INSTITUTE FOR TRANSLATIONAL MEDICINE

Institute for Translational Medicine

REQUEST FOR APPLICATIONS

Pilot Translational and Clinical Studies Development Program

The Institute for Translational Medicine (ITM), a partnership between the University of Chicago and Rush in collaboration with Chicagoland health and research organizations, is requesting **Letters of Intent** for its Pilot Science Development Program. **From among these, the ITM will invite up to ten (10) applicants to engage in a collaborative application process** that seeks to:

- Optimize research teams by connecting applicant researchers with a broad range of academic and community collaborators with diverse expertise and lived experience who can assist in the development of a project that directly supports Healthy Chicago 2025 program areas
- Optimize science, reduce inherent bias, and advance health equity by providing applicants with resources to ensure their study design, rationale, aims, and statistics are rigorous and compelling and include social, environmental, behavioral, and psychological (i.e., "sociome") factors wherever possible
- Optimize an applicant study's engagement by helping applicants connect with community and industry stakeholders who can best benefit from the results of the research
- Encourage collaboration between faculty investigators at ITM institutions

This process will lead to a competitive application for approximately three **one-year awards of $60,000** each. These pilot awards, set to start **July 1, 2023**, will:

- Allow researchers to generate preliminary data for subsequent funding applications
- Stimulate community-engaged research (including but not limited to) community-based participatory research and practice-based research
- Increase utilization of clinical and translational support services
- Advance health equity through the inclusion of sociome factors in research

Proposed projects may fall into any of the following categories:

- **Clinical and Translational Human Subjects Studies:** Studies that directly involve human subjects or human subject-derived materials or information and require IRB approval and develop new knowledge about authentic human diseases. Studies that employ human subjects-derived materials but address issues about basic or normal physiology only are not eligible, and use of purchased or widely available cell lines does not qualify.
- **Community Collaborative Research Studies:** An explicit goal of the ITM is to develop cutting-edge collaborative research programs that stimulate research in the community, specifically including participation by community residents and organizations and by community practitioners. Topics may address any issue and may include (but are not restricted to) community-engaged participatory research, practice-based research, bi-directional knowledge transfer, and research capacity building.
- **Preclinical Pilot Translational Studies:** The ITM will consider promising research projects that incorporate laboratory-based research aimed at clarifying mechanisms of disease; developing measures or markers of disease presence, severity, or improvement; or developing drugs, devices, or interventions to treat disease or to improve health.

- **Technology Advancement and Commercial Development Studies:** An explicit goal of the ITM is to develop cutting-edge research programs that stimulate research to support the creation of new products and services to benefit the public. The ITM will consider applications for projects that support the validation of the commercial potential of early, basic research discoveries; develop novel prototypes; advance the knowledge about the applicability of research findings to the treatment or diagnosis of human diseases; or enhance the value of potential intellectual property built around a technology.

HEALTHY CHICAGO 2025

Healthy Chicago 2025, launched on September 17, 2020, reflects the work of hundreds of community members and organizations to assess the current status of our communities and organizations and develop approaches to strengthen neighborhood vitality and system coordination**. All projects funded by the ITM Pilot Project Development Program must articulate how their research aligns with the themes and priorities of Healthy Chicago, directly impacts priority populations, and/or embodies its stated guiding principles.**

Healthy Chicago 2025 Vision: A city where all people and all communities have power, are free from oppression and are strengthened by equitable access to resources, environments and opportunities that promote optimal health and well-being.

Healthy Chicago 2025 Themes:

- Transform policies and processes to foster anti-racist, multicultural systems
- Strengthen community capacity and youth leadership
- Improve systems of care for populations most affected by inequities
- Further the health and vibrancy of neighborhoods

Healthy Chicago 2025 Priority Areas:

- Housing
- Food Access
- Environment
- Public Safety
- Neighborhood Planning and Development
- Health and Human Services
- Public Health Systems Organizations

Healthy Chicago 2025 Priority Populations, include:

- Black Chicagoans
- Latinx Chicagoans
- Low-income Chicagoans
- Communities disproportionately burdened by pollution
- Disinvested and gentrifying communities

As a partner of the CDPH and an institutional citizen of Chicago, the ITM seeks to align its activities and funding support with the goals of Healthy Chicago 2025 to promote optimal health and well-being. Pilot Research Projects should align with one of the following Healthy Chicago 2025 priority areas, and applicants should consider how their project will integrate Healthy Chicago 2025 guiding principles:

- We actively challenge and redress racist systems through our process and strategies.
- We highlight community strengths as we tell our stories.
- We recognize that trauma affects all individuals, communities, organizations, and systems, and we support resilience and healing.
- We consider who benefits and who is burdened by our proposed solutions.
- We promote equitable wealth building, affordability and belonging.
- We make sure that community members, including youth, have power in decision-making.

KEY DATES

Letters of Intent (LOI) Due	Friday, September 30, 2022, 11:59:59 PM
Review of LOIs	October, 2022
Applicant Invitations Issued	Tuesday November 1, 2022
Full Applications Due	Friday, April 21, 2023, 11:59:59 PM
Applications Reviewed	May - June, 2023
Award Start Date	July 1, 2023

ELIGIBILITY

Individuals at any ITM institution (University of Chicago, Rush, Loyola University Medical Center, NorthShore University Health System, Illinois Institute of Technology, and Advocate Health Care) who are eligible to be a principal investigator on a study with their local IRB are eligible to apply. Physician investigators who are not eligible to be principal investigators, post-doctoral fellows, trainees, residents and graduate students may collaborate with an eligible applicant as part of the study team, but may not apply individually.

The ITM strongly encourages diverse, multidisciplinary study teams from multiple ITM institutions that represent the broadest stakeholder involvement and that promote training of younger scientists, including those underrepresented in our research workforce.

APPLICATION PROCESS

Letter of Intent – DUE FRIDAY, September 30, 2022, 11:59:59 PM

Eligible individuals wishing to apply for the ITM Pilot Science Development Program must complete a short online LOI form, providing a brief description of the project and explaining its potential translational impact, how it is novel, innovative and/or multidisciplinary. Submissions must also include a list of all team members, mentors and advisors involved in the project. Submissions must be uploaded using the LOI Submission Portal (https://redcap.uchicago.edu/surveys/?s=AA7RP74KNT) before the deadline in order to be eligible for review.

Abstract Reviews – October, 2022

Eligible LOIs will be reviewed by the ITM Executive Committee, composed of ITM Principal Investigators/Directors, Cluster Leaders, and Leaders from ITM Affiliate Institutions. For a complete listing of ITM Leadership, please see the ITM website (https://chicagoitm.org/).

Abstracts will be considered for scientific merit, novelty or innovation, multidisciplinary nature, alignment with the Healthy Chicago 2025 goals, and potential impact on the improvement of human health and assigned a score. LOIs will be considered in ranked order. Up to ten (10) abstracts will be selected for invitation to apply. Invitations for applications will be e-mailed to applicants and announced on the ITM website and through the November 2022 ITM Newsletter.

For projects that are invited to apply, the ITM Executive Committee will provide recommendations to the applicants regarding potential areas of improvement that should be considered in preparing the application. Examples include:

- Does the study team have the right members to effectively execute the project?
- Suggestions for expert consultation which could enhance the scientific rigor of the project.
- Are there external (community, patient, industry) stakeholders who could benefit from the outcomes of this project, who might be involved in the project, and who should consequently be consulted in the development of the project?
- Are there ways that this project could better integrate the Healthy Chicago 2025 Guidelines?

No feedback will be provided to LOI submissions that are not invited to develop full applications.

Full Application Development and Submission – DUE FRIDAY, APRIL 21, 2023, 11:59:59 PM

Invited applicants must submit the following complete application by the deadline in order to be considered for review:

1. A brief project summary (no more than 500 words), written in non-scientific, lay language, and suitable for publication.
2. A 30-second to 2-minute illustrative video describing the project (Approach), what makes it novel/innovative (Innovation), how it aligns with Healthy Chicago 2025, how it has the potential to improve human health, and why it's important (Significance). This video should be suitable for viewing by a non-scientific, lay audience and should be in MPEG-4 (MP4) format or streaming over the Internet.
3. A one-page Specific Aims document, suitable for scientific peer review.
4. A six-page Research Plan document, including Significance, Innovation and Approach, suitable for scientific peer review. The research plan should include a clear list of milestones and deliverables, leading to completion of the project within one year.
5. NIH Biosketches of all team members. Please include an ORCID (https://orcid.org/) as well as a Commons ID on each biosketch.
6. A complete budget and justification (see budget notes, below).
7. Letters of support from any stakeholders
8. For projects that involve human subjects research, the following documentation must also be included in the application
    a. **While the protocol does not yet have to have IRB approval, the IRB application must have been submitted in AURA. Applicants must list "ISAP" as a reviewing committee in answering question 2.1.2 of your IRB application. The ITM pilot application must list the project's AURA-IRB number. For applications coming from outside the University of Chicago, a copy of the complete IRB application, including all documents, must be submitted.**
    b. A completed Protection of Human Subjects document, following the instructions in the NIH's Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan (http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf).
    c. List of Eligibility Criteria, including Age Limits
    d. Inclusion plans for Women and Minorities
    e. Inclusion of Individuals Across the Lifespan
    f. Recruitment and Retention Plan
    g. Study Timeline
    h. Targeted Enrollment Table or Inclusion Data Record
    i. Data and Safety Monitoring Plan
    j. Proof of Human Subjects Research and Good Clinical Practice training for all study personnel

    Projects that meet the NIH Definition of a Clinical Trial must also submit the following:

    k. Narrative Study Description
    l. Statement of the Primary Purpose of the Study
    m. Description of the Study Interventions
    n. Study Phase
    o. Description of the Intervention Model

p. Description of Study Masking/Blinding

q. Description of Study Allocation/Randomization

r. Description of Study Outcome Measures

s. Description of the Study's Statistical Power and Design

t. Description of the Study Subject Participation Duration

u. IND/IDE Paperwork or FDA Determination

v. Dissemination Plan

These items must be submitted as separate documents, even if the information is also contained in the protocol document.

Projects that are deemed by the IRB to be Exempt must provide a letter of exemption from the IRB, citing the exemption category.

PLEASE NOTE: All applications involving human subjects research must undergo a regulatory review prior to receiving an award. Applicants **must** have completed an IRB application by the time they submit their pilot application. Failure to provide the requested human subjects research documentation may result in your application being rejected from review. **It's also very important to note**, awards are federally funded and will **require** NCATS prior approval for all human subjects and animal studies. **Not submitting the requested documentation could delay the start of your award and shorten your award period**.

The entire application should be submitted as a PDF document, with no less than ½" margins, and in an Arial/Helvetica-type font of no less than 11 pt. size. Applications must be submitted through the ITM's pilot application portal (https://redcap.uchicago.edu/surveys/?s=JM8LKNR7JL) by the deadline in order to be eligible for review.

Budget Notes

With very few exceptions, budgets may not include requests for faculty salary. Please contact the ITM (contacts are listed below) with questions regarding this policy. Allowable costs include technologist or research staff salary, supplies, use of research cores, use of resources that require a fee for services within the Cores of the ITM (including use of a Clinical Research Center), costs for patient recruitment, and travel that is specifically required for project execution.

Project Development

This program's intention is to engage applicants in a collaborative project development process that results in the strongest application possible. This begins with the ITM Executive Committee providing suggestions for possible areas of improvement to the projects that are invited to apply (see **LOI Review**, above). The ITM will then facilitate the development process by helping applicants avail themselves of the various resources and cores that might improve their project execution. Examples of the facilitation/coordination that the ITM can provide include:

- Providing contact information for potential study team members that are suggested by the Executive Committee, and scheduling initial meetings.
- Scheduling workshops for the applicant team with scientific experts, biostatisticians, study operations/feasibility experts, recruitment experts, ethicists or research subject advocates to advise the applicant on ways to best improve the application.
- Setting up meetings with the potential stakeholders identified by the Executive Committee, to discuss the project and receive feedback/input.
- Providing training in science communications for a diversity of audiences, help with crafting a pitch, and assistance with creating the application video.

Note that all of these development resources are available to invited applicants but are **entirely voluntary**.

Applicants may choose to use any or all of these resources, but are not required to do so. Applicants must contact the Pilot Process Coordinator (see contacts, below) to request this assistance, or it will be assumed that it is not needed.

APPLICATION REVIEW

Applications will be reviewed using the following process:

1. Project summaries and videos will be distributed to the ITM's Community, Patient, and Industry advisory boards. Each group will be asked to assign priority scores (1 highest to 9 lowest) to applications in accordance with the following guidelines:
    a. Community Advisory Board and Patient Advisory Board:
        i. Engagement – Does the application provide a well-justified description of how the research team incorporates stakeholder involvement? Does the study include the right individuals (researchers, patients, clinicians, policy makers, and other healthcare system stakeholders) to ensure that the project will be carried out successfully? Does the application show evidence of active engagement among scientists, patients, community members and others throughout the entire research process (e.g., formulating questions, identifying outcomes, monitoring the study, disseminating, and implementing)? Is the frequency and level of patient and stakeholder involvement sufficient to support the study goals?
        ii. Healthy Chicago 2025 Alignment – Does this project clearly support one or more of the goals of the Healthy Chicago 2025 plan? How likely is this project to improve the Healthy Chicago 2025 indicators and ultimately improve the health and wellness of Chicagoans?
    b. Industry Advisory Board:
        i. Innovation – Does the application challenge and seek to shift current health practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the innovations proposed in the application broadly applicable? Is it likely that this project will lead to new diagnostics, therapeutics or change in clinical practice? Does this project have a high probability of commercialization or scale?
2. Complete applications will be reviewed by two scientific reviewers unconnected with the project. Reviewers will be asked to provide peer review and priority score (1 highest to 9 lowest) in accordance with the following guidelines.
    a. Significance – Is the project likely to exert a sustained, powerful influence in the improvement of human health? Does the project address an important problem or critical barrier? Is there a strong scientific premise for the project? How will the successful completion of the aims change the concepts, methods, technologies, treatments, services or preventative interventions that improve human wellness and health?
    b. Investigators – Are the members of the study team well suited to the project? Does the team contain sufficient expertise from all of the disciplines needed to successfully carry out the project?
    c. Approach – Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Applications that involve human subjects research will be reviewed by program officers at NCATS for

appropriateness of the Human Subjects Protection Plan.

The ITM Executive Committee, together with the external scientific reviewers and representatives of the ITM's advisory boards will meet to consider all applications and review materials and make final funding decisions.

Awards will be announced on the ITM website and through the ITM Newsletter by January 1, 2023.

AWARD CONDITIONS

- Awarded funds must be spent in accordance with the submitted budget. Rebudgeting of funds requires prior approval.
- Awards will start on July 1, 2023 and are for one year. **Projects must be completed within one year and no-cost extensions of awarded funds are not possible.** Study teams must submit written progress reports on milestones and deliverables every three months.
- Within 90 days of the project end date, awardees must submit a written final progress report and produce a video suitable for a lay audience that describes what took place during the project, what has been learned, how this new information can be applied to improve health, and what the next steps for this research might be. Again, assistance with video production is available from the ITM Communications Office.
- Awardees will be expected to present the results of their research at one or more ITM dissemination events during the year following completion of the award.
- All publications arising from the awarded project must cite the CTSA grant that funds the ITM and must promptly comply with the NIH's Public Access Policy. Information about citing the ITM grant can be found on the ITM website (https://chicagoitm.org/make-research-breakthroughs/), and information about the NIH's Public Access Policy can be found at http://publicaccess.nih.gov/index.htm.

RESUBMISSIONS/REAPPLICATIONS

Abstracts that are not invited to apply may be resubmitted annually. Full applications that are not awarded may not be resubmitted, but may be reconsidered for awarding in future funding cycles. It is hoped that this development process will result in more competitive pilot applications that may obtain funding from other sources, even if not awarded by the ITM.

CONTACTS

For questions, contact:

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