COMMUNITY PARTNERSHIP AND COLLABORATION CORE PILOT GRANT PROGRAM
Request for Applications

Summary

Deadline:	**Sunday, May 2, 2021 at 11:59 PM**
Eligibility:	Faculty from three academic institutions: Johns Hopkins University, University of Maryland at Baltimore, and Morgan State University
Budget:	Up to $10,000 in direct costs for **Partnership Development Grants**; up to $50,000 in direct costs for **Engagement Grants**. No faculty salary with exception of Research Associates/Research Assistants/Community Investigators
Grant Period:	Twelve months
Application:	Online at https://jhmi.co1.qualtrics.com/jfe/form/SV_54qtCjpRo4PMogm

A grant information session will be held on April 7 at 12 pm via Zoom.
To register and join the Zoom meeting, use this link: https://jhjhm.zoom.us/meeting/register/tJYld-2urjkpE9QpxTuNtUkWZ-TV7Jkp1FYY

Program Overview

The Community Partnership and Collaboration Core (the "Core") Pilot Grant Program is designed to build and support community engaged research (CEnR) partnerships through relationship-building activities, exploring research interests, and developing infrastructure and governance for research partnerships. The Core will distribute $100,000 per year to advance CEnR science and scholarship as: 1) **Partnership Development Grants** up to $10,000 and 2) **Engagement Grants** up to $50,000.

Partnership Development Grants aim to support partnership-building activities for "new" collaborations between faculty from three academic institutions (Johns Hopkins University, University of Maryland at Baltimore, and Morgan State University) and a community partner (community or faith-based organization or public agency) from the Greater Baltimore area.

Possible Partnership Development Grant activities may include but are not limited to:
- Developing research partnership infrastructure (e.g. advisory boards, partnership roles and responsibilities, policies and procedures, memorandums of understanding)
- Facilitating formal and informal meetings for partners to identify shared goals, priorities, and research interests
- Facilitating open dialogue around challenges and opportunities to address community health needs

- Exploring and seeking involvement of potential partners
- Building research capacity for community partners (e.g., IRB training, training on research design and methods, etc.)
- Building CEnR capacity for academic partners (e.g., principles of community engagement, 10-step Framework, etc.)

The Engagement Grant provides starter funds for projects specifically focused on innovative CEnR that will test novel approaches to addressing health problems through community-engaged implementation. Partnerships are expected to use approaches along the spectrum of continuum of engagement, including community-based participatory research, patient-centered outcomes research, or other engaged research collaborations for collaborative research and grant applications.

- All projects must be designed so that it is feasible to complete the project within the 12-month funding period.
- Applications using an evidence-based framework, such as the 10-step Framework, focused on diverse populations, addressing a priority topic, and/or including collaboration between partner institution(s) (Johns Hopkins University, University of Maryland at Baltimore, Morgan State University, Kaiser Permanente Mid-Atlantic States) will receive bonus points in the ranking process.
- The grant program encourages the participation of new and/or junior faculty investigators and the participation and/or training of new or inexperienced community investigators and doctoral students with an established team.

The research plan must be no longer than five single-spaced pages (including figures) in a font no smaller than 11 points, with margins of at least 0.5 inches on all sides (further details in *Application Process*).

Final deliverables for both grants should include:
1) Research questions jointly developed by academic and community partners;
2) Partnership Agreement or Memorandum of Understanding (MOU),
3) An evaluation of activities,
4) A description of how the results of the pilot project will inform or support subsequent applications for extramural funding.

All of the research teams receiving funds will have regular contact with an assigned Core staff member to discuss best strategies for meeting CEnR goals.

Key Application Information		
Award Categories	Engagement Grant	$50,000
	Partnership Grant	$10,000
Award Duration	Both Grant Awards	12 months
Application Deadline	Both Grants	May 2, 2021 11:59 PM (EST)
Contacts	Sarah Stevens	*ssteve45@jhmi.edu*
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Program Details

Eligibility

Eligible submissions must be oriented towards specific milestones, with clear endpoints and a realistic timeline for completion within the twelve-month funding period.

Projects poised to begin by June 1, 2021 (i.e. with regulatory approvals in place or underway at the time of submission, staffing in place, etc.) will receive additional consideration.

Any faculty member from three academic institutions (Johns Hopkins University, University of Maryland at Baltimore, and Morgan State University) is eligible to apply. Junior faculty in all schools, particularly those new to CEnR, are encouraged to apply and will receive extra consideration.

Undergraduates, graduate students, and postdoctoral fellows are not eligible to apply as Principal or Co- Investigators for pilot grants but are highly encouraged to be involved as team members.

Each project should include one academic PI and one community PI (community or faith-based organization or public agency) and should designate one of the PIs as the main PI.

Applicants identified as the main PI have primary responsibility for the grant submission and, if subsequently selected for funding, all work to be performed, all reporting requirements, and all other stipulations that must be satisfied as a condition of receiving this award. Awards WILL NOT be transferred to another investigator post-award.

Awarded PIs are not eligible to apply for a new grant in the same category (i.e., Partnership Development vs. Engagement) funded by this pilot grant program in the 24-month period following the receipt of their initial award funds.

Resubmission of denied grants is not permitted. However, unsuccessful applicants may apply in consecutive rounds with substantially different proposals.

Regulatory Requirements/Approvals

Regulatory approvals are not required for application submission. However, before the project can start, all applicable institutional (i.e. Institutional Review Board [IRB]) and external (i.e. National Center for Advancing Translational Science' [NCATS]) approvals must be obtained.

Due to the accelerated nature of this program, investigators are strongly encouraged to initiate necessary approvals prior to grant submission or during the grant review period. Projects with regulatory approvals in place or underway at the time of submission will receive additional consideration.

If notified by the ICTR that their human subjects submission has been selected for funding, the applicant must immediately start working to obtain all institutional and external regulatory

approvals and submit their study for IRB review, if they have not done so already. Upon receipt of IRB approval, they will provide further guidance and detailed instructions for preparation of the NCATS document package. **See Appendix I for additional information about the NCATS prior review requirement.**

Conflicts of Interest

At the time of application, before funds are awarded, and throughout the project period, it is the responsibility of the awardee and all members of the study team to report any financial or fiduciary interests that might appear to present a conflict of interest. **These interests must be reported to the ICTR and the University Office of Policy Coordination.** The presence of a conflict of interest does not disqualify investigators from receiving this award but will require the review and management of this conflict by the Committee on Outside Interests. **The failure of any member of the study team to disclose all outside interests could result in the termination of this award and the disallowance of all study costs.**

More information about Johns Hopkins University's Conflict of Interest Policy, including examples of what constitutes an outside interest, may be found at the Office of Policy Coordination website (http://www.hopkinsmedicine.org/Research/OPC/Outside_Interests/).

Funding Restrictions

Requests must be no more than $10,000 in direct costs for Partnership Development grants and $50,000 in direct costs for Engagement grants. Budget estimates must be realistic and proportionate to the scope of the project. Requests for additional funding award approval are not permissible. **Requests exceeding the specified amounts** will not be reviewed.

Core leadership may revise the award amount should the applicant's submitted budget provide funds for activities or expenditures that are either not permitted or deemed to be more than is needed to complete the project. Applicants whose funding requests are revised by leadership for either of the above reasons, will be required to resubmit a revised research plan, budget, and project schedule, if applicable, for approval by Core leadership prior to being permitted to start their project.

Funding will be for 12 months only. No-cost extensions may be granted on a case-by-case basis with strong justification for those with funds remaining at the end of the award period.

For grants that include clinical studies that will be conducted at sites outside of Johns Hopkins, the feasibility of the overall proposal will be prominently considered in any funding decisions. Core leadership may revise the scope of the project and funds awarded if a proposal is not thought feasible within the 12-month funding period.

Indirect costs should <u>not </u>be included in the budget, **except in the case of subcontracts**.

Subcontracts may be permitted on a case-by-case basis. Applicants with projects requiring subcontracts must contact the ICTR Financial Office at (410) 361-7887 for authorization **in advance of submission**. If authorized to include a subcontract in their proposal, applicants may

be asked to provide, in addition to the primary budget, a separate budget and justification for the sub-award detailing the total funds required (including total direct costs and total indirect costs of the outside facility).

- Subcontracts with outside institutions/facilities should be no more than 50% of total requested budget.
- Subcontracts greater than 50% of the total requested budget may be considered with a strong justification.

Core pilot funds may **not** be used for faculty salary with the exception of Research Associates or Research Assistants at Johns Hopkins, University of Maryland at Baltimore, and Morgan State University or Community Investigators.

Core pilot funds may be used with Core leadership approval for travel essential to the conduct of research, but not for travel to present results at established meetings or conferences. If such travel is anticipated, a strong justification must be included in the budget justification document, together with detailed meeting information (e.g. location, approximate date(s)), travel costs being requested, study team attending, etc.) for review and approval by Core leadership.

ALL changes to the original research plan or budget must be submitted **BEFORE IMPLEMENTATION** for review and final approval by the Core Leadership Council and may result in withdrawal of funding if the project no longer meets Core pilot criteria or does not receive the appropriate approvals.

Funded PI Requirements

All funded PIs will be required to participate in: kick-off meeting, regular (e.g., quarterly) check-in meetings with brief written progress and final reports; and CEnR and Team science trainings. Progress reports are reviewed by Core staff to ensure that projects are meeting their milestones and progressing according to the timelines submitted by the awardees. The check-in meetings and progress reports are a means for identifying those groups who might benefit from Core staff/leadership intervention.

Dissemination Plan

Core pilot grant proposals will be accepted annually, with submission deadline announced at least one month in advance. University-wide web and email announcements will be sent at least twice for each application period. In addition, solicitation will be displayed on the ICTR website and sent upon posting to individuals who opt in for ICTR updates via email or news feed. Any changes or alterations to the program and/or the RFA will also be broadcast through these methods. In addition, ICTR-associated faculty, staff, and community partners are encouraged to assist in communications efforts through their own email contacts and word of mouth.

The submission deadline for applications is 11:59 PM on Sunday, May 2, 2021. All application materials must be received by this deadline to be considered. No exceptions will be granted.

Application Process

The grant application is comprised of the seven mandatory application components described below. These documents may be in Microsoft Excel, Adobe PDF or Word format and must be uploaded into the online application form in the corresponding section. Should any of the seven required documents be omitted from the application, the applicant will not be allowed to complete submission of the grant. Questions about the application process should be directed to the Community Engagement Program staff at **ICTRCCPG@jhmi.edu**.

Materials required to be submitted via the application website include:

1) **Abstract**

   The abstract is <u>NOT INCLUDED</u> in the 5-page Research Plan and <u>MUST BE SUBMITTED ON THE</u> <u>ABSTRACT TEMPLATE PROVIDED (Appendix 2)</u>. It must be no longer than 600 words and follow the required font and margin specifications of the Research Plan (See *Research Plan Guidelines* to follow). **The abstract should not contain proprietary or otherwise confidential information**.

   The abstract must include:
   a. a brief background of the project and introduction;
   b. specific aims and objectives with hypothesis (if applicable) being tested;
   c. the proposed methodology (action steps) to be used in each aim/objective;
   d. significance of the proposed project; and
   e. any other information that may be relevant to your project and was not already included in any of the above.

2) **Research Plan** (5-page limit, content and format described below in "*Research Plan Guidelines*")

3) **Comprehensive Budget**

   - The budget **MUST** include an explanation of other funding sources that will be used to cover costs not covered by this pilot grant program.
   - The budget **MUST** include the name and email address of the applicant's financial contact.
   - **If the ICTR Finance Office has authorized inclusion of a budget with a subcontract** *(See Funding Restrictions above)*, the total requested funds (including subsite indirects, if applicable, and directs) for the subcontract must be listed in the overall project budget; **additionally, a separate detailed subcontract budget, justification, and scope of work must also be submitted**. The ICTR Finance Office may request additional documentation as necessary.

4) **Detailed Budget Justification**

   A **detailed** budget justification is required and **MUST** include salary, stipend, supplies, travel, collaborative activities costs (e.g., partnership meetings), and any other expenses required to complete the study.

5) **Detailed Project Timeline**

6) **Biographical Sketch Information**

- A biographical sketch in NIH-format for the PIs (5-page limit)
- A biographical sketch in NIH-format for the Co-Investigator (5-page limit)
- A brief identification and biographical description of all other study team personnel named in the application **(4-page limit total)**
- <u>**MUST**</u> include full "Other support" pages from PIs and all named Co-Investigators

7) Reference List of up to 30 references

Research Plan Guidelines

Presentation and Formatting: The research plan must be <u>no longer than five single-spaced pages (including figures) in a font no smaller than 11 points, with margins of at least 0.5 inches on all sides</u>. **The abstract and references are not included in the five-page limit.** As described above, a bibliography containing up to 30 citations should be uploaded in the Reference List section of the application. The name of the PI should appear in the top right-hand corner of each page. Page numbers should appear on the bottom right-hand corner of each page.

The Research Plan <u>must</u> include the following components:

Brief Introduction: This section is intended to help orient the reviewer to better understand the scientific basis for the project, why the work is being proposed as well as the suitability of the research for Core pilot funding. Any new collaborations or highly innovative aspects should be succinctly noted. Relevance to the CEnR nature of the pilot program should also be indicated.

Project Milestones and Timeline: In the research plan, which is to be no longer than 5 pages in length, a summary of specific milestones and a 12-month timeline of the project must be included. This summary may be presented as a chart, a paragraph, or incorporated throughout the project. Milestones should highlight specific goals to be attained and, when appropriate, hypotheses to be tested. Milestones must include both the scientific objectives of the application and the procedural issues involved in executing them in a realistic and achievable way. If new collaborations, new populations, or new techniques are utilized to reach these milestones, they should be emphasized.

All grants must be organized towards the completion of project- and/or time-dependent milestones.

Background (including Preliminary Results, if available) and Significance: In addition to scientific background and significance, this section may indicate how success of the pilot grant will affect subsequent research and how it enhances CEnR. The material on Significance should clarify how the research will advance the CEnR field and **should also discuss the project's potential for improving the health of target populations or community.**

Design: Method description should be sufficiently detailed to convince reviewers of feasibility and validity. Details should focus on the novel aspects of the CEnR project rather than published or standard techniques. Statistical approaches to data analysis should be outlined where applicable. Quantifiable goals for the completion of each milestone should be delineated.

Anticipated Problems and Possible Solutions: Any anticipated problems should be addressed, with alternative approaches described when possible. The feasibility of using alternative approaches to complete the project within the constraints of the presented pilot budget and the 12-month time limit of this grant must be assured in the application. All risks and drawbacks from using any proposed alternative approach must be addressed, especially if human subjects are involved.

Community Partnership and Collaboration Core Pilot Grant Review Criteria and Process

Applications will be evaluated and scored using the following criteria:

1. Relevance to CEnR: Are there clear plans to develop a new or build on an established academic community partnership to move a project through to the next step?
2. Scientific impact, novelty, and merit
3. Feasibility of project completion within a 12-month period
4. Whether or not the project's academic PI is a junior investigator and/or will promote the development of new CEnR researchers by moving junior, senior, or community investigators into a new research area
5. Applications using an evidence-based framework such as the 10-step Framework, focused on diverse populations, priority topic, collaboration among partner institution(s) (The Johns Hopkins University, University of Maryland at Baltimore, Morgan State University, Kaiser Permanente Mid-Atlantic States) will receive bonus points in the ranking process.

Only complete applications received by the deadline will be considered.

The review process will be conducted as follows:

(1) Administrative Triage: ICTR Core staff will review applications for compliance with budgetary, content, eligibility, and other submission guidelines as described in this document. Incomplete or noncompliant applications will be returned without scientific review.

(2) First Round: Community Partnership and Collaboration Core Leadership Council will assess the application in terms of the fit, feasibility, and CEnR nature of the proposed project. These assessments will each be assigned a numerical score. No reviewer comments will be provided to applicants whose proposals are declined in this round.

(3) Second Round: Applications that achieve a minimum first round score established by Core leadership will be sent for 2nd round review to a minimum of two reviewers with expertise in fields relevant to the science in the proposal. These reviewers will be asked to disclose any relationships to the grant applicant. If not conflicted, they will then be asked to provide written feedback addressing the merits of the application based on the five criteria listed above and scored accordingly. Reviewer comments from this round will be provided to applicants, but reviewer identities will be kept confidential.

Funding Decisions: The Core Leadership Council will evaluate all second-round scores and feedback and make funding decisions. **Funding decisions for those pilot projects involving human subjects' research cannot be finalized until notification of NCATS approval is received** as described above.

Notification and Feedback*: All applicants will be notified of funding decisions approximately 8-10 weeks after the submission deadline. With the exception of projects involving human subjects' research, <u>the start and end date of the 12-month funding period will be included in the notification of award.</u>

Only those applicants who receive second-round reviews will be provided with feedback from the external review process.

Feedback about the Core's Pilot Grant Program may be directed to ICTRCCPG@jhmi.edu.

A grant information session will be held on April 7 at 12 pm via Zoom.
To register and join the Zoom meeting, use this link: https://jhjhm.zoom.us/meeting/register/tJYld-2urjkpE9QpxTuNtUkWZ-TV7Jkp1FYY

Appendix I: Regulatory Requirements/Approvals

All applicants with projects involving human subjects research as defined by NIH must now obtain approval before the study can be started. Approval must be obtained from the National Center for Advancing Translational Science' (NCATS) in addition to an Institutional Review Board (IRB) and must satisfy other institutional requirements (e.g. HSR compliance and HIPAA certification of staff, etc.).

If notified by the ICTR that the submission has been selected for Community Partnership and Collaboration Core pilot funding, then the applicant must immediately start working to obtain all institutional and external regulatory approvals and submit their study for IRB review. Upon receipt of IRB approval, <u>which can take between 3-5 months</u>, the applicant must then prepare a document package to be submitted for NCATS' review. Detailed instructions for preparation of the document package, required file naming conventions, and submission of the materials will be provided by the ICTR staff with the notification of selection of the project for award.

<u>Note: If IRB materials are not submitted within 1 month from the date of notice of funding decision, there is a possibility that the funding may be rescinded and be given to the study team with the next highest score instead.</u>

The NCATS Human Subjects Research Prior Approval (HSRPA) review package will consist of applicable materials that are either already part of the eIRB application, or should be readily available from the applicant including:

a) Brief summary of the specific aspects of the proposed study that will be supported by NCATS funds and include a line-item budget for each aspect (list supplies, services, and personnel costs)
b) IRB approval of the proposed clinical study (if applicable) or institutional exemption determination
c) NIH Biosketch for the pilot project investigator and for each Key Personnel involved in the proposed human subjects research study (if applicable)
d) Complete clinical research protocol-[1]
e) Informed consent document (if applicable)
   1. and assent document (if applicable)
f) If the proposed clinical research protocol is considered an amendment to a parent protocol, and the entire parent protocol is to be included in the NCATS HSRPA submission [1]:
   1. Identification of the specific amendment/ancillary study or portion of the protocol that is supported by the NCATS funding
   2. An explanation of exactly what is being supported by NCATS pilot funding
g) Product information such as the clinical investigator brochure, package insert, or description of the device, if a clinical trial is proposed (if applicable)
h) A new or revised "Protection of Human Subjects" section for the pilot that:
   1. clearly describes the risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities (as detailed in **Section 3.1 in the GENERAL INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES** (See page G-234)" of the NIH competing application instructions (if applicable)-[2]
   2. clearly identifies the information relevant to the pilot project

i)   Inclusion plans for women, minorities, and children (if applicable)
j)   Targeted enrollment table or inclusion data record (IDR) (if applicable)Recruitment and retention plan and recruitment status (if applicable)
k)   Study timeline (if applicable)
l)   Data and safety monitoring plan (DSMP) or Board (DSMB) (as applicable)
m) Assurance or certification that the pilot project awardee and any key personnel directly involved in the study have taken appropriate education in protection of human subjects (if applicable)

[1-] Except for studies meeting the criteria for exemption under **45 CFR 46**

[2-] If the JHM IRB determines that the project is exempt from formal IRB Committee review, in place of a full Protection of Human Subjects section, a document justifying why the research meets the criteria for the exemption(s) claimed and explaining how the proposed research meets the criteria for the exemption claimed will be required.

NCATS Review and Funding Timeline

NCATS has up to 30 days from the date of **receipt of a complete packet,** to review and respond. Every effort is made to expedite the process and grantees are asked to respond promptly to any requests for additional information or clarifying questions.

If approved by NCATS, the start date of a 12-month Core pilot grant will be determined upon receipt of the approval notification. Copies of all approvals, renewals, certifications, protocols and amendments must be made available to the Core staff throughout the course of the grant award period upon request.

IMPORTANT NOTE: Should a project NOT satisfy NCATS' requirements for approval, and the issue cannot be readily resolved, the pilot award will be disallowed despite being selected for funding by the Johns Hopkins ICTR Community Partnership and Collaboration Core Pilot Grant program.

Appendix 2: Abstract Template

Instructions: 600 words, font size >= 11 points, with margins >=0.5 inches on all sides

PI: _____

PROJECT TITLE:

PROJECT BACKGROUND:

SPECIFIC AIMS:

METHODOLOGY:

SIGNIFICANCE OF PROJECT:

OTHER RELEVANT INFORMATION: