

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

Irving Institute for Clinical and Translational Research

2022-2023

Accelerating Discoveries Toward Better Health

irvinginstitute.columbia.edu

Irving Institute *Accelerate* TRx Pilot Award Pre-Proposal Instructions

The Irving Institute for Clinical and Translational Research's *Accelerate* Program is a therapeutic development accelerator platform that plays a central role in translating the outstanding basic science discoveries at Columbia University into commercial therapeutics. Through our [Translational Therapeutics Accelerator \(TRx\) Pilot Award](#), we focus on providing funding, education, partnership and mentorship to Columbia investigators, with a goal of advancing novel therapies from the lab towards the clinic. Advice and project guidance will be provided by a steering committee of academic and industry experts in the field of drug development. We work closely with Columbia Technology Ventures (CTV), Accelerating Cancer Therapeutics (ACT), and the Columbia Biomedical Engineering Technology Accelerator (BioMedX) to provide early stage funding and project development resources to investigators with promising scientific ideas and discoveries looking to advance through the translational spectrum to where outside funding would be available for further commercialization. *Accelerate* invites Columbia University faculty-led teams to submit pre-proposal applications for its annual TRx Pilot Award.

Investigators in all therapeutic areas are encouraged to apply. Of interest are novel therapeutic targets or innovative ideas that have a clear path towards commercialization. Funding from this pilot award is intended to move projects forward to a value inflection point (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) so that they are eligible to explore later stage funding opportunities through Government or Foundation grants and/or industry partnerships. 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.

APPLICATION PROCESS AND PROGRAM STRUCTURE:

Pre-Proposal Submission: The application process is multi-stage, starting with the submission of a pre-proposal. Applicants should submit pre-proposals for their therapeutics projects via the Submittable portal, as described below.

Lab-to-Market Life Science Accelerator Boot Camp: Teams whose pre-proposals are selected will be invited to participate in a Lab-to-Market Life Science Boot Camp, which consists of weekly interactive sessions that will aid in preparation of the full proposal. Required Boot Camp core sessions will run from January 2023 through March 2023, with supplemental sessions offered in April and May 2023. At least one member of the project team (including students and post-docs) must participate in the core boot camp sessions.

Full Proposal Submission: Teams will submit full proposals in March 2023 which will outline the target market and feasible milestones for a 12-month development plan. Details of the full proposal application requirements and format will be provided later.

High scoring full proposals will be invited to "pitch" their therapeutic solution to a panel of industry and academic experts. Teams selected for funding will receive the support of a mentorship 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. An Executive-in-Residence (XIR) or other Industry representative
3. A representative from Columbia's Clinical Trials Office and/or Columbia Technology Venture

ELIGIBILITY:

Principal Investigators (PIs) must have a full-time Columbia University faculty appointment. Graduate students and post doctorate trainees can act as project leads with permission from the 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 and new drugs for known targets and pathways are eligible. PIs with projects that focus on new activities for currently known and/or approved drugs (repurposing) should contact the Program Directors before applying to determine if their project is eligible.

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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 will be given to proposals for the development of novel therapeutics for:

- rare diseases originating from Precision Medicine efforts,
- pain and addiction (e.g., management and treatment),
- emerging infectious diseases (e.g., monkeypox),
- diagnosis, treatment, and long-term management of long COVID-19, and
- unmet needs for diseases and/or public health concerns that disproportionately affect underserved communities, as well as
- applications from Principal Investigators and/or teams of investigators from [underrepresented groups](#).

Therapeutic strategies including small molecules, biologics, novel delivery approaches, gene therapy, and cell therapeutics will be considered.

FUNDING:

At the conclusion of the Boot Camp core sessions, participants will be eligible to submit a full proposal application and pitch for a one-year pilot grant of up to \$75,000 per project, based on the project's needs. Funding should be directed to specific experimental milestone(s) that will make the project eligible for follow on funding through Government or Foundation grants and/ or industry partnerships. We encourage that the majority of funds be utilized for project specific study experiments; a smaller portion of the funds may be used towards post-doctorate researcher, graduate student and technician salary. Funding may not be used towards PI, Co-PI and faculty salary.

PRE-PROPOSAL DIRECTIONS:

Pre-proposals are due **by 11:59PM ET on Tuesday, November 15th**. Pre-proposals should be completed and submitted through an online form found at ColumbiaLSA.submittable.com. *Please allow time to create a Submittable account if you do not already have one.*

1) Areas that will be covered on the online form include:

- Project Title
- PI Name(s)
- Brief Non-Confidential Abstract
- 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) Complete the online form for each section and submit by 11:59PM ET on Tuesday, November 15th to:
ColumbiaLSA.submittable.com.

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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 with consideration of any potential conflicts-of-interest. Each application will be judged based on translational and commercialization potential, scientific and medical merit and feasibility.

QUESTIONS:

For questions about the application process, please contact:

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For questions about the scientific content, please contact:

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NOTE:

All projects involving human subjects and/or vertebrate animal research that are chosen for Irving Institute pilot funding, are conditionally selected until **IRB and/or IACUC approval** and **NIH-NCATS prior approval** are received. IRB/IACUC approval is not required at the time of application but is required in order to receive NIH-NCATS prior approval. Submission to the IRB/IACUC must be completed within thirty (30) days of notification of potential Irving Institute pilot funding. In addition, conditionally selected projects must submit NIH-NCATS prior approval documentation to Irving Institute administration immediately after IRB/IACUC approval is received and within seventy-five (75) days of notification of potential funding of the Full Proposal. Only complete prior approval packets will be sent to NIH-NCATS. Dispersal of funds cannot occur until all required approvals are obtained.

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.