

SOUTHWEST ONCOLOGY GROUP

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Policy Memorandum No. 28

Subject: Guidelines for the Conduct of "Developmental Strategy Review" and Pilot Protocols

Departments Affected: All

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GUIDELINES FOR THE CONDUCT OF "DEVELOPMENTAL STRATEGY REVIEW", REVIEW OF CORRELATIVE SCIENCE AND PILOT PROTOCOLS

Treatment protocols submitted to the National Cancer Institute (NCI - CTEP) for "developmental strategy review" only are studies which do not require full Consensus Review by CTEP. They are submitted to the NCI for advisory review. Pilot studies are studies which may or may not include investigational drugs and are performed to provide data for a future Phase III comparison. CTEP review types and decision tree may be found at <http://ctep.cancer.gov/forms/ReviewTree.doc>. All SWOG protocols are developed according to the SWOG Protocol Guidelines (Policy #13).

The criteria and guidelines for "developmental strategy review" and/or pilot studies conducted within the Southwest Oncology Group are as follows:

1. "Developmental strategy review" studies require accrual of fewer than 100 patients (normally 30 to 40 patients) and no investigational drug(s).
2. There is no limitation for the number of institutions participating on either a "developmental strategy" or a pilot study (i.e., a Group-wide study may be submitted for an advisory review within the NCI).
3. Correlative science proposals generally also require review by CTEP. Guidelines for review of correlative science proposals can be found at http://ctep.cancer.gov/forms/COR-SCI_guidelines.doc.
4. If a pilot concept is planned for eventual use in a Group Phase III comparative study, then it is preferred that the pilot study be performed within the Group.