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:

- Foster the field of Translational Science by funding projects that strongly adhere to Translational Science Principles.
- Advance the goals of the Chicago Department of Public Health's *Healthy Chicago 2025* plan by funding projects that strongly align with its values and priority areas.
- Optimize research teams by connecting applicant researchers with a broad range of academic and community collaborators with diverse expertise and lived experience.
- 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

This process will lead to a competitive application for approximately three **one-year awards of $60,000** each. These pilot awards, set to start **January 1, 2025**, will:

- Advance translational science
- 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.

TRANSLATIONAL SCIENCE

Translational science is the field that generates innovations that overcome longstanding challenges along the translational research pipeline. These include scientific, operational, financial and administrative innovations that transform the way that research is done, making it faster, more efficient, and more impactful. The National Center for Advancing Translational Science (NCATS) defines translational science projects as those that exhibit one or more of the Translational Science Principles.

[Translational Science Principles | National Center for Advancing Translational Sciences (nih.gov)](#)

The ITM seeks to advance translational science at the same time it supports translational research through its pilot program. Pilot finalists are expected to explain how their research project advances the field of Translational Science through its alignment with one or more of the Translational Science Principles.

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. Applicants should download and familiarize themselves with the Healthy Chicago 2025 plan, linked below.

https://www.chicago.gov/content/dam/city/depts/cdph/statistics_and_reports/HC2025_917_FINAL.pdf

The goal of Healthy Chicago 2025 is to advance racial equity to close Chicago's life expectancy gap.

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.

Assessment Themes: Healthy Chicago 2025 will close Chicago's life expectancy gap by…

- Improving systems of care for populations most affected by inequities
- Furthering the health and vibrancy of neighborhoods
- Strengthening community capacity and youth leadership
- Transforming policies and processes to foster antiracist, multicultural systems

Assessment Priority Areas: Healthy Chicago 2025 will create change in…

- Housing
- Food Access
- Environment
- Public Safety
- Neighborhood Planning and Development
- Health and Human Services
- Public Health System Organization

As a partner of the CDPH and an institutional citizen of Chicago, the ITM seeks to use its activities and funding to support the Goal of Healthy Chicago 2025. Pilot applicants' Research Projects should be consistent with the Healthy Chicago 2025 Vision, address one or more of the Healthy Chicago 2025 Assessment Themes, and work to create change in one or more of the Healthy Chicago 2025 Assessment Priority Areas.

We strongly encourage everyone to submit applications, regardless of where their research falls on the translational spectrum. We believe that all health/medical research on the translational spectrum from the most basic T0 or T1 research to clinical research to implementation research <u>can</u> support the goal of Healthy Chicago 2025. We also believe that the goal and values expressed in Health Chicago 2025 are broadly applicable to the entire region served by ITM institutions and can reduce inequities in any community. We are challenging our applicants to conceive of their research and frame it in new ways.

KEY DATES

Letters of Intent (LOI) Due	Sunday, February 25, 2024, 11:59:59 PM
Review of LOIs	March, 2024
Applicant Invitations Issued	April 1, 2024
Full Applications Due	Sunday, September 15, 2024, 11:59:59 PM
Applications Reviewed	October – November, 2024
Pre-Award Notices	December 1, 2024
Award Start Date	January 1, 2025

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 SUNDAY, FEBRUARY 25, 2024, 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.

LOI Reviews – MARCH, 2024

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, 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 April 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 SUNDAY SEPTEMBER 29, 2024, 11:59:59 PM
Invited applicants must submit the following complete application by the deadline 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. This abstract will be reviewed and scored by non-scientific reviewers.

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. A description of how the research project furthers Translational Science by addressing one or more of the Translational Science Principles (2 page maximum).

6. A description of how the research project supports or aligns with the Vision of Healthy Chicago 2025, addresses one or more of the Healthy Chicago 2025 Assessment Themes, and works to create change in one or more of the Healthy Chicago 2025 Assessment Priority Areas whether within Chicago itself or in the broader Chicagoland region. (1 page maximum).

7. NIH Biosketches of all team members. Please include an ORCID (https://orcid.org/) as well as a Commons ID on each biosketch.

8. A complete budget and justification (see budget notes, below).

9. Letters of support from any stakeholders

10. 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 by the application deadline**. Applicants at UChicago must list "ISAP" as a reviewing committee in answering question 2.1.2 of the 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

    k. Projects that meet the [NIH Definition of a Clinical Trial](#) must also submit the following:

       i. Narrative Study Description

       ii. Statement of the Primary Purpose of the Study

       iii. Description of the Study Interventions

       iv. Study Phase

       v. Description of the Intervention Model

       vi. Description of Study Masking/Blinding

       vii. Description of Study Allocation/Randomization

       viii. Description of Study Outcome Measures

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

       x. Description of the Study Subject Participation Duration

       xi. IND/IDE Paperwork or FDA Determination

       xii. 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 these 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 at the contacts 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 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 in the following program areas by the groups listed below. Each program area will be assigned a priority score by that group of reviewers. **All scores will be considered in the selection of awardees.**

1. Scientific Merit: 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?

2. <u>Stakeholder Engagement</u>: 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, Responsiveness, and Feasibility – Does the project seem to address real problems or needs in your community? Do you think the people you know would care about this research project and want to know what was learned? Would you and the people you know want to participate in this research or collaborate with the study team? Does it seem like this study is realistic and able to be accomplished? Does it seem like the study team has worked with the right people in the community in developing this project?

    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?

3. <u>Alignment with ITM Priorities</u>: Applications will be reviewed by members of the ITM Leadership. Reviewers will be asked to provide peer review and priority score (1 highest to 9 lowest) in accordance with the following guidelines. **Note that deficient answers in this section could render an application unresponsive and disqualified from review.**

    a. Translational Science – To what extent does the project embody translational science principles? Will the project generate scientific, operational, financial, or administrative innovations that overcome longstanding challenges along the translational research pipeline? Will the project transform the way that research is done, making it faster, more efficient, and more impactful?

    b. Healthy Chicago 2025 Alignment – Does this project support or align with the Vision of Healthy Chicago 2025, address one or more of the Healthy Chicago 2025 Assessment Themes, and work to create change in one or more of the Healthy Chicago 2025 Assessment Priority Areas?

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, 2025.

AWARD CONDITIONS

- Awarded funds must be spent in accordance with the submitted budget. Rebudgeting of funds requires prior approval.

- Awards will start on January 1, 2025 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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