

TRANSLATIONAL SCIENCE AWARD **Collaborative Research Approach**

This document contains eligibility requirements and application guidelines specific to projects utilizing a Collaborative Research approach. MICHR defines Collaborative Research as an approach that involves the participation of partners (e.g. patients, families, clinicians, community members, community-based organizations) in some aspects of the research process. Applicants using this approach can involve partners to varying degrees throughout the project. For example, some projects may involve partners in study design, planning, and implementation, whereas other projects may involve partners primarily in developing recruitment or dissemination strategies. Applications need to clearly describe the aspects of the project that will involve partners and explain how their input will be included.

AWARD INFORMATION

- Duration:** 1 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. If you are applying from one of the participating units of the Endowment for Basic Sciences, please see page 4 for more information.
- Eligibility:** All active University of Michigan faculty are eligible to apply as Principal Investigator (PI). All community partners who are affiliated with a non-academic organization (e.g. nonprofit, government health agency, federally qualified health center) are eligible to serve as Co-PI. Partners who do not have an organizational affiliation may serve as collaborators, consultants, mentors, and other prominent roles in conducting the project. Although it is not required, academic investigators are encouraged to consider including partners as members of the research team. For more information on how the PGP defines Senior and Early Career faculty, see page 4.
- Restrictions:** Applicants may submit a maximum of one application per round. No more than two separate pilot grants (>\$25K) may be held by one PI during a 5 year period. Multiple proposals (>\$25K) cannot be active at the same time. For questions about eligibility, please contact the [PGP administrator](#).
- Resubmissions:** A maximum of 2 resubmissions are allowed (i.e. A1 and A2).

ROUND 21 TIMELINE:

- Competition Opens:** July 18, 2016
- Applications Due:** **Monday, September 12, 2016 at 11:59pm**
- Outcome Notifications:** ~late November, 2016
- Anticipated Start Date:** January 1, 2017

APPLICATION SUBMISSION

Applications must be submitted in [UMMS Competition Space \(CS\)](#). Please use provided forms and templates when applicable.

APPLICATION COMPONENTS

Face Page and Project Summary: complete using form in CS. The project summary (500 word maximum) should be written using language that can be understood by a non-scientific audience.

Other Support: include for all investigators with the title Principal Investigator, Co-Principal Investigator, or Co-Investigator. Use current NIH format form in CS.

Application: use template(s) provided in CS and combine into one PDF for submission. **Format specifications: Arial, size 11, single-spaced and ½-inch margins.**

1. Rebuttal (1 page maximum, template included in CS): required for resubmissions.
2. Proposal Narrative (page limitations and suggested section lengths are listed below, template included in CS).
 - A. Specific Aims (1 page limit): Describe concisely and realistically the goals of the proposed research and the expected outcome(s), including the impact of the proposed research. Indicate the specific objectives and hypotheses to be tested, a summary of the expected outcomes, and a description of the impact on the field and the potential for improving 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 consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
 - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice and/or community-based intervention 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 of 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, or methodologies, instrumentation, or interventions.
- D. Previous Related Work* (~0.5 pages):
 - Describe how the investigators and partners have already contributed to the proposed project or related project (include preliminary data, if available), the expertise the investigators and partners bring to the projects, 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.
 - Describe the specific aspects of the project that will include collaboration with partners and how partners will be engaged.
 - Discuss potential difficulties and limitations and how these will be overcome or mitigated.
 - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
 - 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 will be accomplished during the award year, including plans for sharing the findings with the partners and participants involved.
- 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 Review Criteria (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 as a “next step” to clinical or translational research in humans. The research “next step” is to take the findings 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 and a significant amount of work will be required to determine if the animal model would serve as a predictive model for human disease.
- J. Human Subjects (if applicable; no page limit):
 - Follow the [NIH guidelines](#):
 1. Protection of Human Subjects
 2. Inclusion of Women and Minorities
 3. Planned Enrollment/Recruitment and Retention Plan
 4. Inclusion of Children
 - **If application is awarded, further documentation will be required to be submitted for NCATS review. For more information, click [here](#).**
- K. Mentoring Plan (0.5 page limit; required for Early Career faculty only): describe the mentoring plan with one or more established clinical, translational, or community-engaged research investigators. Include information about your mentor(s), the particular purpose of the mentoring relationship, and the goals of the mentoring relationship.
- L. New Research Direction (0.5 page limit; required for Senior faculty only): provide a clear explanation of how the current proposal is a new direction in the research of the Principal Investigator.
- M. References (no page limit)

Budget and Justification: complete using form provided in CS.

- Budget and justification must reflect the total budget (MICHR and matching).
- Budget should reflect fair and appropriate compensation for time and involvement of partners on the project.
- The Principal Investigator must devote a minimum of 5% effort to the project (in-kind or charged to project).
- Faculty salaries are allowable on the budget. No salary can exceed 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 items: equipment, cost overruns, retroactive funding, publications, grant preparation costs, graduate student stipends and tuition costs, salary support for Fellows already funded by ACGME program, travel unrelated to the conduct of the research (e.g. conferences), renovations, office supplies, or 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.

Biographical Sketches: include a current [NIH-style biosketch](#) for each investigator with the role of Principal Investigator, Co-Principal Investigator, or Co-Investigator. Partners who are not affiliated with U-M and/or do not have a research background may provide a current resume or curriculum vitae in place of an NIH-style biosketch.

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. For the collaborative research approach, applicants are required to provide a letter of support from each partner and/or community organization involved.

Signature Page: use form provided in CS. Sign-off by the U-M 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.

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

OTHER INFORMATION

PGP Definition of Early Career and Senior Faculty:

Early Career faculty 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.

Senior faculty 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 \(EBS\)](#) 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 and/or management of human disease. This grant mechanism provides funding for promising ideas to identify novel diagnostic or therapeutic targets that may otherwise encounter roadblocks in the translation from bench-to-bedside applicability. **To be eligible for matching from EBS, the Principal Investigator's primary faculty appointment MUST be in one of the participating units in the Endowment for Basic Sciences (EBS). The participating units can be found [here](#).**

APPLICATION REVIEW INFORMATION

The MICHR 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.

In addition to determining whether a proposal meets the goals of the Pilot Grant Program, the Scientific Review Committee will evaluate it for evidence of quality, accountability, and soundness of design. The core values of peer review drive MICHR to seek the highest level of ethical standards. The following main points will be considered:

1. **Significance:** The 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? Please describe the strengths and weaknesses.
2. **Investigators:** Are the PIs, co-investigators, collaborators, partners, and other researchers well suited to the project? If Early Stage Investigators, do they have the appropriate experience and training, and is a mentoring program with an established investigator outlined? If the PI is a Senior Investigator (Associate Prof. and above), has it been clearly demonstrated that the proposed work is a departure from prior research? If the project is collaborative, do the investigators have complementary and integrated expertise; is their leadership approach, governance and organizational structure appropriate for the project? Please describe the strengths and weaknesses.
3. **Innovation:** The potential for this project to develop novel concepts, approaches, methodologies, tools or technologies in the field(s). Are the concepts, approaches, methodologies, instrumentation, or interventions novel to one field of research novel in a broad sense? Please describe the strengths and weaknesses.
4. **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Does the project engage partners in some aspect of the research process, and are those clearly described? Are potential problems, alternative strategies, and benchmarks for success presented? For research not directly involving humans, has the PI clearly described how the next step in the overall research program will be translated into human-based, clinical research? Please describe the strengths and weaknesses.
5. **Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Is there evidence of support from partners involved in the project through letters of support? 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? Does the budget include adequate compensation for time and involvement of partners? Please describe the strengths and weaknesses.
6. **Program:** Overall, does the application meet the objectives of the specific requirements for the Collaborative Research approach and the 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 & translational research path. Or, to assist established basic science investigators to move their research into the translational research arena.
 - To drive translation of scientific concepts from the benches of basic scientists to clinical investigators and from the bedside to community practice.
 - To stimulate research that addresses community-identified health priorities.
 - To positively impact clinical and community health outcomes.

7. **Translation:** Is there a clear and viable plan for dissemination of research findings? Does the plan describe how findings will be shared with the partners and participants involved? What is the likelihood the project will lead to sustained efforts to apply research findings in clinical or community-based settings and/or funding to support future collaborative projects?
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?
- Consideration to Biostatistics will be an important component of successful proposals. Investigators are encouraged to confer with a biostatistician as the proposed study is being developed.

Please note that when applicable, proposals are reviewed by a patient advisor or community member.

The Scientific Review Committee scores applications using the 1-9 point scale used by the NIH.

Score	Guidance on Strengths/Weaknesses	Descriptor	Impact
1	Exceptionally strong with essentially no weaknesses	Exceptional	High
2	Extremely strong with negligible weaknesses	Outstanding	
3	Very strong with only some minor weaknesses	Excellent	
4	Strong but with numerous minor weaknesses	Very Good	Medium
5	Strong but with at least one moderate weakness	Good	
6	Some strengths but also some moderate weaknesses	Satisfactory	
7	Some strengths but with at least one major weakness	Fair	Low
8	A few strengths and a few major weaknesses	Marginal	
9	Very few strengths and numerous major weaknesses	Poor	

CONTACT:

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<http://www.michr.umich.edu/rdc/2016/4/15/translational-science-award>