Section: **Clinical Research Center**

Date Created: **March 2, 2008, replaces POL 23**

Title: Clinical Research Support Fund

SOP Number: AD23

Version Date: December 1, 2024

PURPOSE: The Clinical Research Support Fund was initiated to support research conducted within Nebraska Medicine (NM), on a competitive basis to University of Nebraska Medical Center (UNMC) faculty and NM employed investigators. The intent of this program is to support investigator-initiated clinical and translational research through Pilot Grants, as well as underfunded federal studies and national cooperative group trials. The goal is that this support will lead to extramural funding as well as support extramurally funded research projects that are not fully funded. It is expected that many of these successful initiatives will also lead to publications and innovative clinical techniques or care. The Clinical Research Support Fund was designed to write-off medical procedures and test costs for scientifically sound clinical research studies conducted at Nebraska Medicine. An applicant can request support for studies in any of the above-mentioned categories.

SCOPE: This SOP applies to all research studies utilizing the Clinical Research Support Fund at UNMC and NM.

PERSONNEL RESPONSIBLE: The UNMC Associate Vice Chancellor for Clinical Research/NM Vice President for Research, Clinical Research Center Research Nurse Manager, and Research Billing work with the Committee Chair to administer the Clinical Research Support Fund. The committee is comprised of experienced researchers on campus from all colleges, statisticians, and a research subject advocate creating a committee to review protocols. The Principal Investigator (PI) is ultimately responsible for oversight of the research study.

DEFINITIONS:

Full Committee Review: This review designation requires a full committee review. Examples include investigator-initiated trials (IITs) and consortium trials.

National Cooperative Group Trial: This review designation requires an administrative review. The trial has items not billable to insurance per national coverage analysis performed by Cancer Trials Support Unit or other service entity.

Underfunded Federal Trial: This review designation requires an administrative review. Federal budget provided does not cover Nebraska Medicine Chargemaster fee with a 75% discount.

Mentored Scholars Program (MSP): A program created specifically for UNMC faculty to develop scientists and health professionals at the junior faculty stage into productive and independent clinical and translational researchers.

MXH Number: The number assigned to the account utilized for each approved trial.

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GENERAL GUIDELINES AND POLICIES

- The principal investigator must be a full-time UNMC faculty member (greater than 0.7 FTE). A house officer 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.
- Projects with limited budgets, (less than $5,000), or projects of special urgency may be approved directly by the Associate Vice Chancellor for Clinical Research alone, after consultation with other reviewers, if needed.
- Projects with anticipated budgets of up to $50,000 per year may be approved by the Clinical Research Support Fund committee and Committee Chair. Projects exceeding this amount, regardless of review designation, require written approval from the Associate Vice Chancellor for Clinical Research/NM Vice President for Research.
- No proposals submitted less than 3 weeks prior to the next monthly Scientific Review Committee meetings will be reviewed until the following meeting.
- If the protocol has already undergone peer review (e.g., NIH funded multicenter trial, UNMC Cancer Center Scientific Review Committee or the Cancer Therapy Evaluation Program), only budgetary review will be required. An abbreviated application is required for Underfunded Federal Trials. No application is required for National/Cooperative Group Trials as the need for additional funding is identified by the Research Billing Team.
- Any grant that has not had any activity for a period of 12 months may be deemed inactive unless the investigator can justify the lapse. Inactive studies will be brought to the attention of the committee and determined if they should be closed at the review timepoints noted below.
- Duration of project can be up to two 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 the set review periods notifying the investigator that re-application is now required if they want to continue funding.
- A report of grant activity must be submitted to the committee at the set review periods, including results to date, publications, presentations, grants and future plans. Projects whose 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.
- Follow-up reports of closed funded projects will be requested at the one-year anniversary date of completion.
- Only charges that are included in 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 versus other costs to the research patient at the time of informed consent.

- Approval letters need to be cc'd to the research billers, so they are aware of the approved charges and the assigned grant account number.
- Clinical Research Support Fund/CRC support should be cited in all publications resulting from work utilizing these resources. Copies of any publication resulting from the research should be forwarded to researchsupportfund@unmc.edu. Publications are used as a measure of productivity and will be evaluated when NIH funding is sought.
    - Suggested language to include: This project was supported by the University of Nebraska Medical Center/Nebraska Medicine Clinical Research Support Fund.
- It is the Principal 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. Budgets will be reviewed by Research Billing to ensure accuracy.
- Investigators that do not comply with the above policies will jeopardize current funding and their eligibility for future support from the Clinical Research Support Fund 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 be enrolled in the study and visits linked. Enrollment status will need to be kept up to date in the CTMS.

Guidelines Specific to the Clinical Research Development Fund Application

- The fund will only cover hospital billable items. Honoraria or charges from departments outside of the hospital (e.g., external laboratories, biomedical instrumentation, supplies, communications, salaries etc.) 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 are required to be included in the consent form.

INITIAL REVIEW PROCEDURES:

The Scientific 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 funding. The Clinical Research Center Research Nurse Manager, along with Research Billing, will initially review the proposal, assuring completeness and accuracy of the budget and completeness of the application. Full committee applications will then be assigned to two (2) scientific reviewers, one statistician, the research subject advocate and the Clinical Research Center Research Nurse Manager. The reviews will be discussed by the full Clinical Research Support Fund committee who will make final recommendations of the proposal. This

process can be followed for up to $50,000 in funding write-offs per year. Requests above this amount will be sent to the Associate Vice Chancellor for Clinical Research/NM Vice President for Research for final written approval. Once approved, a cost center (MXH) number is assigned, and an account is created by the Research Billing Team.

In the case of committee approval with minor or major revisions, the principal investigator has the option to alter the proposal based on recommendations or write a rebuttal. Projects rejected by the committee will not be rereviewed.

There are 4 categories of review outcome:

1. Approved - once IRB approval and budget information are received, the investigator can proceed.
2. Approved with Minor Revisions - the investigator will be required to address specific comments, if the response is deemed adequate by the primary reviewers, 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 for review at the next monthly meeting before approval can be obtained.
4. Rejected - the proposal is deemed seriously flawed such that it should not be resubmitted; comments will be shared with the investigator.

Reviews will be written by Committee Chair after the Clinical Research Support Fund meeting. The investigator may request to discuss their protocol with a reviewer for additional feedback and support. It is the goal of this program to give the investigator specific feedback to improve the protocol's likelihood of attracting outside funding.

National/Cooperative Group Trial Review Process

- During initial start-up processes and review by the Research Billing Team, a need for Clinical Research Support Funding may be identified.
- Once identified, the Research Billing team will notify the Clinical Research Center Research Nurse Manager for an administrative review.
- The trial will be reviewed by the Committee Chair and the Clinical Research Center Research Nurse Manager. A confirmation of scientific review and departmental approval is required.
- This process can be followed for up to $50,000 in funding write-offs per year. Requests above this amount will be sent to the Associate Vice Chancellor for Clinical Research/NM VP for Research for final written approval.

Underfunded Federal Trial Review Process

- A request for an administrative review for underfunded federal trials may be made after the department identifies Clinical Research Support Funding need.
- An abbreviated application must be completed and submitted by the division or department.
- The application will be reviewed by the Committee Chair and the Clinical Research Center Research Nurse Manager. A confirmation of scientific review and departmental approval is required.
- This process can be followed for up to $50,000 in funding write-offs per year. Requests above this amount will be sent to the Associate Vice Chancellor for Clinical Research/NM VP for Research for final written approval.

Mentored Scholars Program Review Process

- An application is submitted through the Vice Chancellor for Research MSP application process.
- The Clinical Research Support Fund Scientific Review Committee reviews the project for scientific merit after confirmation with the MSP program.
- If approved, approval letters are sent to the Principal Investigator and the Vice Chancellor for Research office for administration of the funding per an established workflow with the MSP program.

SUBSEQUENT REVIEW PROCEDURES:

- First year reviews will be performed quarterly for all studies with Clinical Research Support Funding who met their first-year anniversary in the previous three months in March, June, September, and December. This review will be completed by the Committee Chair and Clinical Research Center Research Nurse Manager. Utilization will be reviewed, and a request for study status will be sent to the Principal Investigator and at least one member of the study team. A response is required within 30 days to maintain Clinical Research Support Funding. If no response is received, the study account will be suspended.
- Second year reviews will be performed quarterly for all studies with Clinical Research Support Funding who met their second-year anniversary in the previous three months in March, June, September, and December. This review will be completed by the full Clinical Research Support Fund committee. Utilization and outcomes will be reviewed, and a request for study status will be sent to the Principal Investigator and at least one member of the study team. A response is required within 30 days. All future full committee reviews will occur every two years from the second-year reviews.

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CLOSURE:

- A Clinical Research Support Fund, funded trial (MXH) account may be closed for several reasons, including, but not limited to study completion, study abandoned, inactive status, underutilization, or lack of response by the study team.
- If a study account is closed, a billing designation from the study or department must be provided in the event additional charges need to be routed after the account is no longer available. This must be provided to the committee no later than 30 days after the closure letter.
- All closed study documents will be archived, and a final report of support provided will be provided to the investigator and department.

RESOURCES:

Clinical Research Development Fund Website

Clinical Research Development Fund Workflow

Department Approval

Signed Serena Gaines
Research Nurse Manager

Signed: 12/10/2024

Signed
Assistant Vice Chancellor for Clinical Research

Signed: 12/10/2024