INTERGROUP STUDIES

In addition to studies which are coordinated by SWOG, SWOG institutions participate in specified studies that are coordinated by other cooperative groups. Studies on which more than one cooperative group participates are called Intergroup Studies.

These studies are governed by specific guidelines, policies, and procedures established to facilitate data management and patient monitoring according to the philosophy of the particular coordinating group.

Before outlining these guidelines, some basic information will be helpful:

**Definitions**

**Intergroup Studies:** Any study on which more than one cooperative group (e.g., SWOG, ALLIANCE, COG, ECOG-ACRIN, NCIC-CTG, NRG) participates. Only one of these groups coordinates the study.

**Coordinating group:** The Group that writes the study, dictates eligibility, randomizes the patient to a specific treatment, collects and analyzes the data, and publishes the results of the study.

**Objective**

Having more than one cooperative group participating on a study hastens the accrual of patients so that study results may be obtained in a timelier manner. Additionally, the protocol may reference an “INT” number on the title page; this number is the Intergroup Study number assigned by the NCI.

**How to identify an Intergroup Study**

Check the title page of the protocol or the appropriate disease site in the Priority List. If the list of “participants” includes more than one cooperative group, it is an Intergroup Study.

**Which group coordinates the study**

Again, check the title page of the protocol; the name of the coordinating group is capitalized and/or boldfaced and is most likely located near the top of the page.
Differences between SWOG Coordinated and non-SWOG Coordinated Intergroup Studies:

Specific guidelines govern Intergroup studies. Depending on the coordinating group, these guidelines may differ from those used for SWOG studies. The protocol should always be the first point of reference. The table on the next 2 pages lists the most significant differences an Oncology Research Professional (ORP) may encounter between SWOG studies and non-SWOG ("Intergroup") studies.

<table>
<thead>
<tr>
<th>Coordinated by:</th>
<th>SWOG</th>
<th>Non-SWOG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to Registration</td>
<td>Stratification questions and eligibility must be determined by using the SWOG eligibility section of the protocol and completion of the SWOG registration form.</td>
<td>Eligibility must be determined by using the coordinating group’s checklist and/or criteria as stated in the body of the protocol. In addition, all of the usual demographic information needed for a SWOG registration will be requested.</td>
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<tr>
<td>At Registration</td>
<td>Regardless of coordinating Group, all studies use the Oncology Patient Enrollment Network (OPEN) registration system. OPEN can be accessed via the CRA Workbench. Please refer to the registration guidelines in the protocol.</td>
<td>Regardless of coordinating Group, the majority of studies use the Oncology Patient Enrollment Network (OPEN) registration system. OPEN can be accessed via the CRA Workbench. Please refer to the registration guidelines in the protocol.</td>
</tr>
<tr>
<td>Time to Call</td>
<td>6:30am to 4pm PT.</td>
<td>Consult the protocol for coordinating Group contact information.</td>
</tr>
<tr>
<td>Treatment Schedule</td>
<td>As specified in the protocol.</td>
<td>As specified in the protocol.</td>
</tr>
<tr>
<td>Follow Up Schedule</td>
<td>As specified in the protocol.</td>
<td>As specified in the protocol.</td>
</tr>
<tr>
<td>Number of Copies of Data to Submit</td>
<td>Generally ONE (consult the protocol).</td>
<td>As specified in the protocol.</td>
</tr>
<tr>
<td>Data Submission Procedure</td>
<td>From institution to the SWOG Statistics and Data Management Center (SDMC). Refer to Chapter 4 “Data Submission”. All studies activated after April 2012 use the RAVE system for data submission.</td>
<td>From institution to the coordinating group with the exception of COG. For COG, refer to the protocol. All new studies use the RAVE system for data submission.</td>
</tr>
</tbody>
</table>
Coordinated by: SWOG
Data Identification: SWOG study number, SWOG patient number and patient initials.

All of these numbers must appear on every piece of data submitted.

Non-SWOG
Patient initials, Coordinating Group study number, and Coordinating Group patient number.

Quality Control: Performed by SWOG data coordinators.

Performed by the coordinating group.

Evaluations: Performed by SWOG data coordinators.

Performed by the coordinating group.

General Questions: SWOG SDMC

Coordinating group.

General Policies that Apply: SWOG (available at www.swog.org)

Those of the coordinating group. Note that if a patient is “cancelled” from another group’s study, SWOG will not remove that patient from the SWOG database.

Intergroup Contact List

When it is necessary to contact one of the other Lead Protocol Organizations, access the full contact list on the SWOG CRA Workbench under the Tools of the Trade link and click on ‘Lead Protocol Organization (LPO) Contact List.”