

TO: UT Health Cancer Center Membership

FROM: Ruben A. Mesa, M.D., FACP
Director, UT Health San Antonio Cancer Center

DATE: January 23, 2018

Subject: **Request for Letters of Intent for Clinical Translation Pilot Applications**

The UT Health San Antonio Cancer Center is soliciting applications to provide seed funding in the form of pilot grants in clinical translational projects. This is in anticipation of the potential release of a call for these projects from CPRIT. The goal is to assist investigators in gathering preliminary data for future grant applications. Projects must be translational in nature with the goal of leading to a better understanding of clinical efficacy or a therapeutic or device. Ideally, projects will propose innovative clinical studies that are hypothesis-driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patient enrolled in a completed clinical trial where the outcomes are known. This will include but is not limited to:

- Clinical studies of new/repurposed interventions including drugs, immunotherapy, radiation and surgical therapies, or therapeutic devices
- Development and validation of biomarkers for predictive purposes associated with tumor response to treatment or those related to treatment
- Pharmacogenomic studies aimed at identifying genomic profiles associated with increased/decreased efficacy or toxicity during clinical interventions.
- Studies to discover/develop/validate predictive biomarkers using completed clinical trials (such as the list above). Outcomes for clinical trials could be response to therapy, side effects or efficacy in influencing the treatment target. The most attractive such study would include both: a clinical trial incorporating both an intervention and, potentially using novel clinical trial designs, development and/or validation of predictive biomarkers.

Funding Mechanism:

Following submission of a LOI, due in **February 2018**, applicants will then be invited to participate in a clinical research concept review meeting. At this meeting they will be given 10 minutes to present their concept to a panel of reviewers and will be given on sight feedback. Following the meeting reviewers will recommend applications for seed funding.

Members and potential members of the UT Health San Antonio Cancer Center are strongly encouraged to work within the three Cancer Center scientific programs – Experimental and Developmental Therapeutics, Cancer Development and Progression, and Population Sciences and Prevention – to optimize the merit of each clinical trial/biomarker proposal, maximizing the incorporation of cancer center resources.

These Awards will be supported by UT Health SA Cancer Center pilot project funds designated to support translational research. A progress report will be required every 6 months from activation for continuation of funding.

Budget:

The **maximum budget for these one-year awards is \$10,000**. Faculty salaries are **NOT** allowed in the application budget. Budgets **may** include non-faculty salaries, but it should not exceed 25% of the total requested dollars. In addition, budgets may **NOT** include funding for travel or for the purchase of computers or other equipment unless it can be justified as essential to the project.

Letter of Intent requirements and format:

Applications should be prepared using the templates provided (adapted from PHS Form 398). Font size should be no smaller than 11 point, preferably Arial or Times New Roman. The font size for figures, figure legends, charts, and tables may be smaller, but must be legible. Margins should be at least 0.5". Pages should be numbered sequentially. The Letter of Intent (LOI) narrative is limited to one page.

Proposals should be organized as follows:

1. **Cover Page (face page on application form)**
2. **Biographical sketch for PI (limit 4 pages)**
3. **List of Key Personnel (limit 1 page)**
4. Budget and Budget Justification (on application form)
5. **Letter of Intent (limit 2 pages)** should briefly describe:
 - Clinical trial design: Include, as a minimum, an overview of eligibility criteria, availability of patients*, intervention and source of agent/treatment, and a brief overview of study procedures. A statistical section is encourage that should include sample size calculations.
 - Independent biomarker study: Describe the source of biospecimens and source of clinical outcomes to be correlated. Describe methods of assay, information on the validation of the assay techniques(s), and confirm through letter of support, if necessary, the availability of biospecimens and that they have been consented for analysis.
 - For combined interventional clinical trials that include prospective biomarker collection/assay, methods and assay validation plans should be limited.
6. **Impact: In 100 words or less**, describe the impact of the study's results.
7. **Future plans:** As appropriate, describe plans for future peer-reviewed grant applications (could include plans for NCTN clinical trial) that would result from the proposed study.
8. **Literature citations** (limit 1 page)

Letter of Intent Submission:

Submit completed LOIs to UT Health San Antonio Cancer Center via email at ctcregrants@uthscsa.edu by February 12, 2018. **NO LATE APPLICATIONS WILL BE ACCEPTED.**

- Applications must be in **PDF** format. **Applications will not be accepted in any other format.**
- **The application file should be named as follows: “PI Last name, first and middle initials Clinical Translation LOI”.**

Reporting:

A progress report and budget summary is required every 6 months. Continued funding is contingent upon receipt of Progress Report

Progress Reports are submitted to ctcregrants@uthscsa.edu. Principal Investigators will receive notice of the due date a month in advance. If, due to extenuating circumstances, an extension is required, it must be requested **prior** to the progress report due date. Please address any such requests to ctcregrants@uthscsa.edu.

Questions: Questions may be addressed to the UT Health San Antonio Cancer Center Grants & Contracts Manager, Melissa Kyzar, via email at kyzar@uthscsa.edu or by phone 450-1436.

Deadline: February 12, 2018

Award Date: March 1, 2018

UT Health San Antonio Cancer Center Pilot Award Terms and Conditions

Use of Funds:

- Funds may be used for non-faculty salaries, and should not exceed 25% of the total award.
- Faculty salaries are not allowed on Cancer Center Pilot Awards except under special circumstances with prior approval from the Cancer Center.
- Use of more than 25% of the total award in the final quarter is prohibited.
- Any funds remaining at the end of the award period will be returned to Cancer Center and a deficit balance will be the responsibility of the Principal Investigator to cover.

Rebudgeting:

- Rebudgeting within 25% of the approved budget is allowed without prior approval. Rebudgeting over 25% must first be approved by Cancer Center Administration.

Extensions:

- Extension requests must be received by Cancer Center Administration 30 days prior to the award's end date and are granted at the sole discretion of Cancer Center Administration.

General:

- All Cancer Center Pilot recipients are required to participate in future Cancer Center Pilot Reviews.
- Recipients of Cancer Center Pilot Awards are not eligible for another Cancer Center Pilot for a period of 2 years from the date of the award.
- All awardees are expected to cite the Cancer Center as part of their institutional affiliation on all publications and to cite the CCSG (P30 CA054174) in the acknowledgements section of all publications.
- Acceptance of Cancer Center award funding constitutes acceptance of the policies and compliance requirements of the award. This includes the submission of progress reports in the time frame established by the Cancer Center.
- Please be aware that all Cancer Center issued pilot awards now include an administrative review. The failure to comply with the reporting requirements of your award can impact this score on future pilot applications.

Contact info:

- Any questions regarding these terms or requests for prior approval should be directed to Melissa Kyzar, UT Health San Antonio Cancer Center Grants & Contracts Manager at Kyzar@uthsca.edu.