CPRC Initial Cede Review Application

1. **This application is used ONLY for studies previously approved by a Protocol Review and Monitoring System (PRMS) at an NCI-designated Cancer Center** (for reference: <https://www.cancer.gov/research/nci-role/cancer-centers/find>).
   1. With this application the scientific review portion of CPRC will be ceded, but there will still be a feasibility review conducted for MCC.
2. **OnCore access is required to submit to the CPRC**:
   1. Applications must be submitted via ePRMS in OnCore.
      1. 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).
      2. This requirement is exempted for studies not requiring OnCore entry (see <https://z.umn.edu/onc_min_footprint> ).
   2. **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.
   3. 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**:
   1. Statement Documentation of Protocol Review and Monitoring System (PRMS) Approval from the NCI-designated cancer center (may be an email from the Institution’s PRMS Administrator)
   2. Protocol
   3. Investigators Brochure (if applicable)
   4. DSMP Data and Safety Monitoring Plan (if applicable)
4. **Incomplete submissions will be returned** for completion prior to review and may not be processed until after the next CPRC deadline.
5. **Sections with a header followed by “\*\*” are not required for Pediatric non-BMT Oncology**

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| Protocol Title: |
| UMN Principal Investigator: |
| 1. Trial Type: (choose one) 2. **Treatment Interventional**: An interventional trial which involves the treatment of cancer. 3. **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. 4. **Non-Treatment Non-Interventional**: Data registry, blood draw study, survey, focus group, etc. 5. **Retrospective Chart Review, Retrospective Sample Review or Prospective Specimen Repository**   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. |
| 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. 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: |
| 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:  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. Authorship and Funding source(s) – check all that apply:\*\*   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:  Cooperative Group or Consortium - name: - Is the PI a steering committee leader? Yes No  None of the above |
| 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. Required Participant Data Collection:   All cancer related studies ([types A, B or C from Section 1](#Trial_Type)) 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)*.* |