UCI 趙 Chao Family Comprehensive Cancer Center

Protocol Review and Monitoring Committee (PRMC) Application

THIS APPLICATION IS REQUIRED FOR ALL PRMC SUBMISSIONS

Protocol Numbers: **UCI#** **IRB HS#** **ClinicalTrials.gov NCT#**

Lead Researcher's Name:

Protocol Title:

SECTION I: PROTOCOL INFORMATION

Please complete the fields below.

1. Submission Type: ☐ Initial ☐ Renewal ☐ Amendment ☐ Accrual Review
2. Sponsor(s): Principal Sponsor: Additional Sponsors:
3. Sponsor Type: ☐ Externally Peer Reviewed, award # ☐ Industrial ☐ Institutional ☐ National
4. Primary Purpose: ☐ Basic Science (BAS) ☐ Diagnostic (DIA) ☐ Health Services Research (HSR) ☐ Prevention (PRE) ☐ Screening (SCR) ☐ Supportive Care (SUP) ☐ Treatment (TRE) ☐ Other (OTH)
5. Clinical Research Category: ☐ Ancillary (ANC) ☐ Correlative (COR) ☐ Interventional (INT) ☐ Observational (OBS)
6. **Institutional Protocols only**: The PRMC requires a Cancer Center statistician named on the protocol. Request statistical consultation by completing the online form on the Biostatistics Shared Resource website: https://www.cancer.uci.edu/biostatistics/consultation.asp _____ is the statistician included in the study team.

PRMC SUBMISSION REQUIREMENTS

The following documents are required for a complete protocol submission, send to CancerCenter_Committees@hs.uci.edu. **All questions should include a response or "N/A".**

New Protocols	Renewals	Amendments[1]	Accrual Review
☐ PRMC Application	☐ PRMC Application	☐ PRMC Application	☐ PRMC Application
☐ Sponsor/Master Protocol or Protocol Narrative (if a protocol is not available)	☐ Sponsor/Master Protocol or Protocol Narrative (if a protocol is not available).	☐ Clean and tracked Sponsor/Master Protocol or Protocol Narrative (if a protocol is not available).	☐ Sponsor/Master Protocol or Protocol Narrative (if a protocol is not available).
☐ Study DOT/TB Feasibility Application and Scoring Form	☐ IRB Continuing Review Application	☐ Summary of changes. If not available, submit the IRB Modification Request.	
☐ Pharmacy Manual (if applicable)			
☐ Consent Form			

[1] Only significant changes to the protocol need to be submitted (e.g. adding a primary objective or cohort, etc.)

UCI 趙 Chao Family Comprehensive Cancer Center

SECTION II. ACCRUAL INFORMATION

Please complete the fields below. Per NCI Cancer Center Support Grant (CCSG) guidelines, accrual is defined as: **a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for the study, but do not participate in the study, are not considered enrolled unless otherwise specified by the protocol.**

Per *Stern Center SOP - PRMC Research Accrual Policy*, accrual to date is required to be 50% of expected accrual. The expected accrual is calculated by the accrual target divided by the length of the time the study is projected to be open to accrual.
The expected accrual is pro-rated by the amount of time the study has been open to accrual with temporary suspensions taken into consideration. Study accrual must be greater than or equal to 50% of the pro-rated expected accrual to meet policy.

1. PRMC submission date:	
2. Projected accrual end date:	
3. Maximum number of subjects to be consented at UCI (including screen failures):	
4. Accrual target (Minimum, i.e. required sample size):	
5. For basket trials, please indicate which disease sites will be enrolling into the study at UCI.	
SECTION IIA. For multi-center, UCI investigator-initiated protocols only complete the questions below.	
6. List all UCI and non-UCI participating sites:	
7. Multi-center number of subjects to be consented (including screen failures)	
8. Multi-center targeted accrual:	
9. Multi-center consented to date	
10. Multi-center accrual to date:	
SECTION IIB. For all new protocols complete the questions below.	
11. Provide accrual target justification (such as current Cancer Registry data):	
12. Does the research exclude older adults (>65 years)? If yes, describe the scientific or ethical reasons not to include them.	☐ No ☐ Yes (provide rationale):
13. Does this study compete with existing trials? If so list all competing studies and how would one study be prioritized over the other(s)?	
14. DOT/TB protocol priority score If low, provide rationale on why study should be opened	☐ High ☐ Med ☐ Low Rationale for low priority:

UCI 趙 Chao Family Comprehensive Cancer Center

SECTION IIC. For amendments, renewals, and accrual reviews only complete the questions below. All fields are required unless specifically indicated.	
15. Opened to accrual date:	
16. Total consented to date at UCI:	
17. Total accrual to date:	
18. Total consented at UCI since the most recent PRMC review:	
19. Total accrual since the most recent PRMC review:	
20. Describe any accrual concerns and all efforts underway to increase accrual:	
21. List all temporary accrual suspension periods with start and end dates and reasons, e.g. suspension due to analyses, change in availability of resources, etc. (if applicable):	
22. Closed to accrual date (if applicable):	
23. Closed to accrual reason (if applicable):	
24. Interim analysis findings (only for UCI IITs):	

SECTION III. RARE CANCER DOCUMENTATION

1. Does the protocol involve a rare cancer? ☐ Yes ☐ No

Refer to NCI Guidance for more information. PRMC defines rare as a cancer or subtype that has an incidence of ≤ 6 newly diagnosed persons out of a population of 100,000 persons per year (≤ 6/100,000).

If yes, which definition of 'rare cancer' designation has been met?

A. ☐ Is described as rare according to any of the following websites:
   - ☐ RARECARE
   - ☐ NCI Surveillance, Epidemiology, and End Results (SEER) Cancer Stat Fact Sheets
   - ☐ Other, please list: _____

B. ☐ Is described as rare in a peer reviewed article or publication (provide supporting documentation).

C. ☐ A rare molecular subtype if the protocol inclusion criteria require a specific biomarker, gene, or uncommon clinical subsets of more common cancers (provide supporting documentation).

D. ☐ Previous Rare Determination in Approval Memo year _____

SECTION IV. SPONSOR/MASTER PROTOCOL (FOR INSTITUTIONAL PROTOCOLS ONLY)

Please indicate the page number(s) in the Sponsor/Master Protocol where information can be found for review. If not applicable, indicate "N/A".

Page No.	Information
	OBJECTIVES 1. Overall objective(s) stated in a clear and precise language.
	BACKGROUND & PURPOSE 1. Purpose of study stated in clear and precise language.
	DRUG INFORMATION 1. Availability and storage information identified.

	2. Supplier and cost information identified. 3. Dosage and administration information supplies including any special notations re: actual administration (i.e. Phase I & II). 4. Adverse effects clearly identified and specified.
	STAGING CRITERIA 1. Staging criteria identified and supplied in either body of protocol or Appendix. 2. Source of staging criteria referenced if available.
	ELIGIBILITY CRITERIA 1. Criteria are clearly stated objectively measured and be able to be formulated into a checklist format. 2. Exams, labs, etc. to be completed prior to registration outlined with specific time requirement.
	DESCRIPTIVE FACTORS & STRATIFICATION/RANDOMIZATION SCHEME 1. If the study is to be randomized, all relevant issues have been adequately addressed. (e.g. blinding, timing and mechanics of randomization) 2. All issues regarding patient stratification have been adequately addressed.
	TREATMENT PLAN 1. Treatment schedule clearly delineated. 2. Criteria clearly identified for removal and/or evaluation.
	TOXICITIES TO BE MONITORED AND DOSAGE MODIFICATION 1. Toxicity criteria clearly stated and grading system identified. Appendix Attached. 3. All toxicities noted in body of protocol addressed for modification or discontinuation. 4. Contingency plans for dose modification clearly stated. 5. Stopping point procedures in the case of excess toxicities.
	DSM Template 1. Risk level is clearly defined and justified 2. Timeframe for the recording of events defined 3. Clear event definitions 4. Reporting requirements to the CFCCC DSMB 5. Any additional reporting requirements that is applicable to the protocol (i.e. IRB, Sponsor, IDE, etc)
	STUDY CALENDAR (Schema) 1. Calendar in format.
	CRITERIA FOR EVALUATION AND ENDPOINT DEFINITIONS 1. All endpoints are clearly and appropriately defined.
	STATISTICAL CONSIDERATIONS 1. Has a Statistician been assigned as a Co-Researcher on the protocol? 2. Sample size given and defended. 3. Accrual rate and expected duration of study given and supported. 4. Follow-up duration clearly stated. 5. The protocol type (e.g. Phase I) has been clearly stated and supported. 6. The experimental design is appropriate to answer the objectives. 7. Appropriate statistical tests will be used to test the objectives. 8. Adequate interim analyses have been planned for so that the trial can be stopped early if a major effect is observed (if applicable)