Medical College of Wisconsin Cancer Center
New Trial Submission Form

Principal Investigator:	
Full Protocol Title:	
Patient-friendly Title:	
Planned study site(s):	☐ Froedtert ☐ CW ☐ FMF ☐ FWB ☐ Drexel ☐ Moorland ☐ Community
Study Overview	
Type of Study	☐ MCW Investigator-Initiated ☐ NCTN/CTN ☐ External Institutional ☐ Industry/Pharmaceutical ☐ Consortium ☐ Other _____
	☐ Drug ☐ Device ☐ Radiation ☐ Surgical ☐ Behavioral/Education Intervention ☐ Observational ☐ Other _____
	Scope of trial: ☐ Local (MCW/community) ☐ National/Multisite
	☐ Treatment ☐ Diagnostic ☐ Epidemiologic/Observational ☐ Supportive Care ☐ Device Feasibility ☐ Ancillary ☐ Screening ☐ Health Services Research ☐ Correlative ☐ Prevention ☐ Basic Science ☐ Other _____
Phase of Study	☐ I ☐ I/II ☐ II ☐ II/III ☐ III ☐ III/IV ☐ IV ☐ N/A ☐ Early Phase I ☐ Other _____ Pilot study? ☐ Yes ☐ No
Authorship	Is authorship likely? ☐ Yes ☐ No If yes: ☐First/last author ☐ Middle author Comments:
Accrual	
Local accrual	Projected annual accrual Overall accrual duration (months) Overall local accrual goal 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	Overall target accrual goal: Date accrual opened nationally: Current overall enrollment: Expected closed to accrual date:
Rare disease	☐ Check box if annual incidence is ≤4 newly diagnosed persons per 100,000 persons in U.S. (rare cancer, rare molecular subtype of common cancer, or unusual clinical situation)
Competing Trials	
Will this study compete with any currently accruing or pending trials? ☐ Yes ☐ No If yes, indicate which trial(s) and describe prioritization plan for enrollment:	

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Funding Source

☐ NCTN/CTN ☐ Pharmaceutical ☐ MCW Cancer Center ☐ There is no funding for this study.
☐ Consortium ☐ Department ☐ Other_____ ☐ Additional funding is needed.
☐ NCI CTEP ☐ External Institution
Is the budget negotiable? ☐ Yes ☐ No Comments:

For Investigator-Initiated Trials:
Funding Source: _____ Funding Proposal #:_____
Has funding been approved? ☐Yes ☐No Amount of award/approved funding: $_____

Study Complexity

No. of Arms	**Eligibility Review**	**Registration/ Randomization**	**Frequency of Study Tasks**
☐ 1 ☐ 2 ☐ 3 ☐ ≥4	☐ Basic ☐ Complex/multi-step	☐ One step ☐ Multiple steps	☐ Daily ☐ Weekly ☐ Every 21-30 days 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
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 submission, review of source documents for endpoints, etc.
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
Beacon Build needed?	☐Yes ☐No

Additional Comments

Disease-Oriented Team approval to send to SRC:

DOT Chair Signature | Date