**Instructions:** Complete this form and load as an attachment to the full submission in ePRMS. Please refer to submission deadlines for SRC review: <https://www.unmc.edu/cancercenter/clinical/prms.html>

**SECTION I: BASIC PROTOCOL DATA**

|  |  |  |
| --- | --- | --- |
| **IRB#:** | **NCI Protocol Class:  IIT**  **IND**  **NCG  OEPR  Multi-Institutional** |  |
| **Pet Name:**  **PI:**  **Title:** | |  |

**SECTION II: PROTOCOL STATUS**

**Date of initial IRB approval:**   **Approval to enrollment date: Date first subject enrolled:**

**Closed to accrual date:**   **Closed to accrual reason:**

**SECTION III: ACCRUAL INFORMATION**

1. **General Information:**
   1. Did the SRC grant a low accrual waiver for this trial?  **Yes  No** If **NO**, answer question 2.
   2. Did this study receive an initial low accrual warning in an SRC review letter at the time of the last continuing review?

**Yes No**

If **YES**, provide details of corrective action plan or extenuating circumstances provided in PI response to the initial low accrual warning**:**

* 1. Complete Table 1 below for UNMC and associated locations only:

Accrual Table 1



* 1. Complete Table 2 below for UNMC (including associated locations) and participating sites on trials with UNMC as the lead site:

Accrual Table 2



* 1. If the accrual to date at UNMC/NMC and its associated locations *(plus for all participating sites for trials sponsored by UNMC, if applicable)* is less than 30% at the time of continuing review, what plans do you have to improve it? (**Please be specific.)**

1. **Accrual Goal Information for trials where UNMC is the lead site (sponsor) of a multi-site trial:**
   1. Please provide the SRC approved accrual goals at initial review for UNMC and participating sites:
      1. Initial annual accrual goal:
      2. Initial expected duration of accrual (months):
      3. Initial total study accrual:
   2. Were accrual goals revised subsequently?  Yes  No If yes, answer 3 and 4 below.
   3. Date of SRC approval of accrual goal revisions?
   4. Please provide the SRC approved revised accrual goals for UNMC and participating sites:
      1. Revised annual accrual goal:
      2. Revised expected duration of accrual (months):
      3. Revised total study accrual goal:

**SECTION IV: Competing Protocol, Priority Score, and Ranking Table**

1. Provide the priority score for this trial:
2. Does this protocol compete with other ongoing studies at UNMC/NMC and associated locations?  Yes  No
3. Complete the SRC Priority Score and Competing Protocol form below:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Please list any competing studies (i.e. those with similar eligibility criteria) and rank them in the order of priority that they would be offered to the patient (e.g. #1, #2). Please remember to include this protocol submission in the list of studies.   | IRB# | Prioritization Score | Priority Rank | Protocol Classification | Short Title | | --- | --- | --- | --- | --- | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  |   **Scoring criteria guidelines worksheet**:   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Investigator Initiated** | **Cooperative Group** | **Industry** | **Other Externally Peer Reviewed** | |  | **20** | **15** | **10** | **5** | | **4** | High profile clinical trial initiated by a UNMC Investigator of high and broad interest and novel therapies likely to make a substantial impact on disease or quality of life. | High profile cooperative group Phase III or randomized Phase II study with a UNMC Investigator as national PI. | High profile industry sponsored or multi-institutional Phase II or III study with a UNMC Investigator as the national PI. | High profile study for the external peer group sponsoring the study which is likely to make a substantial impact on a disease or quality of life. | | **3** | High interest clinical trials likely to impact disease or quality of life. | | | | | **2** | High interest clinical trials less likely to impact disease or quality of life that, but ask an important question. | | | | | **1** | Studies with competing higher priority trial of interest for rare diseases or expanded access studies. | Low interest studies for rare diseases, expanded access studies or any otherwise priority 2-4 study with a higher priority competing protocol. | | | | **0** | Inadequate Priority | | | |   This study: Multiply green column \_\_\_\_ by blue row\_\_\_\_ = \_\_\_\_\_\_\_ Priority Score  **SECTION V: CONTINUING REVIEW WITH CHANGE**  Yes  No If **YES**, please submit a separate change review through ePRMS |

**SECTION VI: PREVIOUSLY SUBMITTED or APPROVED CHANGES TO THE PROTOCOL**

1. Since the last SRC Continuing Review, have any major changes been made to the protocol? *(Example: drug dosage changes, modifications to the treatment plan, amendments from the sponsor, changes resulting from adverse event, etc.)*  Yes  No

If **YES**:

1. Has the protocol been revised accordingly?  Yes  No

Has the protocol amendment(s) been registered with NCI’s Clinical Trials Reporting Program (CTRP)?

Yes  No

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Principal Investigator** **Date**