NEW PROJECT SUBMISSION FORM

**Instructions:** Complete this form and load 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

​Choose an option for the type of trial: ☐​ Investigator Initiated Trial ☐​ Industry sponsored

​☐​ National Cooperative Group ​☐​ Externally Peer-Reviewed ☐​ Multi-Institutional

|  |
| --- |
| **NCI Protocol Classification:****IRB#:** |
| **PI:****Pet Name:****Title:** |

# SECTION II: SRC EXEMPTION

1. Do you believe this submission qualifies as SRC Exempt based on the information points 1-7 below? **Yes**  **No**

If **NO**, answer Section III below.

* 1. Anonymous survey
	2. Retrospective study (chart reviews and existing specimen studies)
	3. Case study
	4. Analysis of discarded pathological specimens without personal identifiers
	5. Studies involving previously consented patients where no additional consent is required
	6. Proposals involving previously banked materials and/or tissues
	7. Studies to obtain tissue or other biological samples for prospective or undetermined future research

# SECTION III: SUPPLEMENTAL INFORMATION

1. Does the Investigator have primary responsibility for conceptualizing, designing, and implementing the clinical research study and reporting results? **Yes ** **No **
2. Will UNMC be a participating site on another institution’s study? **Yes ** **No **

If **YES**:

* 1. Please list lead Institution:
	2. Is the lead institution an NCI Designated or Comprehensive Cancer Center? **Yes ** **No **
		1. If **YES,** please provide date the lead institution received SRC approval:
1. If an Investigator-Initiated trial, does this proposal require an IND? **Yes ** **No **

If **YES,** please attach all FDA correspondence as attachments to the submission in ePRMS.

1. ACCRUAL MONITORING: Some studies are not subject to accrual monitoring. Does this trial qualify for a low accrual waiver based on the list below? **Yes ** **No **
2. RARE CANCERS: The NCI defines rare cancers as those which occur in <15/100,000 per year (<40,000 new diagnoses a year). Does this protocol enroll only individuals with a rare cancer? **Yes ** **No **
3. Is this protocol for an Expanded Access Program? **Yes ** **No **
4. PEDIATRIC TRIAL: Does this trial enroll a pediatric population? **Yes ** **No **

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

1. Provide the priority score for this trial using the table below:

Multiply green column by 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 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 |

1. Does this protocol compete with other ongoing studies at UNMC/NMC and associated locations? **Yes ** **No ** **If YES,** please 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** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Signature of Principal Investigator (PI) Date of signature**