MICHR TRANSLATIONAL SCIENCE AWARD
Investigator-Initiated Research Approach
Eligibility Requirements, Application Guidelines, and Review Criteria

Definition of Investigator-Initiated Research: Research that is planned, conducted, and led by an academic investigator or team of investigators. Projects can be at any stage of the translational spectrum.

AWARD INFORMATION:
Duration: One year
Budget: MICHR will provide a maximum of $25,000. A minimum 1:1 match is required and may be secured from a single source or multiple sources, including your U-M department, unit or other institutional entities, such as NIH-funded institutes and centers. If you are applying from a unit of the Endowment for Basic Sciences, see page 4.

Eligibility: All active University of Michigan faculty are eligible to apply as Principal Investigator. For more information about faculty eligibility, see page 4.

Restrictions: You are limited to one grant submission per round. No more than two separate pilot grants (>25K) can be held by one Principle Investigator during a 5-year period. Multiple proposals (>25K) cannot be active at the same time. The MICHR Pilot Grant Program cannot accept applications proposing research conducted abroad because NIH-National Center for Advancing Translational Sciences (NCATS) will not provide prior approval for such pilot grants. In addition, NIH-NCATS only permits funding of clinical trials through the end of Phase IIA, with the exception of certain activities involving treatment of a rare disease or condition. For questions, contact the Pilot Grant Program.

Resubmissions: A maximum of 2 resubmissions are allowed (i.e. A1 and A2).

Timelines: If your application is deemed fundable by the MICHR Scientific Review Committee, and it proposes human subjects or vertebrate animal research, it must proceed to a second level of review by NIH-NCATS. NIH-NCATS approval must be obtained before funds are released. From the time you are notified of your fundable score by the Pilot Grant Program, you will have four months to submit your protocol to the IRB or IACUC and six months to obtain approval. If approval is not obtained within this timeframe, the Pilot Grant Program reserves the right to deny funding.

APPLICATION DEADLINE: Tuesday, February 13, 2018 at 5:00pm

APPLICATION SUBMISSION:
Submit applications in UMMS Competition Space. Use provided forms and templates when applicable.

APPLICATION COMPONENTS:
Face Page and Project Summary: Complete using form in Competition Space. The project summary (250-word maximum) should be written using language that can be understood by a non-scientific audience.

Other Support: Include for all investigators with the titles Principal Investigator, Co-Principal Investigator, or Co-Investigator. Use current NIH template in Competition Space.
Application: Use template(s) provided in Competition Space and combine into one PDF for submission.

Format specifications: Arial, size 11, single-spaced, and ½-inch margins.


2. Proposal Narrative (page limits and suggested section lengths below, template in Competition Space)

   A. Specific Aims (1-page limit): Concisely and realistically describe the goals of the proposed research, the specific objectives and hypotheses to be tested, the expected outcomes, the expected impact on the field, and the potential for improving patient and/or community health.

   *6-page limit for sections B-H*

   B. Background and Significance* (~0.5 pages, follow NIH criteria):
   - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
   - Describe the scientific premise for the proposed project, including the strengths and weaknesses of published research or preliminary data crucial to support your application.
   - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
   - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive the field will be changed if the proposed aims are achieved.

   C. Innovation* (~0.5 pages, follow NIH criteria):
   - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
   - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
   - Explain any refinements, improvements, or new applications of theoretical concepts, approaches, methodologies, instrumentation, or interventions.

   D. Previous Related Work* (~0.5 pages):
   - Describe how the investigators have already contributed to the proposed project or related projects (include preliminary data, if available), the expertise the investigators bring to the project, and evidence of the feasibility to accomplish the proposed aims.
   - Preliminary data are not required when submitting an application. However, an explanation for the absence of preliminary data is helpful to the reviewers.

   E. Approach* (~3.5 pages, follow NIH criteria):
   - Provide an overview of the experimental design.
   - Describe the methods and analyses to be used to accomplish the aims of the project.
   - Discuss potential difficulties and limitations and how these will be overcome or mitigated.
   - Describe expected results and any alternative approaches that will be used if unexpected results are found.

   F. Timeline* (~0.25 pages): Describe plans for dissemination and when key research activities, including milestones that will be used to assess progress, will be accomplished during the award year.

   G. Impact Statement and Future Plan* (~0.5 pages): Describe the goal(s) of the specific research proposed and the broad, long-term objectives.
H. Statement of Future Impact on Patient Care and/or the Community* (0.25 pages): Describe how this research will impact patient care and/or the community in the future.

Additional Proposal Narrative Components (not included in 6-page limit for B-H):
I. Animal Model (if applicable; no page limit):
   • Provide reasoning of how the study will lead to “next step” research in humans. The research “next step” is the transition from the pre-clinical model to humans.
   • Studies are eligible for pilot grant funding when the animal model has already been validated as a predictor of how human disease will respond and the pathway toward humans is clearly evident as the next logical step.
   • Studies are not eligible if the animal model has not yet been validated; if a significant amount of work will be required to determine if the animal model would serve as a predictive model for human disease; and/or if human studies are not evident as the next logical step following completion of the proposed pilot grant research.
   • If your application receives a fundable score, you will be required to provide additional vertebrate animal information and approvals.

J. Human Subjects (if applicable; no page limit):
   • Follow the NIH guidelines. Note that you must adhere to the updated instructions associated with FORMS-E):
     1. Protection of Human Subjects
     2. Inclusion of Women, Minorities and Children
     3. Recruitment and Retention Plan
     4. Planned Enrollment Table
   • If your application receives a fundable score, you will be required to provide additional human subjects documentation and IRB approval.
   • Applicants proposing to recruit participants are encouraged to meet with MICHR’s Participant Recruitment Program prior to submission. Awardees proposing to recruit participants will be required to meet with MICHR’s Participant Recruitment Program before funding is released.

K. Mentoring Plan (0.5-page limit; required for Early Career faculty only, see page 4): Describe the mentoring plan, which must include one or more experienced clinical, translational, or community-engaged research investigators. Include information about your mentor(s) and the purpose and goals of the mentoring relationship.

L. New Research Direction (0.5-page limit; required for Established faculty only, see page 4): Provide a clear explanation of how the current proposal is a new direction in the research program of the Principal Investigator.

M. References (no page limit)

3. Budget and Justification: Complete using form provided in Competition Space.
   • Budget and justification must reflect the total budget (MICHR and matching).
   • The Principal Investigator must devote a minimum of 5% effort to the project (in-kind or charged to the project).
   • Faculty salaries are allowable on the budget but cannot exceed 10% for Principal Investigators. For Co-Principal Investigators, the combined effort charged to the grant cannot exceed 10%. Salary requests must adhere to the PHS salary cap.
   • 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.
• **Unallowable budget items:** Subcontracts with associated facilities & administrative costs, 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. If you believe a cost listed above is necessary for the conduct of your research and should be allowed, preapproval must be secured. In most cases, exceptions are not approved.

4. **Biographical Sketches:** Include a current [NIH-style biosketch](#) for each investigator with the role of Principal Investigator, Co-Principal Investigator, and Co-Investigator.

5. **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. It is strongly encouraged that a letter of support is provided for any in-kind support included in the application.

6. **Signature Page:** Use form in Competition Space. Sign-off by the department, school, or center is required for the Principal Investigator and Co-Principal Investigator(s) to indicate agreement of the application budget, faculty effort, and cost-sharing arrangement. Sign-off is also required for the following scenarios:
   - All faculty effort, regardless of role.
   - All matching/cost-share sources (e.g. multiple departments, center, or other institutional entity).
   Note: When the number of applications receiving meritorious scores from the Scientific Review Committee exceeds the available cost-share dollars from a department, the department will have the final approval of which proposals will be funded.

7. **Appendix** (20-page limit): Follow NIH guidelines. Do not use the appendix to circumvent application page limits.

**OTHER INFORMATION:**

MICHR Pilot Grant Program Definitions of Early Career and Established Investigators:

**Early Career Investigator** is defined as a faculty member with an appointment at the level of Assistant Professor (or the equivalent) and below, and includes: Lecturer, Instructor, Clinical Instructor, Research Investigator, Assistant Professor, Clinical Assistant Professor, Research Assistant Professor, or Assistant Research Scientist.

**Established Investigator** is defined as a faculty member with an appointment above the level of Assistant Professor (or the equivalent), and includes: Associate Professor, Clinical Associate Professor, Research Associate Professor, Associate Research Scientist, Professor, Clinical Professor, Research Professor, or Research Scientist.

**Endowment for Basic Sciences:**
The [Endowment for Basic Sciences](#) and MICHR have partnered to fund T1 research that aims to foster the translation of innovative discoveries in molecular-, cell-, or animal-based models or in the creation of novel technology platforms that have direct clinical potential for altering our understanding or management of human disease. For consideration of funding, collaboration between a basic scientist from an EBS unit and a clinical investigator holding an appointment in a department/unit/center outside EBS is required. Participating EBS units can be found [here](#).
APPLICATION REVIEW INFORMATION:
The MICHRR Pilot Grant Program requires all applicants to adhere to the eligibility requirements and application guidelines in order to promote a process whereby submitted grant applications are evaluated on the basis of a process that is fair, equitable, timely, and free of bias. The Scientific Review Committee will determine whether your proposal meets the goals of the Pilot Grant Program and will evaluate your proposal for evidence of quality, accountability, and soundness of design. The core values of peer review drive MICHRR to seek the highest level of ethical standards. The following main points will be considered:

1. **Significance:** Is there high potential for this project to address a significant health care challenge and advance mechanistic, diagnostic and/or therapeutic understanding of a clinical problem? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. **Investigators:** Are the Principle Investigators, Co-Investigators, Collaborators, and other researchers well suited to the project? If Early Stage Investigators (see page 4), do they have the appropriate experience and training, and is a mentoring plan with an experienced investigator outlined? If the Principle Investigator is an Established Investigator (see page 4), is the proposed work a departure from prior research? If there is more than one investigator, do they have complementary and integrated expertise, and is their leadership approach, governance, and organizational structure appropriate for the project?

3. **Innovation:** Is there potential for this project to develop novel concepts, approaches, methodologies, tools, technologies, instrumentation, or interventions in the relevant field(s)? Are these aspects novel to one field of research or novel in a broad sense?

4. **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? For research not directly involving humans, have they clearly described how the next step in the overall research program will be translated into human-based or clinical research?

5. **Environment:** Will the scientific environment contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Are the proposed budget and available resources fully justified and adequate to complete the work in the proposed time period?

6. **Program:** Does the application meet the objectives of the Investigator-Initiated Research guidelines (see page 1) and goals of the Pilot Grant Program? Including, but not limited to:
   - To assist early career investigators by providing funding support that will enable them to establish a clinical and translational research path.
   - To assist basic science investigators to move their research into the translational arena.

7. **Translation:** Is there a clear and viable plan for disseminating research findings? Is it clear how the research will turn observations made in the laboratory, clinic, or community into interventions to improve health?

8. **Patient/Community Consideration:** Does the applicant clearly describe how the proposed research will impact patients and/or the community in the future?
Additional considerations:
- Has the potential overlap with other projects been adequately addressed?
- Did the applicant consider biostatistics in the proposal? We encourage you to confer with a biostatistician as you develop your proposed study.

When applicable, proposals are reviewed by a patient advisor or community member.

The Scientific Review Committee scores applications using the NIH 1-9 point scale:

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<tr>
<th>Score</th>
<th>Guidance on Strengths and Weaknesses</th>
<th>Descriptor</th>
<th>Impact</th>
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<tr>
<td>1</td>
<td>Exceptionally strong with essentially no weaknesses</td>
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<td>Outstanding</td>
<td>Medium</td>
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<tr>
<td>3</td>
<td>Very strong with only some minor weaknesses</td>
<td>Excellent</td>
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<td>4</td>
<td>Strong but with numerous minor weaknesses</td>
<td>Very Good</td>
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<td>5</td>
<td>Strong but with at least one moderate weakness</td>
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<td>6</td>
<td>Some strengths but also some moderate weaknesses</td>
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<td>9</td>
<td>Very few strengths and numerous major weaknesses</td>
<td>Poor</td>
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CONTACT:
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