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

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

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| --- | --- | --- |
| **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 [x] 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 [x] 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:** | [x] 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 CenterBehavioral Medicine & Oncology Program (BMOP) Benign Heme CenterBMT Center Brain Tumor CenterBreast CenterEsophageal/Gastric CenterGI Cancer CenterGynecological Oncology CenterHead and Neck CenterHematological Malignancies CenterLung & Thoracic Malignancies CenterMelanoma CenterNon-Cancer ProgramPediatric Oncology (non-CRS)Phase I (Experimental Therapeutics) CenterProstate & Urologic CancersSarcoma Center **Secondary/Reporting Center *only*:**Leukemia/MDSLymphomaMultiple Myeloma/AmyloidosisRadiation 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:**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 PreventionCompassionate/Emergency UseLong 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:ACOSOG\*Alliance Group\*\*\*(=\*+\*+\*merger)CALGB\*COGECOG-ACRINET-CTN *(other externally peer-reviewed)*GOG**N/A**NCIC CTGNCCTG\*NRGNSABPRTOGSWOG**9. SOURCE CLASSIFICATION:**Administrative Protocols (CRS)Childrens Hospital (CHP)Liver Cancer CenterThoracicTrial not coordinated by UPCI**UPCI**UrologyVA Pittsburgh | **7. CATEGORY:**ConsortiumIndustrial (all pharma trials)Institutional (IIT)National Cooperative GroupOther 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.* |