CPRC Amendment Application

# OnCore access is required to submit to the CPRC:

* 1. **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).
  2. **PI endorsement is required.** PI signature on the form uploaded in ePRMS or submission of the unsigned form via the PI’s x500 email to ccprc@umn.edu prior to the amendment review will satisfy this requirement. The submission will not be processed or added to an agenda until this has been completed.

# Please contact 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/>.

1. **Required Documentation**:

# Protocol showing tracked changes within the document (not as an appendix)

# Protocol with changes incorporated (“clean” version)

For CEDED scientific review \*only\*

if protocol’s scientific review of record was **previously ceded** to the scientific review entity at the lead site (a comprehensive cancer center), *include documentation of the lead site scientific review committee’s approval of the protocol version being submitted.*

if protocol’s scientific review of record was **previously ceded** to the scientific review entity through NCI’s Cancer Therapy Evaluation Program (CTEP) or the  Cancer Control Protocol Review Committee in the NCI Division of Cancer Prevention and Control, *no additional documentation is required.*

# The CPRC does not review amended consents, investigator brochures, or patient supplements.

# Incomplete submissions will be returned for completion prior to review and may not be processed until after the next CPRC deadline.

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**PI Signature** **Date**

*Signature required unless submitted directly from PI via email.*

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| Principal Investigator: |
| CPRC Number: |
| Protocol Title: |
| Amendment Version Date: |
| Revision Type**:**  **Major Changes**:   * This amendment changes the endpoints, statistical section, and/or study design (i.e. adds an arm, adds another patient population, changes study model from single group to crossover, changes therapy, etc.) Please note that simple clarifications of any of the previously listed elements are considered minor changes. * Amendments with major changes will be reviewed by full committee at a CPRC meeting. Please [see our website](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee) for submission deadlines and meeting schedules.   **Minor Changes**: Amendments with minor changes will be reviewed administratively by a CPRC Chair, meeting deadlines do not apply. Review turnaround times is 1-2 weeks. |
| Provide a rationale for the key changes in this revision:    Indicate the location of the summary of changes or a summary below, if a brief summary is not included above. Do not state, “see protocol” if protocol summary is more than 3 pages long. |