University of Nebraska Medical Center
Nebraska Medicine

Center for Clinical and Translational Research
Pilot Grant Program

Application Form (v3-16)

1. Title (should match IRB proposal if applicable)

Principal Investigator	Rank (Faculty)	Department/College	Zip	Phone
Co-Investigator(s)	**Rank (Faculty)**	**Department/College**	**Zip**	**Phone**
Resident/Fellow(s)				
Study Coordinator	**Campus Address**	**Department/College**	**Zip**	**Phone**

What are you requesting from the CCTR? (check all that apply)

- ☐ Outpatient Space
  - ☐ Clinical Research Center
  - ☐ Other (please specify):
- ☐ Inpatient Space (please specify unit):
- ☐ IRB Document Preparation
- ☐ Request for Laboratory Support: ne-biobank@unmc.edu or 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:

2. 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:

3. Does this study require IRB approval?

☐ No (If not, go to #5)
☐ Yes (Please attach copy of approval letter) IRB#:
☐ Yes, approval pending

4. 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 #: Manufacturer:
☐ Yes; IND approval pending

4b. Does this study use an investigational device?

☐ No
☐ Yes; IDE #: Manufacturer:
☐ Yes; IDE approval pending

5. Is this a human cancer trial?

☐ No
☐ Yes (Please attach copy of approval letter)
☐ Yes, SRC pending approval

6. Does this study involve a biosafety hazard?

☐ No
☐ Yes, approved (Please attach copy of approval letter)
☐ Yes, pending approval

7. Funding Source(s): (check all that apply) PLEASE ATTACH BUDGET SHEETS FROM ALL FUNDING SOURCES

☐ NIH ☐ Pending Grant #:
☐ Industry ☐ Pending Sponsor: Grant #:
☐ Other
☐ Unfunded; Describe plan for extramural grant funding or potential funding source(s), such as NIH RFA, etc.

8. Completion of Clinicaltrials.gov and UNMC Clinical Trials Database:

Is this study registered? Registration #:

☐ 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:

9. Please answer each of the following if requesting personnel or space support:

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. Number of encounters per patient:
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):

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

10. 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).
Please attach statistical plan which includes:

a. Primary and secondary endpoints, including times of measurement
b. 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
c. 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
d. 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.
e. e. Estimate of the number of potentially eligible subjects.

11. 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.

Hospital Code (8 digit)	CPT/Pro fee Code (5 digit)	Procedure Description	Quantity	Full Hospital Charge	Total

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

For questions email the Pilot Grant Review Committee or call 402-559-0965.