

SWOG
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Policy Memorandum No. 11

Subject: Job Description/Study Chair

Departments Affected: All

Page 1 of 3 pages

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JOB DESCRIPTION OF A STUDY CHAIR

Investigators in SWOG who chair a Group trial must be a member of SWOG (unless a special membership dispensation has been allowed) and must adhere to the requirements listed below. In addition, the primary Study Chair for any Group study must complete SWOG Study Chair Training prior to receiving approval to chair a SWOG trial. This training is available online within the Study Chair Workbench and the training link 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 Chair 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 Chair may not be primary chair of more than one SWOG-coordinated Phase III clinical trial at a time. By Group definition, chairing a clinical trial means involvement from the concept stage to the submission of a manuscript.

All Nurse Oncologist Study Chairs must be a member of the Oncology Research Professionals Committee, must have completed the online Study Chair training, and must be able to attend SWOG meetings.

PROTOCOL DEVELOPMENT

1. Prior to developing a draft protocol for a proposed study, the Study Chair prepares a Capsule Summary (brief description) in conjunction with the Research Committee Chair and the Committee Statistician and the Research Support Committee Chair (as appropriate). 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 and a matching slide set is submitted to the Operations Office and reviewed by the Executive Committee (comprised of representatives of SWOG leadership, the Group Chair's Office, Operations Office and Statistical Center). If approved, the study is assigned a priority within the appropriate research committee by the Research Committee Chair.

3. Once the study reaches sufficient priority for development within the research +/- research support committee, the Study Chair 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 Chair, Research +/- Research Support 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 Chair's responsibility to evaluate patient records to ensure that eligibility, toxicity, treatment adherence, and study endpoints are correctly reported. On an ongoing basis, evaluation forms will be generated for the Study Chair 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 Chair Evaluation Application is also found on the Study Chair Workbench for this purpose.

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), and/or until the maximum follow-up time specified in the protocol.

Evaluations of patient eligibility for a screening step of a protocol will occur only after the patient has been registered to a treatment step. A spot check of eligibility for patients who are screened but do not go on to treatment may be generated by the SDMC if specific issues are identified.

2. The Study Chair is the primary advocate for the study within the Group and (as applicable) in the NCTN system. The Study Chair is expected to monitor accrual closely at all sites and strategize with other team members about actions that could be taken to address slow accrual. The Study Chair is expected to rapidly open the study locally, and to lead by example by personally participating in patient accrual.
3. Attendance at Group Meetings is required so that the Chair 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.
4. The Study Chair must monitor the progress of the study regularly to determine need for protocol revisions and amendment. The Study Chair must provide explicit wording for revisions and amendment to the Protocol Coordinator to aid the amendment process.
5. The Study Chair must be available to answer medical questions concerning patients on trial. The Study Chair must also identify another investigator to be responsible to answer medical questions when the Study Chair is not available. Whenever a Study Chair 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.
6. The Study Chair must be aware of and comply with general Group policy. In particular, the Study Chair may not grant exceptions to eligibility criteria.

7. A manuscript outlining the results of the study is required from the principal Study Chair 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 Chairs may be required to work in close association with the pharmaceutical industry and the Rare Cancers Committee in the development process for Phase I studies. Study Chairs 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: 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 Chair 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 Chair in the Study Chair 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 Chair 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 may be no formal data and safety monitoring committee for Phase II studies (unless the study is a large, randomized trial). Toxicity and accrual monitoring are routinely done by the Study Chair, study statistician, and the research committee chair. Response monitoring is done by the study statistician and Study Chair.

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 Chair 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.