Clinical Research Support Fund
Submission Guidelines

Please submit your application, here.

Questions? Email Serena Gaines or call 402.559.5417.

Nebraska Medicine, in partnership with the UNMC College of Medicine and the Center for Clinical & Translational Research established the Clinical Research Support Fund, a mechanism to provide support for clinical and translational research. The fund will provide support over a two-year period to support investigator-initiated research that is either leading to or is supported in part by an extramural grant. The fund will also provide support to underfunded federal or national/cooperative group trials, as appropriate.

Funding for investigator-initiated research will depend on the 1) scientific and technical merit of the proposed project as determined by Review Committee, 2) availability of funds, and 3) submission of all regulatory approvals and required documents.

The primary goal of this funding mechanism is to provide funds to enable the investigator to complete a pilot study to gain preliminary data that will then enable them to compete for larger funding.

Application Deadline: The Third Tuesday of Each Month

Funds for the Clinical Research Support Fund are provided through an agreement with Nebraska Medicine.

A full application is required for investigator-initiated trials seeking funding >$10,000. Funding requests less than $10,000 or federally funded trials with a budget shortfall may use the administrative approval process to apply for funding.

Administrative Application Process:
This process is intended for small research and exploratory projects with budgets < $10,000. In addition, this process may be used for underfunded federally funded and consortium trials and IIT trials that had funding cuts.

For underfunded federal and consortium trials and trials that had funding cuts:

- Submit:
  - The application form found here.
  - The protocol and consent form.
  - Funding sheet(s) if this is supplementing a funded trial.

- A letter explaining the gap the funding is intended to fill.
- Study Intake Form to request required coverage analysis.

For research and exploratory projects with budgets < $10,000:

- Submit
  - The application form found here.
  - Project summary (limited to 30 lines or less of text, .5 margins, Arial size 11).
    - Include the project's broad, long-term objectives and specific aims. Include a description of the research design and methods for achieving the stated goals as well as the potential long-term impact the study could have on population health. If there in an IND or IDE with this protocol include that number and the manufacturer. Write the summary in plain language so a non-scientist can understand the importance and impact of the project.
  - Study Protocol (including aims, hypotheses to be tested, rationale, and study methods).
  - A statistical plan should include the following:
    - Primary and secondary endpoints, including times of measurement.
    - 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.
    - Estimate of the number of potentially eligible subjects.
    - Additional biostatistical consultation may be required upon review.
  - IRB approval.
  - Study Intake Form to request required coverage analysis.

Full Application Process:

Submit the information below in the following order:

- The application form found here.
- An NIH format Biosketch to include other support must be included in the submission for all PI's, Co- PI's, Co-I's and any other key personnel(current version can be downloaded here).
- Project summary (limited to 30 lines or less of text, .5 margins, Arial size 11).
  - Include the project's broad, long-term objectives and specific aims. Include a description of the research design and methods for achieving the stated goals as well as the potential long-term impact the study could have on population health. If there in an IND or IDE with this protocol include that number and the manufacturer. Write the summary in plain language so even a non-scientist can understand the importance and impact of the project.
  - If your application is a resubmission, you must also include an introduction that summarizes substantial additions, deletions and changes to the application and responds to the issues and criticism raised in the prior reviews. This does not count towards the five-page limit for the Research Plan.
- Research Plan: this portion is limited to ***five pages in total***
  - Specific Aim(s) (one page maximum)
  - Research Strategy
    - Significance: a) The scientific premise of the proposed research--the strengths and weaknesses of the research that is used to form the basis for the proposed research question; b) can include preliminary data, although not required; c) relevance to clinical translational research.
    - Innovation: A brief summary of how the research project moves the current field forward and incorporates novel concepts, approaches, methodologies, instrumentation or interventions.
    - Approach: Experimental design, including steps taken to ensure scientific rigor and reproducibility (robust and unbiased experimental design), sample, measures,

procedures, analysis, interpretation and reporting of results, explained as appropriate for a pilot project, and consideration of key biological variables, if applicable (please see guidelines here).
        - Team: Describe the identity and role each team member (including all principal investigators, co-investigators (if applicable) and collaborators (if applicable)) will play in the proposed research project. Provide a description of the leadership structure of the team, the expertise of each team member, and the plan for interaction and communication amongst team members. Provide evidence of prior productivity of the team (including prior publications and/or funding). If applicable, provide rationale for the addition of new team members to the previously existing research team.
    - Plans for extramural funding applications (e.g., to NIH or other agencies, please specify) upon successful completion of this project. Needs to clearly demonstration how this preliminary data will move you forward to the next study and enable you to submit an IIT to the NIH or other extramural type funding.
        - If the study is partially funded, include the budget pages &/or contract documents.
- All applications must submit a study protocol. Any interventional study requesting > $50K per year must use the format shown in the NIH eProtocol writing tool or a format very similiar. Depending on the type of protocol, all sections may not be appropriate. The NIH e-Protocol Writing Tool is highly recommended.
    - If your project meets the NIH definition of human subjects research, you must include a Protection of Human Subjects section (as required by NIH grants; follow the "A Protection of Human Subjects section" which can be accessed via the link above). The Protection of Human Subjects section should also include sections for Inclusion of Women & Minorities and Inclusion of Children.
- Literature cited (not part of the 5 pages).
- Statistical Analysis Plan.
    - Applicants must consult with a biostatistician in preparation of the full application. If a statistician is not included on the team you must provide justification why this was excluded. A biostatistician or other statistical support can be obtained a couple ways:
        - By completing a request for services form through the Center for Collaboration on Research Design and Analysis (CCORDA), here, so that they can identify the appropriate statistical consultant for your work. Projects must be reviewed by a biostatistician prior to submission. If you have questions, please contact Dr. Fang Yu, or call 402-559-9436.
        - Contacting the Biostatistics, Epidemiology & Research Design (BERD) core of the GP IDeA-CTR is another resource and is funded to support the pilot project investigators on developing the pilot proposals and data analysis for the awarded pilot projects.
    - A statistical plan should include the following:
        - Primary and secondary endpoints, including times of measurement
        - 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
        - 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.

        - 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.
        - Estimate of the number of potentially eligible subjects.
- Regulatory approvals: Institutional IRB approval is required before funds can be released. If you are conducting a study that has a cancer component at UNMC and involves human subjects research, your protocol must be submitted simultaneously to the IRB and Scientific Review Committee (SRC) for approval from both. Please complete the "SRC New Project Form" that can be downloaded from the Protocol Review and Monitoring System (PRMS) website. For questions regarding this process, contact the PRMS office at 402-559-4232.
- Submit a study intake form to request required coverage analysis. Additional CRC services could be requested on this form as well if needed.
- Budget
    - Complete the budget on the application form. Include all technical and professional fees you would like considered.
    - Attach budget sheets from all funding sources if there is other funding supporting this trial.
    - We recommend that protocols keep budgets < $50,000 per year. Any protocols requesting greater than $50K per year must contact the Associate Vice Chancellor of Research for approval prior to submission.
    - Complete a Budget Justification (click here for an example) outlining the rationale for all research costs is required (NIH format; on a separate page, explain all expenses that appear in the budget).
    - The only costs allowed are hospital billable items.
    - No salary support, equipment, renovation or honorariums are allowed.
    - Appendices will not be accepted.

Review Process of Full Proposals

- Three reviewers, including two content experts and one biostatistician, will each provide a critique for your application using the NIH review criteria (*Significance, Investigator(s), Innovation, Approach, Environment),* modified as appropriate for this funding program. Additionally, the CRC will review the budget to ensure accuracy and completeness and the Research Subject Advocate will review ethical considerations.
- The overall impact score will include other considerations, such as scientific merit, relevance, and feasibility as well as the strength of the research team and potential for obtaining extramural funding.
- The Scientific Review Committee will provide feedback.
- You will be notified within a week of your application status.

Expectations of Clinical Research Support Fund Awardees

- Remain current on all regulatory training and approvals.
- Write and conduct a rigorous enough study to have substantial data to move forward.
- Complete annual updates and a final report at the conclusion of the two year funding period.
- Provide progress after the pilot study completes to show if funding was obtained using the Clinical Research Support Fund process.
- Cite the Clinical Research Support Fund in funding, publications, and presentations.
- If your project involves an existing or potentially new invention, you must notify the appropriate commercialization office at our institution (UNeMed (Matthew Boehm for UNMC and UNO investigators.