

SWOG

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. 11
Subject: Job Description/Study Coordinator
Departments Affected: All

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JOB DESCRIPTION OF A STUDY COORDINATOR

Investigators in SWOG who coordinate a Group trial must be a member of SWOG and must adhere to the requirements listed below. In addition, the primary Study Coordinator for any Group study must complete SWOG Study Coordinator Training prior to receiving approval to coordinate a SWOG trial. This training is available online within the Study Coordinator Workbench at www.swog.org and provides a detailed overview of each responsibility (Protocol Development, Study Monitoring, Study Evaluation, Reporting of Results, etc.). A primary Study Coordinator must annually disclose any potential conflict of interest(s) in accordance with the Conflict of Interest Policy (Policy No. 35). Except in unusual circumstances, a Study Coordinator may not be primary coordinator of more than one SWOG-coordinated Phase III clinical trial at a time. By Group definition, coordinating a clinical trial means involvement from the concept stage to the submission of a manuscript.

All Nurse Oncologist Study Coordinators must be a member of the Nurse Oncologist Committee, must have completed the online Study Coordinator training, and must be able to attend SWOG meetings.

PROTOCOL DEVELOPMENT

1. Prior to developing a draft protocol for a proposed study, the Study Coordinator prepares a Capsule Summary (brief description) in conjunction with the Disease Committee Chair and the Committee Statistician. Answers should be developed for the following questions:
 - a. Is the study feasible for the Group to pursue?
 - b. Is the study innovative (not repetitive of other studies in this or other groups or institutions)?
 - c. Does it compete with other Group studies for limited patient resources?
 - d. Is there interest among the Group members?
 - e. How many patients are needed to complete the study and what is the estimated accrual rate? How long will it take to complete the study?
2. The study Capsule is submitted to the Operations Office, and reviewed by the executive conference (comprised of members of the Group Chair's Office, Operations Office and Statistical Center). If approved, the study is assigned a priority within the appropriate disease committee by the Disease Committee Chair.

3. Once the study reaches sufficient priority for development within the disease committee, the Study Coordinator develops the proposed protocol following the SWOG guidelines for protocol development and format (i.e., Protocol Guidelines, Radiation Therapy Guidelines, etc.). Selected protocols may first require submission of a Letter of Intent (LOI), or a Concept Sheet to CTEP. At all steps in the protocol development process, there should be ongoing dialogue between the Study Coordinator, Disease Committee Chair, Committee Statistician, and Protocol Coordinator. Once the first protocol draft is completed, it is submitted to the Operations Office where the document is put into Group format, circulated for additional comments, revised, submitted to CTEP, further revised, and finally circulated to institutions for activation. It should be noted that a protocol may undergo several drafts prior to submission to CTEP for approval.

FOLLOWING ACTIVATION

A. For All Studies

1. It is a Study Coordinator's responsibility to evaluate patient records to insure that eligibility, toxicity, treatment adherence, and study endpoints are correctly reported. On an ongoing basis, evaluation forms will be generated for the Study Coordinator for all active and closed (but unpublished) studies. These should be completed, signed electronically, and submitted to the Statistical Center in a timely fashion. The Study Coordinator Evaluation Application is also found on the Study Coordinator Workbench for this purpose.
2. Attendance at Group Meetings is required so that the Coordinator may give an up-to-date review of the study at a Committee Chair's request. Any problems or unexplained phenomena should be outlined at that time for Committee members' input. No outcome information should be reported unless the study has closed, and the data have been approved for release to the members.
3. The Study Coordinator must monitor the progress of the study regularly to determine need for protocol revisions and amendment. The Study Coordinator must provide explicit wording for revisions and amendment to the Protocol Coordinator to aid the amendment process.
4. The Study Coordinator must be available to answer medical questions concerning patients on trial. The Study Coordinator must also identify another investigator to be responsible to answer medical questions when the Study Coordinator is not available. Whenever a Study Coordinator has a change of address and/or phone number or is leaving the Group, the Operations Office must be contacted **ASAP** so that appropriate changes can be made to the protocol and Group Roster of Investigators.
5. The Study Coordinator must be aware of and comply with general Group policy. In particular, the Study Coordinator may not grant exceptions to eligibility criteria.
6. An ongoing evaluation (review of data) of the study will continue on all active and closed studies until all patients have reached the primary endpoint for the study (response, progression, survival), *or until the maximum follow-up time specified in the protocol.*

7. A manuscript outlining the results of the study is required from the principal Study Coordinator within one year of closure date, unless publication at that time as advised by the Committee Statistician or Data and Safety Monitoring Committee is premature. Refer to Policy No. 24, Publication Guidelines, for the proper procedure.

B. Phase I Studies

Study Coordinators may be required to work in close association with the pharmaceutical industry and the Early Therapeutics Committee in the development process for Phase I studies. Study Coordinators involved in Phase I studies must review toxicity and response criteria on an ongoing basis. Reports are made available to all participating institutions and are provided to NCI on a regular basis through a variety of mechanism, including: the Early Therapeutics computer application, electronic reporting via CTEP systems, and via the Report of Studies.

Closure of a Phase I trial is typically determined by a joint decision between the Study Coordinator and Committee Statistician, made as to early closure or modification of the study due to adverse toxicity reactions. Serious adverse events are reported immediately to the NCI.

C. Phase II New Agent and Phase II (other) Studies

Study forms are available to the Study Coordinator in the Study Coordinator Evaluation Program and prompt return of evaluation forms is critical for Phase II studies (with frequency to be determined prior to study activation). This will allow early recognition of significant adverse toxicity and careful monitoring of the total case accrual on Phase II studies. Additionally, prompt Study Coordinator review of patient outcome is critical to the conduct of two-stage designs that rely on response information to determine total accrual goals. However, as specified in Section A.2, outcome information should not be reported until the study has closed, and the data have been approved for release.

There is no formal data and safety monitoring committee for Phase II studies. Toxicity and accrual monitoring are routinely done by the Study Coordinator, study statistician, and the disease committee chair. Response monitoring is done by the study statistician and Study Coordinator.

D. Phase III Studies

Evaluation of study data from Phase III studies must also be reviewed periodically (with frequency to be determined prior to study activation).

A Phase III trial is developed and monitored as described for other Group trials. In addition to the toxicity and accrual monitoring that is conducted by the Study Coordinator and study statistician, Phase III trials are monitored by the Data and Safety Monitoring Committee, whose members and responsibility are outlined in Policy No. 21.