**CTMA PROTOCOL # REQUEST FORM – (**for non-therapeutic and/or PRC C/exempt trials **only)**

**↓** Section to be completed by staff indicated

|  |  |  |  |
| --- | --- | --- | --- |
| **Regulatory Specialist** | **PI Name:** |  | |
| **Source of support** (list all – if *no* funding, designate ‘UPCI’/dep. funds)**:** | | |
| **Study Title:** | | |
| **Clinical Research Manager** | **CRS Disease Center1**: | **Primary:** Choose an item. | **Secondary**: |
| **Anatomic DiseaseSite(s)2** (≥1 may apply)**:** |  | |
| **AJCC Staging** (list all that apply)**3**: |  | |
| **Treatment Line 4** (≥1 may apply): |  | |
| **Trial Phase5**: | N/A | |
| **Trial Type6** (non-therapeutic)**:** | Choose an item. | |
| **CCSG Program10:** | Choose an item. | |
| **CCSG Clinical Research Category12:** | Choose an item. | |
| **CCSG Trial Type13:** | Choose an item. | |
| **Coordinating center study?** | No Yes If yes, via: Hillman MWH | |
| **Multiple Coop. Groups receiving credit?** | No Yes N/A | |
| **Is this a CTRP trial?** | No Yes *(yes- if interventional)* | |
| **Will subjects be consented / enrolled in CTMA?** | No *(status will remain “CTMA events only – no data available”)* Yes | |
| **Does this study require expedited (Chair) PRC review, per Pitt IRB?** | No  Yes | |
|  | **Category Classification7**: | Choose an item. | |
|  | **Group Classification** (only if Category = Consortium or Natl. Coop Group)**8:** | Choose an item. | |
|  | **Source Classification9:** | Choose an item. | |
|  | **Therapeutic Intervention(s):** | Yes No | |
| **Regulatory Specialist** | **Sub-Investigator**:  (Note: Please list all if exempt) |  | |
| **Regulatory Specialist / CRS Safety Spec.**: |  | |
| **Study submitted to:** | OSPARS Pitt NCI CIRB VA | |
| **Local IRB11:** | Choose an item. | |
| **Sponsor-designated IRB11:** | Choose an item. | |
| **CTRC:** | No Yes If yes: Inpatient Outpatient | |
| **Local/National Study:** | Local National | |
| **Multi-Institutional Study:** | Yes No | |
| **Target Accrual:**  (\*Contract # excludes screenings; IRB target # = eligible+screenings\*) | Contract target (required for all trials):  IRB target (for Pitt IRB *only*): | |
| **Multi-Center Target** (# enrolled in entire study) |  | |
| **Gender:** | Male Female Both | |
| **Protocol #** (i.e. ECOG) if applicable – N/A if IIT. |  | |
|  | **NCT#** (if applicable) | N/A | |

**Reference List**

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| --- | --- | --- |
| **1. CRS DISEASE CENTER (core):**  All Core Center  Behavioral Medicine & Oncology Program (BMOP)  Benign Heme Center  BMT Center  Brain Tumor Center  Breast Center  Esophageal/Gastric Center  GI Cancer Center  Gynecological Oncology Center  Head and Neck Center  Hematological Malignancies Center  Lung & Thoracic Malignancies Center  Melanoma Center  Non-Cancer Program  Pediatric Oncology (non-CRS)  Phase I (Experimental Therapeutics) Center  Prostate & Urologic Cancers  Sarcoma Center  **Secondary/Reporting Center *only*:**  Leukemia/MDS  Lymphoma  Multiple Myeloma/Amyloidosis  Radiation Oncology Center  Liver CC / Thoracic (non-CRS) | **3. AJCC Staging (multiple may apply):**  **T:**  (a, [CIS](http://en.wikipedia.org/wiki/Carcinoma_in_situ),(0),1–4): size or direct extent of the primary tumor  **OPTIONS = T0, T1, T2, T3, T4.**  **N** : (0–3): degree of spread to regional [lymph nodes](http://en.wikipedia.org/wiki/Lymph_node)   * **N0**: tumor cells absent from regional [lymph](http://en.wikipedia.org/wiki/Lymph) [nodes](http://en.wikipedia.org/wiki/Lymph_node) * **N1**: regional lymph node metastasis present; (at some sites: tumor spread to closest or small number of regional lymph nodes) * **N2**: tumor spread to an extent between N1 and N3 (N2 is not used at all sites) * **N3**: tumor spread to more distant or numerous regional lymph nodes (N3 is not used at all sites)   **M:**  (0/1): presence of [metastasis](http://en.wikipedia.org/wiki/Metastasis)   * **M0**: no distant metastasis * **M1**: metastasis to distant organs (beyond regional lymph nodes)   **All T,N,M stages**  **Not Applicable** | **5. TRIAL PHASE:**  Pilot  Phase I  Phase I/II  Phase II  Phase II/III  Phase III  Phase IV  Not Applicable (see #6 if non-therapeutic) |
| **6. TRIAL TYPE: 🡪 (only applies to non-therapeutic trials and single use)**  Cancer Control and Prevention  Compassionate/Emergency Use  Long Term Follow-Up  **N/A**  Prospective  Quality of Life  Questionnaire  Registry  Retrospective  Tissue/Blood banking |
| **2. ANATOMIC DISEASE SITE (≥1):**  All Cancers  Anal Cancer  Biliary Tract, other  Bladder  BMT Non-specific  Bones, joints  Brain  Breast  Cervix  Colon  Connective Tissue  Endocrine glands  Esophagus  Gallbladder  Head-Neck  Hodgkin’s Disease  Kidney/Renal  Leukemia  Liver  Lung, Trachea, Bronchus  Melanoma  Multiple Myeloma  Nasopharynx  Non-cancer  Non-Hodgkin’s Lymphoma  Ovary  Pancreas  Penis  Prostate  Rectum  Sarcoma  Skin  Solid tumors  Stomach  Testis  Thyroid Gland  Ureteropelvic Junction  Uterus/Corpus  Vagina  Vulva | **4. TREATMENT LINE (≥1):**  Adjuvant  Advanced  Advanced, Human Refractory  Advanced, Hormone Sensitive  Ancillary  Extensive Stage  First Line  In Situ  Limited Stage  Localized  Locally Advanced  Metastatic  N/A  Neoadjuvant  Newly Diagnosed  Prevention  Recurrent  Refractory  Relapsed  Screening  Second Line  Stage I  Stage II  Stage III  Stage IIIB/IV (Metastatic)  Third Line  **8. GROUP (if category = Consortium or National Cooperative Group):**  Consortium:  ABTC  California Cancer Consortium – CTEP  CERN  MRFBC  NMDP  Sarah Cannon Research Institute (SCRI)  SARC  TBCRC  National Cooperative Group:  ACOSOG\*  Alliance Group\*\*\*(=\*+\*+\*merger)  CALGB\*  COG  ECOG-ACRIN  ET-CTN *(other externally peer-reviewed)* GOG **N/A**  NCIC CTG  NCCTG\*  NRG  NSABP  RTOG  SWOG  **9. SOURCE CLASSIFICATION:**  Administrative Protocols (CRS)  Childrens Hospital (CHP)  Liver Cancer Center  Thoracic  Trial not coordinated by UPCI  **UPCI**  Urology  VA Pittsburgh | **7. CATEGORY:**  Consortium  Industrial (all pharma trials)  Institutional (IIT)  National Cooperative Group  Other Externally Peer Reviewed (NCI/NIH only)  Other University-Hospital Supported |
| **10. CCSG PROGRAM:**  -Biobehavioral Oncology Program (BOP)  -Breast and Ovarian Cancer Program (BOCP)  -Cancer Epidemiology & Prevention Program (CEPP)  -Cancer Therapeutics Program (CTP)  -Head and Neck Cancer Program (HNCP)  -Lung Cancer Program (LCP)  -Melanoma Program (MP)  **Note:** select CTP for BMT, Benign Heme, Brain, Esophageal, Gastric, GI, Hematologic,  **Non-ovarian** Gynecologic trials, Phase I, Prostate, Sarcoma and Thyroid trials. |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **11. LOCAL/SPONSOR-DESIGNATED IRB:**  -Chesapeake IRB  -Copernicus Group IRB  -IntegReview IRB  -MaGil IRB  -NCI CIRB  -New England IRB  -Quorum Review IRB  -Schulman IRB  -Sterling IRB  -University of Pittsburgh IRB  -Western IRB |
| **12. CCSG Clinical Research Category:**   * Observational/Epidemiologic- *(studies focus on cancer patients and healthy populations that involve no intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants).* * Interventional **OR** * Ancillary/Correlative- *studies are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported. Laboratory based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc.* | **13. CCSG Trial Type:**  Diagnostic (DIA): *Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition.*  Health Services Research (HSR): *Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.*  Other (OTH): *Not in other categories*  Prevention (PRE): *Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition* | **13.** CCSG Trial Type:  Screening (SCR): *Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).*  Supportive Care (SUP): *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 participant’s health or function. In general, supportive care interventions are not intended to cure a disease.*  Basic Science (BAS): *Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.* |