2020 Request for Applications
Clinical Translational Research Services (CTRS) Pilot Funding Program
Released March 2, 2020

AWARD DESCRIPTION & CRITERIA

The University of Minnesota (UMN) Clinical and Translational Science Institute (CTSI) announces the Clinical Translational Research Services (CTRS) Pilot Funding Program to support the successful preparation and implementation of prospective pilot clinical trials. It is expected that data gathered through this funding mechanism will be used to inform the design of subsequent larger clinical trials.

For the purposes of this funding program, a prospective pilot clinical trial is a research study in which human subjects are prospectively assigned to one or more interventions (with or without a placebo or other control) to evaluate methods and procedures to be used in a subsequent larger clinical trial. Studies that are observational and/or secondary research with existing specimens or health information will not be funded by this mechanism.

Prospective pilot clinical trials typically seek to assess:

▪ The feasibility and acceptability of a larger scale study
▪ Recruitment and retention rates
▪ Whether treatment effects/outcomes are consistent with expectations/previous literature

PROJECT FUNDING

This program will be funded in two stages. Stage I: Up to six months - preparation, Stage II: Up to 18 months - implementation. Consideration of Stage II funding will be contingent on successful completion of Stage I. Continued funding within the grant period is contingent upon submitted documentation of progress. Deviation from the established milestones or lack of progress may result in termination of project funding. All other support for the project must be disclosed.

STAGE I FUNDING The goal of Stage I is to prepare for Stage II. This includes assembling a study team, preparing an IRB application and securing IRB, NCATS and other regulatory approval. Up to $5,000 will be awarded during this stage. The Principal Investigator may not charge effort to this grant. Any funds not spent during Stage I may be rolled over to Stage II.

The Clinical Research Support Center (CRSC) can provide guidance (i.e., protocol feasibility review and regulatory support) throughout this Stage at no cost. Stage I must be completed within six months. An IRB approved protocol and NCATS Prior Approval will be required to successfully complete Stage I and be eligible for Stage II funding.
STAGE II FUNDING The goal of Stage II is to successfully implement and complete the proposed prospective pilot clinical trial. Up to $70,000 will be awarded during this stage. The Principal Investigator may not charge effort to this grant.

The Clinical Research support Center (CRSC) can provide additional guidance and support throughout this Stage at no cost, however, the CRSC will not be available to coordinate the study. Stage II must be completed within 18 months. No cost extensions are not typically awarded. It is expected that successful completion of Stage II will lead to at least one peer-reviewed publication to be submitted within one year of completing the study.

The Biostatistical Design and Analysis Center (BDAC) can provide statistical and data management support throughout Stage I and Stage II, from study design to final analysis and publication of results. There is no charge for up to 20 hours during Stage I if BDAC personnel are written into Stage II at reasonable levels of support.

NUMBER OF AWARDS

CTRS anticipates funding two to four Stage I awards in 2020. Eligibility for Stage II funding will be contingent on successful completion of Stage I.

ELIGIBILITY

- Applicant/PI must be a University of Minnesota faculty researcher (Assistant, Associate, Full Professor or a PhD Research Associate).
- Proposal must describe a prospective pilot clinical trial.
- Proposal must be feasible given the time allotted for Stage I and Stage II.
- Proposal must be feasible given the budget allotted for Stage I and Stage II.

APPLICATION PROCESS

PRE-APPLICATION A mandatory Letter of Intent (LOI) is due by March 27, 2020 (5:00pm CST).

Letters of Intent must be submitted electronically using this link: https://redcap.ahc.umn.edu/surveys/?s=XXJHWE3FAA

The LOI should include:

- Project title | PI and Co-Investigators
- Brief summary of the long-term goals of the project (i.e., description of the future larger-scale trial) (100 word maximum)
- Brief description of the proposed pilot clinical trial (including estimated study goals, sample size, timeline, budget; 250 word maximum)

Letters of Intent will be reviewed. Invitations to submit full proposals will be sent within approximately three weeks.
PROPOSAL SUBMISSION (by invitation only)

Full proposals are due by **May 22, 2020 (5:00pm CST)** and must include point-by-point the following information. Proposals must be submitted electronically. The link to the proposal submission form will be provided to those applicants invited to submit proposals.

**Full Proposal Contents**

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Pages Maximum</th>
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<tbody>
<tr>
<td>A. Overall Research Goals:</td>
<td>PI and Co-Investigators · Brief summary of the long-term goals of the project including a description of the future larger-scale interventional trial.</td>
<td>1 page maximum</td>
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<tr>
<td>B. Pilot Study Description</td>
<td>Project title · Specific aims · Significance · Impact</td>
<td>3 pages maximum</td>
</tr>
<tr>
<td>C. Pilot Study Approach</td>
<td>Overview · Participants · Recruitment plan · Retention plan · Protection of human subjects plan · Procedures · Intervention(s) · Participant compensation · Primary outcomes · Secondary outcomes · Measures · Schedule of events · Statistical analysis plan · Limitations/Challenges · Environment/Resources · IND/IDE status · Timeline</td>
<td>6 pages maximum</td>
</tr>
<tr>
<td>D. Budget(s) w/ justifications</td>
<td>Stage I budget summary up to $5,000 · Stage II budget summary up to $70,000</td>
<td>3 pages maximum</td>
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<td>E. Study Personnel:</td>
<td>Outline the study team members and each role. Briefly describe the experience and qualifications to make the role well suited for the proposed project.</td>
<td>1/2 page maximum per investigator</td>
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<tr>
<td>F. Biosketches &amp; Other Support:</td>
<td>Provide NIH Biosketches and Other Support for Principal Investigator, Co-Principal Investigator(s) and Co-Investigator(s)</td>
<td>5 page maximum per investigator</td>
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REVIEW CONSIDERATIONS

Proposals will be evaluated and scored based on the following criteria:

- **Significance**: Does the project address an important problem or a critical barrier to progress in the field? How will successful completion of this project lead to a larger clinical trial and future funding?

- **Investigator(s)**: Are the PIs, collaborators, and other researchers well suited to the project? If the project is collaborative or multi-/PI, do the investigators have complementary and integrated expertise?

- **Innovation**: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

- **Approach**: Is the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are there plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?

- **Feasibility**: Is the project feasible given the logistics, timeline, and recruitment goals?

- **Environment**: Will the scientific environment in which the work will be done contribute to the probability of success? Are equipment and other physical resources available to the investigators for the project proposed?

AWARD NOTIFICATION

After the committee completes their review, all applicants will be notified of their funding status. Proposals receiving the highest scores will be awarded Stage I funding. Applicants selected for funding will be expected to work with a CTRS Clinical Research Specialist to make appropriate revisions to their study plans that reflect feedback from the review committee.

The funds for the award will be available through an account within the CTRS and awardees will be granted access to these funds after the terms of agreement are accepted. Funding will be provided with the understanding and expectation that these funds will be spent on services outlined in the application budget.
**KEY DATES**

- **RFA Posted date:** March 2, 2020
- **Letter of intent (LOI) due:** March 27, 2020 (5:00pm CST)
- **Invitations to submit full proposals sent out:** Approximately April 17, 2020
- **Full proposals due:** May 22, 2020 (5:00pm CST)
- **Stage I awards announced:** Approximately August 1, 2020

**PROGRAM CONTACT INFORMATION**

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