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Policy Memorandum No. 44
Subject: Early Closure of Studies **Original Release Date:** October 2007
Departments Affected: All

EARLY CLOSURE OF STUDIES

1. BACKGROUND

SWOG trials may be terminated prior to full study accrual under a variety of situations, including (but not limited to) poor accrual, lack of or reductions in funding, concern over patient safety, or based on results of formal interim analyses. For Phase III studies, the Data and Safety Monitoring Committee (DSMC) may recommend closure based on procedures outlined in SWOG Policy 21, Data and Safety Monitoring. For Phase I-II trials, early closure recommendations may result from (among other situations) the Executive Committee routine review of accrual as provided by the Statistical Center, from a Study Committee review of adverse events, feasibility, or accrual, or after first stage temporary closure if the protocol specified events required for opening to the next stage of accrual are not met.

The early closure of a study requires timely communication, particularly in the event of patient safety concerns. This policy discusses the procedures necessary to close studies prior to planned completion of accrual.

2. PROCEDURE

2.1 *Early Closure Approvals.* For Phase III trials, the DSMC recommendation for early closure is presented to the Group Chair, who is responsible for communication with the Study Chair, Study Statistician, and/or Disease Committee Chair. The Group Chair or designee must notify CTEP (or DCP for Cancer Control/Prevention studies), of the decision and discuss with the appropriate Program Manager prior to formal study closure. Where appropriate, discussions with any companies or service providers with whom the Group has contracted (if applicable) will be conducted. Once these communications are made, the study will be formally closed, with notification to investigators, and to study patients and the public, as appropriate. Note that closures due to slow accrual of Phase III trials in which CTEP is not the IND sponsor and NCI is not the drug distributor, there is no requirement to notify CTEP prior to public notification, provided the CTEP or DCP representative was present during the DSMC review.

For any Phase I or II trial for which CTEP is the IND sponsor of one or more of the study agents, the Group Chair or designate will notify and ensure CTEP approval for the closure of a study. If CTEP is supplying/distributing a non CTEP IND/commercial agent, the Group Chair or designate is required to notify the appropriate CTEP staff (i.e., Clinical Investigation Branch staff member responsible for the disease portfolio) of study closure prior to public notice. For all other Phase I or II studies, the Group is required to notify CTEP if the closure is related to adverse events/ patient safety.

2.2 *Timeline.* SWOG Policy 21, Data and Safety Monitoring (Section 2.3, Recommendations) outlines the requirement for the Group Chair to implement changes as quickly as possible for recommendations received by the DSMC and accepted by the Group Chair.

2.3 *Disclosure of Data*. SWOG Policy 21 (Section 2.4, Access to and Release of Data) Outlines the requirements for non-disclosure of data until publication unless authorized by the DSMC.

In the event that a change in the status of a trial is recommended for patient safety reasons or extreme results (and patients are still receiving treatment on the trial), the Group will act to implement the status change and provide investigator and patient information to the sites as quickly as possible, preferably within days of Group knowledge of the results. In the event that patients are no longer receiving treatment on the trial, patient and physician information will distributed only in the event of a known long-term side-effect. Otherwise, institutions are expected to monitor the Group's Report of Studies and publications and inform their IRBs and patients of study results according to their institutional requirements.

Decisions regarding the need for and timing of any public notification (press release) will be made on a case-by-case basis. Discussions regarding the need for a press release will be prompted by the Group Chair’s Office and will include the Group Chair, the study statistician, the DSMC as needed, and CTEP or DCP. Any contractual obligation for review of a press release will be honored.