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. Disease / stage / first-line, second-line, third-line or other.

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

3. Why is this trial important to open at UPMC Cancer Centers 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. For trials in which costs are not covered, a strong case for opening the trial needs to be provided.

4. 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).

5. Number of patients who potentially fit eligibility criteria (number should be broken down by patients that you and/or other fulltime faculty personally see and an estimate of the number of patients from all sites that have access to protocol).

6. How many patients per year have been enrolled on similar clinical trials in your disease center?

7. If a multi-center trial, what is the total target accrual, over what period of time and how many patients are to be enrolled at UPMC Cancer Centers per year and for entire trial? If successful enrollment at UPMC Cancer Centers, will our site PI be an author on manuscript?

8. Accruals are monitored at six month intervals by the DSMC and PIs advised if study is below 50% of annual 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?

Center/Program Director: (Printed Name) ______________________________
(Signature)________________________________________ (Date) ____________________

Center/Program Director sign-off required. Copy of approval letter/memo or email from the director to Brandon Kaukus at kaukusbm@upmc.edu can be used in lieu of signature.
UPCI PROTOCOL PROCESSING CHECKLIST

Incomplete information may slow down the 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:**
Address (campus):
Phone #:
Fax #:
E-mail address:

**Co – PI (if applicable):**
Address (campus):
Phone #:
Fax #:
E-mail address:

**UPCI Regulatory Staff:**

**CRC Staff:**

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**Required Documents**

- [ ] Full Protocol
- [ ] Investigator’s Brochure *(If applicable)*
- [ ] Sponsor or UPCI consent form
- [ ] Center/Program Director signature/email/letter
- [ ] Biostatistician sign-off *(If in-house study or IIT)*
- [ ] Listing of competing protocols

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**Title of Protocol:**

**Short Title:**

**Phase**

- [ ] I
- [ ] II
- [ ] III
- [ ] IV
- [ ] I/II
- [ ] II/III
- [ ] Pilot
- [ ] Lab or Banking
- [ ] Other (specify)

**Co-Investigators:** *(Include all CRNP and PA staff who will be seeing patients)*

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

**Type of study:**

- [ ] Industry Sponsored
- [ ] Cooperative Group
- [ ] Investigator initiated - requires statistician sign off if local protocol.

Biostatistician:  

(Name)  

(Signature)  

(Date)

**IRAT Physician**

(Name)  

(Signature)  

(Date)

*Biosstatistician sign-off required for Investigator-Initiated studies.* E-mail from statistician to Brandon Kaukus at kaukusbm@upmc.edu can be used in lieu of signature.

*IRAT physician(s) signoff is required for Investigator-Initiated studies that require MRI, CT and PET Scans for Research.*

**Source(s) of Financial Support (if multiple, please indicate what each is funding):**

- 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 with submission.*

- Is an investigator-initiated IND application required?  
  - [ ] Yes
  - [ ] No
To review guidelines for FDA exemption of IND applications, please refer to: [http://www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm)

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<tr>
<th># of patients PI expects will be seen in the clinics or physician offices that would meet the eligibility criteria of this protocol? / year</th>
<th>Anticipated accrual rate? / year</th>
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<th>Number of patients to be enrolled at all UPCI sites (include planned screenings+enrolled):</th>
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<th>Number of patients to be enrolled in entire study (if multi-institutional):</th>
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<th>Duration of study treatment (per subject):</th>
<th>☐ days ☐ weeks ☐ months ☐ years</th>
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<tr>
<th>Duration to achieve study accrual (locally):</th>
<th>☐ days ☐ weeks ☐ months ☐ years</th>
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<th>Subjects to be admitted as an: ☐ inpatient and/or ☐ outpatient to receive the investigational therapy.</th>
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<th>Gender of subjects: ☐ Female ☐ Male</th>
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### Performance sites requested:

- ☐ Hillman Cancer Center (includes 2nd and 3rd floor)
- ☐ John P. Murtha Pavilion ☐ UPMC Passavant
- ☐ Magee-Womens Hospital ☐ UPMC Presbyterian
- ☐ UPMC Jefferson ☐ UPMC St. Margaret’s
- ☐ UPMC Palmer ☐ UPMC Wexford
- ☐ Other (please specify):

### CTRC:

- Does this study require the services of the CTRC? ☐ No ☐ Yes If yes, please indicate: ☐ Inpatient ☐ Outpatient
- CTRC Hillman Cancer Center? ☐ Yes ☐ No CTRC Montefiore University Hospital? ☐ Yes ☐ No
- Will PK samples be performed by the CTRC? ☐ Yes ☐ No
- Will the monitoring of vital signs be performed frequently by the CTRC? ☐ Yes ☐ No Routinely? ☐ Yes ☐ No
- Is the drug infusion required to be administered by the CTRC? ☐ Yes ☐ No
- Is other patient monitoring (be specific) to be performed on the CTRC? ☐ Yes ☐ No
- Is administration of drug cost covered? ☐ Yes ☐ No
- Will routine care costs billed to 3rd party be involved with an inpatient stay on the CTRC? ☐ Yes ☐ No
- Will PK samples and/or drug administration be performed at the Community Sites? ☐ Yes ☐ No
- Is radiation involved for research purposes? ☐ Yes ☐ No
- Is the frequency of radiation procedures in this protocol greater than standard of care? ☐ Yes ☐ No
  - If yes, please list the procedures: ___________________________________________________________________
  - If yes, does this trial need to go to the Radiation Safety Committee? ☐ Yes ☐ No
- Does 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: ____________________________________________________________

### Labs and shipping:

- Are lab kits required for this study? ☐ Yes ☐ No If so, are they provided? ☐ Yes ☐ No
  - If no, what items are needed: ☐ Tubes ☐ Vials for storage ☐ Styrofoam container for shipping frozen samples
  - Freezer packs ☐ Cardboard boxes for shipping ☐ Dry ice for frozen samples shipping
- Is shipping account with: ☐ FedEx ☐ UPS ☐ Other: ____________________________________________________________________________
- Are labs to be billed as: ☐ SOC ☐ Research
- Are funds needed for lab processing if not SOC? ☐ Yes ☐ No
- Does this trial involve Leukapheresis? ☐ Yes ☐ No
If yes, has Dr. Joseph Kiss (kissj@upmc.edu) been notified?