Information sheet for PRC on the proposed clinical trial

(To be filled out by **Program Director/Leader**)

Title of protocol:

Site PI for protocol:

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

1. Are there competing trials? [ ]  Yes [ ]  No

a. If yes, please provide rationale for considering this trial. Will this replace an existing trial or will the competing trial be closed?

1. Why is this trial important to open at UPMC Hillman CancerCenter and in your disease center (e.g., important in your research or research interest of your disease center, offers unique and especially promising therapy to patients, important new class of agents, personal involvement in developing trial, etc.)?

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

b. For an industry- sponsored trial, how many accruals are required to cover start-up costs?

c. If Cooperative Group trial, will this participate in the [ ]  LAPS grant or [ ]  non-LAPS?

d. For trials in which costs are not covered, a strong case for opening the trial needs to be provided.

1. Where does this trial fit in the algorithm of trials for your disease site program (e.g. after failure of protocol #1, patients enter protocol #2, etc.)?
2. Number of patients who potentially fit eligibility criteria (number should be broken down by patients that you and/or other full-time faculty personally see and an estimate of the number of patients from all sites that have access to protocol).
3. How many patients per year have been enrolled on similar clinical trials in your disease center?
4. a. If a multi-center trial, what is the total target accrual, over what duration and how many patients are to be enrolled at UPMC Hillman CancerCenter per year and for entire trial? b. If multiple disease centers are involved with this trial *(list below)*, do you have agreement from each to participate, and if not, why? [ ]  N/A [ ]  Yes, **Click here to enter text.** [ ]  No:

 c. If successful enrollment at UPMC CancerCenter, will our site PI be an author on manuscript? [ ]  Yes [ ]  No

1. Accruals are monitored at 3-4 month intervals by the PRC and PI’s advised if study is below 50% of total target accrual. At the end of one year, barring an interim analysis or other temporary closure, what number of accruals will you consider insufficient and hence agree to close the trial?
2. Does this clinical trial have therapeutic intent? [ ]  Yes [ ]  No

Center Program Director: (printed name)

(Signature) (Date)

*Note: Center/Program Director (or Co-Director if PI=Director) signature is required.*

**UPMC Hillman CC PROTOCOL PROCESSING CHECKLIST**

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.

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| PI: Address (campus): Phone #: Fax #: E-mail address:  | Required Documents:[ ]  Full Protocol[ ]  Investigator’s Brochure *(If applicable)*[ ]  Sponsor or UPMC HCC consent form [ ]  Center/Program Director signature/letter[ ]  Biostatistician sign-off *(If in-house study or IIT)*[ ]  Listing of competing protocols [ ]  If *industry*-sponsored: also require draft budget, contract, lab manual & study equipment-vendors questionnaire |
| Co – PI (if applicable): Address (campus): E-mail address: UPMC Regulatory Staff: CRC Staff (if assigned):  |
| 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), please specify which portions we will participate in: (i.e. I, II, **or** both): |
| Co-Investigators: CRNP/PA-C’s:Does the Principal Investigator or any Co-Investigator or Research Coordinator involved in this study have a conflict of interest in participating in this study? [ ] Yes [ ]  No |
| Category: [ ]  Industry Sponsored [ ]  Cooperative Group [ ]  Institutional (IIT) - requires statistician sign-off if local protocol.  [ ]  Consortium [ ]  Other Ext. Peer-Reviewed (NCI/NIH **only**) [ ]  Other University-Hospital Supported\*Biostatistician: (Name) Click here to enter text. (Signature) (Date) \_\_\_\_\_\_\_\_\_\_***\*Biostatistician sign-off required for Investigator-Initiated studies****.*  |
| Sponsor / Source(s) of support (if multiple, please indicate what each is funding): Click here to enter text. |
| Are trial expenses included on a grant? [ ]  Yes [ ]  No If yes, grant # (or name of grant – i.e. ECOG, CA Consortium, NABTC, etc.):  |
| Is this a multi-center study that is locked into the design as provided? [ ]  Yes [ ]  No  |
| Is there an FDA / IND number for any study drug or device (provided by sponsor)? [ ] Yes, and the IND # is: [ ]  No*If Yes, please provide a copy of the Investigator’s Brochure(s) with submission.*Is an investigator-initiated IND application required? [ ]  Yes [ ]  NoTo review guidelines for FDA exemption of IND applications, please refer to: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm362743.htm> |
| # of patients PI expects will be seen in the clinics or physician offices that would 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 – Contract target (required for all submissions): Click here to enter text.IRB target (for Pitt *only*): Click here to enter text. Interim target (optional): Click here to enter text.Number of patients to be enrolled in entire study *(if multi-institutional):*Duration of study treatment (per subject): Click here to enter text. [ ]  days [ ]  weeks [ ]  months [ ]  years [ ]  until disease progressionDuration to achieve study accrual (locally): Click here to enter text. [ ]  days [ ]  weeks [ ]  months [ ]  yearsGender of subjects: [ ]  **Both** [ ]  Female [ ]  Male |
| Will this study use Clinical Pathways? [ ]  Yes [ ]  NoWill this study be opened in the Community if the sponsor and the IRB of record permit? [ ]  Yes [ ]  NoIf Performance Sites have been pre-determined (i.e. Donna Haney confirmed), please list each network site below\*: [ ] N/A [ ] TBD\***UPMC Hillman Cancer Center Radiation Oncology**Subjects to be admitted as an: [ ]  inpatient and/or [ ]  outpatient at: [ ] Shadyside [ ] Magee [ ] Presbyterian [ ] Hillman (2nd & 3rd FL.) [ ] Shadyside [ ] Magee [ ] Presbyterian [ ] Eye & Ear Institute  **\*Note\*:** *If sites are unknown at this time****,*** *please provide list to* upciregulatory@upmc.edu *when finalized (****or*****CC:** *on this submission if all Community sites have been indicated above).*  |
| **CTRC:** Does this study require the services of the CTRC? [ ]  No [ ]  Yes If yes, please indicate: [ ]  Inpatient [ ]  OutpatientUsing: CTRC Hillman CC? [ ]  Yes **/**  CTRC Montefiore? [ ]  Yes **/**  CTRC Magee? [ ]  YesDay(s) needed for CTRC visits: Projected duration of study in the CTRC (years):  |
| Does this trial need to go to the Radiation Safety Committee? [ ]  Yes [ ]  No |
| Does this trial require submission to the IBC (Institutional Biosafety Committee)? [ ]  Yes [ ]  NoDoes this trial include a Data Safety Monitoring Plan and is this included with the protocol or summary? [ ]  Yes [ ]  No If no, please include plan below:  |
| Are lab kits required for this study? [ ]  Yes [ ]  No If yes, are they provided? [ ]  Yes [ ]  NoAre labs to be billed as: [ ]  SOC [ ]  ResearchIf research, are funds needed? [ ]  Yes [ ]  No |
| Does this study involve Leukapheresis? [ ]  Yes [ ]  No  If yes, has Dr. Joseph Kiss (kissj@upmc.edu) been notified? [ ]  Yes [ ]  No  |
| \*\*This section is for trials not coordinated by UPMC Hillman CC only (**non-CRS staff**)\*\* Will this study require the resources of CRS (Clinical Research Services)? [ ]  Yes [ ]  No  If yes, which of the following resources will you require: [ ]  Billing [ ]  CTMA/patient data [ ]  Regulatory [ ]  Budgeting [ ]  CRC Coordination |