



COLUMBIA UNIVERSITY
MEDICAL CENTER

IRVING INSTITUTE FOR

clinical and translational research

Translational Therapeutics (TRx) Resource: Pilot Award Pre-Proposal Instructions

Irving Institute for Clinical and Translational Research

2017

Accelerating Discoveries Toward Better Health

irvinginstitute.columbia.edu

2017 Irving Institute TRx Pre-Proposal Instructions

The Irving Institute Translational Therapeutics (TRx) Resource is a therapeutic development accelerator program focused on providing funding, education and mentorship to Columbia Investigators, with a goal of advancing novel therapies from the lab towards the clinic. Mentorship will be provided by a steering committee of academic and industry experts in the field of drug development. The TRx Resource is inviting Columbia University Faculty to apply for its inaugural pilot awards. Investigators in all therapeutic areas are encouraged to apply, with the goal of advancing novel therapeutic targets and ideas towards commercialization. Funding from this pilot award is intended to move projects forward to an inflection point of value (e.g. high throughput screen (HTS) for hit to lead, dosing studies of small molecules including proteins and chemical compounds, assay development for target mechanism/engagement, pivotal small animal study, design of clinical study). Although not mandatory, applicants are strongly encouraged to present a complementary team comprising of at least a basic scientist and a clinical scientist as part of the pre-proposal application.

Selected pre-proposal applications will be required to attend a TRx Boot Camp, which consists of five interactive evening sessions that will aid in preparation of a full proposal. During the training period, additional resources (business consultants, core facility resources, etc.) can be provided as needed to the project teams. The full proposal will outline the target product profile (TPP) and identify feasible milestones for the one-year development project. Details of the full proposal application requirements and format will be provided at a later date.

Full proposals selected to receive funding will receive the support of a TRx Development Team to guide project progression. Typically, the team will include the following members but will be customized to the project need:

1. The applicant clinical and basic scientists
2. A core facility representative (if needed) e.g., The Biomarkers Core Laboratory for metabolomics, Proteomics Shared Resource for qualitative and quantitative protein analysis, The Organic Chemistry Collaborative Center for drug design and chemistries.
3. An industry representative
4. A representative from Columbia's Clinical Trials Office and/or Columbia Technology Venture

ELIGIBILITY:

Applicants must have a full-time Columbia University faculty appointment. Graduate students and post doctorate trainees can act as project leads with permission from the principal investigators (PIs). Projects must focus on translating a validated target toward commercialization and clinic and also address a clear unmet medical need. Projects that focus on new treatments for novel disease targets, new drugs for known targets and pathways, and new activities for currently known and/or approved drugs (repurposing) are eligible.

AREAS OF INTEREST:

All therapeutic projects with a valid target in any stage of development with translational/commercialization trajectory are encouraged to apply. Special consideration may be given to the development of therapeutics for rare diseases originating from Precision Medicine efforts. Therapeutic strategies including small molecules, biologics, novel delivery approaches, gene therapy, and cell therapeutics will be considered.

FUNDING:

At the conclusion of the TRx Boot Camp, participants will be eligible to submit a full proposal and application for a one-year pilot grant of up \$ 75,000 per project, based on the project's needs.

PRE-PROPOSAL DIRECTIONS:

*We are currently accepting pre-proposals for the 2017 funding cycle, **due electronically by 5:00 PM EST on Monday, November 14, 2016.***

2017 Irving Institute TRx Pre-Proposal Instructions

- 1) **Prepare a project description (4-page maximum, 1-title page, 3-project pages; minimum 11-point font) as follows:**

TITLE PAGE

- Project Title
- Project area: drug development, rare disease, gene therapy, protein therapy, cell therapy, others.

PROJECT PAGES

- Project Team
A brief description of the clinical and basic scientists and their area of expertise. Please do not include biosketches.
- Project Description and Clinical Need
A summary of the project, the current stage of development and plan to reach the next stage. Also, a description of the medical need and desired indication.
- Competitive Landscape
A brief description of the current standard of care and how this therapy, if developed, is an improvement over currently available treatments.
- Project Needs
Describe the resources and expertise needed to progress the project and the amount of funding required to support this next stage of development (max \$75,000).
- Intellectual Property
List if there are patents covering this idea or invention reports with Columbia Technology Ventures.

- 2) **Convert to a PDF and submit by 5:00pm EST on Monday, November 14th to:**
trxresource@columbia.edu, with the subject heading “2017 TRx Pre-Proposal”.

REVIEW PROCESS:

Pre-proposals will be reviewed for basic eligibility and feasibility. Proposals will be reviewed by a panel of faculty and industry members. Each application will be judged on the basis of translational and commercialization potential, scientific and medical merit and feasibility.

NOTE:

IRB/IACUC approval is not required at the time of the pre-proposal application. However, if a candidate is awarded a grant and the project involves the use of data from human and/or animal subjects, an IRB/IACUC approval number must be forwarded prior to receipt of funding. In order to avoid any delays if funding is awarded, candidates are encouraged to apply and obtain IRB/IACUC approval in advance.

The pre-proposal will be confidential; however, we suggest you discuss the application and project with your Columbia Technology Ventures licensing officer prior to applying. If you do not have a licensing officer, please reach out to techventures@columbia.edu.

FAILURE TO FOLLOW THESE INSTRUCTIONS WILL RESULT IN THE PROPOSAL BEING RETURNED, WITHOUT REVIEW.

PLEASE DO NOT INCLUDE APPENDICES.

APPLICATION DEADLINE: Monday, November 14, 2016, 5:00 PM EST

BOOTCAMP START DATE: January 2017

FULL PROPOSALS DUE: March 2017