**Instructions: Complete** this form and load it as an attachment to the full submission in ePRMS. Please refer to submission deadlines for SRC review: [Protocol Review and Monitoring System | The Fred & Pamela Buffett Cancer Center | University of Nebraska Medical Center](https://www.unmc.edu/cancercenter/research/protocol-review-monitoring-system.html)

**SECTION I: BASIC PROTOCOL DATA**

|  |  |  |  |
| --- | --- | --- | --- |
| |  | | --- | | **NCI Protocol Class**  **National Cooperative Group**  **Investigator Initiated Trial**  **Industry**  **Externally Peer-Reviewed**  **Multi-Institutional** | |  |  |
| **IRB:**  **Pet Name:**  **PI:**  **Title:** | |  |

**SECTION II: PROTOCOL STATUS**

**Date of initial IRB approval:**   **Approval to enrollment date:**

**Actual open to enrollment date:**

**Date first subject enrolled:**

**Date of most recent enrollment:**

**Closed to accrual date:**

**Closed to accrual reason:**

**SECTION III: ACCRUAL INFORMATION**

1. **General Information:**
   1. Is this study exempt from accrual monitoring (i.e., pediatric or rare cancer, expanded access program)? **Yes No** If **NO**, answer question 2.
   2. Have there been any holds on accrual since initial approval or last Continuing Review?
      1. Yes No
      2. If yes, Dates
      3. Reason
         1. Data Safety Monitoring Committee hold
         2. Sponsor-initiated
         3. Drug shortages
         4. Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   3. Did this study receive a 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. 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 fill out Low Accrual Supplementary Worksheet at end of Continuing Review form.)**

1. **Accrual Goal Information:**
   1. Please complete the following as approved during the initial review for UNMC and participating sites only for trials where UNMC is the lead site of a multi-site trial:
      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 approval of accrual goal revisions?
   4. Please complete the following as approved during the initial review for UNMC and participating sites only for trials where UNMC is the lead site of a multi-site trial:
      1. Revised annual accrual goal:
      2. Revised expected duration of accrual:
      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 are less likely to impact disease or quality of life than 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**

**SRC Low Accrual Supplementary Worksheet**

**Instructions for Completing the SRC Low Accrual Monitoring Form:** To ensure the efficiency and robustness of our clinical trials portfolio, the SRC monitors studies for patient accrual. If your study has accrued **no patients within six months of opening** or has accrued **<30% at annual continuing review**, please complete this form to identify and address any barriers to accrual.

Section 1: Study Information

1. **IRB#:** Enter the Institutional Review Board (IRB) number assigned to your study.
2. **Study Title:** Provide the full title of your study.
3. **PI:** Enter the name of the Principal Investigator (PI) overseeing the study.

Section 2: Reporting Dates

1. **Date of report:** Enter the date you are completing this report.
2. **Date of study opening to accrual:** Provide the date when the study was opened for patient accrual.
3. **Accrual to date:** Indicate the total number of patients accrued to date.

Section 3: Reasons for Low Accrual

Please select the reason(s) for the current low accrual from the options below:

**Accrual held by sponsor:** Check this box if accrual was paused by the sponsor due to protocol revisions or other administrative changes.

**Overestimation of referral population:** Check this box if the initial referral population was overestimated.

**Higher than anticipated screen failures:** Check this box if there were more screen failures than expected due to unanticipated issues (e.g., molecular markers affecting eligibility).

**Concurrent trials:** Check this box if other trials opened concurrently and accrued subjects ahead of your study.

**New FDA-approved therapies:** Check this box if newly FDA-approved indications for other Standard of Care therapies reduced accrual.

**Standard of Care drug shortages:** Check this box if there were shortages of Standard of Care drugs which impacted study accrual.

**Other:** Check this box if none of the above reasons apply and provide a detailed explanation in the text box provided.

Section 4: Low Accrual Action Plan

1. **Plans for Addressing Low Accrual -**
2. **Revised accrual goals:** If accrual goals are being revised, check "Yes" and submit a Request for Change form. If not, check "No." **Yes**  **No** 

Section 5: Additional Information

* **Additional information:** Use the text box to provide any additional information you would like to present to the SRC regarding accrual for this study.

Section 6: Signatures

1. **PI Signature:** The Principal Investigator must sign the form.
2. **Signature Date:** Enter the date the form is signed.

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

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