**CTMA PROTOCOL REGISTRATION FORM**

**↓** Section to be completed by staff indicated- (*Note: for questions with superscript* ***#*** *please use options on page 2-3).*

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| --- | --- | --- | --- |
| **Reg Spec** | **PI Name:** |  | |
| **Sponsor / Source(s) of support** (list **all**)**:** | | |
| **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**: | Choose an item. | |
| Trial Type6(N/A or compassionate/emergency use **only**)**:** | N/A | |
| **Treatment Modality**: (check all that apply) | Biologic  Chemotherapy  Gene Transfer  Radiation  Surgical  Drug (non-chemo)  Hormonal  Vaccine  Immunotherapy  N/A | |
| **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 for all interventional trials)* | |
|  | **Category Classification7**: |  | |
|  | **Group Classification** (only if Category = Consortium or Natl. Coop Group)**8:** |  | |
|  | **Source Classification9:** | UPCI | |
|  | **Therapeutic Intervention(s):** | Yes  No | |
| **Regulatory Specialist** | **Sub-Investigator**:  (Note: Please list one only – others can go on Checklist) |  | |
| **Regulatory Specialist / CRS Safety Spec.**: |  | |
| **Study submitted to:** | OSPARS  Pitt  NCI CIRB  VA | |
| **Local IRB11:** |  | |
| **Sponsor-designated IRB10:** |  | |
| **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/SWOG) if applicable |  | |
| **NCT#** (required prior to OTA) |  | |
| IND # or IDE # (if applicable)  *\*If* ***UPCI*** *is checked, please indicate who (MD) is sponsor and/or sponsor-investigator* ***(for IIT’s ONLY).*** | No  Yes; If yes IND #  UPCI\* ↓  Non-UPCI  IND sponsor\*:  IND sponsor-investigator\*: | |
| **Does protocol involve Radiation Oncology/therapy?** | Yes  No. If yes, specify date protocol sent to Karen [Holeva](mailto:holevakd@upmc.edu):  Click or tap to enter a date. | |

**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  Immune Therapy Center  Hematological Malignancies Center  Lung & Thoracic Malignancies Center  Melanoma Center  Non-Cancer Program  Pediatric Oncology (non-CRS)  Phase I (Experimental Therapeutics) Center  Phase II Center  Prostate & Urologic Cancers  Radiation Oncology Center  Sarcoma Center  Supportive Care Center  **Secondary/Reporting Center only:**  Leukemia/MDS  Lymphoma  Multiple Myeloma/Amyloidosis  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:  Alliance Group  COG  ECOG-ACRIN  ET-CTN *(other externally peer-reviewed)* GOG **N/A**  NCIC CTG  NRG  NSABP  RTOG  SWOG | **7. CATEGORY:**  Consortium  Industrial (all pharma trials)  Institutional (IIT)  National Cooperative Group  Other Externally Peer Reviewed (NCI/NIH/ET-CTN only)  Other University-Hospital Supported |
| **9. SOURCE CLASSIFICATION:**  Administrative Protocols (CRS)  Childrens Hospital (CHP)  Liver Cancer Center  Thoracic  Trial not coordinated by UPCI  **UPCI**  Urology  VA Pittsburgh |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **10. 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 |