Request for Applications to Establish a Multidisciplinary Translational Team (MTT)

I. General Information

Solicitation Number: ITS-2016-MTT
Mechanism of Support: ITS Multidisciplinary Translational Team Grant

Applications Due: February 10, 2017
Earliest Funding: April 1, 2017

The award issued under this RFA is contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

Eligible Applicants: Awards are available to well-described teams with experienced leadership. Applicants who have had prior ITS Pilot projects must be in good standing (all progress reports submitted and final budget close-out reconciled).

Number of Applications: A PI may submit only one MTT application per annual funding cycle**.**

Budget and Project Period: Up to 2 years of support may be requested at $75,000/year for a total not to exceed $150,000. Continued funding during the award period is contingent upon reasonable progress in accomplishing the proposed aims. Carryover of funds is not allowed. For any equipment that is intended solely for use by the PI's MTT, the ITS will transfer depreciation costs to the PI's home department upon its acquisition.

Cost Sharing or Matching: Cost sharing is not required. However, applicants should describe any project support from their department or other sources.

II. Purpose of this RFA

MTT grants are partnership agreements intended to provide teams of investigators with access to the resources of the ITS and the CTSA consortium, allowing them to be even more effective in developing and conducting collaborative research and mentoring trainees, and promoting networks.

To be considered for funding, an MTT must:

- Focus on translational advancement of a drug, device, diagnostic, or practice-based intervention to human disease
- Include investigators from diverse disciplines and departments
- Be led by an established senior investigator
- Include both senior and junior level investigators

Funded teams are expected to:

- Conduct a specific investigator-initiated human subjects research project (clinical trial) involving direct interactions with human subjects or identifiable human samples. Outcomes studies using comparative effectiveness approaches or implementation science are also responsive.

- Demonstrate collaboration among team members
- Pursue opportunities for securing extramural funding
- Enhance partnerships with other researchers, UTMB departments and Centers, industry, or the community
- Develop a plan for mentoring junior investigators
- Develop and disseminate new research findings through peer reviewed publications, conferences, CTSA networks, and community engagement activities

III. Funding Restrictions

- Pre-award costs are not allowable.
- Carryover of funds is not allowed.
- Faculty salary support is not allowable.
- Capital equipment purchased with these funds will be transferred to your departmental inventory, along with the associated depreciation expense.

IV. Submitting an Application

Deadline: Applications must be received by **5:00 p.m., CST on February 10, 2017.** No extensions will be given. *Applications received after the deadline will not be reviewed.* Once submitted, an application cannot be revised. Applications must be submitted electronically to ebruiz@utmb.edu.

Format: Use 11 point Arial font with 0.5 inch margins. Tables and figures must be readable. Pages must be single-spaced. *Applications will not be reviewed if page limits are exceeded, applicable section(s) are omitted, or formatting recommendations are not followed*.

NOTICE: A complete application consists of a single .pdf file containing the components listed below.

1. Project Title. *(200 characters, maximum)*

2. Applicant Information Table. *(Example below)*

Team Leader/PI	Degree	Title	ITS Affiliation
Administrative Support Person	**Route #**	**Email**	**Phone Number**
Co-Investigator	**Degree**	**Title**	**ITS Affiliation**

3. Abstract. *(30 lines, maximum)*

4. Research Strategy. All Sections are required and must be limited to the number of pages indicated below.

Section	**Pages**
Aims	1
Approach – *Include all subsections listed below.* **Team Description** • PI: qualifications, experience in team building or leading; track record in mentoring. • Team Members: brief description of qualifications/expertise, roles. • Trainee Involvement: levels of trainees are involved, proposed trainee project manager. • Team Interaction: meeting management, evidence of ongoing interaction/collaboration. • Junior Faculty Development Plan **Trial Design** • Questions asked, major endpoints, interventions, measurements • IRB status, anticipated enrollment, inclusion/exclusion criteria • Analysis Plan: data, statistical, and power analysis **Timeline** **References** *(not included in page limit)*	5

5. Human Subjects. *For projects involving the use of human subjects, address the following topics. (2 pages, maximum)*

- **Risks to the Subjects**
  - **Human Subjects Involvement and Characteristics:** *Describe the number of subjects to be enrolled, special characteristics, such as if they belong to a vulnerable population. State inclusion and exclusion criteria.*
  - **Sources of Research Materials:** *Describe all subjects-related information to be collected, including personal information, protected health information, and biological specimens.*
  - **Potential Risks:** *Include all risks to subjects from participation in the study. For example, risks from blood draw may include discomfort, bleeding, bruising, syncope, and infection. Interventions to be tested may pose risks to participants, such as discomfort and side effects.*
- **Adequacy of Protection against Risks**
  - **Recruitment and Informed Consent:** *Describe how subjects will be recruited and from where. Describe who will be responsible for obtaining informed consent and the informed consent process.*
  - **Protection against Risk:** *How will potential risks be minimized? How will data confidentiality be protected?*
- **Potential Benefits of the Proposed Research to the Subjects and Others**: *Describe if there are direct benefits from this study to volunteers. What are the benefits to society as a whole?*
- **Importance of Knowledge to be Gained:** *Describe how questions answered by this research will benefit participants and others.*

- **Inclusion of Women and Minorities**: *State if women and subjects from minority groups are included or provide a justification if they are excluded. Fill out the Targeted/Planned Enrollment Table. (Example below).*

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category: Total of All Subjects*			
Racial Categories			
Ameican Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects*			

- **Inclusion of Children**: *State if children are include or provide a justification for not including them*
- **Data and Safety Monitoring Plan (DSMP)**
    - **Determination of the level of risk:** State if the study is minimal risk or more than minimal risk (moderate-risk, high-risk). Provide rationale for your classification.
    - **Description of the study monitoring process:** Name the individual responsible for monitoring the study and the monitoring process.
    - **Description of anticipated adverse events and a plan for reporting anticipated, unanticipated and serious adverse events:** Provide a description of the adverse events (AE) from study-related procedures and a plan for grading (mild, moderate or severe) and reporting them. Per IRB policy, all serious adverse events (SAEs) should be reported to the IRB within 24 hour of their occurrence or recognition.
    - **Description of the plan for data management, including the collection, storage, protection, and analysis of data:** Include a plan for data management. Where will research data be stored? How will the integrity and confidentiality of the data be assured?
        - **Protection of subject privacy:** State measures in place to assure the privacy of subjects. The plan may include restricting access to subject-related data to only personnel directly involved with the study, password protection of data, and anonymizing of data before reporting.

6. Vertebrate Animals. *Will your project involve the use of vertebrate animals? If so, please address the five major components of the* Vertebrate Animal Section:

1. Provide a detailed description of the use of animals in the research. Identify species, strains, ages, sex, and numbers of animals to be used.
2. Justify the use and number of animals and choice of species with additional justification if animals are in short supply or are costly or if you plan to use large numbers.
3. Provide information on veterinary care for the animals.
4. Describe procedures for ensuring that discomfort, pain, and injury will be limited to what is unavoidable. Describe the use of analgesic, anesthetic, tranquilizing drugs, and restraining devices to minimize discomfort, distress, pain, and injury.

5. Describe any euthanasia method to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association Guidelines for the Euthanasia of Animals. If not, justify not following the recommendations.

7. Approvals. *Enter relevant IRB or IACUC approval information below.*

IRB #_____ **Approval Date**_____ **IACUC#**_____ **Approval Date**_____

8. IRB Approval Letter. *If you have an IRB approval letter, include it in your single pdf file.*

9. Budget. *Include all costs. The budget must be adequate to complete the proposed work. (Example below)*

Item/Description	Quantity	Unit Price	Amount

Total Amount Requested $ _____

10. Budget Justification. *Explain how expenses will contribute to success of the project. (1 page, maximum)*

11. Extramural Funding. *Describe your plans to secure extramural funding for this project. How will ITS funding contribute? (1/2 page, maximum)*

12. Required Resources. *Describe any departmental or other resources needed to complete the proposed project.*

13. Biosketches. *Provide a biosketch [5 page maximum] in the current NIH format for each Investigator*. Include all current support and effort.

V. Review of Applications

Review and Selection Process: The Scientific Review Committee will evaluate applications for the strength and organization of the team and for the scientific and technical merit of the human subjects study. Highly ranked applications will be recommended for funding to the CTSA Executive Committee.

Review Criteria: Two evaluations will be conducted. The team will be evaluated for leadership, vision, discipline appropriateness, involvement of junior faculty, and the junior faculty development plan. The human subjects research plan will be assessed for overall impact, significance, innovation, and approach. Reviewers will also be asked to comment on adequacy for protection of human subjects and appropriateness of the budget to accomplish the aims of the application. The review committee will weigh the assessments of the team and clinical study in reaching an overall score. Applicants must be able to complete the project within the proposed timeline and budget.

In addition, applicants must clearly describe: how the work is translational, how investigators will interact with ITS resources, how team members will interact to enhance the MTT project, and how the project will lead to extramural funding.

VI. Award Administration

Award Notices: All applicants will be notified in March.

Progress Reports: Funded projects will be required to submit progress reports 6, 12, 18, and 24 months from the award date. Awardees will be required to present progress and research findings at ITS meetings and the Clinical and Translational Research Forum (http://www.its.utmb.edu/CTR_Forum/index.html).

VII. Additional Information and Inquiries

- Visit the ITS Website for information regarding Research Resources, Team Science, ITS, the CTSA, and Previously Funded Pilot Projects: http://www.its.utmb.edu/index.html
- Contact us: CTSA@utmb.edu or (409) 747-2872 with questions.