Operations and Informatics Branch
Protocol and Information Office
Cancer Therapy Evaluation Program, DCTD, NCI
6130 Executive Blvd., Rm. 7000, Executive Plaza North
Rockville, MD 20852
Phone: 301-496-1367
E-mail: pio@ctep.nci.nih.gov

CTEP Protocol Submission Worksheet v4.4

Complete all relevant sections. Submit protocol and informed consent electronically to pio@ctep.nci.nih.gov.

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)/ Study Chairperson Name: _____ NCI Investigator No.:[2] _____

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

PI Mailing Address: _____

Principal Investigator (PI) *- The individual ultimately responsible for monitoring the progress of the clinical trial. Responsibilities include registration of all participating investigators, monitoring the scientific integrity of the trial, overseeing all submissions to the sponsor, compliance with regulatory affairs, keeping CTEP comprised of the trial status, and analyzing and publishing study results.*
Study Chairperson *– The common name for Principal Investigators in Cooperative Group trials.*

Study Coordinator Name: _____ Study Coordinator Phone No.: _____

Study Coordinator Email Address: _____ Study Coordinator Fax No.: _____

Is this a multicenter (Non-Cooperative Group) study? ☐ yes ☐ no If yes, refer to the Multicenter Trials guidelines in Section 7.2.15 of the Investigator Handbook or at http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_multicenter.htm, for further instructions.

Is CCOP credit requested? ☐ yes ☐ no

Study Phase (check one): ☐ 0 ☐ 1 ☐ 1/2 ☐ 1/3 ☐ 2 ☐ 2/3 ☐ 3 ☐ Pilot ☐ Other, specify: _____

Does this study have a blinded component to it? ☐ yes ☐ no

Have you submitted a **LETTER of INTENT** for this study? ☐ yes ☐ no ***OR*** Have you submitted a **CONCEPT** for this study? ☐ yes ☐ no

If yes, provide the **NCI LOI/Concept Number**: _____

1.B Funding Information:

Is or will this study 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(Grant and Cooperative Agreement Number example: U01 CA 12345; Do not cite P30 Cancer Center Support/Grant)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 study 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: _____

NCI Sponsor (i.e., provides IND/Funding): ☐ CTEP ☐ DCP ☐ CIP ☐ Other (Specify): _____

1.C Study Objectives:

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 study.)

Specify the Study Type to be used to address the PRIMARY OBJECTIVE of the study (check one):

☐ Treatment	☐ Economic	☐ Epidemiology	☐ Imaging	☐ Laboratory Correlation
☐ Quality of Life	☐ Registry	☐ Supportive Care	☐ Symptom Amelioration	☐ Tissue Banking
☐ Cancer Control	☐ Prevention	If **Prevention**, please specify:	☐ Primary Malignancy	☐ Secondary Malignancy

Definitions: Treatment - An intervention to reduce the morbidity and mortality of cancer. The focus of the intervention is the primary cancer diagnosis.
Cancer Control - intervention to reduce the morbidity and complications of cancer or its treatment focusing on supportive care, not the primary cancer diagnosis.
Prevention - An intervention to reduce the risk of developing cancer.

Specify the Study Type to be used to address the SECONDARY OBJECTIVES of the study (check all that apply):

☐ Treatment	☐ Economic	☐ Epidemiology	☐ Imaging	☐ Laboratory Correlation
☐ Quality of Life	☐ Registry	☐ Supportive Care	☐ Symptom Amelioration	☐ Tissue Banking
☐ Cancer Control	☐ Prevention	If **Prevention**, please specify:	☐ Primary Malignancy	☐ Secondary Malignancy

[1] See http://ctep.cancer.gov/protocolDevelopment/codes_values.htm for a complete list of Organization (Group, Consortium and Institution), IND and NSC Numbers, and Disease Names and Codes.
[2] Contact the Pharmaceutical Management Branch (PMB) at (301) 496-5725 to obtain NCI Investigator Numbers, or email them at: pmbafterhours@mail.nih.gov.

1.D Specify the Agent(s) to be used in this Study:*

Agent Name	Request for CTEP/PMB distribution?	Is the agent Investigational?	IND Number	IND Holder	IND Sponsor	NSC No.[1] (NSC Numbers must be provided if agent is Investigational)	Placebo Controlled?
	☐ yes ☐ no	☐ yes ☐ no		☐ CTEP ☐ Site ☐ Investigator ☐ Company ☐ Other (Specify): ______			☐ yes ☐ no
	☐ yes ☐ no	☐ yes ☐ no		☐ CTEP ☐ Site ☐ Investigator ☐ Company ☐ Other (Specify): ______			☐ yes ☐ no
	☐ yes ☐ no	☐ yes ☐ no		☐ CTEP ☐ Site ☐ Investigator ☐ Company ☐ Other (Specify): ______			☐ yes ☐ no
	☐ yes ☐ no	☐ yes ☐ no		☐ CTEP ☐ Site ☐ Investigator ☐ Company ☐ Other (Specify): ______			☐ yes ☐ no
	☐ yes ☐ no	☐ yes ☐ no		☐ CTEP ☐ Site ☐ Investigator ☐ Company ☐ Other (Specify): ______			☐ yes ☐ no

** For treatment studies, include only anti-cancer agents. If additional space is required, please include as an attachment.*

1.E Specify the type(s) of Therapy(ies) to be used in this study (*check all that apply*):

☐ Drug and/or Immunotherapy ☐ Gene Transfer ☐ Image Directed Local Therapy ☐ Radiation Therapy ☐ Hematopoietic Stem Cell Transplantation ☐ Surgery

1.F Study Disease:

Phase 1 Studies (*check one below*):

☐ Disease-Specific

☐ Hematologic Malignancy (NOS)

☐ Solid Tumor (NOS)

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.G Study Age Population (specify in years):

Lower Age Limit: ____________ Upper Age Limit: ______________

[1] See http://ctep.cancer.gov/protocolDevelopment/codes_values.htm for a complete list of Organization (Group, Consortium and Institution), IND and NSC Numbers, and Disease Names and Codes.

SECTION 2: EMBEDDED CORRELATIVE STUDIES *Required for ALL Treatment Studies (if applicable)*

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, "EGFR testing" is insufficient. A more appropriate title would be "EGFR testing and gene expression analysis (ERCC-1, EGF-R, XPD, VEGF, COX-2, XRCC-1, and GST-P1) on paraffin embedded tissue using laser capture microdissection and PCR."

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 10 characters (alpha and/or numeric). Example Correlative Study Identification Code: P-123.

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

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

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

SECTION 3: 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 subgroup. Subgroup codes should be limited to a maximum of 10 characters (alpha and/or numeric). If a study has only a single subgroup then all patients will be entered on subgroup "SG1".

Subgroup Description: Patients are stratified by either disease or other classification (example: prior therapy, age). If by disease, indicate what disease(s) will be included in each subgroup. Use Medical Dictionary for Regulatory Activities (MedDRA) codes. Please see the *List of Codes and Values* from the CTEP home page for a comprehensive list of MedDRA terms and codes. If by classification other than disease, describe what patient characteristics will be used to uniformly group patients for treatment or analysis. *Example Subgroup Description: Patients with previously untreated gliomas.*

	Subgroup Identification Code	Description
1.		
2.		
3.		
4.		
5.		

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

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

Please see the Treatment Assignment Instructions and Guidelines available from the CTEP home page for a complete description of Treatment Assignment Code (TAC) and Treatment Assignment Description (TAD) requirements. Include agent name, dose, route, duration, and schedule (i.e., Cisplatin 100mg/m2 IV over 1 hour on Day 1, every 21 days and Taxol 130mg/m2 IV over 3 hours on Day 1, every 21 days).

	Treatment Assignment Code	Description
1.		
2.		
3.		
4.		
5.		

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

SECTION 5: GENDER AND MINORITY ACCRUAL ESTIMATES *Required for ALL Phase 2, Phase 3, and Pilot 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)

Accrual Rate: _____ pts/month **Total Expected Accrual:** _____ Min _____ Max

Projected Start Date of Study: _____

SECTION 6: 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 non-small 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 7: TRIAL COMPLEXITY ELEMENTS *Required for ALL Phase 3 Treatment Studies.*

In accordance with the CTWG recommendations, all phase 3 treatment studies will be evaluated for complexity of the work needed to be done by sites implementing these trials. Additional capitation payments may be available for select highly complex trials depending on available funds. Trial Complexity supplements will be determined on an annual basis.

Please enter a score for each trial complexity tier element in the chart below using the scoring system of 0 for standard complexity element, 1 for moderate complexity, 2 for high complexity. To determine scores, please use the Trial Complexity Elements & Scoring sheet, which includes the element names, descriptions, and scoring examples located on the CTEP web site at:
http://ctep.cancer.gov/protocolDevelopment/docs/trial_complexity_elements_scoring.doc

	Element 1	Element 2	Element 3	Element 4	Element 5	Element 6	Element 7	Element 8	Element 9	Element 10	TOTAL
Score											

Additional comments on trial complexity: _____

_____

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

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

Signature *(not required for electronic submissions)* ***Date***