Objective

The primary purpose of the Early Phase Clinical Research Support (EPCRS) pilot grant award program is to assist groups of Cancer Center investigators in the development of investigator-initiated, early phase clinical trial protocols. Initiated from the Clinical Working Groups, pilot projects must be a multidisciplinary collaboration between several Cancer Center members that links together existing areas of research strength and expertise within the Cancer Center and focuses on a problem that is related to the strategic goals of the Cancer Center. Projects may be focused on the identification of novel targets and biomarkers, drug discovery and/or the development of novel imaging technologies and should have the ultimate goal of improving prevention, detection, and treatment of cancers that impact the multi-ethnic populations served by the UNM Comprehensive Cancer Center (UNMCCC). This pilot grant will support the costs associated with early phase trials, including but not limited to: purchase of imaging time related to the clinical trial, pharmacokinetic and pharmacodynamics studies, support for IND or IDE applications, unreimbursed radiologic and laboratory studies, and non-faculty salary support. Preclinical experiments that support the final development of an early phase clinical trial will also be eligible, and projects that will use clinical specimens to validate laboratory observations will also be considered with the explicit goal of initiating a clinical trial within 12 months. Only concepts or full protocols for clinical trials ranked as high priority by the Protocol Review and Monitoring Committee (PRMC) will be considered for review.

Eligibility

All UNMCCC members are eligible to apply. In addition to Cancer Center members, all UNM-associated faculty, as well as faculty at our collaborating institutions (LRRI, Sandia, and Los Alamos National Laboratories) are encouraged to form collaborative teams to submit.

Term of Funding

This pilot grant will be for a one-year period with a maximum budget of $50,000 (direct costs only). Successful applicants may apply for one additional year of funding that will be based upon productivity during the initial funding period and competition with new applications. Expenditures may begin at any time after the official start date but generally all funds should be expended within one year of receipt. Successful applicants must produce a 1-2 page 6-month progress report as well as a 2-3 page final report within 30-days of completing the project.

The number of projects awarded will depend on the quality of applications and the availability of funds.
Applications for this pilot grant mechanism are accepted, reviewed, and awarded on a rolling basis. Projects for consideration should be submitted in accordance with PRMC processes.

**Allowable Costs**

The award(s) must be used for research activities and cannot be used for faculty salary support or for the purchase of large equipment. Funding is available for salaries and fringe benefits of post-doctoral fellows, students, technicians, and other non-faculty project personnel costs. Laboratory supplies and other related research non-personnel expenses are appropriate with the exception of: travel to scientific meetings (local research travel is allowed); office furniture and equipment; and, computers.

**Format**

Proposals should be submitted as either a concept using the PRMC Pre-Clinical and Clinical Study Concept Proposal Form or a full protocol using the PRMC clinical trial template.

**Funding Consideration Components**

1. **Cover letter** that addresses the following aspects of the proposal:
   a. Title and focus of proposed investigator-initiated, early phase clinical trial protocol.
   b. Collaborative team members.

2. **PRMC Decision Letter and Prioritization**. Obtain a copy of the PRMC Decision Letter indicating approval of concept or research project.

3. **Project Concept (3 page limit) or Full Protocol**. Provide the PRMC Concept or Protocol including any revisions requested by the PRMC.

4. **Literature Cited** (No page limit).

   **Budget and Budget Justification**. After PRMC approval of the concept, develop a budget. The investigator may work with Jennifer Castro, Clinical Research Office, Senior Program Manager, JCastro@salud.unm.edu to develop the budget.

* The EPCRS Committee will review the concept or protocol, the PRMC Decision Letter and Prioritization Scores, and the budget. If the concept is approved for funding, the investigator will be notified and instructed to complete the development of the final protocol for submission to the PRMC for final approval and eventually to the Institutional Review Board (IRB). Similarly, protocols approved for funding will need to be approved by the PRMC and IRB.

**Application Process**

1. Proposals and required components should be submitted electronically, after PRMC approval, in one PDF to Jennifer Castro icastro@salud.unm.edu and UNMCC-PilotProgram@salud.unm.edu

2. Jennifer Castro will forward proposals to the EPCRS Committee for their consideration.

3. Incomplete proposals or those that exceed the page limits (not including attachments) will not be considered.

**Application Review Process**

The applications will be reviewed by EPCRS Review Committee and invited content-expert members as needed. Selected applicants may be requested to present their project as part of the final review.
**Award Management**

*All funds must be spent within the 12 month period; unused funds will be returned to the central Cancer Center budget for redistribution during the next budget cycle. If the Cancer Center Senior Leadership terminate an award for non-compliance or non-performance, remaining balances will be returned to the Cancer Center for redistribution within the next award cycle.*

**Change In Status Of Awardee**

Awards must remain solely with the designated awardee and cannot be transferred to any other personnel. If a recipient decides to discontinue his or her work in the UNMCCC, the award will be terminated as described above, and unused funds will be returned to the UNMCCC. Likewise, if an investigator awardee changes institutions during the funding period, the award cannot be transferred and the remaining balance will be returned to the central UNMCCC budget.

**Expectations of Award Recipients**

Recipients of these awards are expected to actively participate in UNMCCC activities such as clinical working groups, seminars, meetings, and retreats. Additionally, Awardees are expected to maintain compliance with Clinical Research Office and NM Cancer Care Alliance policies and procedures, including Data Safety Monitoring plan oversight, data analysis and submission (including federally required reporting to clinicaltrials.gov and the Clinical Trial Reporting Program [CTRP]), and monitoring. Awardees will be expected to present their research findings at an applicable Cancer Center retreat and/or meeting. All correspondence should be sent to Jennifer Castro (jcastro@salud.unm.edu) and UNMCCC-PilotProgram@salud.unm.edu including:

- All required progress reports, and all additional requests for updates from the Cancer Center Senior Leadership and/or Administration.

Additionally, recipients are expected to appropriately acknowledge the pilot funding. *All material derived from the research supported by UNMCCC funding that is published or presented must carry a statement that credits the Cancer Center Support Grant P30CA118100 and Shared Resources, where appropriate.* Publications that cite the Cancer Center Support Grant funding will be included in progress reports to NCI.

Any questions about this pilot grant program should be directed to Olivier Rixe, Associate Director, Clinical Research (orixe@salud.unm.edu).