Protocol Information Office
Division of Cancer Prevention, NCI
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This form must accompany all protocol document submissions.

For internal use only:
NCI Protocol #:

DCP Protocol Submission Worksheet v1.0

Please print or type. Complete all relevant sections. Attach to protocol and submit to the above address.

Section 1: Overview of Protocol Information

Organization (local) Protocol No.:

Protocol Title: _____

Name of Lead Organization (institution holding funding agreement):

Name of Principal Investigator:

PI Phone No.:	PI Fax No.:	PI E-mail Address:

Is this a Multi-Center Protocol? ☐yes ☐no

Will CCOPs be participating in this protocol? ☐yes ☐no

- If yes, indicate name of CCOP Research Base(s):

Is this protocol part of an NIH Grant or Cooperative Agreement (CA)? ☐ yes ☐ no ☐ pending

- If yes, provide the Grant No. or CA No: (*NCI U01 CA-12345*)

Is this protocol part of an NIH Contract? ☐ yes ☐ no ☐ pending

- If yes, provide the Contract No. and Workstatement No.
- If yes, provide the Contract performance period dates:

Are you receiving support from non-NCI sources (i.e., industry, ACS) for this study? ☐ yes ☐ no ☐ pending

- If yes, specify the source:

Will this study by submitted to an IND? ☐ yes ☐ no ☐ unknown

IND Sponsor: ☐ DCP ☐ Investigator (name): _____ ☐ Pharmaceutical Company (name): _____

IND Number (if known):

Data and Safety Monitoring: Has the Data & Safety Monitoring Plan for this study been submitted to the NCI for approval? ☐ yes ☐ no

Section 2: Purpose of Protocol Submission

☐ First Submission of this Protocol to DCP PIO	Document date:	Version Number:	IRB Submission Date (if applicable):	PIO Submission Date:
☐ Revised Protocol (changes made to the protocol prior to final NCI approval)	Document date:	Version Number:	IRB Submission Date (if applicable):	PIO Submission Date:
☐ Amended Protocol (changes made to protocol following activation)	Document date:	Version Number:	IRB Submission Date (if applicable):	PIO Submission Date:
☐ Other: (specify)	Document date:	Version Number:	IRB Submission Date (if applicable):	PIO Submission Date:

Is this document submitted in response to a DCP review? ☐ yes ☐ no

If yes, date of DCP review letter:

Section 3: Overview of Protocol Design

Study Phase : ☐ I ☐ I/II ☐ II ☐ III ☐ Other

Study Population (describe):

Study Endpoints (select ALL that apply):

☐ Single dose Pharmacokinetics	☐ Dose Selection for Phase II	☐ Safety	☐ Intermediate Biomarkers
☐ Multi dose Pharmacokinetics	☐ Drug Effect Measurements	☐ Efficacy	☐ Feasibility

☐ Other _____

Study Participant Accrual Details:

Projected Start Date:	Total Sample Size:	Projected Accrual Rate:
Projected Completion Date:	Estimated # evaluable:	Estimated # withdrawals:
Average # subjects/site:	#Case Report Forms per subject:	

Section 4: Gender and Minority Accrual Estimates

NOTE: In accordance with the NIH guidelines on the inclusion of women and minorities as subjects in clinical research, the Dept. of Health and Human Services (HHS) requires that all Phase II and III trials must include accrual targets for males, females and minorities. The accrual targets should reflect the expected accrual over the life of the study. Additional information: http://grants.nih.gov/grants/funding/women_min/women.min.htm

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, Not of Hispanic Origin	Hispanic	White, not of Hispanic origin	Other or Unknown	Total:
Female:							
Male:							
Unknown:							

Enter actual estimates (not percentages)

Section 5.0: Study Agents

Agent Name	Request for DCP-Supplied	Dose & Schedule	CAS Registry No. (if known)
	☐yes ☐no		
	☐yes ☐no		
	☐yes ☐no		
	☐yes ☐no		

Section 6: Person Completing Worksheet

Provide the following information.

Print Name	*Phone No.*	*E-mail Address*	*Date*