CPRC Initial Full Review Application Overview

1. **The CPRC conducts scientific review of all cancer-related protocols at the University of Minnesota prior to IRB review.**
   * Protocols may not receive IRB review until they are granted approval or approval with minor stipulations from the CPRC.
2. **OnCore access is required to submit to the CPRC**:
   * Applications must be submitted via ePRMS in OnCore.
     + Instructions for ePRMS submission and PI Signoff are available on the [CPRC website](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee).
     + This requirement is exempted for studies not requiring OnCore entry (see <https://z.umn.edu/onc_min_footprint> ).
   * **PIs are responsible** **for completing PI Signoff in the ePRMS console by logging into OnCore**. This cannot be done by study staff on their behalf.
   * Please contact [oncore@umn.edu](mailto:oncore@umn.edu) or 612-626-3080 if your OnCore password has expired or you require OnCore training. The CPRC does not provide OnCore technical support or training. The OnCore new user request form is at <https://oncoreuser.ahc.umn.edu/secure/>.
3. **Required Documentation**:
   * Protocol
   * Investigators Brochure *(if applicable)*
   * Data and Safety Monitoring Plan *(if applicable)*
     + If the protocol has a Data and Safety Monitoring Board (DSMB), submitting the DSMB Charter and membership list (or providing a statement confirming that these will be submitted to the CPRC when available) will prevent a stipulation from the CPRC.
4. **Submission deadlines** are posted on the [CPRC website](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee).
5. **Incomplete submissions will be returned** for completion prior to review and may not be processed until after the next CPRC deadline.
6. **Send any CPRC-related questions** to [ccprc@umn.edu](mailto:ccprc@umn.edu). *(Note the extra “c.”)*

CPRC Initial Application

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| Protocol Title: |
| UMN Principal Investigator: |
| 1. UMN Co-Investigators (investigator initiated) or Sub-Investigators (sponsored study): |
| 1. Trial Type\*   **Treatment Interventional**: An interventional trial which involves the treatment of cancer.  **Non-Treatment Interventional**: An interventional trial which does not involve the direct treatment of cancer, i.e. treats a symptom of cancer, treats a side-effect of cancer treatment, supportive care (i.e. GVHD) etc.  **Non-Treatment Non-Interventional**: Data registry, blood draw study, survey, focus group, etc.  NCI Definition of Interventional: Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.  **\***If your study is a Retrospective Chart Review, Retrospective Sample Review, or Prospective Specimen Repository, please fill out the [CPRC Expedited Application](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee) instead. |
| 1. IND/IDE/ITP   Does this study involve an IND, IDE, or ITP?Yes No *If yes and UMN held***,** name of IND, IDE, or ITP holder: |
| 1. MCC Resourcing Needs(if applicable): Not Applicable   CTO Project Manager Biostatistician Clinical Informatics Shared Services  CTO Regulatory Specialist Finance (Budget/Contract) Translational Therapy Lab  CTO Study Coordinator(s) IND/IDE Management Molecular and Cellular Therapeutics  CTO Affiliate Management Data Management: REDCap, OnCore eCRFs, etc.  Minnesota Cancer Clinical Trials Network (MNCCTN)  Other: |
| 1. Fairview Resourcing Needs(if applicable): Not Applicable   Clinic Services Pathology/Immunohistochemistry Radiology  Laboratory Radiation Interventional Radiology  IDS Treatment Room Services Nuclear Medicine  BMT Database Apheresis  Other: |
| 1. Study Locations   MHealth CSC: Masonic Solid Tumor Gyn-Onc BMT Masonic Heme Breast Urology ENT  UMMC Inpatient: 7D BMT 5C 7C  Masonic Children’s Hospital Inpatient  Pediatric Outpatient: Discovery Clinic Journey Clinic  Other:  **Fairview (FV) Community Sites**: Southdale Maple Grove Ridges Lakes Not Applicable   * **If N/A,** FV sites, does it fit into one of the following categories?: Phase I BMT PEDS * **If N/A, and it does not fit into one of the categories** in the previous question, please provide justification for not opening at a FV site:   **Affiliate Sites** (for Investigator Initiated studies only): Not Applicable |
| 1. Study Personnel Please identify **all staff** that could possibly **enroll or manage patients for purposes related to this study**. |
| **Advanced Practice Providers (APPs) - NPs & PAs**:   |  |  |  | | --- | --- | --- | | **Clinics and Surgery Center APPs:**  Solid Tumor  Heme  BMT  Gynecology | **Hospital 7D APPs:**  Solid Tumor  Heme  Gynecology | **Other APPs:**  Hospital 5C BMT APPs  Peds BMT APPs  Peds Heme/Onc APPs | |
| **Physician Groups**:  BMT Adult Transplant MDs (clinic or 5C)  Heme Malignancy MDs (clinic or 7D)  BMT Pediatric MDs (Masonic Children’s or Journey/BMT clinic)  Oncology Service Line Affiliate Site Staff (i.e. Southdale) |
| **Study Staff** (list all that apply if not CTO Managed):  Regulatory Specialist:  Coordinator:       Project Manager:  Comments: |
| 1. Patient Population and Accrual Goals   Yearly accrual goal at UMN (CSC, UMMC, etc.):  Yearly accrual goal at community sites (Fairview, etc.), *if applicable*:  Yearly accrual goal at affiliate sites (non-Fairview), *if applicable*:  Number of months expected open to enrollment at UMN:  Number of subjects potentially eligible for this study seen at UMN in the last year, *if applicable*:  Number of subjects potentially eligible for this study seen at Community Sites in the last year, *if applicable*:  How was this number of potential subjects determined?:  Multicenter Trials:   * 1. What is the national total accrual goal?:   2. How many sites (including UMN) will be open?:   3. How many enrollment slots are still available?:   Is this study targeted to study minority or under represented populations? Yes No  If yes, please explain: |
| 1. Prioritization Plan for Competing Studies   No competing trials are open or in startup/pipeline to open at UMN for this study.  There are competing trials open or in startup/pipeline at UMN for this study:   * Prioritization plan for competing studies: * List mechanism by which or colleagues with whom this prioritization plan was developed (i.e. with disease team, etc.): |
| 1. Funding Support:   At this time funding is anticipated to be: Complete Partial Unfunded   * *If partial or unfunded*, please list plans to obtain support:   **Authorship and Funding source(s)** - check all that apply:   1. UMN Investigator-Initiated Trial (IIT-study idea conceived by UMN Investigator):   IIT NIH or grant - grant name:  IIT Non-NIH grant - grant name:  IIT/industry - sponsor name: IIT other funding - name:   1. Industry - sponsor name: 2. Cooperative Group or Consortium - name: - Is the PI a steering committee leader? Yes No 3. Other:   **If CTO Managed**, are there timeline commitments for funding that need to be met? Yes No If yes, please summarize: |
| 1. Strategic Goals *The choices below represent current strategic goals for the MCC.*   **Check all boxes that apply to this protocol and explain below:**  Based on MCC Translational Work (our bench created it).  Trial targets unmet clinical need (i.e. rare tumors with no established SOC).  PI is junior faculty (assistant professor).  Trial participation is a pre-requisite for academic partnership w/ B&I. Explain partnership:  Immunotherapy/cellular therapy for solid tumor trial  Functional genomics/precision medicine trial  Evidence-based cancer prevention strategy trial  Chemoprevention agent trial  Trial uses biomarkers to individualize cancer prevention and personalize treatment  Biospecimen cohort trial that includes the collection of biospecimens for investigation of genetics, epigenetics, microbiome, and immunity associated with cancer.  Survivorship, quality of life, or palliative care trial without administering agent.  Trial targets disease burden specific to the state of Minnesota:   * Targets one of the top five highest cancer incidences in Minnesota: Breast, Colorectal, Corpus/Uterus NOS, Prostate, Lung * Targets on of the top five cancers with higher than US average incidence in Minnesota: Leukemia, Melanoma, Mesothelioma, Non-Hodgkin Lymphoma, Testis |
| 1. Academic Advancement   Highlight how this trial will help your academic career development or advancement (tenure, promotion, etc.) |
| 1. PI Experience 2. Have you been the Principal Investigator of ≥ 3 clinical trials? Yes No 3. Have ≥ 8 subjects enrolled total across all the clinical trials where you served as Principal Investigator? Yes No |
| 1. Mentorship - Only if PI is Junior Faculty (Assistant or Associate)   Do you have a mentor on this project? Yes No  If yes, who is your mentor?:  Is this trial part of a Mentored Career Development (K) Award? Yes No  If yes, please list award number: |
| 1. OnCore Study Registration   The [AHC now requires a minimum footprint in OnCore](http://www.ctsi.umn.edu/researcher-resources/clinical-trial-management-system/studies-enter-oncore) (please click the link to see if your study is applicable). **All studies that fit within the AHC requirement will need to be entered into OnCore prior to CPRC review.** Please contact [oncore@umn.edu](mailto:oncore@umn.edu) if you need access to &/or training in OnCore. This will not be provided by the CPRC.  Before submitting this application, please make sure that:   1. Your study has been entered into OnCore (if required) and 2. The user: “CPRC” has been added as the role: “Submitter” in the Staff tab so we are able to access your study.   Enter your study’s OnCore protocol number here: |
| 1. Required Participant Data Collection:   All cancer related studies approved by CPRC are required to have individual subject accrual data entered into one of two supported databases: OnCore or REDCap. Even if you have registered you study in OnCore (as requested above) you need to confirm where you will be recording your accrual data.  **Please indicate your choice**:  OnCore1  REDCap2   1. *If you do not already use OnCore, investigators and research team members must request access and training from:* [*oncore@umn.edu*](mailto:oncore@umn.edu). *This will not be provided by the CPRC.* 2. *If using REDCap:*    1. *You are required to* ***add Vidhya Ramesh*** *(rames007@umn.edu) from MCC OMIS to the project within REDCap in order to generate accurate data for NIH reporting requirements.*    2. *You are required to use the* ***UMN MCC Subject Registration Template*** *within REDCap. Instructions on how to import the template in REDCap and an accompanying Code Book can be found on* [*our website*](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee)*.* |