CPRC Initial Cede Review Application

1. **This application is used ONLY for:**
   1. Protocols approved by the NCI’s Cancer Therapy Evaluation Program (CTEP) or the Cancer Control Protocol Review Committee.
   2. Multi-site investigator initiated trials (IITs) where UMN is a participating site and the lead site is an [NCI-designated Cancer Center](https://www.cancer.gov/research/nci-role/cancer-centers/find) whose Protocol Review and Monitoring System (PRMS) has approved the study.
      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. **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. For studies described in category 1b above:
      1. Documentation of lead site Protocol Review and Monitoring System (PRMS’s) scientific approval of the protocol version being submitted.
      2. Documentation that lead site’s PRMS is fully approved by the NCI (a letter or email from the PRMS Chair is acceptable). This documentation should include the end date of the current approval period (tied to the grant cycle).
   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. **Section headers followed by “\*\*” are not required for Pediatric Oncology (non-BMT)**

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| Protocol Title: |
| UMN Principal Investigator: |
| 1. Previous Scientific Review: (choose one)   NCI’s Cancer Therapy Evaluation Program (CTEP) or the Cancer Control Protocol Review Committee  NCI Designated Cancer Center approved Protocol Review and Monitoring System (PRMS)\* from lead study site  - Lead Site Name:  *\*Please attach the PRMS approval letter and proof of current NCI PRMS approval (i.e. letter or email from the PRMS administrator or chair stating approval status.)* |
| 1. Trial Type: (choose one)   **Treatment**: One or more interventions\* are being evaluated for treating a disease, syndrome, or condition.  **Prevention**: One or more interventions\* are being assessed for preventing the development of a specific disease or health condition.  **Diagnostic**: One or more interventions\* are being evaluated for identifying a disease or health condition.  **Supportive Care**: One or more interventions\* are evaluated for maximizing comfort, minimizing side effects, or mitigating against a decline in the participant's health or function.  **Screening**: One or more interventions\* are assessed or examined for identifying a condition, or risk factors for a condition, in people who are not yet known to have the condition or risk factor.  **Health Services Research**: One or more interventions\* for evaluating the delivery, processes, management, organization, or financing of healthcare.  **Basic Science**: One or more interventions\* for examining the basic mechanism of action (for example, physiology or biomechanics of an intervention).  **Device Feasibility**: An intervention\* of a device product is being evaluated in a small clinical trial (generally fewer than 10 participants) to determine the feasibility of the product; or a clinical trial to test a prototype device for feasibility and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.  **Observational**: Studies in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the study participants. This includes when participants receive interventions as part of routine medical care, and a researcher studies the effect of the intervention. Includes data registry, blood draw study, survey, and focus group studies.  **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   **All studies must be entered into OnCore prior to CPRC review** to submit your application in our electronic committee management system: ePRMS**.** 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. 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).  Before submitting this application, please ensure that:   1. The study has been entered into OnCore under protocol number:  - and - 2. The CPRC Management Group has been added to your study - choose below depending on Organizational Unit:    * + Cardiovascular: CV-CPRC      + M Health Community: MHC-CPRC      + Masonic Cancer Center: ONC-CPRC      + MNCCTN: MNCCTN-CPRC      + UMN TC General: UMN-CPRC |
| 1. Required Participant Data Collection:   All cancer related studies approved by CPRC are required to have **individual subject accrual data including race, ethnicity, and gender** entered into one of two supported databases: OnCore or REDCap. Even if you have registered your study in OnCore (as requested above) you need to confirm where you will be recording your accrual data.  Accrual database choice:  OnCore1  REDCap2  N/A: Retrospective Chart/Sample Review or Prospective Specimen Repository   1. **OnCore is the preferred choice** to easily satisfy both CPRC and CTSI accrual reporting requirements.    1. For CTSI accrual requirements, refer to the "Is my study required to be entered in OnCore?" quiz or decision tree on the [OnCore website](https://sites.google.com/umn.edu/oncoredecisiontree/home) for further information.    2. 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).    3. You will still be required to enter accrual in OnCore if the study meets [CTSI accrual entry requirements](https://sites.google.com/umn.edu/oncoredecisiontree/home). |
| 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 FV Sites N/A:** does the study fit into one of the following categories?:  Phase I  BMT  PEDS * **If N/A, and it does not fit into one of the categories above**, 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:\*\* 2. 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: |
| 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 |