

**Center for Clinical and Translational Research**

**Pilot Grant Program**

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| **Application Form (v3-16)** | | | | |
| 1. **Title (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)** | **Rank (Faculty)** | **Department/College** | **Zip** | **Phone** |
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| Resident/Fellow(s) |  |  |  |  |
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| **Study Coordinator** | **Campus Address** | **Department/College** | **Zip** | **Phone** |
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| **What are you requesting from the CCTR? (check all that apply)** | | | | |
| Outpatient Space  Clinical Research Center  Other (please specify): Click here to enter text.  Inpatient Space (please specify unit): Click here to enter text.  IRB Document Preparation  Request for Laboratory Support: [ne-biobank@unmc.edu](mailto:ne-biobank@unmc.edu) 402-559-7649  Current tests available: <http://www.unmc.edu/cctr/crc/fees.html>  Research Support Funding  Phlebotomy/Processing  Research Nurse Coordinator Support  Provide Information Regarding Personnel Needs: 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  Comparative Effectiveness Research  Investigator Initiated  Other; Describe: Click here to enter text. | | | | |
| 1. **Does this study require IRB approval?** | | | | |
| No (If not, go to #5)  Yes (Please attach copy of approval letter) IRB#: Click here to enter text.  Yes, approval pending | | | | |

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| 1. **Does this require Pharmacy and Therapeutics approval?** |
| No (If not, go to #5)  Yes, approved  Yes, approval pending |
| 4a. 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 |
| 4b. 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 (Please attach copy of approval letter)  Yes, SRC pending approval |
| 1. **Does this study involve a biosafety hazard?** |
| No  Yes, approved (Please attach copy of approval letter)  Yes, pending approval |
| 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 and UNMC Clinical Trials Database:** |
| 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  Has this study been entered into UNMC Clinical Research Database?  Yes  Not completed, I understand this will need to be completed to obtain final approval  Not required; Reason for exemption: Click here to enter text. |
| 1. **Please answer each of the following if requesting personnel or space support:** |
| 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. Number of encounters per patient: Click here to enter text.  g. Is phlebotomy part of the protocol?  Yes  No  h. Is this within the parameters specified below?  Yes  No  If yes, amount of blood to be drawn from each patient (include mLs 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 |

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| 1. **Statistical Analysis: Researchers conducting investigator initiated multicenter clinical trials should consider consulting the Center for Collaboration on Research Design and Analysis (CCORDA) to develop a statistical analysis plan (402-559-6825 or** [**http://www.unmc.edu/publichealth/centers/ccorda**](http://www.unmc.edu/publichealth/centers/ccorda) **).**   **Please attach statistical plan which includes:** |
| 1. Primary and secondary endpoints, including times of measurement 2. Sample size justification for each primary endpoint, including a specification of the alpha level (usually 0.05), allowance for attrition. power (usually 0.80 to 0.95), the anticipated treatment difference or effect size, an indication of the variability of the response where appropriate, and 3. Summary of the statistical analysis plan, including the name of the statistical test(s) that will be used to analyze the primary and secondary endpoints, plans for analysis of missing data, in the justification of the sample size). and significance (should agree with the criteria used 4. The criteria for statistical Summary of interim monitoring procedures (if applicable) for early stopping of the study due to efficacy findings or safety concerns including the method of analysis, criteria for early stopping, and number of planned interim analyses. 5. e. Estimate of the number of potentially eligible subjects. |
| 1. **Budget request** |
| Complete the budget table below if requesting financial support.  Provide a separate written justification for each item requested, including rationale for the number requested for each test, or variance between tests requested and number of individuals to be recruited. The application will not be considered without a justification for each item. 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 | Quantity | Full Hospital Charge | Total |
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| **CCTR Pilot Grant Checklist required for review:** |
| Study Protocol (including aims, hypotheses to be tested, rationale, and study methods)  IRB Application, letter of approval, all consent documents, and research matrix  CCTR application form including:  Statistical Analysis section (including sample size justification)  Detailed Budget with procedure codes listed for each item  Budget justification for each item requested on budget  Copy of grant budget pages or contract documents for any extramurally funded proposal  If outside funding was received include the budget  Send application and documents to the Pilot Grant Review Committee at [pilotgrantprogram@unmc.edu](mailto:pilotgrantprogram@unmc.edu) .  For questions email the Pilot Grant Review Committee or call 402-559-0965. |