

SWOG Leadership and Project Development Course

Scientific Plan

In 3-5 pages, please describe the following:

1. Underlying study hypothesis (*In many cases, the hypothesis can be expressed by stating succinctly what 'conclusion' you expect to draw from the study results, if positive.*)
2. Primary study objective(s)
3. Secondary study objective(s)
4. Background and rationale:
 - a. Knowledge gap/clinical need to be addressed
 - b. How the study results will help patients or lead to new paradigms in clinical cancer research
 - c. Background data to support the intervention and/or endpoint measurements selected
 - d. How the study fits into the current trends of research and NCI research priorities, including work being done in the same arena by other groups
 - e. References
5. Eligibility Criteria (*If populations of particular interest to the NCI, such as HIV+ or Hep+, are not eligible, be sure to include a rationale for exclusion. Also, consider whether it is possible to include younger populations of patients.*)
6. Treatment/Intervention
7. Endpoint(s) to be measured
8. Statistical Plan and Analysis: (*This section should be completed in conjunction with the Primary Committee Statistician*)
 - a. Study Design Justification
 - b. Estimate of Sample Size
 - c. Estimate of Accrual Rate (*This section should provide justification that the accrual is feasible and can be completed within an acceptable time frame. State whether the study will be done at limited institutions, in SWOG only, or across the NCTN. State also whether international accrual is expected, and if international participation is required to meet accrual goals.*)
9. Accrual Plan (*Discuss potential barriers to recruitment and potential ways to address them.*)