**CTMA PROTOCOL REGISTRATION FORM**

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

|  |  |  |
| --- | --- | --- |
| **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 [x]  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):**  | [x]  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: Click or tap to enter a date. |

 **Reference List**

|  |  |  |
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| **1. CRS DISEASE CENTER (core):**All Core CenterBehavioral Medicine & Oncology Program (BMOP) Benign Heme CenterBMT Center Brain Tumor CenterBreast CenterEsophageal/Gastric CenterGI Cancer CenterGynecological Oncology CenterHead and Neck CenterImmune Therapy CenterHematological Malignancies CenterLung & Thoracic Malignancies CenterMelanoma CenterNon-Cancer ProgramPediatric Oncology (non-CRS)Phase I (Experimental Therapeutics) CenterPhase II CenterProstate & Urologic CancersRadiation Oncology Center Sarcoma Center Supportive Care Center**Secondary/Reporting Center only:**Leukemia/MDSLymphomaMultiple Myeloma/AmyloidosisLiver 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:**PilotPhase IPhase I/IIPhase IIPhase II/IIIPhase IIIPhase IVNot 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**ProspectiveQuality of LifeQuestionnaireRegistryRetrospectiveTissue/Blood banking |
| **2. ANATOMIC DISEASE SITE (≥1):**All CancersAnal CancerBiliary Tract, otherBladderBMT Non-specificBones, jointsBrainBreastCervixColon Connective TissueEndocrine glandsEsophagusGallbladderHead-NeckHodgkin’s DiseaseKidney/Renal LeukemiaLiverLung, Trachea, BronchusMelanomaMultiple MyelomaNasopharynxNon-cancerNon-Hodgkin’s LymphomaOvaryPancreasPenisProstateRectumSarcomaSkinSolid tumorsStomachTestisThyroid GlandUreteropelvic JunctionUterus/CorpusVaginaVulva | **4. TREATMENT LINE (≥1):**AdjuvantAdvancedAdvanced, Human RefractoryAdvanced, Hormone SensitiveAncillaryExtensive StageFirst LineIn SituLimited StageLocalizedLocally AdvancedMetastaticN/ANeoadjuvantNewly DiagnosedPreventionRecurrentRefractory RelapsedScreeningSecond LineStage IStage IIStage IIIStage IIIB/IV (Metastatic)Third Line**8. GROUP (if category = Consortium or National Cooperative Group):**Consortium:ABTCCalifornia Cancer Consortium – CTEPCERNMRFBCNMDPSarah Cannon Research Institute (SCRI)SARCTBCRCNational Cooperative Group:Alliance GroupCOGECOG-ACRINET-CTN *(other externally peer-reviewed)*GOG**N/A**NCIC CTGNRGNSABPRTOGSWOG | **7. CATEGORY:**ConsortiumIndustrial (all pharma trials)Institutional (IIT)National Cooperative GroupOther Externally Peer Reviewed (NCI/NIH/ET-CTN only)Other University-Hospital Supported |
| **9. SOURCE CLASSIFICATION:**Administrative Protocols (CRS)Childrens Hospital (CHP)Liver Cancer CenterThoracicTrial not coordinated by UPCI**UPCI**UrologyVA 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 |