MICHR Pathway to First Grant 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 academic unit. If you are applying from a unit of the Endowment for Basic Sciences, see page 5.

**Eligibility:** All active University of Michigan faculty who have not served as Principal Investigator on an extramural grant are eligible to apply as Principal Investigator.

**Restrictions:** You are limited to one grant submission per round. No more than two separate MICHR pilot grants (> $25K) can be held by one Principal 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 IIB, 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.

**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 MICHR notifies you of your fundable score, you will have six months to obtain IRB/IACUC approval (protocols must be submitted within four months). If approval is not obtained within this timeframe, the Pilot Grant Program reserves the right to deny funding.

**Contact:** For questions about this funding opportunity, contact MICHR-PilotGrants@umich.edu. For assistance developing your project, request a consultation with the MICHR Research Development Core.

**APPLICATION DEADLINE:** Monday, April 15, 2019 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 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.

1. Rebuttal (resubmissions only; 1-page limit, template in Competition Space): Required for resubmissions.

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.

   "Combined 5-page limit for sections B-I"

   B. Background and Significance* (~0.5 pages, modeled after 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* (~0.25 pages, modeled after 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* (~2.75 pages, modeled after 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 alternative approaches that will be used if unexpected results are found.
F. Impact* (~0.25 pages):
   - Describe the immediate impact of the proposed research.
   - Explain how the research will impact patient care and/or the community in the future.

G. Timeline and Milestones of Success* (~0.25 pages):
   - Describe when key research activities will be accomplished, and milestones of progress assessed, during the award year. Use a table format as needed.

H. Career Plan* (or Research Successes* or New Research Direction*) (~0.25 pages):
   - Early Career Investigators (see designations on page 5): Describe the mentoring plan, which must include at least one clinical, translational or community-engaged faculty. Include information about the mentor(s) and the purpose and goals of the mentoring relationship specific to both your research and career development. As applicable, describe training activities (eg, didactic, professional, etc.) that support your scientific development.
   - Established Investigators (see designations on page 5): Describe your research successes and challenges to date.
   - Faculty seeking their first extramural grant in a new area of research: Explain how the proposed research is a significant departure from previous efforts. If you are also an Early Career Investigator, address the career plan requirements.

I. Future Funding and Research Program* (~0.25 pages):
   - Identify the extramural grant (eg, K, R21, specific foundation, etc) you intend to apply for in the future and explain how this funding, and completion of the proposed project, will help you to submit a competitive extramural application.
   - Describe the vision for your future research program, including long-term goals, and how your experience to date and MICHR funding will support your success.

Additional Proposal Narrative Components (not included in 5-page limit for B-I):

J. 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.

K. Human Subjects (if applicable; no page limit):
   - Follow the NIH guidelines for completing the following sections.
     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.

L. **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 (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. 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.
   - 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.
   - If mentors charge effort to the pilot grant, their roles beyond mentoring need to be well justified.
   - **Unallowable budget items:** 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. 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. **Letters must be submitted for any effort that is not charged to the pilot grant budget.**

6. **Signature Page:** Use 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, faculty effort, and cost-sharing arrangement. 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.
   - All matching/cost-share sources (e.g. multiple departments).
   - 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 page limits.
Endowment for Basic Sciences:
The Endowment for Basic Sciences and MICHRI 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.

MICHRI Pilot Grant Program Definitions of Early Career and Established Investigators:
**Early Career Investigator:** Assistant Professor, Lecturer, Instructor, Clinical Instructor, Research Investigator, Clinical Assistant Professor, Research Assistant Professor, or Assistant Research Scientist.

**Established Investigator:** Associate Professor, Clinical Associate Professor, Research Associate Professor, Associate Research Scientist, Professor, Clinical Professor, Research Professor, or Research Scientist.
APPLICATION REVIEW INFORMATION:

The MICHR Pilot Grant Program requires applicants adhere to eligibility requirements and guidelines to promote a process whereby submitted grants are evaluated using a process that is fair, equitable, timely, and free of bias. The core values of peer review drive MICHR to seek the highest level of ethical standards. The Scientific Review Committee scores applications using the NIH 1-9 point scale and, when applicable, proposals are reviewed by a patient advisor of community member. These 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 Principal Investigators, Co-Investigators, Collaborators, and other researchers well suited to the project? If seeking their first extramural grant, do they have the appropriate experience and training, and is a career plan with an experienced mentor outlined? If seeking their first extramural grant in a new area of research, is the proposed work fully justified as a departure from their prior research? If more than one investigator, do they have complementary and integrated expertise?

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 studies not directly involving humans, have they clearly described how the results will be translated into human studies as a next step?

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. **Funding Goals:** If the study goals are attained, will the investigator be positioned to submit a competitive extramural grant?

7. **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.