

MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH

UNIVERSITY OF MICHIGAN

<u>Community-University Research (CURES)</u> <u>Partnership Award</u>

Funding Opportunity Description, Eligibility Requirements & Application Guidelines Round 19

Application Deadline: 12:00 PM (NOON) on Friday, September 11, 2015

MICHR Communities Engagement Program http://www.michr.umich.edu/community/communityengagementandresearch

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

> > UMMS Competition Space https://umms.infoready4.com/



This document contains eligibility requirements and application guidelines that are specific to the Community University Research Partnership Award (CURES) funding mechanism only.

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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 researchers at the university and community and practice-based organizations, 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, as well as community-based organizations and practice-based network partners who seek to collaborate on 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.

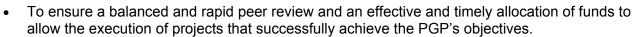
The following eligibility requirements and application guidelines are specific to the Community University Research Partnership Award (CURES) funding mechanism.

Section I. Pilot Grant and Communities Engagement Program Goals

The Community-University Research Partnership Award (CURES) is supported by both the MICHR Pilot Grant and Communities Engagement Programs. CURES applications are assessed, in part, based on whether they meet the goals of both programs.

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-ofconcept studies critical to moving basic laboratory findings into clinical and communitybased 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 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.

MICHR's Communities Engagement Program goals for the CURES funding mechanism are:

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- To build capacity of community-based organizations and university-based partners to engage in research partnerships.
- To combine the knowledge, wisdom and experience in communities and at UM to make a positive impact on local health.
- To enhance networks and infrastructure that will promote community research that not only takes place in the community, but engages the community in all phases of research.

Section II. CURES Funding Opportunity Description

The following funding opportunity description applies specifically to the T3 Community University Research Partnership Award (CURES) funding mechanism only. For descriptions of all other MICHR pilot funding opportunities, please visit the MICHR Pilot Grant Program Site (<u>http://www.michr.umich.edu/funding/pilotgrant</u>). Please note that all funding opportunities are for a period of one year.

MICHR's Communities Engagement requests applications for community-engaged translational research projects that promote community involvement and address community-identified health needs. The purpose of the Community-University Research (CURES) partnership award is to support one-year pilot and/or feasibility research studies that develop ideas for new model programs and/or techniques designed to improve health in communities across the State of Michigan. CURES pilot projects should represent a first step in testing a new approach and gathering preliminary data to examine its effectiveness.

Justification of Need

Community engagement in research is a process that fosters mutual respect, open communication, and recognizes the knowledge, expertise, and capacities of all partners involved. CURES applicants must address how their project utilizes a community-engaged approach and demonstrate shared leadership and engagement in research activities. Academic investigators need to demonstrate community involvement and/or how community partners were encouraged to be involved in all stages of the research (e.g. proposal writing, research question development, study design, data collection, analysis, and dissemination). Applications must clearly show that the research topic is a health priority to the community partner organization (e.g. via Letters of Support) and provide evidence for how the focal community was engaged in identifying the topic (e.g. via town halls, assessment of local health data).

Definitions

For the purposes of the CURES funding description only, "community partner" refers to members of the research partnership team who are not affiliated with U-M. Community partners must represent one of the following types of community-based organizations: Nonprofits; Small Business; For-Profit Organizations; Indian/Native American Tribal Government; Indian/Native American Tribally Designated

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Organizations; Minority-serving institutions; Governmental health agencies; Faith-based organizations. A list of abstracts and investigators from previously funded CURES projects can be viewed <u>here</u>.

"Community" is defined more broadly as a group of people affiliated by similar characteristics, such as identities (e.g. social/economic backgrounds), geographic location (e.g. city of Flint), special interests (e.g. coalition to reduce childhood obesity), and/or situations that affects the well-being of that group. Applicants must clearly describe the specific community that represents the focus of the project. MICHR's Community Engagement Program is specifically interested in applications that seek to reduce health disparities and improve health among groups that experience worse health outcomes (e.g. racial/ethnic minorities, low-income families).

Support for these awards must be justified by a detailed budget that shows equitable distribution of funds between academic and community partners. The budget should reflect fair and appropriate compensation for time and effort of community partners and participants involved in the study. Ensuring fair compensation for community partners is a critical element for community-engaged research projects, especially those similar to CURES that require a high level of community involvement. Awards cannot exceed \$30,000. Academic department cost-share is not required.

CURES funding is specifically intended for projects that represent a first step in building a foundation for future research. Applications that request supplemental funds to support currently funded, ongoing research studies will not be considered. Applications must clearly show how pilot data and CURES funding will be used to apply for competitive grant proposals and secure a greater likelihood of obtaining additional funding through governmental and private sources.

Research Plan

CURES funding will support research projects that study a broad variety of methods and interventions. Examples include, but are not limited to, developing and piloting disease management programs, increasing opportunities for community partner participation in academic research priority-setting, patient safety initiatives, and community- or employer-based programs, increasing health research literacy, and identifying ways to increase the community's access to, and understanding of, research results. Projects can also study how a new type of diagnostic method (e.g., using techniques previously tested in a research setting) can be implemented and evaluated in a community setting or clinical practice.

<u>All applications need to demonstrate how the project utilizes a community-engaged approach</u> (e.g. shared leadership and engagement of all partners in all stages of the research). Applications should clearly show that the research topic is a priority to both the community partner organization and the community of focus, and demonstrate that the project is a collaborative effort between the community and academic partners.

Section III. Key Dates

Request for Proposals: Application Deadline (for all mechanisms): Award Announcement: Earliest Anticipated Project Start: Project Funding Period: Monday, July 13, 2015 **12:00 PM on Friday, September 11, 2015** ~ December 2015 – January 2016 January 15, 2016 One Year



Part 2. Eligibility Requirements

The following guidelines apply specifically to the CURES funding opportunity.

CURES applications must be submitted on behalf of <u>at least two investigators</u>; <u>an academic partner</u> representing a school/department at the University of Michigan <u>and a community partner</u> representing a community-based organization. CURES applicants may propose a Principal Investigator (PI) and Co-Investigator (Co-I) or Co-Principal Investigators, as long as the proposed project demonstrates collaboration, joint ownership, and shared leadership between both academic and community partners.

All academic faculty (12 month and 9 month appointments) with lecturer or instructor appointments or higher from all schools and colleges at the U-M 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 Academic 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 <u>mentoring plan</u> 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 <u>letter of support</u> 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 Academic 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 <u>significant departure</u> from their previous research direction. Senior faculty should include this justification as part of their application.



Section III. Eligibility of Community Partners

For the purposes of this funding opportunity, "community partner" refers to members of the research partnership team who are not affiliated with U-M. Community partners must be affiliated with one of the following types of organizations: Nonprofits; Small Business; For-Profit Organizations; Indian/Native American Tribal Government; Indian/Native American Tribally Designated Organizations; Minority-serving institutions; Governmental health agencies; or Faith-based organizations.

Community partners must be directly affiliated with a community-based organization located within the State of Michigan.

Examples of community-based organizations that have received CURES funding include the Flint Neighborhood Roundtable, Ann Arbor Community Center, American Indian Health & Family Services of Southeastern Michigan (AIHFS), and HIV/AIDS Resource Center (HARC) in Ypsilanti.

Section VI. Eligibility of Investigators for Multiple Awards

Previously CURES-funded investigators who seek funding for a new CURES project must demonstrate successful completion of their first project, and show effort to secure external funding (e.g. submission of grant applications), and appropriate follow-up with respective community and/or academic partners (e.g. dissemination of research findings in community-based settings).

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

Principal Investigators (PIs) may receive up to two separate MICHR pilot awards 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 will become eligible for subsequent awards, provided that both projects awarded during the initial five years were completed satisfactorily. Only in rare instances will a second pilot grant be awarded for the same project. The applicant must provide clear rational for additional funding.

Multiple award restrictions are not applicable to Seed awards. All other eligibility criteria are applicable.



Part 3. Applicant Responsibilities

Section I. Funding

Although CURES funding does not require matching dollars from the academic investigator's department, school, or college, academic investigators are encouraged to secure additional departmental support, if needed. If the academic principal investigator chooses, s/he may request matching departmental funds; however, it is the responsibility of the applicant to garner departmental support prior to submission.

The departmental sign-off secured by the applicant prior to submission indicates the department's agreement to match MICHR Pilot Grant Program dollars (1:1). The portion not covered by the MICHR contribution may be divided between the collaborators' departments. It is the responsibility of applicants to communicate with all sponsoring department Research Administrators as to their intent to apply to this program in order to allow time for departmental consideration prior to sign-off.

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 preexisting U-M IRB application, you are required to amend your Sponsor section to include MICHR as an Internal funding source.

Section III. Application

It is the responsibility of the applicant to secure and complete all application components prior to submission. We strongly encourage early submissions.

For more information about the application, please refer to Part 4 of this document.



Part 4. Application & Submission Information

To be considered for funding, your complete application <u>must</u> be submitted in Competition Space by 12:00 P.M. on Friday, September 11, 2015.

We strongly encourage early submissions. No applications will be accepted after the deadline. The system will provide immediate notification upon successful completion.

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Section I. Competition Space

Applicants will use **UMMS Competition Space** (<u>https://umms.infoready4.com/#homePage</u>) 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.

<u> 1. Login</u>

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 <i>register</i> 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 designate any number of Proxies 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. Academic 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. Names of community-based organizations are included in this section.
- 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 <u>significant departure</u> from their previous research.
- 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



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 Principal Investigators and Co-Investigators. 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. This requirement is necessary for avoiding 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. Rebuttal Form (For Resubmissions ONLY)

A rebuttal is REQUIRED for re-submissions. The rebuttal form should be submitted using the form provided on Competition Space. The rebuttal should not exceed 2 pages.

The rebuttal should respond to the prior reviewers' comments, point by point. Any changes or modifications to the body of the grant (narrative) should be highlighted. A proposal will be considered a maximum of three times; the original submission and TWO resubmissions.

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.

It is strongly suggested that the applicants of unfunded grants contact the Pilot Grant Program to discuss the resubmitted application. PI's within 3 years of their appointment at the Assistant Professor level or younger should strongly consider using MICHR's Research Development Core for project design advice.

4. 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. 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.
 - Recommended length: 1 page
- B. Background and Significance

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- Explain the importance of the health problem or describe the critical barrier to progress in the field that is being addressed. Provide evidence that the problem is a community-identified health priority. Explain how the proposed project will benefit the community participating in the study, how the partnership will build capacity for the community-based organization partner, and how it 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.
- Recommended length: 1-2 pages
- 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.
 - Recommended length: 0.5-1 page
- 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 that both the community partners and academic investigators bring to the project and evidence of the feasibility to accomplish the proposed aims.
 - Recommended length: 0.5-1 page
- E. Description of Proposed Collaborative Partnership
 - Describe the history and/or formation of the proposed community-academic partnership. Describe the guiding framework, approach, and/or community engagement principles that the partnership will be grounded in. Explain how community partners and academic investigators will share responsibility for research activities throughout the project.
 - Recommended length: 1-2 pages
- F. 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 an interpreted; and (6) a description of any new methodology used and why it represents an improvement over existing ones. Provide a clear explanation of how both community partners and academic investigators will be involved throughout study design and implementation.



- Recommended length: 9-10 pages
- G. Recruitment & Retention Plan
 - Describe and justify the characteristics of the participant 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 participants (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.
 - Recommended length: 1-2 pages
- H. Impact Statement
 - Describe the goal(s) of the specific research proposed and how the community will benefit from short- and long-term objectives.
 - Recommended length: 1 page
- I. Timeline
 - Describe when key research activities will be accomplished during the award year.
 - Recommended length: 0.5-1 page
- J. Dissemination Plan
 - Describe how the research outcomes and findings will be communicated to the community partner organization, community of focus, and through other venues.
 - Recommended length: 0.5-1 page
- K. Future Plan
 - Describe specifically how this grant will lead to future grant funding should be provided and how the pilot data will support future research, intervention, and/or policy efforts.
 - Recommended length: 0.5 page
- L. Mentoring Plan (for Junior 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).
 - Recommended length: 0.5 page
- M. 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.



5. Budget

CURES partnership teams must establish an equitable distribution of funds between community partners and academic investigators. CURES applications will be assessed, in part, on whether the budget is distributed fairly between the partners, and on whether study participants are compensated appropriately for their time. The budget should be submitted using the form provided on Competition Space.

The budget for a CURES application can be for any amount up to \$30,000 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 <u>http://www.michr.umich.edu/home</u>.

6. 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.

All effort commitments submitted as part of an application must be appropriately documented as part of your effort certification process and <u>may not exceed the NIH cap</u>. 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 reviewers 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.

7. Biographical Sketches

Biographical sketches should be submitted using the form provided on Competition Space. The biographical sketch for each investigator should not exceed five pages. A current NIH style biographical sketch is required for each <u>academic</u> Principal Investigator and Co-Investigator listed on the project. Community partners may choose to use either the NIH style biographical sketch or submit a CV/resume that contains sufficient information for reviewers to determine their professional



and educational history, and related background and expertise in partnering in clinical and translational research studies.

8. 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. **CURES applicants are strongly encouraged to provide Letters of Support from each community-based organization partner involved in the project.**

9. Signature Page

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

Sign-off by the Department/School Chair or Director of a Center and/or other Institutional Entity for all Principal Investigators and Co-Investigators is required. Sign-off by the Department/School Chair, or Director of a Center and/or other Institutional Entity attests that the application budget and faculty effort is endorsed and that the cost-sharing requirement has been agreed to. Administrative sign-off is required for all faculty effort.

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.

Notes: For the T3-CURES mechanism, sign-off for the community partner is not required.

10. 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 <u>not</u> be included in the appendix.
- Applications may include graphic images of gels, micrographs, photographs, etc. in the Research Plan; however, these images may <u>not</u> be included in the Appendix (except when part of a qualifying publication).



Section III. Application Checklist & Submission

To be considered for funding, your complete application <u>must</u> be submitted in Competition Space by 12:00 P.M. on Friday, September 11 2015.

We strongly encourage early submissions. No applications will be accepted after the deadline. The system will provide immediate notification upon successful completion.

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. Rebuttal (for resubmissions only) Do not exceed 2 pages. 	
 Do not exceed 21 pages. 	
□ 3. Budget	
 4. Budget Justification Do not exceed 5 pages. 	
 5. Biographical Sketches Do not exceed 5 pages for each biosketch. 	
□ 6. Letters of Support	
□ 7. Signature Page	
 B. Appendix Do not exceed 20 pages. 	



Part 5. Application Review Information

The MICHR Pilot Grant and Community Engagement Programs require 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 core values of peer review drive MICHR to seek the highest level of ethical standards.

CURES applications will be reviewed by academic faculty and community partners with expertise in community-engaged research. In addition to determining whether your proposal meets the specified goals of the MICHR Pilot Grant and Communities Engagement Programs, academic and community peer reviewers will evaluate and score applications based on the following:

- **Significance:** Does the research address a significant clinical or health-related challenge that is viewed as important by the community of focus?
- **Innovation:** Does the project include innovative approaches to addressing a communityidentified health issue? Does the project describe how novel approaches or strategies could potentially be scaled up for use in other similar communities or populations?
- **Approach:** Does the project use the appropriate methods to engage and work with the community throughout the research process? Are concepts and principles of community-engaged research integrated into the study design?
- **Investigators/Partnership:** Do the investigators and other project collaborators have complementary experience and expertise? What unique skills and expertise do community and academic partners bring to the project?
- **Community Involvement:** Is there evidence that the community was involved in shaping the research question? Have the applicants explained how the community will be engaged in all phases of research (proposal development, study design, data collection, analysis, dissemination)?
- **Community Benefit:** How will the project benefit the community partner organization and participants involved? Will knowledge obtained from the study be used to enhance the economic, environmental, and/or social conditions within the community?
- **Budget:** Is the budget appropriate and realistic considering the work proposed? Is the budget distributed equitably between the community and academic partners?
- **Sustainability:** How will the community-university partnership be sustained beyond the scope of the one-year funding period? If funded, what is the likelihood that this award will lead to external funding and/or positive changes in community health?



Part 6. Award Information & Awardee Responsibilities

If a proposal is approved for funding, the applicant will be notified by email after all applications for the round have been considered. Funding notification letters will be sent via email containing an anticipated start date of **January 15, 2016**.

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 incurred during the grant term. 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 welljustified 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 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 <u>MUST BE OBTAINED WITHIN 3 MONTHS</u> of the award start date (e.g. IRB, UCUCA, FDA, Technology Transfer, Conflict of Interest, etc.).**

The start date that begins the <u>one year funding period</u> 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. Progress Updates

The MICHR Pilot Grant and Communities Engagement Programs require all CURES academic principal investigators and community partners to submit a 6-month and one-year update providing a summary of the progress made to date: including partnership outcomes, 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.

Section V. Peer Review Mentorship Opportunity

Faculty within the first 3 years of their appointment as an Assistant Professor (or earlier), may be asked to participate in the review process for an upcoming cycle of the PGP. At which time, you will be assigned an application to review in partnership with a senior reviewer on our Scientific Review Committee.

Section VI. Research Symposium

All funded CURES applicants will be invited to present the findings of their work at a MICHR-sponsored event. More detailed information regarding this aspect of the program may be forthcoming.



Part 7. Frequently Asked Questions

1. What are the types of translational research that are being referred to in the different PGP funding mechanisms?

There are three types of translational research that the MICHR Pilot Grant Program funding opportunities refer to. They are:

Type 1 (T1) – translation to humans

With T1 translational research, finding from basic research are tested for clinical effect and/or applicability. T1 research yields knowledge about human physiology and the potential for intervention.

Type 2 (T2) – translation to patients

With T2 translational research, investigators test new interventions under controlled environments to form the basis for clinical application and evidence-based guidelines. T2 research yields knowledge about the efficacy of the interventions in optimal settings.

Type 3 (T3) – translation to practice

With T3 translational research, investigators explore ways of applying recommendations or guidelines in practice. T3 research yields knowledge about how interventions work in real-world settings.

2. I do not see the application posted on the mGrants site. Where can I find the application portal?

Applicants will use UMMS Competition Space (<u>https://umms.infoready4.com/#homePage</u>) to browse and apply for open funding opportunities. 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.

3. Do I need to submit a Letter of Intent this Round?

Applicants do NOT have to submit a Letter of Intent (LOI). The LOI is not a part of the application process for this round.

4. When are Resubmissions due?

Resubmissions are due by the same deadline as regular applications, by 12:00 PM on Friday, September 11, 2015.

Applicants are required to disclose if their proposal is a resubmission. A Rebuttal is REQUIRED for re-submissions. The rebuttal form should be submitted using the form provided on Competition Space and should not exceed 2 pages. The rebuttal should respond to the prior reviewers' comments, point by point. Any changes or modifications to the body of the grant (narrative) should be highlighted. A proposal will be considered a maximum of three times; the original submission and two resubmissions.



5. My appointment is ______. Am I eligible to apply as a Junior Investigator or Senior Faculty?

Junior investigators are faculty with the appointment of Assistant Professor and below. A comprehensive list of allowable junior investigators follows:

- Lecturer
- Instructor
- Assistant Professor
- Clinical Instructor
- Clinical Assistant Professor
- Research Investigator
- Research Assistant Professor
- Assistant Research Scientist

Senior faculty is faculty with the appointment above the level of Assistant Professor. A comprehensive list of allowable senior faculty follows:

- Associate Professor
- Professor
- Clinical Associate Professor
- Clinical Professor
- Research Associate Professor
- Research Professor
- Associate Research Scientist
- Research Scientist

6. Are Adjunct Faculty allowed to apply to MICHR Funding Opportunities as Principal Investigators?

Adjunct faculty are NOT eligible to serve as Principal Investigators on any PGP project; however, adjunct faculty are eligible to serve as Co-Investigators and they may play a prominent role in conducting the project.

7. Are Postdoctoral trainees and/or Fellows allowed to apply to MICHR Funding Opportunities as Principal Investigators?

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

8. Are Co-Principal Investigators allowed?

Co-Principal Investigators are allowed. Please be aware that a person's participation in a project as a Co-PI may affect his/her eligibility to receive future awards.



9. What information is required in the Mentoring Plan?

Applicants are asked to 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).

The MICHR Pilot Grant Program does not provide mentors to applicants. It is the responsibility of the applicant to secure a mentor.

10. Can a collaborator serve as a mentor on a project?

A collaborator may serve as a mentor on a project.

11. What do I do if my primary Department or Unit is not listed on the drop-down list of the Face Page?

ONLY if your primary Department or Unit is not listed on the drop-down list of the Face Page, you may type in your response.

12. Do we have to create a PAF and route the proposal through our grants administrator?

A Proposal Approval Form (PAF) is not required for applicants to MICHR Pilot Grant Program Awards.

13. What is meant by an "equitable distribution" of the budget between community partners and academic investigators?

CURES awards require shared leadership and responsibility of research activities between community and academic partners on the research team. Thus, the budget should reflect fair and appropriate compensation for time and effort of community partners and participants involved in the study. Ensuring fair compensation for community partners is a critical element for community-engaged research projects, especially those similar to CURES that require a high level of community involvement. Although there is no specific dollar amount defined in the CURES funding opportunity description, projects that allocate at least half of the requested funds to the community partner organization typically receive priority in funding decisions.



Part 8. Contacts & Other Information

For general assistance regarding the MICHR Pilot Grant Program, please contact: Kate Althouse at 734-998-7626 or MICHR-PilotGrants@umich.edu

For specific mechanism related questions, please contact:

Kate Althouse **T1 Bench-to-Bedside Translation Award** • 734-998-7626 **T1 Endowment for Basic Sciences Partnership** MICHR-PilotGrants@umich.edu Accelerating Translation Award T2 Translational Science Award T3 Community University Research (CURES) Partnership Adam Paberzs 734-763-8880 Award adampabe@umich.edu **T3 Research into Practice Award** Kent Key 734-998-7474 T3 Implementing Research-Based Practices to Improve kentk@umich.edu **Quality of Care Award**

Useful Links

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

Other MICHR Resources

Research Development Core (RDC)

Provides free services and consultation to strengthen study design and grant proposals

Clinical & Health Research Recruitment Program

Provides expertise, tools, and resources to facilitate participant recruitment in clinical and health research studies

Biostatistics

Provides state-of-the art knowledge, service, education, and methodology in the areas of biostatistics and outcomes measurement

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/servic es/researchdevelopment

http://www.michr.umich.edu/servic es/recruitmentprogram

http://www.michr.umich.edu/servic es/biostatistics

http://www.michr.umich.edu/servic es/mcru