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**:
   * [Clinical Research Resource Review (CR3)](https://med.umn.edu/research/resources-researchers/clinical-research-resource-review-process) approval form/letter *(only applicable for studies in which the PI has a tenure home in a Medical School department).*
   * Protocol
     + Protocols utilizing tools (e.g., instruments or surveys) to collect patient-reported outcomes data, please ensure that the protocol includes (1) a copy of all tools, (2) a reference validating each tool and (3) description of how the tool will be implemented (who will administer the tool and their training; time frames for tool administration etc.)
     + Protocols using focus groups, please ensure that focus group activity is clearly documented, including facilitator background/training, provide copies of tools/scripts used in focus groups, and what data will be collected.
   * 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 #4 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

As of August 30, 2022, all studies with PIs with a tenure home in the Medical School must include the [Clinical Research Resource Review (CR3)](https://med.umn.edu/research/resources-researchers/clinical-research-resource-review-process) approval with the CPRC application.

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| 1. Protocol Title: |
| 1. UMN Principal Investigator: |
| 1. UMN Co-Investigators (investigator initiated) or Sub-Investigators (sponsored study): |
| Phase I trial operating characteristics documentation applicability Is this study a Phase I trial with a dose-escalation 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, CPRC review is no longer required. When submitting for IRB review, *CPRC ancillary review* in ETHOS may be used to communicate to the IRB that CPRC approval is not applicable. |
| Investigational Product or Device 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: |
| 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 to be open to enrollment at UMN:  Is this study targeted to study minority or under represented populations? Yes No  If yes, please explain: |
| Funding Support  1. **Sponsor Name(s):** 2. **Sponsor Type**: 3. UMN Investigator-Initiated Trial (IIT), *i.e.* *study idea conceived by UMN Investigator* 4. IIT/Industry Co-Sponsorship, i.e. *study idea conceived by UMN Investigator with funding, investigational agent, etc. provided by industry sponsor.* 5. Industry 6. Cooperative Group or Consortium 7. Other |
| 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 entry reflects a CPRC or CTSI number in the “Protocol No.” field (please fill in):  - and - 2. The “Management Group” field reflects a CPRC group to ensure that CPRC has access to your entry - choose from the list below based on your Organizational Unit:    * + Masonic Cancer Center: **ONC-CPRC**      + Cardiovascular: **CV-CPRC**      + M Health Community: **MHC-CPRC**      + MNCCTN: **MNCCTN-CPRC**      + UMN TC General: **UMN-CPRC** |
| 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 data needs to be entered in real time** to allow for ongoing metrics reporting to Cancer Center Leadership.  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). |
| MNCCTN Is this protocol potentially appropriate for MNCCTN (Minnesota Cancer Clinical Trials Network)?  Yes  No  MNCCTN Criteria:   1. If therapeutic, should be late phase 2 or phase 3 trials. 2. Should be funded. 3. Should generally be interventional, but a registry or observational study that has a planned subsequent interventional component may be acceptable. 4. The catchment area of the MNCCTN is the entire state of Minnesota. Therefore, trials addressing the cancer burden in Minnesota are a priority, including breast (among women), prostate (among men), lung, colon, uterine/bladder, and skin (for both sexes combined). |