

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](mailto:kaukusbm@upmc.edu) can be used in lieu of signature.*



To review guidelines for FDA exemption of IND applications, please refer to: <http://www.fda.gov/cder/guidance/index.htm>

# of patients PI expects will be seen in the clinics or physician offices that would meet the eligibility criteria of this protocol? / year

Anticipated accrual rate? / year

Number of patients to be enrolled at all UPCI sites (include planned screenings+enrolled):

Number of patients to be enrolled in entire study (if multi-institutional):

Duration of study treatment (per subject):  days  weeks  months  years

Duration to achieve study accrual (locally):  days  weeks  months  years

Subjects to be admitted as an:  inpatient and/or  outpatient to receive the investigational therapy.

Gender of subjects:  
 Female  Male

**Performance sites requested:**

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

**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 3<sup>rd</sup> 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: \_\_\_\_\_

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 study involve Leukaphoresis?  Yes  No

If yes, has Dr. Joseph Kiss ([kissj@upmc.edu](mailto:kissj@upmc.edu)) been notified? \_\_\_\_\_