Protocol and Information Office
Division of Cancer Prevention, NCI
6130 Executive Blvd., Rm. 2053, Executive Plaza North
Rockville, MD 20892
Phone: 301-496-0090
E-mail: parrecol@mail.nih.gov

For internal use only:
NCI Protocol #:

Protocol Submission Worksheet v4.0

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

SECTION 1: GENERAL INFORMATION *Required for ALL protocols*

1.A Overview of Protocol Information:

Organization (local) Protocol No.: _____

Protocol Title: _____

_____

Name of Lead Organization: _____ NCI Institution Code[1]: _____
(e.g., Group, Consortium, Institution)

Principal Investigator (PI) Name: _____ NCI Investigator No.[2]: _____

PI Phone No.: ( ) _____ PI Fax No.: ( ) _____ PI E-mail Address: _____

PI Mailing Address: _____

Is this a Multi-Center (Non-Cooperative Group) Protocol? ☐ yes ☐ no If yes, refer to the Multicenter Trials guidelines in Part C, Section 7.2.15 of the Investigator Handbook, at http://ctep.cancer.gov/monitoring/multicenter.html, for further instructions.

Study Phase (check one): ☐ 1 ☐ 1/2 ☐ 2 ☐ 3 ☐ pilot ☐ Other

Have you submitted a Letter of Intent or Concept for this protocol? ☐ yes ☐ no If yes, provide the **NCI LOI/Concept Number**:

_____

Is or will this protocol be funded by a Grant or Cooperative Agreement? ☐ yes ☐ no ☐ pending If yes or pending, provide the **Grant** or **Cooperative Agreement Number**: *(Grant and Cooperative Agreement Number example – U01 CA 12345; Do not cite P30 Cancer Center Support/Grant)*

_____

Is this protocol funded by an NIH Contract? ☐ yes ☐ no ☐ pending If yes, provide the **Contract Number**: (*Contract Number example – N01 CM 12345*)

_____

Are you receiving support from non-NCI/non-NIH sources (i.e., Institutional Funds, Industry, ACS) for this study? ☐ yes ☐ no If yes, specify the source:

_____

Will inpatient therapy be required for the investigational portion of this study? ☐ yes ☐ no
(*Inpatient therapy - >24hrs in a medical facility for investigational intervention. Answer 'No' if inpatient therapy is only required as part of the standard therapy portion of the*

Projected Start Date of Study: _____ NCI Sponsor (i.e., provides IND/Funding) (circle one) CTEP, DCP, Other (Specify): _____
Format: mm/dd/yyyy

Specify the Study Type (select ALL that apply):

☐ Treatment* (*An intervention to reduce the morbidity and mortality of cancer. The focus of the intervention is the primary cancer diagnosis.)*

☐ Cancer Control (*An intervention to reduce the morbidity and complications of cancer or its treatment focusing on supportive care, not the primary cancer diagnosis.)*

☐ Prevention, please specify: ☐ primary malignancy ☐ secondary malignancy (*An intervention to reduce the risk of developing cancer.)*

☐ Age-Related	☐ Flow Cytometry	☐ Pathology	☐ Sentinal Node Biopsy
☐ Cell Kinetics	☐ Functional Imaging (PET/MRI/Nuc Med/other)	☐ Pharmacologic Assays	☐ Statistical Methodology
☐ Cytogenetics		☐ Photodynamics	☐ Supportive Care/ Symptom Management
☐ Diagnostic Imaging	☐ Immunologic Assay	☐ Psycho-Social	
☐ Drug Sensitivity	☐ Laboratory Correlation	☐ Quality of Life	☐ Tissue Banking
☐ Early Detection	☐ Marker Study	☐ Race Related	☐ Tissue Sampling
☐ Economic	☐ Molecular Biology	☐ Radiation Immunotherapy	☐ Tumor Marker
☐ Epidemiology	☐ Morphologic Imaging (CT/CXR/US/other)	☐ Screening	

Cooperative Group and CCOP Research Bases Studies Only: Will this study be open to CCOP(s)? ☐ yes ☐ no

Protocol Chairperson: _____ Phone No.: _____

NCI Investigator No.[2]: _____ E-mail: _____

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1.B Specify the Agent(s) to be used to address the Primary Objectives of the Study:

Agent Name	Request for NCI-Supplied? (Y/N)	Investigational? (Y/N)	*NSC Numbers must be provided if agent is Investigational* NSC No.[1]
	☐ yes ☐ no	☐ yes ☐ no	
	☐ yes ☐ no	☐ yes ☐ no	
	☐ yes ☐ no	☐ yes ☐ no	
	☐ yes ☐ no	☐ yes ☐ no	
	☐ yes ☐ no	☐ yes ☐ no	
	☐ yes ☐ no	☐ yes ☐ no	

If additional space is required, please include as an attachment.

1.C Study Disease:

Phase 1 Studies (check one below):

☐ Solid Tumor (NOS)

☐ Hematologic Malignancy (NOS)

☐ Disease-Specific

Phase 2, 3, and Disease-specific Phase 1 studies (specify the Name and Code of the Study Disease below):

Disease Name[1]	Disease Code[1]

1.D Statistical Design (check all that apply):

Accrual Rate: _____ pts/month Total Expected Accrual: _____ min _____ max

☐ 1-Stage Design	☐ Cohort Study	☐ Historical Controls	☐ Randomized
☐ 2-Stage Design	☐ Crossover	☐ Non-Randomized	☐ Single Blind
☐ 3-Stage Design	☐ Double Blind	☐ Open/blinded	☐ 2 x 2 Factorial Design
☐ Case Control	☐ Early Stopping Rule	☐ Pre-Randomized	☐ 4 x 4 Factorial Design

1.E Specify the Types of Therapy(ies) to be used to Address the Primary Objectives of the Study (check all that apply):

☐ Anti-retroviral Therapy	☐ Chemotherapy multiple agents systemic	☐ Chemotherapy non-cytotoxic	☐ Immunotherapy	☐ Therapy (NOS)
☐ Antisense		☐ Chemotherapy (NOS)	☐ Oncolytic Virotherapy	☐ Vaccine
☐ Bone Marrow Transplant	☐ Chemotherapy single agent systemic	☐ Gene Transfer	☐ Radiotherapy	
		☐ Hormonal Therapy	☐ Surgery	

SECTION 2: EMBEDDED CORRELATIVE STUDIES *Required for ALL Treatment Protocols*

An Embedded Correlative Study is a trial that is incorporated into a larger trial. The embedded study is included as a sub-trial or secondary end-point of the larger trial (i.e., obtaining pharmacokinetics during a treatment trial). The primary objective of collecting a description of embedded correlative studies is to document and recognize the important contributions to basic science that investigators are performing within a larger trial. This information may be utilized as a resource to improve collaboration between investigators and as a potential aid to improve funding of the NCI and its collaborators.

A brief description of all correlative studies embedded in this trial must be provided in the space below. The description of all correlative studies must have enough information to determine what the purpose of the study is. The same business rules that apply to writing the title of the primary trial should be employed. For example “pharmacokinetics” is insufficient. A more appropriate title would be “A pharmacokinetic study of taxol in combination with CTX in women with stage 3 metastatic breast cancer.”

Does this study include an embedded correlative study(ies)? ☐ yes ☐ no If yes, complete the following.

Description	Correlative Grant Number (*if different from Treatment Grant Number*)	Anticipated Number of Samples Analyzed	Estimated Cost/Sample Analyzed
1.			
2.			
3.			
4.			
5.			
6.			

If additional space is required, please include as an attachment.

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SECTION 3: CORRELATIVE STUDY CODE INFORMATION *The information requested in this section is OPTIONAL*

Refer to Section 2 for a description of a Correlative Study. Please provide the following Correlative Study Identification Code(s) and Study Title(s) if embedded correlative studies were specified in Section 2 (see page 2).

Correlative Study Identification Code: Each correlative study should have a unique identification code. Please provide a unique code for each correlative study. Correlative study codes should be limited to a maximum of 8 characters (alpha and/or numeric). *Example Correlative Study Identification Code: P-123.*

Correlative Study Title: Please indicate the title of each correlative study (laboratory, pharmacokinetic or other correlative studies) embedded within this trial. *Example Correlative Study Title: O^6-benzylguanine concentrations in plasma.*

1. Correlative Study Identification Code: _____ Correlative Study Title: _____

2. Correlative Study Identification Code: _____ Correlative Study Title: _____

3. Correlative Study Identification Code: _____ Correlative Study Title: _____

If additional space is required, please include as an attachment.

SECTION 4: SUBGROUP CODE INFORMATION *The information requested in this section is OPTIONAL*

A subgroup (stratum) code is a unique patient characteristic that will be utilized to uniformly group patients for separate analysis or treatment. Please provide the following Subgroup Identification Code(s) and Subgroup Description(s) if subgroups are specified in the protocol.

Subgroup Identification Code: Each subgroup should have a unique identification code. Please provide a code for each correlative study. Subgroup codes should be limited to a maximum of 8 characters (alpha and/or numeric). If a protocol has only a single subgroup then all patients will be entered on subgroup "A". *Example Subgroup Code: A.*

Subgroup Description: Patients are stratified by either disease or other classification (ex. prior therapy, age). If by disease, indicate what disease(s) will be included in each subgroup. Use International Medical Terminology (IMT) terms. If unsure of the appropriate IMT term please check the CTEP home page for a comprehensive list of IMT terms. If by by other classification, describe what patient characteristics (other than disease) will be used to uniformly group patients for treatment or analysis. *Example Subgroup Description: Patients with previously untreated gliomas.*

1. Subgroup Identification Code: _____ Subgroup Description: _____

2. Subgroup Identification Code: _____ Subgroup Description: _____

3. Subgroup Identification Code: _____ Subgroup Description: _____

If additional space is required, please include as an attachment.

SECTION 5: TREATMENT ASSIGNMENT CODE INFORMATION *The information requested in this section is OPTIONAL*

A Treatment Assignment Code is a unique treatment characteristic that will be utilized to uniformly group patients for separate analysis or treatment. Each arm or dose level should be considered a distinct treatment assignment. Please provide the following Treatment Assignment Identification Code(s) and Treatment Assignment Description (s) if applicable to the protocol.

Treatment Assignment Identification Code: Each treatment assignment (arm or dose level) should have a unique identification code. Please provide a code for each treatment assignment included in this study. Treatment assignment codes should be limited to a maximum of 8 characters (alpha and/or numeric). If a protocol has only a single treatment assignment then all patients will be entered on treatment assignment "1". *Example Treatment Assignment Code: Level 1.*

T**reatment Assignment Description, (Agent(s)/Dose Regimen/Schedule/Route):** Provide a complete description of each treatment assignment. Include the agent name, dose, route and schedule for every agent within a treatment assignment. In addition any non-pharmacologic treatment modality(s) (radiation, surgery, etc.) should also be described. *Example Treatment Assignment Description: Cisplatin 100mg/m^2 IV over 1 hour for one dose on day one and Taxol 130mg/m^2 IV over 3 hours for one dose on day one. Repeat every 21 days.*

1. Treatment Assignment Code: _____ Treatment Assignment Description: _____

2. Treatment Assignment Code: _____ Treatment Assignment Description: _____

3. Treatment Assignment Code: _____ Treatment Assignment Description: _____

If additional space is required, please include as an attachment.

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SECTION 6: GENDER AND MINORITY ACCRUAL ESTIMATES *Required for ALL phase 2 and 3 studies*

In accordance with the NIH guidelines on the inclusion of women and minorities as subjects in clinical research, the Department of Health and Human Services (HHS) requires that all Phase 2 and 3 trials must include accrual targets for males, females and minorities. The accrual targets should reflect the expected accrual over the life of the study.

The policy states that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rational and justification establishes inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The NCI suggests that the accrual targets be based on data from similar trials completed by your organization during the previous five years. It is hoped that the accrual targets will resemble the gender, ethnic and racial composition of the U.S. population as closely as possible. Please see the **Ethnic and Racial Categories** listed below for a complete description of ethnic and racial categories.

Ethnic Categories:

Hispanic or Latino – a person of Cuban, Mexican, Puerto Rico, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino."

Not Hispanic or Latino

Racial Categories:

American Indian or Alaskan Native – a person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Asian – a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American – a person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

Native Hawaiian or other Pacific Islander – a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White – a person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

EXAMPLE

Accrual Targets

Ethnic Category	Sex/Gender				
	Females		Males		Total
Hispanic or Latino	20	+	10	=	30
Not Hispanic or Latino	40	+	30	=	70
Ethnic Category: Total of all subjects	60 (A1)	+	40 (B1)	=	100 (C1)
Racial Category					
American Indian or Alaskan Native	1	+	0	=	1
Asian	1	+	1	=	2
Black or African American	1	+	0	=	1
Native Hawaiian or other Pacific Islander	7	+	9	=	16
White	50	+	30	=	80
Racial Category: Total of all subjects	60 (A2)	+	40 (B2)	=	100 (C2)
	(A1 = A2)		(B1 = B2)		(C1 = C2)

Enter actual estimates, whole numbers only (percentages, fractions, or decimals are not acceptable).
The totals provided for each Ethnic/gender or Ethnic/total combination must match those given for each Race/gender or Race/total combination (i.e., A1 must match A2, B1 must match B2, and C1 must match C2).

Accrual Targets

Ethnic Category	Sex/Gender				
	Females		Males		Total
Hispanic or Latino		+		=	
Not Hispanic or Latino		+		=	
Ethnic Category: Total of all subjects	(A1)	+	(B1)	=	(C1)
Racial Category					
American Indian or Alaskan Native		+		=	
Asian		+		=	
Black or African American		+		=	
Native Hawaiian or other Pacific Islander		+		=	
White		+		=	
Racial Category: Total of all subjects	(A2)	+	(B2)	=	(C2)
	(A1 = A2)		(B1 = B2)		(C1 = C2)

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SECTION 7: COMMON DATA ELEMENTS (CDE) *Required for Cooperative Group Phase 3 Studies in the following diseases: gastrointestinal (pancreatic, gastric, esophageal and colorectal), genitourinary (bladder and prostate), gynecological (ovarian, endometrial and cervical), breast, lung (small cell and nonsmall cell), leukemia (MDS, acute and chronic), and melanoma*

CDE Dictionary is available from the CTEP home page (http://ctep.cancer.gov)

Submission of Case Report Forms Using Common Data Elements: It is strongly recommended that Case Report Forms (CRFs) be submitted with the original protocol submission. If necessary, CRFs may be submitted at a later date to allow for scientific review of the protocol document, which may have an impact on data points in the CRFs. However, CTEP will not approve a protocol until the CDE compliance review is completed and the CRFs are approved by CTEP.

The CRF CDE Compliance Review Committee will provide the Cooperative Groups with an evaluation of CDE usage and, if necessary, a protocol-specific spreadsheet of new terms determined during review. After receiving the CRF CDE Compliance Review, the Groups will revise the CRFs in accordance with the Committee's recommendations and return them along with the spreadsheet of new terms. The Group may also provide alternative CDE terms along with strong justification for their use. Completed attributes must be included for each new term that will be used on the CRFs.

SECTION 8: PERSON COMPLETING WORKSHEET *Provide the following information*

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

Additional copies of the Protocol Submission Worksheet can be printed from: http://ctep.cancer.gov/forms/index.html.

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