UPMC | HILLMAN CANCER CENTER

Information sheet for PRC on the proposed clinical trial
(To be filled out by **Program Director/Leader**)

Title of protocol:
HCC #:

Site Principal Investigator (PI):

1. a. Disease(s) / stage / first-line, second-line, third-line or other?

   b. Will the majority of subjects/cohorts being enrolled on this study include "rare cancers/molecular markers" as confirmed by the PI? ☐ Yes ☐ No
   NOTE: Anatomic site of metastasis or specific treatment modality do not qualify as a rare cancer.

2. Does the trial meet the criteria for Institutional Biosafety Review? ☐ Yes ☐ No

3. Please identify via flow chart the trials by line of therapy within the disease center portfolio with the approximate accruals over the previous year (window allowance of 1 month). If there are competing trials with ≤ 3 accruals during the previous year, consider closing the slow accruing trial(s) in conjunction with considering a new one.

NOTE: Exceptions could exist which include but not limited to studies undergoing extensive amendment or having limited accrual availability (i.e. – dose escalation phase I studies).

4. Why is this trial important to open at UPMC Hillman CancerCenter and in your disease center – select all that apply:

☐ Important in your research or research interest of your disease center
☐ Offers unique and especially promising therapy to Hillman patients
☐ Important new class of agents
☐ Personal involvement in developing trial
☐ Supports LAPS grant or UM1 (ETCTN) grant

5. Will our site PI be a possible author on manuscript(s)? ☐ Yes ☐ No ☐ Authorship TBD
   -If authorship will not be obtained, provide rationale for opening the study.

6. Do you have the capability to enroll at least 5 patients onto this trial within the next 24 months? **If not, justify why this trial should be open.**

7. What is our Hillman target accrual for the life of this study? If greater than 10, please provide justification for this figure.

NOTE: Accruals are monitored semi-annually by the PRC and Principal Investigators are informed if study is below 50% of the annual target accrual.

8. How many months will this study remain open for enrollment and total target accrual across all sites? (consider CT.gov for this information)

9. Are there sufficient funds to support this trial (sponsored, cooperative group or IIT)?

   ☐ Yes ☐ No If no, explain and provide documentation of conversations with disease center and cancer center leadership on attempts to find funding and justification for opening the trial). NOTE: If this trial is un/underfunded, it must be administratively reviewed prior to PRC review.

10. If multiple disease centers would be involved in enrolling patients, explain why the study would not be run through the Immunotherapy and Drug Development Center.

11. If a disease site cohort(s) from a multi-cancer basket study is to be pursued within a disease center, provide documentation that the sponsor has provided agreement.

12. Identify the category of research involved:

    ☐ Treatment Interventional
    ☐ Non-treatment Interventional

Printed Name of Center Program Director: _____

Signature and Date: _____

Note: Center/Program Director (or Co-Director if PI=Director) signature is required (or email stating approve of the new submission).

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UPMC Hillman Cancer Center Protocol Processing Checklist (Non-CRS teams ONLY)

Incomplete information may delay the submission process. Please provide as much information as possible to facilitate the review of your protocol. If protocol crosses centers, relevant information must be provided for each center.

PI: Phone #: E-mail address: Regulatory specialist: CRC (if assigned):	Required Documents: ☐ Full Protocol ☐ Investigator's Brochure (if applicable) ☐ Sponsor or UPMC HCC consent form ☐ Center/Program Director signature/letter ☐ Biostatistician sign-off (if IIT) ☐ If industry-sponsored: also require draft budget, contract, lab manual
Phase**: ☐ I ☐ II ☐ III ☐ IV ☐ I/II ☐ II/III ☐ Pilot ☐ N/A* (*only for non-interventional or Compassionate/Emergency use Trial Types) ** If multiple phases are listed in the protocol (i.e. I/II, Ib/II), please specify which portions we will participate in: (i.e. I, II, or both):	
Co-Investigators: Indicate which Medical or Radiation Oncologists have agreed to support this trial if these modalities will be included in the research.	
Does the Principal Investigator or any Co-Investigator or research staff member involved in this study have a conflict of interest in participating in this study? ☐ Yes ☐ No	
Category: ☐ Industry Sponsored ☐ Cooperative Group ☐ Institutional (IIT) ☐ Consortium ☐ Other Ext. Peer-Reviewed (NCI/NIH only) ☐ Other University-Hospital Supported **Required Biostatistician Sign-off for IITs** Name: Click here to enter text. Signature: _____ Date: Click here to enter text.	
Sponsor(s) / Source(s) of support (if ≥ 1, please indicate what each is funding): Click here to enter text.	
Is the study grant funded? ☐ No ☐ Yes, grant # (or name of grant – i.e. ECOG, CA Consortium, NABTC, etc.): Click here to enter text.	

Is this a multi-center study that is locked into the design as provided? ☐ Yes ☐ No

Is there an IND number for any study drug or device (provided by sponsor)?
☐Yes, and the IND # is: Click here to enter text. ☐ No

Is an investigator-initiated IND application required? ☐ Yes ☐ No

# of patients expected to meet the eligibility criteria of this protocol: Click here to enter text. / year	Anticipated accrual rate: Click here to enter text. / year

Number of patients to be enrolled at all UPMC HCC sites:
eligible (contract target): Click here to enter text.
consented (IRB target for Pitt *only*): Click here to enter text.

Number of patients to be enrolled in entire study *(if multi-institutional):* Click here to enter text.

Duration to achieve study accrual (locally): Click here to enter text. ☐ weeks ☐ months ☐ years

Duration of study treatment (per subject): Click here to enter text. ☐ weeks ☐ months ☐ years
☐ until disease progression

Sex of subjects to be enrolled: ☐ Female ☐ Male ☐ Both female and male subjects will be enrolled

Will this study use Clinical Pathways? ☐ Yes ☐ No

Will this study be opened in the Community if the sponsor permits? ☐ Yes ☐ No
Please list each network site below as confirmed by the Community Clinical Research Manager / Supervisor: ☐N/A ☐TBD ☐ Copy of CRS Sites & Staff Directory included with submission

Treatment will be administered ☐ inpatient / ☐ outpatient at:
☐Hillman ☐Shadyside ☐Magee ☐ Presbyterian ☐Eye & Ear Institute ☐ N/A

Radiation therapy will be administered at: ☐Shadyside ☐Magee ☐ Presbyterian ☐ N/A

For trials involving radiation therapy: has the study been submitted for Tier 1 Radiation Review?
☐ No ☐ Yes – date submitted: Click here to enter text.

Does this study require the services of the CTRC? ☐ No ☐ Yes: ☐ Outpatient ☐ Inpatient

Please indicate CTRC location: ☐ Hillman ☐ Magee ☐ Montefiore

Day(s) / visits needed for CTRC: Click here to enter text.

Or refer to CTRC budget: ☐

Does the protocol include a Data Safety Monitoring Plan? ☐ Yes ☐ No
If no, please include plan below / with the submission:

Does this study involve leukapheresis? ☐ No ☐ Yes and Dr. Kiss was notified ☐ Yes ☐ No
For non UPMC HCC / CRS trials: Will this study require the resources of CRS (Clinical Research Services)? ☐ No ☐ Yes: ☐ Billing ☐ CTMS / patient data ☐ Regulatory ☐ Budgeting ☐ CRC Coordination