**Protocol Review and Monitoring Committee (PRMC) Submission Form**

PRMC meets once a month on the first Thursday. Please complete and submit this form along with the protocol to Toukie at PRMS@gwu.edu at least 2 weeks prior to the meeting date. Please attach additional page or documentations, if needed.

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Review Type
 | [ ]  Initial | [ ]  Resubmission | [ ]  Amendment |
| 1. Title of the protocol:
 |  |
| 1. Protocol version and date:
 |  |
| 1. Principal Investigator (PI):
 |  |
| 1. If multidisciplinary, has this been discussed at a disease-oriented group level?
 | [ ]  Yes | [ ]  No | [ ]  N/A |
| 1. Please identify all Sub-Is from each discipline involved and support this study.
 |  |
| 1. Study type
 | [ ]  NCI Cooperative Group. Group name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Industry-Sponsored Trial. Name: \_\_\_\_\_\_\_\_\_\_\_[ ]  Investigator Initiated Trial[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Interventional Protocol
 | [ ]  Pilot | [ ]  Phase I | [ ]  Phase I/II |
| [ ]  Phase II | [ ]  Phase III | [ ]  Phase IV |
| [ ]  N/A |  |  |
| 1. Study Format

  | [ ]  Interventional (check all applicable) |
|  | [ ]  Chemotherapy |
|  | [ ]  Oral | [ ]  Parenteral |
| [ ]  Biologic Therapy |
|  | [ ]  Oral | [x]  Parenteral |
| [ ]  Cellular Therapy[ ]  Stem Cell Transplantation[ ]  Radiation Therapy[ ]  Surgery |
| [ ]  Device[ ]  Tissue[ ]  Registry[ ]  Retrospective Data Analysis[ ]  Observational[ ]  Behavioral[ ]  Other: |
| 1. Briefly describe the study (objective and significance)
 |  |
| 1. How many subjects do you expect to enroll?
 | Total accrual at GWCC: \_\_\_\_\_\_\_\_\_Duration of the study: \_\_\_\_\_\_\_ [ ]  months or [ ]  yearEstimate accrual: \_\_\_\_\_ / [ ]  month or [ ]  yearEstimate is based on: |
|  | [ ]  Prior study accrual[ ]  Physician estimate | [ ]  Patient database[ ]  Other: |
| 1. Industry/NCI Trials:
 | Is this study open to accrual? [ ]  Yes [ ]  NoIf yes, when was this study open? \_\_\_\_\_\_\_\_\_If no, expected date first subject enrollment \_\_\_\_\_\_\_Total expected enrollment:\_\_\_\_\_ Current enrollment: \_\_\_\_\_\_Total number of sites: \_\_\_\_\_\_\_\_Plan to enroll women and members of minority groups?[ ]  Yes [ ]  No |
| 1. Are there other competing protocols?
 | [ ]  Yes [ ]  NoIf yes, please list and prioritize: \_\_\_\_\_\_Justification for competing trials: \_\_\_\_\_\_ |
| 1. Are there adequate resources to conduct the study?
 | Pharmacy? Yes [ ]  No [ ] Pathology? Yes [ ]  No [ ] Are GWCC samples sent to other sites? Yes [ ]  No [ ] Are samples sent from other sites to GWCC? Yes [ ]  No [ ] Are samples collected for research? Yes [ ]  No [ ] If any of the above are answered Yes, please list and identify adequate plans to facilitate. |
| 1. Are adequate staff available to support this trial?
 |  |
| 1. Disease site group
 | [ ]  Breast[ ]  GI and colorectal [ ]  Hematologic [ ]  Head and Neck[ ]  Neurologic[ ]  Urologic | [ ]  Dermatologic[ ]  Gynecologic[ ]  Hepatocellular Carcinoma[ ]  Lung[ ]  Sarcoma[ ]  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Has the protocol been reviewed and approved by a nationally recognized peer review committee?
 | [ ]  No[ ]  Yes, specify: \_\_\_\_\_\_\_\_\_ (e.g., CTEP, NIH) |
| 1. Likelihood of authorship:
 | [ ]  Yes, based on scientific input into study design/development[ ]  Likely, based on accrual[ ]  Unlikely |
| 1. We should do the study because:
 | [ ]  Important clinical and/or scientific question[ ]  Important to have available for our patients[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_ |

I acknowledge that I have read, understand the responsibilities of principal investigator and agree to abide by the policy.

PI name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_