

Section: Clinical Research Center

Date Created: March 2, 2008 replaces POL 23

Title: Clinical and Translational Research (CCTR) Pilot Grant Program (Research Support Fund)

Date Reviewed/Modified: April 1, 2019

SOP Number: SOP- 59

Version Number: 2

Clinical Research Center

The Clinical Research Center (CRC) and the Clinical & Translational Research Pilot Grant Program were initiated to foster clinical research at University of Nebraska Medical Center (UNMC) and Nebraska Medicine (NM). The intent of these programs is to support investigator-initiated clinical and translational research that will lead to extramural funding as well as support extramurally funded research projects. It is expected that many of these successful initiatives will also lead to publications and innovative clinical techniques or care. The CRC is a place to perform clinical research and the CCTR Pilot grant program was designed to write-off research costs. An applicant can request support from either or both programs for any given clinical study.

The CRC Director of Clinical Research Operations administer the CCTR Pilot Grant program. The Clinical & Translational Research Pilot Grant Review Committee directed by the Chair of that committee. The committee is comprised of experienced researchers on campus, statisticians and research subject advocate.

Categories of Supported Projects

- Extramurally funded research requiring CRC support
- Funded seed grant proposals from other regional sources
- Investigator initiated protocols to generate preliminary data for future applications
- “Self limited” clinical investigations of once in a lifetime or unusual cases such as family studies or investigation of an epidemic. “Spontaneous” opportunities to study unusual single patients.

CCTR Pilot Grant Review Committee Process

The CCTR Pilot Grant Review Committee is charged with the responsibility to review the scientific merit, relevance, feasibility and validity of each proposal submitted for CRC support and/or grant funding. The Director of Clinical Research Operations will initially review the proposal, assuring completeness and accuracy of the budget. It will then be assigned to 3 reviewers, including at least one clinical advisory committee member and a statistician. The reviews will be discussed by the full CCTR Pilot Grant Review Committee who will make final recommendations of the proposal.

In the case of rejection, the principle investigator may either alter the proposal or write a rebuttal. Projects with limited budgets, (< \$5,000), or projects of special urgency may be approved directly by the CRC director alone, after consultation with other reviewers. All other projects will be discussed by the full CCTR Pilot Grant Review committee at the next regular

Section: Clinical Research Center

Date Created: March 2, 2008 replaces POL 23

Title: Clinical and Translational Research (CCTR) Pilot Grant Program (Research Support Fund)

Date Reviewed/Modified: April 1, 2019

SOP Number: SOP- 59

Version Number: 2

meeting. A pre-review process whereby an applicant can get an initial review of the application in order to make revisions prior to a formal review is also available. More details concerning this process should be directed to LuAnn Larson, RN, Director of Clinical Research Operations of the CRC at 402-559-8555.

There are 4 categories of review:

1. Approved - once IRB approval and budget information is received, the investigator can proceed; reviewer comments will still be forwarded with the approval letter.
2. Approved with Minor Revisions - the investigator will be required to address specific comments, if the response is deemed adequate by the primary reviewer, the protocol can be approved without returning to the full committee.
3. Approved with Major Revisions - the investigator is required to address significant problems such that the revised protocol and application will need to return to the full committee at the next quarterly meeting before approval can be obtained.
4. Rejected - the proposal is deemed seriously flawed such that it should not be resubmitted unless the protocol is markedly revised; comments will be transmitted to the investigator.

Reviews will be compiled after the CCTR Pilot Grant Review Committee Meeting and sent out to the investigator. The investigator may contact the Research (CCTR) Pilot Grant program to discuss the protocol as it is the goal of this policy to give the investigator specific feedback to improve the protocol's likelihood to attract outside funding.

CRC and CCTR Pilot Grant Program Guidelines and Policies

- The principal investigator must be a full-time UNMC faculty member (>0.7 FTE). A resident or student cannot submit a proposal although they can be a co-investigator.
- IRB approval is required for final approval although an application may be submitted prior to IRB approval.
- No proposals submitted < 3 weeks prior to the monthly CCTR Pilot Grant Review Committee meetings will be reviewed at the next meeting.
- For internal and extramurally funded proposals, scientific review can be abbreviated but the clinical protocol itself in the Research (CCTR) Pilot Grant program format and budget will be reviewed. If the protocol has already undergone peer review (e.g., NIH funded multicenter trial, UNMC Cancer Center Scientific Review Committee or the

Section: Clinical Research Center

Date Created: March 2, 2008 replaces POL 23

Title: Clinical and Translational Research (CCTR) Pilot Grant Program (Research Support Fund)

Date Reviewed/Modified: April 1, 2019

SOP Number: SOP- 59

Version Number: 2

Cancer Therapy Evaluation Program), only budgetary review will be required. You are still required to submit a complete application in the CCTR Pilot Grant Program (Attachment A) to be reviewed.

- Any grant that has not had any activity for a period of 12 months will be deemed inactive unless the investigator can justify the lapse.
- Duration of project can be up to three years unless supporting an extramurally funded project, then the project can be submitted for the duration of the funding (i.e., a 5 year NIH study). A notice will be sent out in advance of the end date notifying the investigator that re-application is now required.
- An annual report of grant activity must be submitted to the committee, including results to date, publications, presentations, grants and future plans. Projects whose annual reports are delinquent will be suspended until reports are complete.
- If there is a change in protocol, budget, or IRB approval an amended proposal must be submitted at least thirty days prior to recruiting patients or incurring additional charges.
- Copies of all serious adverse event reports must be forwarded to the CCTR Pilot Grant Review Committee when the event occurs.
- Follow-up reports of closed CCTR Pilot Grant projects will be requested at the one year anniversary date of completion.
- Only charges that are included on the approved budget will be covered; all other charges are the responsibility of the patient and/or third party payers for the services rendered. It is the principal investigator's responsibility to delineate research costs vs other costs to the research patient at the time of informed consent.
- CRC should be cited in all publications resulting from work utilizing any CRC resources (including those that use minimal resources or CCTR Pilot Grant Program). Forward copies of any publication resulting from your research to the CRC. Publications are used as a measure of productivity and thus translate into budget dollars and will be evaluated when NIH funding is sought.
- It is the Primary Investigator's responsibility to account for research billing including assignment of costs appropriate to the research protocol on the research account number and clinical care costs on appropriate clinical reimbursement accounts.
- Investigators that do not comply with the above policies will jeopardize their eligibility for future support from the CCTR Pilot Grant Program and/or the CRC.
- Any charges specific to an extramural grant will be submitted to that grant or arrangements made for inter-departmental billing.
- Study participants will need to have a grant account set up prior to being seen in the CRC.
- Scheduling rooms or other facilities should be done through the CRC Office Associate at

Section: Clinical Research Center

Date Created: March 2, 2008 replaces POL 23

Title: Clinical and Translational Research (CCTR) Pilot Grant Program (Research Support Fund)

Date Reviewed/Modified: April 1, 2019

SOP Number: SOP- 59

Version Number: 2

9-7685.

- When requesting the development of a new laboratory assay, one or more of the following criteria are needed to consider development of the assay:
 - It must be a unique molecular-based tool that will clearly enhance the CRC.
 - It must be a tool likely to be used by a minimum of three investigators or important to the development of proposed or currently externally funded protocols.
 - It must be a tool that is necessary for the study of a unique once-in-a-lifetime event.

Guidelines Specific to the CCTR Pilot Grant Program Application

- Professional and clinic fees are not covered under this program and remain the responsibility of the individual patients involved.
- Honoraria or charges from departments outside of the hospital (e. g., external laboratories, biomedical instrumentation, copy center, communications) are not covered under this program.
- Individual grants in general are meant to be “seed money” and should exclude costs which are deemed standard patient care which will be billed to a third party carrier. Designation of these charges is done on the budget page and need to be included in the consent form.

ASSOCIATED FORMS:

CCTR Pilot Grant Application pdf

CCTR Pilot Grant Application word

SOP-59 cctr-pilot
grant-application-p

SOP-59 cctr-pilot
grant-application-w

CCTR Pilot Grant Instructions

SOP-59 cctr-pilot
grant-instructions.p

RESOURCES:

Web site for the CCTR Pilot Grant Program

Section: Clinical Research Center

Date Created: March 2, 2008 replaces POL 23

Title: Clinical and Translational Research (CTTR) Pilot Grant Program (Research Support Fund)

Date Reviewed/Modified: April 1, 2019

SOP Number: SOP- 59

Version Number: 2

Staff Accountability:

Developed By: Director of Clinical Research Operations, Clinical Research Center
Associate Vice Chancellor for Clinical Research, Clinical Research Center

Reviewed By: Director of Clinical Research Operations, Clinical Research Center

Department Approval

Signed 
Director of Clinical Research Operations

Signed 
Medical Director of Clinical Research Center

Instructions for Application to the Center for Clinical and Translational Research (CCTR) Pilot Grant Program (v2/2015)

What is the CCTR Pilot Grant Program?

The CCTR Pilot Grant Program is a collaborative research support program of Nebraska Medicine and UNMC that is intended for investigator initiated research that is either leading to or supported by an extramural grant.

What do I need to submit to be considered for a grant?

A complete application includes the following:

- CCTR Pilot Grant application form
- Study protocol (including aims, hypotheses to be tested, rationale, and study methods)
- IRB Application, informed consent documents, copy of the research matrix, and IRB letter of approval, once received. The application does not have to be approved by the IRB at time of submission but must be approved before receiving final approval.
- A separate Statistical Analysis (section 10) that answers questions a. through e. Sample size justification should be included.
- A Protocol schema is helpful for any protocol that includes more than one arm, or involves complex testing.
- The Budget pages or contract documents relevant to the grant funding any part of the study must be submitted. Include FDA letter assigning the experimental drug (IND) or device number (IDE), where applicable.
- Budget justification for each item requested. Professional Fees may be included in the budget.
- Submit 1 hard copy and 1 electronic copy of these documents to LuAnn Larson, CRC Nurse Manager to Zip 1230 and/or llarson@unmc.edu.

If I have questions or want to discuss the budget, who should I call?

If you need help with this application, including hospital or professional charges, call either LuAnn Larson, RN, nurse manager of the CRC at 9-7685 or email llarson@unmc.edu or Katie Penas, MHA, finance analyst at 2-6601 or email kpenas@nebraskamed.com.

How is the budget for this application different than the Research Matrix?

The budget for this application is requesting those items that you wish the pilot grant to pay for and therefore may not include all charges associated with the study since some charges may be covered by a different grant or billed to insurance.

The Matrix is designed to assist in accurate billing of research participants and designates which charges are being paid by which entity (the study, participant, insurance, or other). The matrix is designed to assist all those involved in the billing process to determine

accurate billing for each research participant. A subject list is kept on each study so charges can be verified accordingly.

When and how do I submit a proposal?

Submit all required documents electronically to llarson@unmc.edu and send one hard copies to the Clinical Research Center, Zip 1230, Attn: LuAnn Larson, RN, Nurse Manager, CRC. The CCTR Pilot Grant Review Committee meets the second Tuesday of each month. To be considered at the next meeting, a complete proposal needs to be submitted by 5pm three weeks prior to the meeting. Proposals that are not complete will be tabled until the next months's meeting.

**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)				
<input type="checkbox"/> Outpatient Space <ul style="list-style-type: none"> <input type="checkbox"/> Clinical Research Center <input type="checkbox"/> Other (please specify): <input type="checkbox"/> Inpatient Space (please specify unit): <input type="checkbox"/> IRB Document Preparation <input type="checkbox"/> Request for Laboratory Support: ne-biobank@unmc.edu or 402-559-7649 <small>Current tests available: http://www.unmc.edu/cctr/crc/fees.html https://www.unmc.edu/cctr/resources/crc/fees.html</small> <input type="checkbox"/> Research Support Funding <input type="checkbox"/> Phlebotomy/Processing <input type="checkbox"/> Research Nurse Coordinator Support Provide Information Regarding Personnel Needs:				
2. Type of Study (check all that apply)				
<input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> Feasibility <input type="checkbox"/> Multi-center Trial <input type="checkbox"/> Comparative Effectiveness Research <input type="checkbox"/> Investigator Initiated <input type="checkbox"/> Other; Describe:				
3. Does this study require IRB approval?				
<input type="checkbox"/> No (If not, go to #5) <input type="checkbox"/> Yes (Please attach copy of approval letter) IRB#: _____ <input type="checkbox"/> 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. 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 CRC Nurse Manager:
 - LuAnn Larson, RN, BSN, CCRP
 - llarson@unmc.edu
 - 559-8555

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)				
<input type="checkbox"/> Outpatient Space <ul style="list-style-type: none"> <input type="checkbox"/> Clinical Research Center <input type="checkbox"/> Other (please specify): Click here to enter text. <input type="checkbox"/> Inpatient Space (please specify unit): Click here to enter text. <input type="checkbox"/> IRB Document Preparation <input type="checkbox"/> Request for Laboratory Support: ne-biobank@unmc.edu 402-559-7649 Current tests available: https://www.unmc.edu/cctr/resources/crc/fees.html <input type="checkbox"/> Research Support Funding <input type="checkbox"/> Phlebotomy/Processing <input type="checkbox"/> Research Nurse Coordinator Support Provide Information Regarding Personnel Needs: Click here to enter text.				
2. Type of Study (check all that apply)				
<input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> Feasibility <input type="checkbox"/> Multi-center Trial <input type="checkbox"/> Comparative Effectiveness Research <input type="checkbox"/> Investigator Initiated <input type="checkbox"/> Other; Describe: Click here to enter text.				
3. Does this study require IRB approval?				
<input type="checkbox"/> No (If not, go to #5) <input type="checkbox"/> Yes (Please attach copy of approval letter) IRB#: Click here to enter text. <input type="checkbox"/> 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 #: [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

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 #:** [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.](#)

8. 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.](#)

9. 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

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. 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 CRC Nurse Manager:
 LuAnn Larson, RN, BSN, CCRP
llarson@unmc.edu
 559-8555