**Clinical Research Support Fund**

**Full Review**

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| **Application Form (v10/24)** | | | | |
| 1. **Title & IRB # (should match IRB proposal if applicable)** | | | | |
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| **Principal Investigator** | **Rank (Faculty)** | **Department/College** | **Zip** | **Phone** |
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| **Co-Investigator(s)** |  |  |  | **Phone** |
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| Resident/Fellow(s) |  |  |  |  |
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| **Statistician** | | | | |
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| **Study Coordinator** | **Campus Address** | **Department/College** | **Zip** | **Phone** |
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| **1. 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](https://www.unmc.edu/cctr/resources/crc/intakeform.html): …………………………………………………………   * Outpatient Space: Click here to enter text. * IRB Document Preparation: Click here to enter text. * Phlebotomy/Processing: Click here to enter text. * Research Nurse or Non-Nurse Coordinator Support: Click here to enter text. * Other (please specify): Click here to enter text. | | | | |
| 1. **Type of Study (check all that apply)** | | | | |
| Phase I  Phase II  Phase III  Phase IV  Feasibility  Multi-center Trial  Investigator Initiated  Other; Describe: Click here to enter text. | | | | |
| 1. **Does this require Pharmacy and Therapeutics approval?** | | | | |
| 3a. Does this study use an investigational new drug?  No  Yes; IND #: Click here to enter text. Manufacturer: Click here to enter text.  Yes; IND approval pending | | | | |
| 3b. Does this study use an investigational device?  No  Yes; IDE #: Click here to enter text. Manufacturer: Click here to enter text.  Yes; IDE approval pending | | | | |
| 1. **Is this a human cancer trial?** | | | | |
| No  Yes, will require oncology SRC approval – When approved please submit approval letter. | | | | |
| 1. **Funding Source(s): (check all that apply) PLEASE ATTACH BUDGET SHEETS FROM ALL FUNDING SOURCES** | | | | |
| NIH  Pending Grant #: Click here to enter text.  Industry  Pending Sponsor: Click here to enter text. Grant #: Click here to enter text.  Other  Unfunded; Describe plan for extramural grant funding or potential funding source(s), such as NIH RFA, etc.  Click here to enter text. | | | | |
| 1. **Completion of Clinicaltrials.gov:** | | | | |
| Is this study registered? Registration #: Click here to enter text.  Pending  Not completed, I understand this will need to be completed to obtain final approval  Not required by IRB | | | | |
| 1. **Please answer each of the following:** | | | | |
| a. Projected Start Date: Click here to enter a date.  b. Total # of subjects to be recruited: Click here to enter text.  c. How long will study be open? Click here to enter text.  d. # of subjects to be supported by/seen in the CRC: Click here to enter text.  e. Duration of an individual subject’s involvement: Click here to enter text.  f. Is phlebotomy part of the protocol?  Yes  No  g. Is this within the parameters specified below?  Yes  No  If yes, amount of blood to be drawn from each patient (include ml and number of weeks): Click here to enter text.  The maximum volume for a single phlebotomy is:  Term newborn – Age 18: 3 mL/kg, up to a maximum of 150 mL  Age 19 – 85: Maximum of 150 mL  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 | | | | |
| 1. **Budget request** | | | | |
| Complete the budget table below if requesting financial support.  Include all **technical and professional** fees that you would like considered. | | | | |

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| Hospital Code  (8 digit) | CPT/Pro fee Code  (5 digit) | Procedure Description (include location of service) | Quantity | Full Hospital Charge | Total |
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| **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](https://www.unmc.edu/cctr/resources/crc/intakeform.html)  Send application and documents to the Clinical Research Support Fund at [researchsupportfund@unmc.edu](mailto:researchsupportfund@unmc.edu).  For questions call Serena Gaines 402-559-5417 |