MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Medical College of Wisconsin Cancer Center
New Trial Submission Form

This form must be filled out by the Principal Investigator.

Principal Investigator:	
Full Protocol Title:	
Patient-friendly Title:	
Planned study site(s):	☐ FMLH ☐ CHW ☐ CMH ☐ West Bend
Study Overview	
Type of Study	☐ MCW Investigator-Initiated ☐ Cooperative Group ☐ Institution (IIT from outside) ☐ Industry/Pharmaceutical ☐ Consortium ☐ Other _____
	☐ Drug ☐ Device ☐ Observational ☐ Community Research
	Scope of trial: ☐ Local ☐ National
	☐ Treatment ☐ Ancillary or Companion ☐ Epidemiologic/Observational ☐ Prevention ☐ Supportive Care ☐ Health Services Research ☐ Correlative ☐ Screening ☐ Other _____ ☐ Diagnostic ☐ Basic Science
Phase of Study	☐ Pilot ☐ I ☐ I/II ☐ II ☐ II/III ☐ III ☐ III/IV ☐ IV ☐ N/A ☐ Treatment Use* ☐ Expanded Access* ☐ Other _____ *Also fill out Appendix in Management of Expanded Access and Treatment Use Protocols SOP
Academic Credit	☐ Multi-institutional trial with no chance of authorship or credit ☐ Multi-institutional trial with no chance of authorship but with associated institutional credit (e.g., cooperative group trial) ☐ Multi-institutional trial with likelihood of authorship (named investigator or high accrual expectations) ☐ MCW investigator-initiated trial with likelihood of authorship
Value to Patients	☐ Little or no clinical importance, registry or post-licensing marketing study ☐ Phase I-III trial with potential to change clinical practices ☐ Phase II-III trial likely to change clinical practices
Accrual	
Local accrual goal	Local target accrual goal: ☐ Accrual Duration (Months): ☐ How many patients with this specific disease are seen at our institution per year (include source of data for expected enrollment, e.g. tumor registry, EPIC, CDW, etc.)?
National accrual goal	Overall target accrual goal: ☐ Current overall enrollment: ☐ Date study opened nationally: ☐ Expected closing date: ☐
Rare disease	☐ Check box if annual incidence is ≤3 newly diagnosed persons per 100,000 persons in U.S.

Funding	
Sponsor: ☐ Department ☐ Cooperative group ☐ Pharmaceutical ☐ NCI CTEP ☐ Other_____ ☐ There is no funding for this study. ☐ Additional funding is needed.	
For Investigator-Initiated Trials: Funding Source: _____ Funding Proposal #:_____ Has funding been approved? ☐Yes ☐No Amount of award/approved funding: $_____	
Study Complexity	
No. of Arms	☐ 1 ☐ 2 ☐ 3 ☐ 4 or more
Department/Team Impact	☐ One or two departments involved – Standard clinical research team ☐ Three or more departments involved – Complex coordination needed ☐ Inpatient Care Required
Radiology	Is there an imaging requirement in the protocol? ☐Yes ☑No
	If Yes- The requirements are: ☐ standard ☐ study-specific For IITs, has a radiologist been identified as a collaborator? ☐Yes ☐No
Eligibility Review	☐ Basic eligibility ☐ Complex with multi-step eligibility review
Registration/ Randomization Tasks	☐ One step ☐ Multiple steps with possible pathology/ancillary review
Frequency of Study Tasks	☐ Every 21-30 days or more ☑ Weekly ☐ Daily
Beacon Build needed?	☐Yes ☐No
Ancillary Studies	☐ Banking ☐ QoL ☐ PK samples ☐ Other
Data Collection on Treatment	☐ Basic – No AE reporting, batching of data ☐ Standard – AE reporting and data collection ☐ Complex – Real time data submission, review of source documents for endpoints, multiple data sources
Follow-up Requirements	☐ Annual or minimal follow-up ☐ At each time point of clinical activity ☐ Complex multiple clinical points
Special Requirements	☐ IND application
	☐ Clinicaltrials.gov
	☐ Coordinating center for multi-site study
	☐ Other

Faculty Research Committee approval to send to SRC:

FRC Chair Signature	Date