CPRC Initial Full Review Application

Overview

1. **The CPRC conducts scientific review on 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).
   * **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.
   * Phase I Operating Characteristics *(if applicable - see question 19 in the application below)*
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.”)*

Application

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| 1. Protocol Title: |
| 1. UMN Principal Investigator: |
| 1. UMN Co-Investigators (investigator initiated) or Sub-Investigators (sponsored study): |
| 1. Phase I trial operating characteristics documentation applicability   Is this study a Phase I trial with dose-escalation using a 3x3 design?  No *(Check “No” if study is Phase I/II and Phase I portion is complete/maximum tolerated dose has been identified.)*  Yes:  **If yes, review** [*Appendix A*](https://cancer.umn.edu/sites/cancer.umn.edu/files/2021-02/CPRC%20Initial%20Application%20-%20Appendix%20A%20v.1.pdf) **and indicate where the operating characteristics are documented:**   1. In the protocol, starting on page #: 2. Attached in a separate document. |
| 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 human beings 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.  \*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 one of the following?: [IND](https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application)  [IDE](https://www.fda.gov/medical-devices/how-study-and-market-your-device/investigational-device-exemption-ide)  [ITP](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-investigational-tobacco-products)  *If yes and UMN held***,** name of IND, IDE, or ITP holder: |
| 1. MCC Resourcing Needs   *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 Case Report Forms, etc.  Minnesota Cancer Clinical Trials Network (MNCCTN)  Other: |
| 1. Fairview Resourcing Needs   *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 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:   **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**:  *Not Applicable*   |  |  |  | | --- | --- | --- | | **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**:  *Not Applicable*  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:       *(will receive all CPRC correspondence in addition to the PI)* * Coordinator: * Project Manager:       *(will receive all CPRC correspondence in addition to the PI)* * Other: |
| 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   1. 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   **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   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). |