

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

Irving Institute for Clinical and Translational Research

2024 - 2025

Accelerating Discoveries Toward Better Health

irvinginstitute.columbia.edu

Irving Institute TRx Pilot Award Pre-Proposal Instructions

The Irving Institute for Clinical and Translational Research's *Accelerate* Resource 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 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) 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 attend a Lab-to-Market Life Science Accelerator Boot Camp, which consists of interactive sessions, running from January through April 2025, that will aid in the preparation of the full-proposal submission. See below for full-proposal details.

At least one member of the project team (including graduate students and post-docs) must participate in the core boot camp sessions.

As an additional resource during the boot camp, we can assign graduate students (including MBA, engineering, and biotechnology students) who are enrolled in the course for credit to faculty-led project teams to help research the business case for their technology. Students are overseen and managed by the course instructors. Project team PIs are required to meet with their assigned students 2-3 times (outside of regular class time) over the course of the boot camp to discuss their project and provide direction for the student research. In past cohorts, students have been an invaluable resource to team success. Teams accepted to the boot camp will have the opportunity to "opt-in" to confirm participation in this aspect of the program prior to kickoff.

Full Proposal Submission: Teams will submit full proposals in March 2025 which will outline the budget and targeted feasible milestones for the one-year development of the project. Details of the full proposal application requirements and format will be provided later.

A subset of applicants 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. A TRx/ACT Steering Committee member, Executive-in-Residence (XIR), or other Industry representative
3. A representative from Columbia Technology Ventures and/or Columbia's Clinical Trials Office

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ELIGIBILITY:

Principal Investigators (PIs) must have a full-time Columbia University faculty appointment. Graduate students and post-doctoral 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 Managers before applying to determine if their project is eligible. Projects must use IP developed at Columbia University and have a strong business case and IP strategy to be 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 will be given to proposals for the development of novel therapeutics for:

- rare diseases originating from Precision Medicine efforts,
- emerging infectious diseases, 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, or faculty salary.

PRE-PROPOSAL DIRECTIONS:

Pre-proposals are due **by 5:00PM ET on Tuesday, October 29, 2024**. 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

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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 include a high-level budget. 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 5:00PM ET on Tuesday, October 29, 2024 to:

ColumbiaLSA.submittable.com

REVIEW PROCESS:

Pre-proposals will be reviewed by program leadership for eligibility, feasibility. Full proposals will be reviewed by a scoring committee comprised 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:

Sherry Bermeo, PhD
Program Manager, Translational Therapeutics Accelerator
Business Development Associate, Columbia Technology Ventures
sb4774@columbia.edu

For questions about the scientific content, please contact:

Serge Cremers, PharmD, PhD
Professor of Pathology & Cell Biology
Director, Clinical Pharmacology and Toxicology
Laboratory

Co-Director, Accelerate - Translational Therapeutics
Accelerator (TRx),
Irving Institute for Clinical and Translational Research
Columbia University Irving Medical Center
Editor-in-Chief, British Journal of Clinical Pharmacology
sc2752@cumc.columbia.edu

Akiva Mintz, MD, PhD
Professor and Vice Chair of Translational Research,
Radiology
Director, Columbia PET Center

Co-Director, Accelerate - Translational Therapeutics
Accelerator (TRx),
Irving Institute for Clinical and Translational Research
Columbia University Irving Medical Center
am4754@cumc.columbia.edu

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.

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RECENT AWARD RECIPIENTS:

2023-2024

- Tingting Yang & Stephen Tsang – Ophthalmology
- John Hunt – Biological Sciences
- Brent Stockwell – Biological Sciences
- Caghan Kizil & Abid Hussain – Neurology

2022-2023

- Hans-Willem Snoeck & Nicolino Dorrello – Medicine & Pediatrics
- Barry Fine & Donald Landry – Medicine
- Ai Yamamoto & Katherine Croce – Neurology
- Dieter Egli, Zev Williams, & Stepan Jerabek – Pediatrics & Obstetrics

2021-2022

- Stephen Marx & Manu Ben-Johny – Medicine, Physiology, & Cellular Biophysics
- Jennifer Bain & Christopher Ricupero – Neurology
- Kam Leong – Biomedical Engineering
- Peter Quinn & Stephen Tsang – Ophthalmology
- Elisa Konofagou & Lawrence S. Honig – Biomedical Engineering & Neurology

2020-2021

- Tal Danino & Nicholas Arpaia – Biomedical Engineering, Microbiology, & Immunology
- Catherine Spina & Andrea Califano – Radiation Oncology
- Riccardo Dalla Favera & Claudio Scuppo – Pathology
- Anjali Saqi & Keith Yeager – Pathology, Cell Biology, & Biomedical Engineering
- Mohsen Maharlooei & Megan Sykes – Medicine & Surgery
- Harris Wang & Mary Rosser – Systems Biology
- Alex Dranovsky & Amy Margolis – Psychiatry

2019-2020

- Harmen Bussemaker & Chaitanya Rastogi – Biological Sciences
- Fatemeh Momen-Heravi – Dental Medicine
- Christine Ann Denny – Psychiatry
- Giovanni Ferrari & Antonio Frasca – Surgery
- Jeffrey Kysar & David Kalfa – Mechanical Engineering & Surgery