Center (QARC) and provides a check of the radiation therapy at the beginning or prior to the start of RT Treatment. The QARC may request corrections if necessary.

- All protocols with RT review are reviewed by a radiation therapy study coordinator after completion of RT. That reviewer checks the entire treatment for protocol compliance for each patient who receives Radiation Therapy.
For information on specific SWOG RT policies, refer to Policy Memorandum No. 26 of the SWOG Policies and Manuals at https://swog.org/Visitors/Download/Policies/Policy26.pdf. This explains radiation therapy guidelines, outlines the criteria that must be met for institutions to be involved in RT protocols and describes quality control procedures for RT materials. Radiation therapy for SWOG patients must ALWAYS be given at a SWOG approved radiation therapy facility.

Data Submission and Review

The Discipline Review section of each RT protocol specifies the radiation therapy data and films that must be submitted. This section also provides the addresses to which RT materials should be sent and the schedule for submission.

SWOG RT forms are included in the appendix of protocols that require RT review. The treatment prescription, the treatment diagram, the daily dose record and dosimetry calculations are all obtained directly from the radiation therapist's treatment records. No films or RT data need to be sent in for protocols that do not have RT review. RT total dose and the start and stop dates should be documented on the Radiation Therapy Summary Form for those protocols.

The Confirmation of Registration (see Chapter 4) contains a list of expectations for data submission. The amount of time allowed for the submission of the radiation therapy materials is based on the registration date and the length of treatment. With the exception of rapid review, 30 days following completion of RT are allowed to complete and submit the data.

When a protocol involves RT review, it is recommended that the CRA forwards to the radiation department/facility a copy of the confirmation of registration, a copy of the treatment plan from the protocol and copies of any RT forms. The CRA should insure that these forms are labeled with the patient’s initials, study number, registration step and SWOG patient number. The RT facility should be instructed to label the films with the patient’s demographic information as well as with the date of the film and the type of film (e.g. Sim, Port, CT, etc.)

If rapid review of RT is required for a protocol, the clinical research associate must alert the radiation therapy department that RT materials must be submitted to QARC within 48 hours following the first treatment fraction. The QARC's rapid review of RT helps to ensure that the treatment will be given correctly. QARC may request that the patient's radiation therapy be modified based on this early review. If the material cannot be sent to QARC within 48 hours of starting treatment, send it as soon as possible with an explanation for the delay. After the QARC has completed the initial review, the QARC will forward RT materials to the radiation oncologist performing the final RT review.

All studies with RT review get a final RT study chair review. After the final review is complete, the result of this review is entered into the SWOG database.
Radiation Therapy Reports

Approved Radiotherapy Facilities Report
The Operations Office maintains the Approved Radiotherapy Facilities Report. This report includes the radiotherapy facility location (city and state), number, name, contact person and approval status. Each facility is listed as having either "P" (provisional approval) or "F" (final approval). The stereotactic radiosurgery approval status is also indicated for those facilities that have also been approved as stereotactic radiosurgery facilities. Provisional six-month approval may be granted by the QARC office on review of an RT facility's application and final approval is determined at the semi-annual Southwest Oncology radiation therapy committee meetings. The report can be downloaded from the SWOG Web site, www.swog.org.

Some Radiation Therapy Definitions

AP-PA
Refers to radiation directed at the patient from the front (AP) and back (PA).

BOOST
An additional treatment or treatments given to a reduced volume to increase the dose to that volume. A boost may be given at the end of, or concurrently with, the main treatment.

COMPENSATING FILTERS
A device placed between the treatment machine and the patient to help achieve a uniform radiation dose. It is used when the area of the body being treated is not flat; for example, head and neck treatments. Compensating filters are usually designed on a per-patient basis. Some compensators can be used on more than one patient, when the shape of the patient, although not flat, is regular and predictable. These are most often used to correct for sloping surfaces in the chest area for lung patients.

DOSIMETRY
There are two main aspects to radiation dosimetry: first, measurement of the quantity of radiation emitted by various sources and second, measurement of the quantity of radiation absorbed by body tissue as a result of the radiation therapy. The dosimetry calculations required by SWOG are those that derive monitor units (MU).

FRACTION
One treatment session. If a patient's treatment of 30 Gy is given in 10 equal treatment sessions, the patient is said to have received 10 fractions of 3 Gy each.

FRACTIONATION
Total Dose/Total Number of Treatments = Fractionation (daily dose). In the above example, the fractionation is 3 Gy.

Gy (GRAY)
A Gy is the unit used to describe the dose given to the patient. (1 Gy = 100 rads, 1 cGy (centigray) = 1 rad).
### Some Radiation Therapy Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEMI-BODY IRRADIATION</td>
<td>Half of the body (upper or lower) encompassed in one field.</td>
</tr>
<tr>
<td>ISODOSE CURVE</td>
<td>A series of lines drawn on a cross sectional representation of the patient. Each line connects points that received the same dose. Thus, it is a representation of dose levels within the patient.</td>
</tr>
<tr>
<td>JUNCTION</td>
<td>The point where two adjacent fields meet.</td>
</tr>
<tr>
<td>LOADING</td>
<td>Breakdown of total dose by field. If two fields are used to treat the same area (right and left, or AP and PA) and both fields deliver the same dose to the center of the patient, the fields are equally loaded or loaded one to one (1:1). If one field gives twice as much dose as the other, the loading is two to one (2:1).</td>
</tr>
<tr>
<td>LOCALIZATION FILM</td>
<td>Film taken on the treatment machine for planning purposes.</td>
</tr>
<tr>
<td>MODALITY</td>
<td>Type of radiation used to treat the patient; Cobalt-60, 4 MV X-rays, 9MeV electrons, etc.</td>
</tr>
<tr>
<td>PALLIATIVE</td>
<td>Treatment given to a patient in an attempt to improve his/her quality of life by alleviating symptoms (e.g., for bone pain).</td>
</tr>
<tr>
<td>PARALLEL-OPPOSED</td>
<td>Fields directed at the patient from opposite sides of the body.</td>
</tr>
<tr>
<td>PLAN OF TREATMENT</td>
<td>Information describing the anatomical location, size, dose, and any other technical data required to follow the physician's treatment prescription.</td>
</tr>
<tr>
<td>PORT</td>
<td>Radiation field; port film taken on the treatment machine showing the shape of the area being treated; port films are often referred to as &quot;ports.&quot;</td>
</tr>
<tr>
<td>RAD</td>
<td>Unit used to describe the dose of radiation given to the patient.</td>
</tr>
<tr>
<td>SAD (SOURCE-AXIS DISTANCE)</td>
<td>Distance from the source of radiation (within the treatment machine) to the tumor. It is one way to indicate the distance the patient was from the treatment machine.</td>
</tr>
<tr>
<td>SIMULATOR FILM</td>
<td>Film taken on a special X-ray machine with the outline of the field shown on it. Similar to port film but shows the anatomy in much greater detail. Used to determine if the radiation field will treat the appropriate area.</td>
</tr>
</tbody>
</table>
Some Radiation Therapy Definitions

SSD (SOURCE-SKIN DISTANCE)  Distance from radiation source (within the treatment machine) to the patient's skin surface. The SSD can be different for different points in the field if the surface of the patient is not flat.

TOTAL BODY IRRADIATION  The entire body encompassed in one field.

WEDGE  Wedge-shaped piece of lead placed between the treatment machine and the patient to produce an uneven dose across the field. The dose under the thicker part of the wedge is lower than the dose under the thinner parts. Wedges are usually used in pairs, to produce a small high-dose area where the beams under the thin parts of the wedges cross.

Surgical Review

When surgery is part of a protocol, the surgery is reviewed by the surgical study coordinator to confirm that the surgical technique used was sound and that it followed the guidelines contained in the protocol.

Surgery requirements can be found at different points in a protocol. Often a surgery does not take place while a patient is on study but takes place prior to registration. An evaluation of this type of surgery is called qualifying surgical review and for these types of studies, surgical procedure is reviewed for eligibility. If the surgery was not done according to the protocol guidelines, the patient will be declared ineligible for the protocol.

In other protocols, an objective may be to see if a certain surgical technique is a reasonable treatment for a specific cancer, whether the addition of chemotherapy or radiation therapy to a known effective surgical treatment improves survival or if a surgical treatment is superior to chemotherapeutic or radiotherapeutic treatment. For these types of surgical treatment protocols, it is important to review the surgical procedure so that statements about the quality of surgery and the consistency of technique across many institutions can be made and supported. In these cases, the surgery is not reviewed for eligibility but is reviewed for technique and protocol compliance. This is called protocol surgery review. Determinations of violations or deviations from the surgical guidelines set forth in the protocol are recorded.

Another type of protocol surgery that may take place is second-look surgery. This type of surgery is used to determine response to a previous modality used in the protocol. In this case, the surgery is reviewed to confirm that the correct surgical technique was used so that the proper pathologic specimens are collected to verify the response.

Surgical Data Submission

A study can have both types of surgical review, either type of surgical review or none at all. The type of surgical review required (if any) and data submission requirements will be specified in the Discipline Review section of the protocol.
For studies requiring surgical review, the registering institution sends the operative and pathology reports as well as any other required documentation (e.g., surgery-specific checklist) to the SWOG Data Operations Center. Any surgical complications should be noted on the Surgical Complication Toxicity Form.

Expectations for the required surgical information will be posted at registration. The surgery expectations will appear with the other expectations on the Confirmation of Registration.

For surgery done prior to study entry (qualifying surgery) the required forms (operative and pathology reports and if applicable, disease specific forms) are to be received at the SWOG Data Operations Center within 7 days after registration (along with the initial forms set). For surgery done as treatment while the patient is on the protocol (protocol surgery), the forms are to be received at the SWOG Data Operations Center within 21 days after the procedure. When pathology review is also required, additional copies of the operative and pathology reports are sent to the pathology reviewer as well. Please refer to the pathology review guidelines earlier in this chapter.

For some protocols with surgery, there is no surgical review but operative and pathology reports may still be requested as documentation that the surgery was done. They are included as part of the patient's data which will be used when the study chair evaluates the protocol treatment. Expectations for these forms are posted with the other expectations listed on the Confirmation of Registration and also require receipt at the SWOG Data Operations Center within 14 days after registration (along with the initial forms packet). To determine whether extra reports are required, review the Data Submission section of the protocol.

Review Process

When the surgical data are received at the SWOG Data Operations Center, the expectations for the forms are resolved. Data is then forwarded to the surgery study chair for review. If the review is for qualifying surgery, the surgical study coordinator is responsible for evaluating the patient's surgery documentation to verify that the surgery required for eligibility was performed in accordance with criteria noted in the protocol. If the review is for protocol surgery, the surgical coordinator is responsible for evaluating the patient's surgery documentation for the following:

1. Whether the correct surgery was done and if not, why not;
2. Whether the surgery was performed according to the protocol guidelines; and
3. Whether an evaluation for surgical complications was performed. Any complications noted are entered in the patient's record as toxicities.

The study surgical reviewer returns the results of his or her review to the SWOG Data Operations Center. The SWOG Data Operations Center Data Coordinator then enters the results into the database; a copy of the surgical evaluation form is filed in the patient's chart. If you have a question about the outcome of the review, a copy of the surgical chair's evaluation is available upon request from the SWOG Data Operations Center. If you disagree with the outcome and you have additional reports that weren't submitted previously, submit these to the SWOG Data Operations Center with a note; they will be resent for review.