NEW PROJECT SUBMISSION FORM

FRED & PAMELA BUFFETT CANCER CENTER

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

NCI Protocol Classification: Choose an option below

IRB#:

PI:

Pet Name:

Title:

SECTION II: SRC EXEMPTION

A. 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

A. Does the Investigator have primary responsibility for conceptualizing, designing, and implementing the clinical research study and reporting results? Yes ☐ No ☐

B. 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 ☐
   a. If YES, please provide date the lead institution received SRC approval:

C. 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.

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

A. 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 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			

B. 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 _____