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

**↓** Section to be completed by staff indicated (please ensure ALL sections are answered)

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| **PI Name:**  |  |
| **Sponsor/Source of support** (list all – if *no* funding, designate ‘UPCI’/dep. funds)**:**  |
| **Study Title:**  |
| **CRS Disease Center1**: | **Primary:** Choose an item. | **Secondary**:  |
| **Anatomic DiseaseSite(s)2** (≥1 may apply)**:** |  |
| **Trial Phase3**: | N/A  |
| **Trial Type4** (non-therapeutic)**:** | Choose an item. |
| **CCSG Clinical Research Category9:***\*If Interventional, must be PRC reviewed\** | Choose an item. |
| **CCSG Trial Type10:** | Choose an item. |
| **Coordinating center study?**  | [x] No [ ] Yes If yes, via: [ ] Hillman [ ] MWH |
| **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 PRC review, per Pitt IRB/PittPRO?  | [ ] No 🡨 *check no if Pitt IRB exempt\* or submitting to OSPARS\**[ ] Yes  |
| **Category Classification5**: |   |
| **Group Classification** (only if Category = Consortium or Natl. Coop Group)**6:** | N/A |
| **Source Classification7:** | UPCI |
| **Sub-Investigator**:(Note: Please list all if non-interventional🡪) |  |
| **Regulatory Specialist / CRS Safety Spec.**: |  |
| **Study submitted to:** | [ ] OSPARS [ ] Pitt [ ] NCI CIRB  |
| **Local IRB8:** |   |
| **Sponsor-designated IRB8:** |   |
| **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) | N/A |
| **Gender:** | [ ] Male [ ] Female [ ] Both |
| **Protocol #** (i.e. ECOG OR IRB PRO#) |  |
| **NCT#** (if applicable) | N/A |
| **Performance Site(s)** | [ ] Hillman CC [ ] Magee [ ] Others: |

 **Reference List**

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| **1. CRS DISEASE CENTER (core):**All Core CenterBehavioral Medicine & Oncology Program (BMOP) BMT Center Brain Tumor CenterBreast CenterEsophageal/Gastric CenterGI Cancer CenterGynecological Oncology CenterHead and Neck CenterHematological Malignancies CenterImmune Therapy CenterLung & Thoracic Malignancies CenterMelanoma CenterNon-Cancer ProgramPediatric Oncology (non-CRS)Phase I (Experimental Therapeutics) CenterPhase II CenterProstate & Urologic CancersRadiation OncologySarcoma Center Supportive Care Center**Secondary/Reporting Center *only*:**Leukemia/MDSLymphomaMultiple Myeloma/AmyloidosisLiver CC / Thoracic (non-CRS) | Non-cancerNon-Hodgkin’s LymphomaOvaryPancreasPenisProstateRectumSarcomaSkinSolid tumorsStomachTestisThyroid GlandUreteropelvic JunctionUterus/CorpusVaginaVulva**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****3. TRIAL PHASE:**PilotPhase IPhase I/IIPhase IIPhase II/IIIPhase IIIPhase IVNot Applicable (see #4↓ if non-therapeutic)**4. 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**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****5. CATEGORY:**ConsortiumIndustrial (all pharma trials)Institutional (IIT)National Cooperative GroupOther Externally Peer Reviewed (NCI/NIH only)Other University-Hospital Supported**10. CCSG Trial Type:***(Note: this equates to “Primary Purpose” listed on clinicaltrials.gov if study has an NCT#)*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*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.* | **6. 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. SOURCE CLASSIFICATION:**Administrative Protocols (CRS)Childrens Hospital (CHP)Liver Cancer CenterThoracicTrial not coordinated by UPCI**UPCI**Urology**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****8. 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 |
| **2. ANATOMIC DISEASE SITE (≥1):**All CancersAnal CancerBiliary Tract, otherBladderBMT Non-specificBones, jointsBrainBreastCervixColon Connective TissueEndocrine glandsEsophagusGallbladderHead-NeckHodgkin’s DiseaseKidney/Renal LeukemiaLiverLung, Trachea, BronchusMelanomaMultiple MyelomaNasopharynx *list continued-->***9. 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.*
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