MICHR Clinical & Translational Science Pilot Award

Application Deadline: February 13, 2023

Purpose: The MICHR Clinical & Translational Science Pilot Award is designed to support new and innovative research projects relevant to clinical & translational science (CTS). CTS is a field of investigation focused on understanding a scientific or operational principle that underlies a step of the translational process, with the goal of developing generalizable principles to accelerate translational research. A key tenet of CTS is to understand common causes of inefficiency and failure in translational research projects (e.g., incorrect predictions of the toxicity or efficacy of new drugs, lack of data interoperability, lack of incentives for team science, non-optimal strategies for patient/community engagement). Projects are intended to: (1) explore possible innovative new leads or new directions for established investigators; (2) stimulate investigators from other areas to lend their expertise in research in CTS; and (3) provide initial support to establish proof of concept. Projects must be feasible within the proposed timeframe, have high methodological and scientific quality, and answer important scientific questions. Clinical and translational research (CTR) projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, are not allowed.

Using an example from NIH-National Center for Advancing Translational Science (NCATS) to illustrate the difference between CTR and CTS, consider the following: An investigator testing the effect of a specific drug on outcomes in diabetes will need to recruit sufficient underserved participants; this is a CTR problem that will explore the effects of a drug in the diabetes community using established recruitment methods. In contrast, an investigator interested in understanding fundamental barriers to recruitment for clinical trials may test an intervention directed at those hypothesized causes – this is a CTS study. To test the hypothesis, the CTS investigator may choose a use case that mirrors the one used by the CTR researcher – a drug for diabetes – but the question to be answered is whether the intervention more effectively and efficiently accomplishes recruitment of the underserved population.

Examples of activities that may be funded under this FOA include:

• Development of new research methodology and/or new technologies/tools/resources that will advance CTS and thus increase the efficiency and effectiveness of translation
• Early-stage development of new therapy/technology with generalizable application to an identified translational roadblock
• Demonstration in a particular use case(s) that the new methodology or technology advances translational science by successfully making one or more steps of the translational process more effective or efficient
• Dissemination of effective tools, methods, processes, and training paradigms
• Feasibility/proof of concept studies to support future CTS projects
• Secondary analysis of existing data (e.g., projects using the National COVID Cohort Collaborative (N3C) Data Enclave)

To learn more about CTS, please visit the [NIH-NCATS Translational Science Resources page](#).
Funding: Each award will provide $50,000 (no cost share) in funding for one year (extensions will not be allowed), which is contingent upon MICHR receiving its NIH Clinical and Translational Science Award Notice of Award by April 1, 2023. The earliest anticipated funding start date is April 1, 2023, and is subject to change based on MICHR’s Notice of Award and NIH approval of human subjects/vertebrate animal-related research (see Timeline below).

Eligibility: Faculty members with primary appointments at the University of Michigan are eligible to serve as Principal Investigators (PIs). Staff, faculty from regional institutions, M-M affiliate physicians, community partners and patient advisors are eligible to serve as Co-PIs. KL2 scholars whose KL2 funding is active during the pilot project period are not eligible to apply.

Restrictions: This mechanism is not intended to support CTR projects and large projects by established investigators that would otherwise be submitted as separate research grant applications. Applicants are limited to one grant submission per round. No more than two separate MICHR pilot grants (≥ $25K allowable budget per FOA) can be held by one Principal Investigator during a 5-year period; budgeting below $25K for submission cannot be used to obviate this restriction. Principal Investigators cannot have multiple proposals active at the same time. NIH policy prevents us from funding research conducted outside of the United States. Any restrictions noted in MICHR’s Notice of Award will be communicated as soon as possible following receipt.

Awardee Responsibilities: All funds must be spent within the budget period (anticipated to be one year, subject to change based on MICHR’s Notice of Award and NIH human subjects/vertebrate animal approvals). Applicants are required to provide progress reports upon request as well as respond to brief surveys on a yearly basis once funds are expended. Awardees must also adhere to any tailored plans of support/timelines that MICHR develops for the project; examples include consultations with specific MICHR programs, trainings, dissemination opportunities, among others, as beneficial to advancing the proposed study.

Grant Development and Submission: Applicants should prepare their applications using the guidelines on page 3. Applicants will use the U-M Medical Schools’ Competition Space, and the forms provided on the site, to submit their applications.

Timeline: If your application is deemed fundable following scientific review, and it proposes human subjects or vertebrate animals, it must proceed to a second level of review by NIH-NCATS before funds can be released. You will be required to submit human subjects documentation and IRB approval and/or vertebrate animals documentation and IACUC approval to MICHR by April 17th. If materials are not sent to MICHR by this deadline, MICHR reserves the right to deny funding.

MICHR Resources to Support Investigators: MICHR is available to support investigators both pre- and post-award, and we encourage you to partner with us on the development and implementation of your pilot award and the dissemination of your results. If you have questions about whether your project is an appropriate fit for this FOA, or you want to learn more about MICHR support services for your pilot grant, please contact the MICHR Pilot Grant Program.
Application Guidelines

1. **Face Page**: Include an abstract in the space provided.

2. **Research Plan**: A maximum THREE-page, single-spaced document (Arial 11, minimum of 0.5-inch margins) describing the project concisely and completely. Use the following overall format and note the suggested page limits.
   - **Background and Significance** (0.5 pages): Describe 1) the significance of the CTS problem/roadblock being addressed, which should be supported by the most up-to-date science in the field, 2) the proposed hypothesis, and 3) how successful completion of the project is expected to address the CTS problem/roadblock.
   - **Innovation** (0.25 pages): Explain 1) how the application challenges and seeks to shift current research or clinical practice paradigms and 2) how the Principal Investigator and/or research team is uniquely positioned to support the advancement of CTS.
   - **Approach** (2 pages): Include 1) preliminary data (not required); supporting data from the literature can be used if available, 2) study design, data collection and data analysis methods, 3) description of the study population (as applicable), 4) expected results and alternative approaches to potential problems, and 5) project timeline.
   - **Generalizable Knowledge and Dissemination Plans** (0.25 pages): Describe 1) how the expected outcomes will produce generalizable knowledge shared among diseases and translational processes that, when implemented, will accelerate translation and 2) how you will disseminate results to ensure this generalizable knowledge is widely available.

3. **References**: No page limit.

4. **Biographical Sketch**: Include an NIH-style biosketch for each investigator with the role of Principal Investigator, Co-Principal Investigator, and Co-Investigator. A template can be found in Competition Space.

5. **Budget and Justification**: A template can be found in Competition Space.
   - Applicants can request any amount up to $50,000 (no cost share); all items and personnel must be fully justified.
   - Principal Investigators must devote a minimum of 5% effort to the project (charged to the pilot grant or concurrent with their U-M faculty position).
   - Faculty salaries are allowable on the budget but cannot exceed 10% for Principal Investigators (Co-PIs limited to 10% combined). Salary requests must adhere to the PHS salary cap [https://grants.nih.gov/grants/policy/salcap_summary.htm](https://grants.nih.gov/grants/policy/salcap_summary.htm).
   - Include all personnel in the justification, regardless of whether salary support is requested. Provide a clear explanation for all personnel by position, the role they will play on the project, and the level of effort (if applicable). In most cases, positions labeled "TBD" will not be accepted.
   - Individuals who commit to contribute to the scientific development or execution of the project, but do not commit any specified measurable effort (i.e., person months) to the project, should be designated as Other Significant Contributor.
   - Unallowable items include subcontracts with associated facilities & administrative costs, administrative/clerical staff expenses, postage, telephones, memberships, hosting, equipment, cost overruns, retroactive funding, grant preparation costs, graduate student stipends and tuition costs, salary support for Fellows already funded by the Accreditation Council for Graduate Medical Education program, travel unrelated to the conduct of the research (e.g. conferences), renovations, office supplies, and computers. This list may not be comprehensive, and the MICHR Pilot Grant Program reserves the right to deem costs unallowable.
6. **Signature Page**: Use the form in Competition Space. Sign-off by the academic unit is required for the Principal Investigator and Co-Principal Investigator(s) to indicate agreement of the application budget and faculty effort. Sign-off is also required for the following scenarios:
   - All faculty effort regardless of role. Designating a Co-Investigator at zero person months effort should not be used to circumvent academic unit sign-off. Individuals who commit to contribute to the scientific development or execution of the project, but do not commit any specified measurable effort (i.e., person months) to the project, should be designated as Other Significant Contributor.

7. **Letters of Support**: Collaborators with a significant role on the project should provide a letter of support for their participation. Letters are not required for Co-Investigators. Letters must be submitted for any effort that is not charged to the pilot grant budget.

8. **Current/Pending Support**: Include current and pending support for all key personnel. Please follow the NIH format. A sample can be found in Competition Space.

*Items 2-8 must be combined into one PDF.*

**Review Process**: Reviewers will score each application on 1) significance, 2) innovation, 3) investigator(s), 4) approach, 5) likelihood the result(s) will broadly impact translational research and 6) overall impact. All applications will be reviewed by faculty and community/patient representatives.