Population Science Initial Application Overview

for scientific review of cancer-related or tobacco use protocols

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.”)*

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| Protocol Title: |
| UMN Principal Investigator**:** |
| 1. UMN Co-Investigators (investigator initiated) or Sub-Investigators (sponsored study): |
| 1. Trial Type\*   **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, etc.  **Non-Treatment Non-Interventional**: 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 this study is a Retrospective Chart Review, Retrospective Sample Review, Prospective Specimen Repository, please fill out the [CPRC Expedited Application](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee) instead.  \*If this study is Treatment Interventional, please fill out the [CPRC Initial Standard 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/ITP holder: |
| 1. MCC Resourcing Needs(if applicable): Not Applicable   CTO Project Manager Biostatistician Data Manager (OnCore e-CRFs, REDCap support, etc.)  CTO Regulatory Specialist Finance (Budget/Contract) Minnesota Cancer Clinical Trials Network (MNCCTN)  CTO Study Coordinator(s) IND/IDE/ITP Management Other:  CTO Affiliate Management |
| 1. [MCC Shared Resources](https://www.cancer.umn.edu/for-researchers/shared-resources) *(if applicable)*: Not Applicable   Analytical Biochemistry Clinical Pharmacology Glasswashing  Biostatistics Comparative Pathology Mouse Genetics Laboratory  Cancer Genomics Flow Cytometry Translational Therapy Lab (TTL)/Immune Monitoring  Cancer Informatics Genome Engineering X-RAD 320 Biological Irradiator |
| 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 Other: |
| 1. Patient Population and Accrual Goals   Yearly accrual goal:  Yearly accrual goal at affiliate sites, *if applicable*:  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: |
| 1. Funding Support:   At this time funding is anticipated to be: Complete Partial Unfunded  *If partial or unfunded*, please list plans to obtain support:  **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/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. Scientific Recognition & Strategic Goals *Please document how your involvement as PI for this trial will provide scientific recognition/credit for you, the Masonic Cancer Center, and/or support MCC strategic goals.*   **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   **Additional information or comments to support the scientific recognition or importance of this protocol** (not covered above)**:** |
| 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 a “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)*.* |