**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:**  **Current 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: IDENTIFY CHANGES REQUESTED**

1. Does the change include an amendment or version change? Yes  No

If **YES,** version/date:

* 1. Does it involve changes to the design, method or procedures?  Yes  No
  2. Does it involve changes to drug dosage or delivery?  Yes  No
  3. Does it involve changes to eligibility criteria?  Yes  No
  4. Does it involve changes to the Investigator Brochure (IB)?  Yes  No

1. Are the proposed changes the result of a request for funding/grant application?  Yes  No
   1. If **YES**, please attach a copy of the schema and abstract from the grant including title page to the submission in ePRMS.
2. Has the protocol amendment(s) been registered with NCI’s Clinical Trials Reporting Program (CTRP)?

Yes  No, provide justification:  Pending

**SECTION IV: JUSTIFICATION FOR REQUESTED CHANGE(S).**  Indicate changes requested from Section I.1.a-d:

| **Prior -** | **New change requested -** | **Justification for change:** |
| --- | --- | --- |
| **See attached Summary of Changes provided by Sponsor** | | |
|  |  |  |
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|  |  |  |
|  |  |  |
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|  |  |  |
|  |  |  |
| **\*complete additional page if necessary** | | |

**SECTION V: IMPACT OF CHANGES REQUESTED**

1. If this is an **Investigator-Initiated Institutional or Multisite w/UNMC as Sponsor** whereprotocol and accrual has been changed, has a biostatistician been consulted to ensure that the statistical considerations are appropriate?

Yes  No  NA, provide justification:

**SECTION VI: CTMS CHANGES REQUESTED**

1. Are there proposed changes to the previously approved fields in the PC Console in the CTMS?  Yes  No If **YES**, list changes below:

| **CTMS Information** | **Current Value** | **Proposed Change** |
| --- | --- | --- |
| Title |  |  |
| Short Title |  |  |
| Objectives |  |  |
| Phase |  |  |
| Scope (Local vs. National) |  |  |
| Investigator Initiated (Yes or No) |  |  |
| Protocol Type |  |  |
| Data Table 4 Report Type |  |  |
| Multi-Site Trial (Yes or No) |  |  |
| Pilot (Yes or No) |  |  |
| Protocol Target Accrual |  |  |
| RC Total Accrual Goal (Lower) |  |  |
| RC Total Accrual Goal (Upper) |  |  |
| RC Annual Accrual Goal |  |  |
| Affiliate Accrual Goal |  |  |
| Accrual Duration (Months) |  |  |
| Priority Score |  |  |
| Oncology Group |  |  |
| Management Group |  |  |
| Principal Investigator |  |  |
| Sponsor |  |  |
| Disease/Diagnosis |  |  |
| Institution |  |  |
| **\*add additional rows if the proposed change is not included above\*** | | |

**SECTION VII: COMPETING PROTOCOL, PRIORITY SCORE, AND RANKING TABLE**

1. **If the requested** **changes involve eligibility**, do these new changes now cause the study to compete with other ongoing studies at UNMC/NM and their 1Associated Locations?

Yes  No

If **no**, provide reasoning:

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. 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 | | --- | --- | --- | --- | --- | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  |  1. Complete the scoring criteria worksheet for this study    1. Multiply green column  blue row  = Priority Score  |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **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 | | | | |

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