## Clinical Research Support Fund Full Review (for investigator-initiated trials)

Application Form (v10/24)						
1. Title & IRB # (should match IRB proposal if applicable)						
Principal Investigator	Rank (Faculty)	Department/College	Zip	Phone		
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Co-Investigator(s)				Phone		
Resident/Fellow(s)						
Statistician						
Statisticiali						
Study Coordinator	Campus Address	Department/College	Zip	Phone		
What are you requesting from the Clinical Research Support Fund? (check all that apply)						
Research Support Funding						
Clinical Research Center Services – Submit study intake form:						
Outpatient Space:						
IRB Document Preparation:						
Phlebotomy/Processing:						
Research Nurse or Non-Nurse Coordinator Support:						
Other (please specify):						
2. Type of Study (check all that apply)						
Phase I Phase II Phase III Phase IV Feasibility						
Multi-center Trial						
☐ Investigator Initiated						
Other; Describe:						
3. Does this require Pharmacy and Therapeutics approval?						
3a. Does this study use an investigational new drug?						
☐ No						
Yes; IND #: Manufacturer:						
Yes; IND approval pending						
3b. Does this study	use an investigation	nal device?				
☐ No						
Yes; IDE #: Manufacturer:						
Yes; IDE approval pending						

4. Is this a human cancer trial?						
□ No						
Yes, will require oncology SRC approval – When approved please submit approval letter.						
5. Funding Source(s): (check all that apply) PLEASE ATTACH BUDGET SHEETS FROM ALL FUNDING SOURCES						
☐ NIH ☐ Pending Grant #:						
☐ Industry ☐ Pending Sponsor: Grant #:						
Other – Please describe what extramural grant funding is being provided (include approved funding sheets):						
Unfunded; Describe plan for extramural grant funding or potential funding source (such as NIH RFA, etc):						
6. Completion of Clinicaltrials.gov:						
Is this study registered? YES – Registration #:						
Pending						
Not completed, I understand this will need to be completed to obtain final approval						
☐ Not required by IRB						
7. Please answer each of the following:						
a. Projected Start Date:						
b. Total # of subjects to be recruited:						
c. How long will study be open?						
d. # of subjects to be supported by/seen in the CRC:						
e. Duration of an individual subject's involvement:						
f. Is phlebotomy part of the protocol?   Yes   No						
If yes, is this within the parameters specified to the right?  ———————————————————————————————————						
If yes, amount of blood to be drawn from each  • Age 19 – 85: Maximum of 150 mL						
patient (include ml and number of weeks):  • Age 86 and above: Maximum of 100 mL  24- hour period should be limited to 5 mL/kg with balanced						
consideration of patient safety and clinical needs						
8. Budget request						
IF REQUESTING FINANCIAL SUPPORT: complete the budget table below. Include all technical & professional fees that you would like considered						
Hospital CPT/Pro fee Code Full Hospital						
(8 digit) (5 digit) Procedure Description (include location of service) Quantity Charge Total						

CCTR Clinical Research Support Fund Checklist required for review:				
NIH Biosketch				
Project Summary and Research Plan				
Study Protocol (including aims, hypotheses to be tested, rationale, and study methods) and literature cited				
Statistical Analysis Plan (including biostatistician consultant or justification for consult exclusion)				
☐ IRB approval				
Consent form				
If extramural funding was received include a copy of grant budget pages or contract documents				
Study intake form				
Send application and documents to the Clinical Research Support Fund at <a href="mailto:researchsupportfund@unmc.edu">researchsupportfund@unmc.edu</a> .				
For questions call Serena Gaines 402-559-5417				