Protocol Information Office, DCP, NCI

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*Submit documents electronically to:*

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Cancer Care Delivery Research Studies

NCI Community Oncology Research Program (NCORP)

Document Submission Worksheet v3.0

# SECTION 1: GENERAL INFORMATION

## 1. A. Overview of Document Information

Please indicate type of submission:  Concept Revised Concept  New Protocol Revised Protocol Amendment Other

Research Base Concept/Protocol No.: ­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ If new protocol submission, indicate the Concept number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­

Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Name of Research Base: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NCI Institution Code:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Chair Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NCI Investigator No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Chair Phone: (\_\_\_\_) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Study Chair Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Coordinator Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone No.: (\_\_\_\_\_)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Will this study be in RSS?  yes  no CTSU?  yes  no OPEN?  yes  no RAVE?  yes  no

Is this study monitored by a Data Monitoring Committee?  yes  no

Will this study allow registration of Non-IND/Non-treatment (NINT) Investigators?  yes  no \*Note: NINT investigator participation requires DCP/DCCPS approval.

*The NINT registration type applies to investigators (e.g., MD, DO, NP, PA, PhD, PharmD) who wish to exclusively participate in non-treatment and/or non-IND studies. A NINT investigator may serve as site PI/investigator and is responsible for recruiting, consenting and/or enrolling participants. Studies that are eligible for NINT participation are primarily limited to screening and surveillance (e.g., TMIST, FORTE); and select CCDR studies.*

## 1. B. Funding Information

Is this study supported by one or more federally funded grants?  Yes  no

Grant Number and agency (NIH, DoD, AHRQ): ­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Start Date:\_\_\_\_\_\_\_\_\_\_ End Date:\_\_\_\_\_\_\_\_\_\_

Grant Number and agency (NIH, DoD, AHRQ): ­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Start Date:\_\_\_\_\_\_\_\_\_\_ End Date:\_\_\_\_\_\_\_\_\_\_

Is this study supported by one or more non-federally funded grants (PCORI, ACS, etc.)?  Yes  No

Please specify funding source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Start Date:\_\_\_\_\_\_\_\_\_\_ End Date:\_\_\_\_\_\_\_\_\_\_

Please specify funding source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Start Date:\_\_\_\_\_\_\_\_\_\_ End Date:\_\_\_\_\_\_\_\_\_\_

## 1. C. Study Type:

Interventional

Multi-level: The study is evaluating interventions at multiple levels of the health care system such as the provider and the patient, patient and the organization, provider and organization or all three; the primary aim may be on one of the levels but they may be interventions at multiple levels

Single-level (the study may collect data at multiple levels but the intervention is focused on a single level such as provider, patient, teams, or organization)

Observational

Multi-level

Other, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is this study randomized?  Yes  no If yes, randomized by: Patient\_\_\_\_ Non-Patient\_\_\_\_ Practice\_\_\_\_

## 1. D. Primary Purpose

Health Services Research/ Cancer Care Delivery: protocol designed to evaluate the delivery, processes, management, organization, or financing of health care (As Per CT.Gov)

## E. Secondary Purpose (May choose more than one):

**Treatment**: treatment of in-situ disease

**Prevention**: protocol designed to assess one or more interventions for preventing the development of a specific disease or health condition. Limited to secondary prevention in CCDR protocols (Examples: detection of new cancers in cancer survivors, or surveillance for recurrent cancer)

**Diagnostic**: protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition

**Supportive Care**: protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease

**Behavioral**: protocol designed to improve care by studying the interactions between patients and their healthcare providers or between patients, families, providers and the health care system

**Cancer Health Disparities**: differences in the incidence, prevalence, mortality, and burden of cancer and related adverse health conditions that exist among specific population groups in the United States

Other, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1. F. Study Disease/Organ:**

| Disease Name | Disease Code |
| --- | --- |
|  |  |
|  |  |

Disease-Specific

Specify Target Organ: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## 1. G. Study Age Population (specify in years):

Lower Age Limit: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Upper Age Limit: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# SECTION 2: SUBGROUP CODE INFORMATION *The information requested in this section is for protocols only.*

A subgroup (stratum) code is a unique patient characteristic that will be utilized to uniformly group patients/clinician/organization/system for separate analysis or intervention. 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. *Example Subgroup Description: Patients with previously untreated gliomas.*

|  | **Subgroup Identification Code** | **Description** |
| --- | --- | --- |
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# SECTION 3: GENDER AND MINORITY ACCRUAL ESTIMATES

***Enter actual estimates, whole numbers only (percentages, fractions, or decimals are not acceptable). The total provided for Ethnicity must match the total given for Race.***

**Planned Accrual:**

**Domestic Planned Enrollment Report FOR PATIENTS**

**(Complete this section if patients are being enrolled on the study)**

| **Racial Categories** | Not Hispanic or Latino:  Female | Not Hispanic or Latino:  Male | Hispanic or Latino:  Female | Hispanic or Latino:  Male | Total |
| --- | --- | --- | --- | --- | --- |
| American Indian/Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White |  |  |  |  |  |
| More Than One Race |  |  |  |  |  |
| Total |  |  |  |  |  |

Accrual Rate: \_\_\_\_\_ pts/month Total Expected Accrual: \_\_\_\_\_\_ Min \_\_\_\_\_\_Max

**Domestic Planned Enrollment Report FOR NON-PATIENTS**

**(Complete this section if the study is enrolling non-paid caregivers, and or clinicians such physicians, nurses, pharmacists)**

| **Racial Categories** | Not Hispanic or Latino:  Female | Not Hispanic or Latino:  Male | Hispanic or Latino:  Female | Hispanic or Latino:  Male | Total |
| --- | --- | --- | --- | --- | --- |
| American Indian/Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White |  |  |  |  |  |
| More Than One Race |  |  |  |  |  |
| Total |  |  |  |  |  |

Accrual Rate: \_\_\_\_\_ non-patients /month Total Expected Accrual: \_\_\_\_\_\_ Min \_\_\_\_\_\_Max

**Domestic Planned Enrollment Report FOR oRGANIZATIONS/pRACTICES**

**(Complete only if organizations or practices are being enrolled on the study; specify at the affiliate or sub-affiliate level)**

| **Number of minority/underserved affiliate/sub-affiliate** | **Number of community affiliate/sub-affiliate** | **Total** |
| --- | --- | --- |
|  |  |  |

**Study Timeline**

Projected Start Date of Accrual: \_\_\_\_\_\_\_\_\_\_\_\_\_ Projected End Date of Accrual: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**The Study Dates below must be the same dates entered in eRA Commons (HSS) and CT.gov. Please provide the applicable Study Dates below if protocol does not use CTSU’s RSS:**

**Actual Study Start Date\* : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** \*Required Study Date for all NCI Active protocols.

***Actual Study Start Date Definition: The date the first participant*** ***(any patient or non-patient human subject) was enrolled.***

**Anticipated Primary Completion Date\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** \*Required Study Date for all New/Revised Protocols awaiting Final DCP Approval.

**Actual Primary Completion Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Primary Completion Date Definition: The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.***

**Anticipated Study Completion Date\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** \*Required Study Date for all New/Revised Protocols awaiting Final DCP Approval.

# SECTION 4: INTERVENTION ASSIGNMENT CODE INFORMATION

# *The information requested in this section is OPTIONAL*

Please include intervention name, dose, route, duration, and schedule (i.e., modality, length of time).

|  | **Treatment Assignment Code** | **Description** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

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

SECTION 5: PERSON COMPLETING WORKSHEET *Provide the following information*

***Print Name Phone No. Email Address***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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