**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?** | 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 Center  Behavioral Medicine & Oncology Program (BMOP)  BMT Center  Brain Tumor Center  Breast Center  Esophageal/Gastric Center  GI Cancer Center  Gynecological Oncology Center  Head and Neck Center  Hematological Malignancies Center  Immune Therapy 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  Sarcoma Center  Supportive Care Center  **Secondary/Reporting Center *only*:**  Leukemia/MDS  Lymphoma  Multiple Myeloma/Amyloidosis  Liver CC / Thoracic (non-CRS) | 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  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **3. TRIAL PHASE:**  Pilot  Phase I  Phase I/II  Phase II  Phase II/III  Phase III  Phase IV  Not Applicable (see #4↓ if non-therapeutic)  **4. 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  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **5. CATEGORY:**  Consortium  Industrial (all pharma trials)  Institutional (IIT)  National Cooperative Group  Other 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:  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. SOURCE CLASSIFICATION:**  Administrative Protocols (CRS)  Childrens Hospital (CHP)  Liver Cancer Center  Thoracic  Trial 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 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 *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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