





Protocol #:	SWOG tes		
Priority #:			
Title:			
Disease Committee:	Immunomolecular The	rapeutics	
SCs: Drs.			
Notes:			
I. CAPSULE SUMMARY: It is the responsibility of the Study Coordin requirements are completed prior to submissummary Template for requirements)			
Approval Date			
Comments			
II. PROTOCOL DEVELOPMENT: All of these steps must be completed before a protocol can be activated.			
a. Letter of Intent: Phase II w/NCI-supplied drug OR go to	o II.c		
Primary Committee's Review	Submission	Approval	
Comments			
b. Concept Submission Form: Phase III only			
Review	Submission	Approval	
Comments			
c. Inital Protocol Draft/Review: This process may be repeated until the final protocol is drafted.			
Protocol Review		Date/N/A	
Study Coordinators/Committee Chair(s)			
Statistical Center			
	Statistical Center		
Other Comm	Statistical Center ittee SCs (if needed)	v	
		v	
	ittee SCs (if needed)	V	
Drug	ittee SCs (if needed) Company (if needed)	V	
Drug	company (if needed) Other Reviews	V	
Drug (ittee SCs (if needed) Company (if needed) Other Reviews Draft Forms Inserted	V	
Drug (Other Reviews Draft Forms Inserted S Consistency Check	V	
Drug (Other Reviews Draft Forms Inserted S Consistency Check Ubmission Worksheet PRC Review	v tergroup CTSU: QARC: RPC:	
Drug (Other Reviews Draft Forms Inserted S Consistency Check Ubmission Worksheet PRC Review		
Op: NCI Protocol Su	Other Reviews Draft Forms Inserted S Consistency Check Ubmission Worksheet PRC Review		
Op: NCI Protocol Su Comments	Other Reviews Draft Forms Inserted S Consistency Check Ubmission Worksheet PRC Review		
Open NCI Protocol Succession Succ	ittee SCs (if needed) Company (if needed) Other Reviews Draft Forms Inserted s Consistency Check ubmission Worksheet PRC Review In	tergroup CTSU: QARC: RPC:	

Others			
CTEP/DCP (copy for IND anf contracts, if needed)		Submission: Consensus Review Received: Consensus Review Response: Approval on hold (if applicable): Final Approval:	
CIRB (if needed)		Submission: CIRB Review Received: CIRB Response Submitted: Approval:	
Final Ops Consistency Check			
Final PRC Review (if needed)			
Activation Amend (CTEP)			
Final Forms Inserted			
FFS Inserted			
Activation Memo/HIPAA			
Web Documents Prepared			
	Database Flags Set		
Comments			
III. ADMINISTRATIVE: (if needed) Contract and IND will be completed by Dir. of Ops and Pharm. Liaison.			
Budget for Drug Distribution		Date finalized:	
Budget for Additional Support		Date finalized:	
Budget for Correlative Studies		Date finalized:	
Contract Signed		Date finalized:	
IND Assigned		Date finalized:	
Other Last Minute Issues?		Membership: Intergroup: Financial: Correlates: Drug Issues: Other:	
Comments			
IV. ACTIVATION:			