PILOT GRANT PROGRAM

Seed Grant
(Up to $5,000)

Application Cycle: Continual Basis

MICHR Pilot Grant Program
http://www.michr.umich.edu/funding/pilotgrant

UMMS Competition Space
https://umms.infoready4.com/
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Part 1. Overview Information

The Michigan Institute for Clinical & Health Research (MICHR) is here to enable clinical & translational research at the University of Michigan. Our vision is to be a catalytic partner for clinical and translational researchers at the university, resulting in improved health for local, national and global communities.

MICHR’s Pilot Grant Program (PGP) provides funding to assist early career, basic, clinical and social scientists for bench-to-bedside and bedside-to-practice translational research. The goal is to promote development of novel solutions that will ultimately improve patient and community health outcomes. In addition to clinical and translational research, we welcome proposals for studies on health services, health outcomes, and health policy that inform practice, development and testing of new hypotheses or interventions, as well as proposals relevant to developing new methods or best practices.

Section I. Pilot Grant Program Goals

MICHR’s Pilot Grant Program goals are:

- To assist early career investigators by providing funding support that will enable them to establish a clinical and translational research path.
- To assist established basic science investigators to move their research into the translational research arena.
- To support clinicians interested in pursuing innovative research questions in the clinical setting or in the community.
- To facilitate innovative, pilot, multidisciplinary, and collaborative projects in translational investigations with an emphasis on the development of innovative methodologies, technologies and therapeutic targets.
- To prioritize pilot projects that best respond to the specific requirements of the Request for Proposals. In doing so, the PGP aims to:
  - CREATE INNOVATION - Identify and accelerate the translation of novel technologies, therapeutic strategies or research methodologies by supporting preliminary and proof-of-concept studies critical to moving basic laboratory findings into clinical and community-based applications that can improve health.
  - SECURE FUNDING SUPPORT - Augment the competitiveness of research to secure a greater likelihood of obtaining extramural funding.
  - ENSURE MENTORING/TRAINING - Link emerging investigators with established investigators through their period of pilot grant funding to ensure new investigators are armed with the skill set necessary to succeed in building a career in clinical and translational research.
  - CREATE COLLABORATION - Foster a multidisciplinary, team-science approach reflected by the inclusion of investigators from different fields and representation from different schools.
- To ensure a balanced and rapid peer review and an effective and timely allocation of funds to allow the execution of projects that successfully achieve the PGP’s objectives.
- To define and track metrics that reflect the impact of this program including: impacting clinical outcomes and community health, driving translation of scientific concepts from the benches of basic scientists to clinical investigators, establishing new research/educational programs, augmenting the number of clinical/translational research investigators, and increasing extramural funding and publications.
Section II. Funding Opportunity Description

Seed Grants, sometimes called Mini-Pilots are small grants that have flexibility in allowable expenses and will support any aspect of promising and innovative research.

Seed Grant requests are accepted and reviewed on a continual basis with no set submission deadline. The review process usually takes 6-8 weeks. When the review process is complete, the Principal Investigator will receive an e-mail notification of the outcome.

Proposals must clearly demonstrate how the funds will be used for a new stand-alone project or to enhance an existing research project, as opposed to simply offsetting previously anticipated or unanticipated costs. All research proposals should be specifically aimed at obtaining sufficient preliminary results as to facilitate the applicant’s subsequent pursuit of extramural research funding in the area of clinical and translational research.

Funding decisions will be made based on scientific merit, relevance to program goals, potential for extramural support and academic rank (with junior investigators receiving priority).
Part 2. Eligibility Requirements

All faculty (12 month and 9 month appointments) with lecturer or instructor appointments or higher from all schools and colleges at the University of Michigan are eligible to apply as Principal Investigators, including all basic, clinical and social scientists. Applicants must have a faculty appointment at the time of the application deadline.

Adjunct faculty, Post-doctoral trainees and Fellows are NOT eligible to serve as Principal Investigators on PGP projects; however, they are eligible to serve as Co-Investigators, and they may play a prominent role in conducting the project. PGP funding may not be used to support effort (salary & benefits) for Fellows who are already supported by ACGME or equivalent programs.

Section I. Eligibility of Junior Investigators (Assistant Professors & Below)

In order to promote the advancement of junior faculty, proposals from eligible junior investigators will receive relative priority as established by the Pilot Grant Program Faculty Advisory Board with approval by the Michigan Institute for Clinical & Health Research (MICHR) Director. Evidence that the investigator is moving toward a career in clinical & translational research is essential.

Junior investigators are faculty with the appointment of Assistant Professor and below. This includes but is not limited to Instructors, Assistant Professors, and Assistant Research Scientists.

The junior faculty member will also be required to provide evidence of a mentoring plan with one or more established clinical/translational investigators. This mentoring committee may be the same as one established by the School, Department or Division of the faculty. Investigators at or below an Assistant Professor level should provide information in the Budget Justification section about their prior research experience and describe any plans to acquire clinical and translational research skills. A letter of support from a mentor or Department Chair attesting to their commitment to the development of the mentees’ long-term career plan is favorable to the success of the application.

Section II. Eligibility of Senior Investigators (Above the level of Assistant Professor)

Senior investigators are faculty with the appointment above the level of Assistant Professor. This includes but is not limited to Associate Professors, Professors, Associate Research Scientists, and Research Scientists.

Senior faculty applying for PGP funds must provide a clear and concise explanation on how the proposed research is a significant departure from their previous research direction. Senior faculty should include this justification as part of their application.

Section III. Eligibility of Investigators for Multiple Awards

Principal Investigators (PIs) and Co-Investigators (Co-Is) may submit only one application per round. That is, Principal Investigators (PIs) or Co-Investigators (Co-Is) may only apply to one funding mechanism per round.

Principal Investigators (PIs) or Co-Principal Investigators (Co-PIs) may receive up to two separate pilot awards of $25,000 or more during any five year period commencing with the start date of the first award, provided that the first project is completed (including possible extensions) prior to the start date of the second project. Any applications received after the second proposal is awarded will not be reviewed. After expiration of the period ending five years after the start date of the first project, the PI or Co-PI will become eligible for subsequent...
awards, provided that both projects awarded during the initial five years were completed satisfactorily. Multiple award restrictions are not applicable to Seed awards. All other eligibility criteria are applicable.

Section IV. Eligibility of Stem Cells Studies

In general, work with human-derived stem cells or induced pluripotent stem cells are not considered translational research for the purposes of the PGP. A proposal may be turned down administratively if it is felt that it does not comply with the intent of the PGP.

Section V. Eligibility of Animal Studies

If the work involves animals, it is required that the investigator show how the studies will lead as a next step to a clinical or translational research project. The research “next step” is to take the findings from the pre-clinical model to humans. If 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, the study is eligible for pilot grant support. If the 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, it is not eligible for pilot grant support. Nude mice or other immune-compromised animals may be appropriate as ‘vehicles’ for human tissues for assessing effects of drugs or other interventions.

Note: The PGP review committee will take into account the extent of animal work compared to work in humans or human-related material in scoring the application. It is strongly suggested that investigators discuss anticipated proposals using animal models with MICHR PGP personnel prior to submission of the application.

A proposal may be turned down administratively if it is felt not to comply with the intent of the MICHR Pilot Grant Program. Applicants are encouraged to contact the PGP staff with specific questions about eligibility.
Part 3. Application & Submission Information

Section I. Competition Space

Applicants will use UMMS Competition Space (https://umms.infoready4.com/#homePage) to browse and apply for open funding opportunities. UMMS Competition Space runs on IE 9+, Chrome, Firefox 3+, and Safari for Macintosh.

Application forms and other relevant information may be found on UMMS Competition Space. The application should be submitted using the forms provided on Competition Space.

1. Login

Applications must be submitted to Competition Space by the Principal Investigator or by a designated Proxy. Applications submitted under a name other than the Principal Investigator’s will not be accepted.

For University of Michigan Users: Use your University of Michigan Username and Kerberos Level 1 Password to login to Competition Space.

For Other Users: If you are not a University of Michigan User, you must register to use Competition Space. Registration requires that you provide an email address and enter a password to create an account to login to Competition Space.

2. Assigning a Proxy

Applicants may only designate ONE Proxy to apply to any competition on their behalf through Competition Space. In order to designate a Proxy, please complete the following steps:

1) The person who will serve as a Proxy must first login to Competition Space once before he/she can be assigned as a Proxy.
2) The applicant (i.e. Principal Investigator) will need to login to Competition Space.
3) Once the applicant is logged in, he/she should see their name in the upper right-hand corner of the page. Click on the applicant name to go to the Profile Page.
4) Once on the Profile Page, click on the checkbox that states “I want to designate an applicant proxy, who can apply to competitions on my behalf.”
5) Enter the email address of the Proxy. The name field should automatically populate.
6) Click Save.

Section II. Application Components

The application should be submitted using the forms provided on UMMS Competition Space. Other forms will not be accepted and will result in the delay and/or potential rejection of your application.

Format Specifications: Unless otherwise indicated, use Arial Font and Font Size 11. A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies. Text is single spaced. Use standard size (8.5” x 11”) paper.
1. Face Page

The Face Page should be submitted using the Excel form provided on Competition Space. In the form, fields marked with a * are required. Submit the Face Page as an Excel file. Other file formats will not be accepted and will result in the delay and/or potential rejection of your application.

The components of the face page include:

I. Pilot Grant Funding Opportunity Information
II. Principal Investigator Information
III. Other Investigators and Collaborators
   - A list of the names of all personnel who are involved on the project, regardless of whether salary support is requested, is required. Starting with any co-principal investigators, include all co-investigators and collaborators such as mentors and research staff.
IV. Grant Administrator Information
V. Project Information
   - Applicants must disclose if their application is a re-submission. Proposals that were previously submitted under a different Principal Investigator, Proposal Title, or Grant Mechanism are also considered re-submissions.
   - Applicants are asked to respond to series of Yes and No questions about their proposal.
VI. Project Abstract; complete with Aims
   - Describe succinctly every major aspect of the proposed project (i.e. brief background of the project, specific aims or hypotheses, significance and relevance of the proposed research, any unique features and innovation of the project, etc.). Contain a statement of objectives and methods to be employed.
   - The abstract, complete with aims, should not be more than 500 words (to be entered in the text box).
VII. Significant Departure from Previous Research (For Senior Faculty ONLY)
   - Senior faculty applying for PGP funds must provide a clear and concise explanation on how the proposed research is a significant departure from their previous research direction.
VIII. Human Subjects IRB
   - If your IRB Status has been approved for your project, the IRB approval document is required as an attachment.
IX. Vertebrate Animals UCUCA
   - If your UCUCA Status has been approved for your project, the UCUCA approval document is required as an attachment.
X. Cost Share
XI. MICHR Contribution
XII. Suggested Peer Reviewers
   - Suggest 3 internal peer reviewers with relevant content expertise.

2. Other Support

To complete this section, applicants should use the form provided on Competition Space. This information is required for EACH Principal Investigator and Co-Investigator listed on the project. Submit the Other Support document as a PDF file. Other file formats will not be accepted and will result in the delay and/or potential rejection of your application.

Provide active support for all key personnel. Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research.
endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, and gifts need to be included. This requirement is necessary for determining time commitments to projects and for avoiding effort and scientific overlaps. Current and pending support must be disclosed whether or not salary support is being requested as part of this budget.

Submit all following and other components of this application together as a SINGLE PDF file, in the following order. Other file formats will not be accepted and will result in the delay and/or potential rejection of your application.

3. Proposal Narrative

The proposal narrative should be submitted using the form provided on Competition Space. The proposal narrative should not exceed 21 pages.

The proposal narrative should include sufficient information needed to evaluate the project and should be specific, informative and avoid redundancies. Unless otherwise noted in the RFP, the components of the proposal narrative include:

A. Specific Aims
   - Describe concisely and realistically the goals of the proposed research and summarize the expected outcome(s), including the impact of the proposed research. The specific aims should cover the specific objectives and hypotheses to be tested, a summary of the expected outcomes, and a description of the impact on the field.

B. Background and Significance
   - Explain the importance of the problem or describe the critical barrier to progress in the field that is being addressed. Explain how the proposed research 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 this field will be changed if the proposed aims are achieved. This section should cover the state of existing knowledge, rationale of the proposed research, an explanation of the gaps that the project is intended to fill, and potential contributions of this research to the scientific field(s) and public health.

C. Innovation
   - 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 or methodologies, instrumentation, or interventions.

D. Previous Related Work
   - 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.
E. Research Design and Methodology
   • The purpose of the approach section is to describe how the research will be carried out. This section is crucial to how favorably an application is reviewed. The research design and methods section should include, but is not limited to: (1) an overview of the experimental design; (2) a description of methods and analyses to be used to accomplish the specific aims of the project; (3) a discussion of potential difficulties and limitations and how these will be overcome or mitigated; (4) expected results and alternative approaches that will be used if unexpected results are found; (5) a detailed discussion of the way results will be collected, analyzed and interpreted; and (6) a description of any new methodology used and why it represents an improvement over existing ones.

F. Animal Model – Next Step Validation
   • If your study involves an animal model, please 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. Please refer to the section about the eligibility of animal studies for further details.

G. Recruitment & Retention Plan
   • Describe and justify the characteristics of the subject population, including their anticipated number, age range, and health status if relevant. Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any sub-population. Describe the plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.

H. Impact Statement
   • Describe the goal(s) of the specific research proposed and the broad, long-term objectives.

I. Time-line
   • Describe when key research activities will be accomplished during the award year.

J. Future Plan
   • Describe specifically how this grant will lead to future grant funding should be provided.

K. Mentoring Plan (for Jr. Faculty only)
   • Describe a mentoring plan with one or more established clinical, translational, or community-engaged research investigators. This mentoring relationship may be the same as one established by the School, Department or Division of the faculty. The description should include information about your mentor(s), the particular purpose of the mentoring relationship, the goals of the mentoring relationship, and a tentative agenda for mentoring session(s).

L. References (not included in page limit)
   • References cited in this proposal should be included in the application.

Preliminary data are not required when submitting a proposal. However, an explanation for the absence of preliminary data is helpful to the reviewers.
4. Budget

The budget should be submitted using the form provided on Competition Space.

The budget can be for any amount up to the **maximum noted in the RFP** and must be well justified. **Unallowable items include, but are not limited to:** cost overruns, retroactive funding, publications, grant preparation costs, graduate student stipends and tuition costs, salary support for Fellows already funded by an ACGME accredited program, travel unrelated to the conduct of the research (e.g., to conferences), renovations, office supplies or equipment, including computers. Computer programs may be considered if specialized and directly related to the proposed project.

Researchers are encouraged to contact the PGP staff with specific questions about allowability of specific types of expenses. Any costs associated with services, such as those provided by the Michigan Clinical Research Unit (MCRU) or MICHR must be included in the budget. For a list of available MICHR and MCRU services visit [http://www.michr.umich.edu/home](http://www.michr.umich.edu/home).

5. Budget Justification

A narrative budget justification should be submitted using the form provided on Competition Space. The budget justification should not exceed five pages.

A list of the names of all personnel who are involved on the project, regardless of whether salary support is requested, is required. Starting with the principal investigator, include all co-investigators and collaborating investigators, individuals in training and support staff. Provide a clear explanation for ALL personnel by position, the role that they will be playing on the project, and the level of effort. Post-Doctoral Fellows and Graduate Student personnel who are **To Be Determined** will be turned down. PLEASE do not leave these fields blank or labeled TBD. They will not be accepted.

Salary support for investigator effort is not allowed in budgets less than $25,000. For requests over $25,000, a minimum of 5% effort for the principal investigator is required, even if salary support for that effort is not being requested. All effort commitments submitted as part of an application must be appropriately documented as part of your effort certification process and **may not exceed the NIH cap.** Current and/or pending support for all PIs and Co-Is named in the application must be documented in the Current & Pending Other Support section. It must be clear to PGP administrators and the Scientific Review Committee that there will be no overlap in funding. If this documentation of support suggests that the proposal is NOT responsive to this specification, funding may be declined, or delayed.

*PGP awards are not meant to serve as bridge funding or as supplementary funding for existing grants. The PGP reserves the right to grant a partial award where expenses are not allowable, well justified, or are inflated.*

6. Biographical Sketches

Biographical sketches should be submitted using the form provided on Competition Space. The biographical sketch for each investigator should not exceed four pages. **A current NIH style biographical sketch is required for each Principal Investigator and Co-Investigator listed on the project.**

7. Letter of Support

Collaborators other than Co-Principal Investigators and Co-Investigators, with a significant role on the project should provide a Letter of Support for their participation.
8. Signature Page

The signature page should be submitted using the form provided on Competition Space.

**Sign-off by the Department Chair or Division Head for all Principal Investigators and Co-Investigators is required.** It indicates the application budget and faculty effort is endorsed and the cost-sharing requirement has been agreed to. **If support for faculty effort is not requested as part of the budget, departmental (or other administrative unit) sign-off is still required.**

Where the number of applications receiving a meritorious score from the Scientific Review Committee exceeds available cost-share dollars, the department will have final approval of which proposals will be funded.

9. Appendix

Applicants may submit an appendix, limited to 20 pages. Appendix materials are to encourage applications to be as concise as possible while containing the information needed for expert scientific review. The Appendix may not be used to circumvent the page limitations of the application.

Information that may and may not be included in the Application Appendix are as follows:

- Patents materials directly relevant to the project.
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents may be submitted in the Appendix as necessary.
- Published manuscripts and/or abstracts that are publicly available in a free, online format may be referenced in the application. These publications may **not** be included in the appendix.
- Applications may include graphic images of gels, micrographs, photographs, etc. in the Research Plan; however, these images may **not** be included in the Appendix (except when part of a qualifying publication).
Section III. Application Checklist & Submission

Using the forms provided, applications must be submitted to Competition Space by the Principal Investigator or by a designated Proxy. Applications submitted under a name other than the Principal Investigator's will not be accepted.

Where indicated in Competition Space, submit the Face Page, Other Support, and Application according to the requested file format. Other forms and file formats will not be accepted and will result in the delay and/or potential rejection of your application.

Format Specifications: Unless otherwise indicated, use Arial Font and Font Size 11. A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies. Text is single spaced. Use standard size (8.5” x 11”) paper.

| □ Face Page | Submit the Face Page as an Excel file |
| □ Other Support | Submit the Other Support as a PDF file |
| □ Application | Submit all components of the Application together as a SINGLE PDF file, in the order listed. |
| □ 1. Proposal Narrative | Do not exceed 21 pages. |
| □ 2. Budget | |
| □ 3. Budget Justification | Do not exceed 5 pages. |
| □ 4. Biographical Sketches | Do not exceed 4 pages for each biosketch. |
| □ 5. Letters of Support | |
| □ 6. Signature Page | |
| □ 7. Appendix | Do not exceed 20 pages. |
Part 4. Award Information & Awardee Responsibilities

If a proposal is approved for funding, the applicant will be notified by e-mail.

The duration of an award is one year, by which time all funds must be spent. Any residual funds at the close of the study will be returned to the MICHr Pilot Grant Program; deficits are the responsibility of the department/division/unit. The Principal Investigator and/or his grant administrator will have 90 days beyond the project end date to reconcile any applicable account activity. At which time, MICHr Finance in collaboration with the department grand administrator will facilitate closure.

Awardees will receive a progress report request near the end of the award period. A request for a well-justified MAXIMUM 6 MONTH EXTENSION may be submitted with this progress report. However, if no progress has been made toward completion of the project after the one year period, the Pilot Grant Program reserves the right to request that unexpended MICHr funds be returned. It is the responsibility of the applicant to garner departmental support. It will be the responsibility of the Principal Investigator and his/her respective division/department to monitor funding activity and expenditures.

In the event that the Principal Investigator leaves the institution during the period of the grant, the Principal Investigator and/or his department/division/unit is responsible for notifying the MICHr Pilot Grant Program; at which time, they may either:

1. Designate a new eligible PI (who is NOT a Post-Doctoral trainee or Fellow), who will become responsible for completing the original aims of the initial research, as it was approved by MICHr and provide evidence of an updated IRB documenting the new designee;

2. If no eligible faculty can be named before the faculty departs, the project will be discontinued and any remaining funds returned to MICHr upon the PI’s departure.

Section I. Budgets

Awarded funds are limited specifically to the expenses itemized and approved as part of the original application. Funds may not (without MICHr approval) be utilized for any other expenditure not previously identified.

A request to the change the budget must be accompanied by an updated budget and budget justification form. Any change to the budget must be approved by the MICHr Pilot Grant Program Administration.

Section II. Regulatory Requirements

Institutional Review Board (IRB) approval and any other applicable regulatory requirements are not required at the time of submission but should be initiated immediately following award notification. All regulatory approvals MUST BE OBTAINED WITHIN 3 MONTHS of the award start date (e.g. IRB, UCUCA, FDA, Technology Transfer, Conflict of Interest, etc.).

The start date that begins the one year funding period is set by MICHr Finance and commences with or without IRB approval.

If approvals have not been obtained within this timeframe, the award may be revoked or deferred unless justification of further delay can be made to the PGP Administration. If you are using a pre-existing IRB application, you are required to amend your Sponsor section to include MICHr as an Internal funding source.
Section III. Publication – Citing MICHR’s Grant Number

As a requirement for accepting a MICHR award and to continue to ensure CTSA support for clinical and translational research, please cite our grant number UL1TR000433 in all relevant publications and presentations.

Section IV. Annual Progress Update

As projects expires and annually thereafter, the MICHR Pilot Grant Program requires all principal investigators submit an annual update providing a summary of the progress made to date: including, resulting peer reviewed publications, applications for extramural funding and, if applicable, an explanation for any project delays. This is also the approved method for requesting an extension.
Part 5. Contacts & Other Information

For assistance regarding MICHR Pilot Grant Program funding mechanisms, please contact:
Lisa Ahrens, the Pilot Grant Program Coordinator at 734-998-7308 or MICHR-PilotGrants@umich.edu.

Useful Links

MICHR Pilot Grant Program Webpage  http://www.michr.umich.edu/funding/pilotgrant
UMMS Competition Space  https://umms.infoready4.com/

Other MICHR Resources

Outreach, Partnerships and Implementation Science (OPIS)
A community engagement and research workgroup  http://www.michr.umich.edu/community/communityengagement

Research Development Core (RDC)
Provides free services and consultation to strengthen study design and grant proposals  http://www.michr.umich.edu/services/researchdevelopment

Clinical & Health Research Recruitment Program
Provides expertise, tools, and resources to facilitate participant recruitment in clinical and health research studies  http://www.michr.umich.edu/services/recruitmentprogram

Biostatistics
Provides state-of-the art knowledge, service, education, and methodology in the areas of biostatistics and outcomes measurement  http://www.michr.umich.edu/services/biostatistics

Michigan Clinical Research Unit (MCRU)
Provides the clinical staff, resources, and infrastructure necessary to conduct human clinical research protocols at the University of Michigan  http://www.michr.umich.edu/services/mcru