Columbia University Medical Center

Irving Institute for clinical and translational research

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

Irving Institute for Clinical and Translational Research

2018

Accelerating Discoveries Toward Better Health

irvinginstitute.columbia.edu

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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 submit pre-proposal applications for its annual pilot awards. Investigators in all therapeutic areas are encouraged to apply. Of interest are unique therapeutic targets or ideas that have a clear path 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). 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 interactive evening sessions that will aid in preparation of the 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 market and 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 Organic Chemistry Collaborative Center for drug design and chemistries ,The Biomarkers Core Laboratory for metabolomics, Proteomics Shared Resource for qualitative and quantitative protein analysis.
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 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. Outstanding projects with excellent progress will be considered for a second year of funding to further advance development towards commercialization. Additional funding is contingent on competitive review and the availability of funds.

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PRE-PROPOSAL DIRECTIONS:

Pre-proposals are due by 5:00 PM EST on Monday, Friday December 1, 2017. Pre-proposals should be submitted to: https://trxresource.fluidreview.com/

Please allow time to create a FluidReview account if you do not already have one.

1) **Prepare a project description** (minimum 11-point font) as follows:
   TITLE PAGE (1 page maximum)
   - Project Title
   - PI Name(s)
   - Project area: drug development, rare disease, gene therapy, protein therapy, cell therapy, others.

   PROJECT PAGES (2 pages)
   - Project Team
     A brief description of the clinical and basic scientists and their area of expertise. Please do not include full 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 brief 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 treatment.
   - 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). Please indicate if a Columbia Core Lab is needed for the project.
   - 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 Friday, December 1st to: https://trxresource.fluidreview.com/**. Please ensure the file title includes the PI name.

REVIEW PROCESS:

Pre-application proposals will be reviewed for eligibility and feasibility. Full 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 a pilot award for their subsequent full proposal 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 addition, for human subjects research selected for potential Irving Institute pilot funding, NIH-NCATS mandated prior approval of human subject research documentation is required before funds can be released. In order to avoid any delays if full proposal funding is awarded, candidates are encouraged to apply and obtain IRB/IACUC approval in advance. Note that all research projects involving human subject selected for potential Irving Institute pilot funding are conditionally selected until **IRB documentation** is submitted and **NIH-NCATS prior approval** is received.

NOTE:

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.