

SOUTHWEST ONCOLOGY GROUP

Group Chair's Office
24 Frank Lloyd Wright Drive
P.O. Box 483
Ann Arbor, Michigan 48106

Operations Office
4201 Medical Drive, Suite 250
San Antonio, Texas 78229

Policy Memorandum No. 14
Subject: Conduct of Intergroup Trials
Departments Affected: All

Page 1 of 3 pages
Original Release Date: July 1985
Revision Date: April 1997

CONDUCT OF INTERGROUP TRIALS

The National Cancer Institute revised its "Guidelines for the Conduct of Intergroup Studies" in January 1991. An outline of these requirements follows:

1. The protocol will be conducted as a single research effort with data from each participating group to be included in the analysis of results. One protocol document will be developed for use by all participating groups. When an intergroup protocol is developed by the Southwest Oncology Group (SWOG), it will follow the SWOG Protocol Guidelines (Policy #13).
2. One overall Study Coordinator (primary author), usually from the coordinating group, must be identified and agreed upon by all participating groups.
3. A coordinating group should be identified as early as possible in the development of the study. The coordinating group is responsible for assuring that all participating groups have reviewed the study and provided input throughout the development of the protocol. A single administrative contact person should be identified at the coordinating group's operations office to serve as a liaison between the Study Coordinator, CTEP and the participating groups.
4. Prior to CTEP review, agreement should be finalized on the following items:
 - a. Registration/randomization procedures, data flow and data management
 - b. Data quality control responsibilities (routinely assigned to the coordinating group's statistical office), and modality quality control procedures
 - c. Analysis (assigned to the coordinating group's statistical office)
 - d. Response criteria
 - e. Data collection forms to be used (including a protocol specific eligibility checklist)
 - f. Drug distribution procedures
 - g. Toxicity criteria and procedures for reporting adverse drug reactions
 - h. Guidelines for presentation of data, publication and authorship
 - i. Identification of contact personnel and demographics on the participating groups (i.e., individual group protocol numbers, participants within the groups, Study Coordinators and modality representatives for each group, and projected activation dates).
5. The coordinating group's operations office should be the only office to distribute new versions of protocols to the participating group offices. The cover page and face sheet of the study should be used by all participating groups and should indicate the NCI protocol number, the

protocol number of each participating group (preferably all groups will use the same number), and the Study Coordinator for all participating groups.

6. After activation, the coordinating group's operations office will be responsible for circulating any changes to the study or status notices to all participating groups and the NCI. Modifications must originate from the coordinating group, so any changes requested by the participating groups must be forwarded to the coordinating group. The coordinating group will obtain approval from the Study Coordinator(s) and CTEP (when appropriate).
7. All groups should use the same forms in an intergroup study. The forms should be distributed to all participating groups. Each page of each form should include the protocol number used by the coordinating group and the patient identification number assigned at the time of registration. In addition, if different, the protocol number used by the participating group should appear on each page of each form. If needed, forms completion instructions should be prepared and included with the forms packet.
8. The coordinating group will handle registration/randomization for all participants as a centralized registration desk. The instructions for registration/randomization must be clearly stated in the protocol document. To ensure that each group is kept informed of all its registrations, an institution should call its own group's randomization office with the appropriate information to enter a patient. The randomization office will then communicate with the central randomization office (of the coordinating group) to enter the patient, will receive the treatment assignment and then communicate this information back to the institution. Each group is responsible for ensuring compliance with federal requirements for its own members (e.g., 1572, 596 forms, informed consent).
9. Each group should receive copies of paper records from their own member institutions. That group should date stamp the data with an identifying date stamp and send the original to the coordinating group's data collection center. The data is sent first to the participating group to allow the group to record any information necessary for evaluating institutional accrual and timeliness and quality of data submission. It is then sent to the coordinating group which is responsible for distribution to modality offices, Study Coordinator and the statistical center, etc. This system also means that an institution will always send all data on all studies to the same office.

Quality control of all data will be done by the coordinating group. Copies of data evaluations, data request and queries should be distributed through the participating group for each institution. Any new data submitted as a result of evaluations, data requests or queries should be submitted following guidelines discussed above.
10. Procedures for reporting adverse reactions should be part of the protocol document. Each group should follow its own mechanism for the immediate reporting of unusual, life threatening or lethal toxicity. Each group should also notify the appropriate person in the coordinating group. Copies of supporting records must be submitted as defined in the protocol. Each group should be responsible for notifying the NCI as they would normally do. The coordinating group should ensure that details of ADRs are circulated to all participating groups.
11. It is strongly recommended that there be one central review body to review modality materials for all group participants. It need not be the review body normally associated with the coordinating group. As far as possible, modality materials should be submitted according to the previously described data submission paths. Deviations from these procedures should be clearly defined in the protocol document.

12. Treatment evaluation criteria (toxicity, response and definitions) should be clearly defined in the protocol document. All participants must use these criteria. The NCI Common Toxicity Criteria (or criteria which may be converted to the NCI Common Toxicity Criteria) should be used whenever feasible with any other criteria included as necessary in the protocol document.
13. Common coding/naming conventions for groups, institutions, protocol numbers and patient identifiers should be implemented whenever possible.

Additionally, if negotiations with industry are involved, all groups should be aware of those negotiations/agreements. In order to ensure the Southwest Oncology Group's involvement in negotiations when another group is coordinating a study, the following paragraph is included in all letters of commitment:

"Our commitment to this study is based on our current understanding of the study's science, design and data or regulatory documentation collection requirements as well as consideration of CCOP credit. If there is industry involvement in this study or extensive data collection required, we expect to be informed and understand all obligations on the part of the Southwest Oncology Group. If significant changes occur regarding the study's science, design and data or regulatory documentation collection requirements after our letter of commitment is signed, our continued commitment to the study will be contingent upon our acceptance of the new information."