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| Operations and Informatics Branch  Protocol and Information Office  Cancer Therapy Evaluation Program, DCTD, NCI    **E-mail: [pio@ctep.nci.nih.gov](mailto:pio@ctep.nci.nih.gov)** | | | | | | | | | | | CTEP Protocol Submission Worksheet v6 | | | | | | | | | | | | | | | | | | | |
| Complete all relevant sections. Submit along with protocol and informed consent electronically to [pio@ctep.nci.nih.gov](mailto:pio@ctep.nci.nih.gov). **SECTION 1: GENERAL INFORMATION** ***Mandatory for ALL studies.*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Overview of Protocol Information:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Organization (local) Protocol No.: | | | | | |  | | | | | | |  | | | | | | | | | | | | | | | | | |
| Protocol Title: |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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 E-mail 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 Phase (check one):  0  1  1/2  1/3  2  2/3  3 | | | | | | | | | | | | | | | | | | | | | | |
| 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. **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. **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 – An 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 | |

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| 1. **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** | | **Placebo Controlled?** | | | | |
| *(NSC Numbers must be provided if agent is Investigational)* | |
|  | | | | | | | 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. **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. **Study Disease:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Phase 1 Studies (*check one below*): | | | | | | | | | | | | |  | Phase 2, 3, and Disease-specific Phase 1 studies (*specify the Name and Code of the Study Disease below*): | | | | | | | | | | | | | | | | |
| Disease-Specific | | | | | | | | | | | | |  | Disease Name**1** | | | | | | | | | Disease Code**1** | | | | | | | |
| Hematologic Malignancy (NOS) | | | | | | | | | | | | |  |  | | | | | | | | |  | | | | | | | |
| Solid Tumor (NOS) | | | | | | | | | | | | |  |  | | | | | | | | |  | | | | | | | |
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| 1. **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: TREATMENT ASSIGNMENT INFORMATION *Optional for ALL studies.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Treatment Assignment Codes (TACs)** and **Treatment Assignment Descriptions (TADs)** are intended to describe the high-level treatment to which the subject was assigned. Please include agent name(s) and other applicable treatment modalities as well as any specific code to be used to identify the treatment assignment (e.g. TAC1, ARM1, DL1, 10, etc.). Only include agent dose when relevant to distinguish between treatment arms. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | **Code** | | | | **Description** | | | | | | | | | | | |
| **Example 1** | | | | DL-1 | | | | Trastuzumab 2mg/kg + Paclitaxel | | | | | | | | | | | |
| DL1 | | | | Trastuzumab 4mg/kg + Paclitaxel | | | | | | | | | | | |
| DL2 | | | | Trastuzumab 6mg/kg + Paclitaxel | | | | | | | | | | | |
| **Example 2** | | | | ARM1 | | | | Pembrolizumab + Radiation Therapy | | | | | | | | | | | |
| ARM2 | | | | Radiation Therapy | | | | | | | | | | | |
|  | |  | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **Code** | | | Description | | | | | | | | | | | | | | | | | | | | | | | |
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| *If additional space is required, please add more rows or include as an attachment.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **SECTION 3: GENDER AND MINORITY ACCRUAL ESTIMATES** ***Mandatory for ALL studies.*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| In accordance with the NIH guidelines on the inclusion of women and minorities as subjects in clinical research, the NIH requires that all NIH defined clinical research studies must include planned enrollment. This includes Pilot, Phase I, Phase 2 and 3 clinical trials. The planned enrollment 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. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | **EXAMPLE**  **PLANNED ENROLLMENT REPORT** | | | | | | | --- | --- | --- | --- | --- | --- | | **Racial Categories** | **Ethnic Categories** | | | | **Total** | | **Not Hispanic or Latino** | | **Hispanic or Latino** | | | **Female** | **Male** | **Female** | **Male** | | American Indian/ Alaska Native | 1 | 0 | 1 | 1 | 3 | | Asian | 3 | 2 | 0 | 0 | 5 | | Native Hawaiian or Other Pacific Islander | 1 | 0 | 0 | 0 | 1 | | Black or African American | 6 | 5 | 0 | 0 | 11 | | White | 40 | 25 | 1 | 1 | 67 | | More Than One Race | 4 | 3 | 3 | 3 | 13 | | **Total** | 55 | 35 | 5 | 5 | 100 | | | | | | | | | | | | | | | | | | | | | | | |

***Enter actual estimates, whole numbers only (percentages, fractions, or decimals are not acceptable). If your study has a screening and treatment component, both screening and intervention planned accruals should be filled out. If your study only has a screening or treatment component, only the relevant table should be completed.***

| **DOMESTIC PLANNED ENROLLMENT REPORT (SCREENING)** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Ethnic Categories** | | | | **Total** |
| **Not Hispanic or Latino** | | **Hispanic or Latino** | |
| **Female** | **Male** | **Female** | **Male** |
| American Indian/ Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White |  |  |  |  |  |
| More Than One Race |  |  |  |  |  |
| **Total** |  |  |  |  |  |

| **INTERNATIONAL (including Canadian participants) PLANNED ENROLLMENT REPORT (SCREENING)** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Ethnic Categories** | | | | **Total** |
| **Not Hispanic or Latino** | | **Hispanic or Latino** | |
| **Female** | **Male** | **Female** | **Male** |
| 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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| **Accrual Rate:** |  |  | | pts/month | **Total Expected Accrual:** | |  | Min |  | Max |
|  | | |  | |  |  | | | | |

***Enter actual estimates, whole numbers only (percentages, fractions, or decimals are not acceptable).***

| **DOMESTIC PLANNED ENROLLMENT REPORT (TREATMENT)** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Ethnic Categories** | | | | **Total** |
| **Not Hispanic or Latino** | | **Hispanic or Latino** | |
| **Female** | **Male** | **Female** | **Male** |
| American Indian/ Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White |  |  |  |  |  |
| More Than One Race |  |  |  |  |  |
| **Total** |  |  |  |  |  |

| **INTERNATIONAL (including Canadian participants) PLANNED ENROLLMENT REPORT (TREATMENT)** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Ethnic Categories** | | | | **Total** |
| **Not Hispanic or Latino** | | **Hispanic or Latino** | |
| **Female** | **Male** | **Female** | **Male** |
| 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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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Accrual Rate:** |  |  | | pts/month | | **Total Expected Accrual:** | |  | | Min |  | Max | |
| Projected Start Date of Study: | |  | | | Anticipated Primary Completion Date: | | | |  | | | |  |
|  | |  | | |  | | | |  | | | |  |
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