

MEMORANDUM

TO: Members of SWOG

FROM: SWOG Operations Office

DATE: December 15, 2022

SUBJECT: Policy Revisions

The following SWOG policies have been revised as summarized below. These and all policies can be viewed and printed from the Group's web site at https://www.swog.org/about/policies-procedures.

Policy Revision Summation

Policy 7 **New Investigator Process**

This policy was changed to reflect the requirement that all SWOG members (not just investigators) must register through the Cancer Therapy Evaluation Program - Identity and Access Management (CTEP-IAM) registration system and those who are significant contributors to research must also register in the Registration and Credential Repository (RCR) system. The policy name was also changed to Individual Membership Process.

Policy 8 **Committee Membership Nominations**

This policy was rewritten to add information related to the mission, expectations of committee members, committee membership criteria, and durations of membership. The committee membership nomination process was also updated.

Policy 11 Job Description of a Study Chair

Per the current Policy 11 requirements, SWOG SDMC has been generating study chair evaluations to verify eligibility for all patients registered to screening protocols, which represents a high-burden for Study Chairs (SC), wherein most of the screened patients may not go on to register to a treatment step (e.g. Lung-MAP). The policy is being updated to a) limit study chair verification of eligibility for patients enrolled to a screening step to occur only after the patient has subsequently been registered to a treatment step, and b) to provide a related allowance for SDMC to generate spot check SC evaluations for patients registered to a screening step that do not go on to a treatment registration step in event that specific issues are noted.

Protocol Guidelines Policy 13

As a result of discussions in the Quality Initiative meeting, this policy was revised to move to a three-year requirement for completion of the existing Study Chair and Committee Chair training. The Study Chair Workshop must now have been completed by the Study Chair or sub-Study Chair within three years prior to triage.

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Policy 23 Serious Adverse Events

The SWOG physician reviewer has traditionally reviewed SAE reports for deaths on NCI-held INDs. This practice was in place prior to AdEERS/CTEP-AERS. This is a duplication of NCI's physician review, in which they review all SAEs on NCI-held INDs and provide feedback to SWOG by email. Therefore, the policy was revised to remove the SWOG physician review as it is a duplication of effort and the NCI's review will supersede SWOG's.

Policy 24 Procedural Guidelines for All SWOG Publications

This policy was revised to update the requirements for accrual authors.

Policy 29 had minor editorial (non-substantive changes).