**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](mailto:PRMS@gwu.edu) at least 2 weeks prior to the meeting date. Please attach additional page or documentations, if needed.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 | | 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  year  Estimate accrual: \_\_\_\_\_ /  month or  year  Estimate is based on: | | | | | | | |
|  | | Prior study accrual  Physician estimate | | | | Patient database  Other: | |
| 1. Industry/NCI Trials: | Is this study open to accrual?  Yes  No  If 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  No  If 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_