Protocol Information Office, DCP, NCI

Phone: 240-276-7130

*Submit documents electronically to:*

[*nci\_dcp\_pio@mail.nih.gov*](mailto:nci_dcp_pio@mail.nih.gov)

NCI Community Oncology Research Program (NCORP)

Clinical Trials Document Submission Worksheet v4.0

# 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:\_\_\_\_\_\_\_\_\_\_

BIQSFP STUDY APPLICATION

a) Is a BIQSFP application being submitted in conjunction with this concept for an **INTEGRAL** study(ies) ? If a BIQSFP application is being submitted with the concept, the information on the investigational integral study(ies) should be provided in the application and not in this concept form.

Yes  No

b) Will an **INTEGRATED** BIQSFP study application be submitted in conjunction with this concept?

Yes  No

If so, please identify each proposed integrated study assay/test/assessment/instrument \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

The completed BIQSFP integrated study application packet must be received by the DCP PIO within 3 months of official notification of parent concept approval.

## 

## 1. C. Study Type and Phase

Interventional  Observational

Study Phase (check one)  Pilot  1  2  2/3  3  N/A

Is this study randomized?  Yes  no

Does this study have a blinded component to it?  Yes  no

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# SECTION 1: GENERAL INFORMATION (CONTINUED)

## 1. D. Primary Purpose (Choose one)

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

**Prevention:** protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition

**Diagnostic**: One or more interventions are being evaluated for identifying a disease or health condition.

**Supportive Care**: One or more interventions are evaluated for maximizing comfort, minimizing side effects, or mitigating against a decline in the participant's health or function.

**Screening**: One or more interventions are assessed or examined for identifying a condition, or risk factors for a condition, in people who are not yet known to have the condition or risk factor.

**Other**: None of the other options applies.

**NOTE:** For Cancer Care Delivery Research, use the separate form, Cancer Care Delivery Research (CCDR) Studies NCI Community Oncology Research Program (NCORP) Document Submission Worksheet v2.4

## 1. E. Secondary Purpose (Choose one or more):

**Treatmen**t: Treatment of in-situ disease

**Prevention**: protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition

**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

**Screening**: protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor)

**Mechanisms/Biomarkers**: Analyses of data (often biomarkers) that will provide insights to underlying biology of the condition and/or mechanisms of action of the intervention (agent, device or behavioral intervention).

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

(SECTION 1 IS CONTINUED ON NEXT PAGE)

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# SECTION 1: GENERAL INFORMATION (CONTINUED)

1.F. Specify the Agent(s) to be used in this Study: Is an IND required? Yes No

| **Agent  Name** | **Request for NCI/DCP distribution?** | **Is the agent Investigational?** | **IND  Number** | **IND  Holder** | **If IND exempt, enter IND Exempt Number** | **NSC No.**  *(NSC Numbers must be provided if agent is Investigational)* | **Placebo Controlled?** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | yes  no | yes  no |  | DCP  Site  Investigator  Company  Other (Specify): |  |  | yes  no |
|  | yes 🞎 no | yes  no |  | DCP  Site  Investigator  Company  Other (Specify): |  |  | yes  no |

## 1. G. Specify Device(s) to be used in this study: Is an IDE required? Yes No

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | **Device Brand Name** | **Device Common Name** | **Is the device investigational?** | **IDE Number** | **IDE Holder** | **IDE Exempt?** | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | |  |  |  |  |  |  | |

## 1. H. Study Disease/Organ:

Phase 2 and 3 studies (*specify the Name and Code of the Study Disease below*):

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

Disease-Specific

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

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

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

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# 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**

| **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 |  |  |  |  |  |

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# SECTION 3: GENDER AND MINORITY ACCRUAL ESTIMATES (CONTINUED)

**INTERNATIONAL (including Canadian participants) PLANNED ENROLLMENT REPORT**

| **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**

**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: TREATMENT ASSIGNMENT CODE INFORMATION

Please include agent name, dose, route, duration, and schedule (i.e., Cure-all 150mg PO QD x 4 weeks, every 28 days).

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

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

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

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

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

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