Clinical Research Center & Research Support Fund
Instructions for Application

Background and Purpose

The Clinical Research Center (CRC) and the Research Support Fund (RSF) have been initiated as a program to foster clinical research at UNMC. The intent of these programs is to provide opportunities for faculty to pursue clinical studies that will lead to extramural funding and 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 RSF is a funding program to write-off research costs. An applicant can request support from both programs for any given clinical study.

The CRC director and Nurse Manager administrate the CRC and RSF programs. The Clinical Advisory Committee directed by the Clinical Research Center Director is responsible for reviewing and approving all proposals. The Clinical Research Center Director reports to the Dean of the College of Medicine. The University Hospital has a representative on the Clinical Advisory Committee (CAC) and annually audits the accounts.

Categories of CRC Supported Projects

♦ NIH supported research projects requiring CRC support
♦ Funded seed grant proposals
♦ Investigator initiated protocols funded by extramural, non-federal sources

Categories of RSF Supported Projects

♦ Pilot data to support a promising extramural application.
♦ “Supplemental” support for studies partially, but inadequately supported by UNMC seed grants or extramural sources.
♦ “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.

Clinical Advisory Committee Review Process

The Clinical Advisory Committee of the Clinical Research Center is charged with the responsibility to review the scientific merit and validity of each proposal submitted for CRC or RSF support. The nurse manager will initially review the proposal, assuring completeness and accuracy of the budget. The director will assign the proposal to be reviewed by at least three individuals, including at least one clinical advisory committee member and a statistician. The reviews will be discussed by the full Clinical Advisory 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 CRC committee at the next regular meeting which will be held the second Tuesday of January, March, May, July, September, and November. Projects must be submitted two weeks in advance of the committee meeting to be reviewed. 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, Nurse Manager of the CRC at 559-8555.

There are 4 categories of review:
1. Approved - once IRB approval and budget information is received, the investigator can proceed although 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 CAC meeting and sent out to the investigator. The investigator may contact the reviewer 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 RSF 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 RSF/CRC approval although an application may be submitted prior to IRB approval.
- No proposals submitted < 2 weeks prior to the bi-monthly CAC 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 CRC format and budget will be reviewed. If the protocol has already undergone peer review (e.g., UNMC Cancer Center Scientific Review Committee or the Cancer Therapy Evaluation Program), only budgetary review will be required. You are still required to submit a complete application in the CRC format 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.

Follow-up reports of closed RSF 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.

Please cite the UNMC Clinical Research Center in all publications resulting from work utilizing any CRC resources (including those that use minimal resources or the Research Support Fund. Forward copies of any publication resulting from your research to the CRC. Publications are used as a measure of productivity and thus translates into budget dollars and will be evaluated when NIH funding is sought. If our CRC is not cited, credit will not be given for providing support to your study.

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 Research Support Fund and/or the Clinical Research Center.

Guidelines Specific to a Clinical Research Center Application

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 secretary at 97685.

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.
- Be a tool that is necessary for the study of a unique once in a lifetime event.

Guidelines Specific to the Research Support Fund 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 (i.e. external laboratories, biomedical instrumentation, copy center, communications, etc.) are not covered under this program.

Individual grants in general are meant to be “seed money” so should not exceed $50,000 (hospital charge dollars), and exclude costs which are deemed standard patient care which will be billed to a third party carrier. Charges that are strictly research will be billed directly to the grant. Designation of these charges is done on the budget page and need to be included in the consent form.

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