

Call for Proposals – Accelerated Translational Incubator Pilot (ATIP)

UMBC is pleased to announce a joint funding opportunity in partnership with the University of Maryland [Institute for Clinical and Translational Research \(ICTR\)](#).

The Accelerated Translational Incubator Pilot (ATIP) Grant Program provides starter funds for projects specifically focused on innovative, translational research that involves faculty from the UMB Schools, UMBC and collaborative partners.

- Notice of Intent (NOI) is due **Monday, December 2, 2019** by 5:00pm. This consists only of the name of the UMBC and UMB collaborators. Submit at <http://bit.ly/atip-noi>.
- A Letter of Intent (LOI) is due on **Monday, December 23, 2019** by 5:00 pm
- The Application Deadline is **Monday, January 6, 2020** by 5:00 pm
- Budget - up to \$50,000 in direct cost.
- The Funding Period will be for 12 months from May 1, 2020 to April 31, 2021
 - Awardees will be announced in April 2020
 - No-cost extensions or carry-overs are not permitted.
- UMBC applicants must have a UMB Co-PI collaborator

For further details on this funding opportunity please see the attached Call for Proposals.

APPLICATION DEADLINE

ATIP GRANT PROGRAM REQUEST FOR

PROPOSALS ATIP GRANT PROGRAM GUIDELINES

- A. UMB ICTR ATIP Funding Opportunities
- B. Eligibility
- C. Regulatory Requirements/Approvals
- D. Potential Project Topics
- E. Funding Restrictions

ROLE OF THE ICTR NAVIGATOR

LETTER OF INTENT

ATIP APPLICATION PROCESS

- A. Cover Letter
- B. Abstract
- C. Specific Aims
- D. Research Plan
- E. Comprehensive Budget/Justification
- F. Biographical Sketch
- G. Project Milestone Timeline
- H. Reference List
- I. Regulatory Approvals

RESEARCH PLAN GUIDELINES

ICTR PILOT GRANT REVIEW CRITERIA

AND PROCESS ACKNOWLEDGING UMB ICTR/CTSA FUNDING

**UNIVERSITY OF MARYLAND, BALTIMORE INSTITUTE FOR CLINICAL AND TRANSLATIONAL
RESEARCH (ICTR)
ACCELERATED TRANSLATIONAL INCUBATOR PILOT (ATIP) GRANT PROGRAM**

- Deadlines:** Letter of Intent (LOI) – Monday, December 23, 2019, 5 pm (EST)
ATIP Application – Monday, January 6, 2020, 5 pm (EST)
- Eligibility:** All University of Maryland, Baltimore (UMB) and University of Maryland, Baltimore County (UMBC) faculty at the level of Assistant Professor, Associate Professor, or Professor
- Budget:** Up to \$50,000 in direct costs
- Grant period:** May 1, 2020 – April 30, 2021; Awardees Announced April 2020
- Application:** Forms templates available at <https://www.umaryland.edu/ictr/funding/atip-grant-program-foa/>

The application and supporting documents are submitted electronically. The application link will be released at the time the Letter of Intent is submitted via this [link].

ATIP GRANT PROGRAM REQUEST FOR PROPOSALS

The University of Maryland, Baltimore (UMB) Institute for Clinical and Translational Research (ICTR) is pleased to announce the **third round** of the UMB ICTR Accelerated Translational Incubator Pilot (ATIP) Grant competition to provide starter funds for projects specifically focused on innovative, **translational research** that involve faculty from the UMB Schools of Dentistry, Law, Medicine, Nursing, Pharmacy, or Social Work; UMBC, and UMB-community partnerships. Funding for the ATIP is through UMB's and Johns Hopkins University's (JHU) partnership in the National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS) Clinical & Translational Science Awards (CTSA) Program, grant number **1UL1TR003098**. The awards aim to accomplish the following objectives:

- To promote innovative translational research by providing starter funds that will support projects specifically focused on the translation of laboratory and/or clinical research into new interventions that improve clinical outcomes (e.g. new diagnostics or approaches to prevention/treatment, or implementation of new advances within communities to improve health and reduce disparities in Baltimore and throughout the state of Maryland).
- To utilize a milestone-driven approach for proposed projects that will ensure timely generation of tangible products and outcomes within the funding support.
- To promote cross-disciplinary (specifically across or within UMB Schools and UMBC) and UMB-community collaborations, especially new and novel types of collaborations. New or junior investigators are encouraged to participate.
- To support investigators in the efficient attainment of translational milestones by providing guidance, resources, and feedback from the ICTR. To generate pilot data for innovative research projects that will support a subsequent major external funding application.

To be considered for one of the UMB ICTR/CTSA ATIP Grant Program opportunities, proposals must be received **by January 6, 2020, 5 pm (EST)**. Applications cannot be accepted after this and incomplete applications cannot be accepted.

For questions regarding application guidelines, please email the ICTR Navigator at ICTR-Navigator@umaryland.edu. Further details are on following pages.

ATIP GRANT PROGRAM GUIDELINES

A. **UMB ICTR ATIP Funding Opportunities**

This Request for Proposals provides funding for three types of ATIP opportunities: The ICTR Innovative Collaboration Pilot Grant, ICTR Artificial Intelligence/Cybersecurity/Machine Learning Pilot Grant, and the ICTR Community-Engaged Research Grant. Awards up to \$50,000 will be funded with at least one Community-Engagement Research Grant award.

- **ICTR Innovative Collaboration Pilot Grant**
Aims to stimulate innovative collaborations among faculty of UMB Schools of Dentistry, Law, Medicine, Nursing, Pharmacy, Social Work and UMBC that will involve research along the translational continuum.
- **ICTR Artificial Intelligence/Cybersecurity/Machine Learning Pilot Grant**
Aims to support new or existing clinical and translational research collaborations between UMB and UMBC School faculty that will test transformative projects that improve healthcare.
- **ICTR Community-Engaged Research Pilot Grant**
Aims to support new or existing collaborations between UMB School faculty and a community partner from the greater Baltimore area that will test innovations that address health problems through community-engaged implementation.

B. **Eligibility**

- Any faculty member at the level of Assistant Professor, Associate Professor, or Professor from the UMB Schools of Medicine, Pharmacy, Dentistry, Nursing, Law, Social Work or University of Maryland Baltimore County (UMBC) is eligible to apply as principal investigator for an ICTR ATIP Pilot Grant. A UMBC Primary/Lead PI must name a UMB Co-PI.
- Multiple PI applications are allowed – limit to 2 Co-PIs – and must include a Multiple PI Leadership Plan to describe respective roles. In multi-PI applications a designated lead PI is required and will serve as the point of contact for communications. New or junior investigators are encouraged to apply and will receive extra consideration.
- Individual investigators may submit only one proposal in response to this Request for Proposals as a PI; however, the PI can serve as a non-PI collaborator on other proposals.
- Undergraduates, graduate students, postdoctoral fellows, and Research Associates/Instructors are not eligible to apply as principal or co-investigators but may be team members on a proposal.
- Eligible submissions are encouraged to include collaborations among faculty from at least 2 of the UMB Schools or between faculty from a UMB School and UMBC, or between UMB and a community partner from the greater Baltimore area. Eligible **community partners** include non-profits such as community service organizations, advocacy groups, neighborhood associations, faith-based organizations, or coalitions, public agencies and private organizations.
- Eligible submissions must include specific milestones, with clear outcome endpoints, and a realistic timeline for completion within the funding period.
- ATIP awards are not meant to be considered supplements to existing grants. We will consider an application to be used in conjunction with an existing grant if it shows the ATIP project could successfully leverage a new award or renewal. As we give priority to collaborative projects, existing grants that do not involve faculty collaborations between UMB Schools or between a UMB School and UMBC, or between UMB and a community partner from the greater Baltimore will be at a competitive disadvantage.
- PIs with previously-funded ATIP awards may not apply for another ATIP grant as a PI or co-PI. They may, however, be involved as collaborators in another PI's application.
- Research projects submitted to a previous ATIP call for proposals but not selected for an

award may be re-submitted. An accompanying cover letter should note how the current proposal differs from the original submission and how the reviewers' comments are addressed.

C. Regulatory Requirements/Approvals

- **Human Subjects Research**

All grants with projects involving human subjects research must obtain Institutional Review Board (IRB) approval as well as satisfy other institutional requirements (e.g. Biosafety registrations, CITI training and HIPAA certification of staff, Clinical Engineering clearance of devices, Radiation Safety registration, etc.) prior to the release of grant funds. Although final IRB approval and training documents are not required at the time of this pilot grant application submission, applicants are strongly encouraged to begin the submission process early. See **New, Additional NCATS Approval Requirements** below.

- **Animal Studies**

All grants that involve animal studies must be approved by the Institutional Animal Care and Use Committee (IACUC) prior to initiating any animal research activities. All other required institutional approvals (e.g. Biosafety registrations, Radiation Safety registration, etc.) must be obtained prior to initiating any research activities for which the certification/registration/approval is required. Although final IACUC approval and training/certification documents are not required at the time of this pilot grant application submission, applicants are strongly encouraged to begin the submission process early. See **New, Additional NCATS Approval Requirements** below.

- **IMPORTANT! NEW, ADDITIONAL NCATS APPROVAL REQUIREMENTS**

Funds cannot be released without NCATS approval. The UMB ICTR strongly advises all applicants to obtain necessary IRB and/or IACUC approvals, and any other required training and certification required by NCATS, prior to the UMB ICTR announcing the awardees. The UMB ICTR will request the required packet of documents from awardees within one week of the award announcement and will submit to NCATS. Links to document packets are below. NCATS may take up to four weeks to review and approve the projects. NCATS project approvals received after the May 1, 2020 start date will shorten the funding period. Additional delays will shorten the funding period correspondingly. **No-cost-extensions or carry-overs are NOT permitted.**

NCATS prior-approval forms and supportive documents can be downloaded from these links:

Human Subjects: <https://ctsa.ncats.nih.gov/governance-guidelines/guidelines/prior-approval-of-planned-research-involving-human-subjects/>

Vertebrate Animals: <https://ctsa.ncats.nih.gov/governance-guidelines/guidelines/prior-approval-of-planned-research-involving-live-vertebrate-animals/>

- **Conflicts of Interest (COI)**

At the time of application, review process, 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 (COI). These interests must be reported to the ICTR and the Conflict of Interest Officer, UMB Research Integrity Office. The presence of a COI does not disqualify investigators from receiving this award but will require the review and management of this conflict by the COI Officer. 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.

You will be required to submit the contact information of two internal reviewers and two external reviewers. Please ensure that no COI exists between the reviewers and the PI(s) and Co-Investigators.

UMB's COI Policy information, including examples of what constitutes an outside interest, may be found at <https://www.umb.edu/oac/areas-of-responsibility/conflict-of-interest/>

UMBC's COI Policy information may be found at <https://research.umbc.edu/office-of-research-protections-and-compliance/>

D. *Potential Project Topics*

Projects may cover a wide range of topics, including but not limited to the representative topics below:

- **Pre-Clinical Translation**
 - Development of pre-clinical research applications
 - Development of novel treatment platforms or therapies
 - Development of novel drug targets for diseases or symptoms associated with disease or treatment
 - Drug screening assays
 - Methods for generation of novel vaccines or peptides
 - Animal models for drug selection
 - Preclinical toxicology markers/assays
 - Surrogate marker assays, including genomic, proteomic assays, and metabolic, imaging methods
 - Key research activities that enhance the commercial potential of UMB intellectual property
- **Clinical Translation**
 - Development of clinically-relevant applications
 - Development and verification of surrogate marker assays
 - Identification of disease or symptom biomarkers
 - Clinical trial design paradigms (e.g. computer simulation)
 - Development or evaluation of diagnostic tests
 - Clinical trials including Pilot/Phase 0 or 1 trials
 - Collection of pharmacokinetics/pharmacodynamics data
 - Clinical physiology and mechanisms/pathophysiology of disease
 - Use of machine learning (ML) and artificial intelligence (AI) to identify patterns in data to improve healthcare delivery with minimal human intervention
 - Develop apps and devices that improve delivery and exchange of health information
- **Post-Clinical Translation**
 - Comparative effectiveness research studies
 - Knowledge transfer to providers or community
 - Novel approaches to partnering with communities to enhance research
 - Community-based research focused on an area of health disparity such as diabetes, cardiovascular disease/hypertension, mental health, cancer, and kidney disease
 - Tests of innovative implementation strategies to optimize uptake of solutions at the community level.

E. *Funding Restrictions*

- Requests must be no more than \$50,000 in direct costs. Budget requests must be realistic and well-justified in the budget justification.
- **Allowable expenses:** Research supplies (purchase or equipment rental; new equipment costs should be no more than 20% of the total budget); recruitment and compensation of study participant costs; research training for community partners. Salary support for all faculty listed on the grant cannot exceed \$7,500 of the budget. The \$7,500 allowance is inclusive of fringe benefits.
- **Unallowable Expenses:** Administrative support, alterations or renovations of laboratory space, purchase of laboratory or office furniture, purchase of periodicals or books, phone services and professional societies membership dues are not allowed.
- ATIP funds up to \$1,000 may be used for travel with strong justification establishing the essential need for the conduct of research. ATIP funds cannot be used for travel to present results at established meetings or conferences.
- **Funding will be for May 1, 2020 – April 30, 2021 only. No-cost-extensions or carry-overs are NOT permitted.**
- We will consider payments to an outside partnering organization, where appropriate, as a “service provider” (not as a sub-award). This expense should be justified and itemized under “Other Expenses” in the budget template form.
- Indirect costs should not be included in the budget.

- Required regulatory approvals (see section C) **must be obtained** prior to disbursement of funds.
- All funded projects will have a touchstone discussion every three months after the award notification and will be required to complete a written progress report every six months to the assigned ICTR Navigator to ensure that projects are meeting their milestones and progressing according to approved timelines. A final progress report will be due within 90 days of the end of the award. Failure to submit progress reports in a timely manner can have significant implications for the project and may result in termination of funding.
- Additional, annual reports will be requested for up to 10 years to track grant applications, publications, and technological/intellectual property development/licensing resulting from the project.
- Funds will be disbursed in two installments, with the second installment contingent upon submission of a satisfactory progress report at 6 months.

ROLE OF THE ICTR NAVIGATOR

Research navigators will provide guidance and answer questions related to the application and review process, the scope of work that is suitable for funding, and post-award activities. They will assist research teams in identifying resources needed for successful completion of research projects, including the referral of researchers to appropriate services, university cores and additional sources of support for translational research. They will review applications to ensure compliance with submission guidelines and may contact investigators to provide additional information. Throughout the award, research navigators serve as project managers, monitoring the progress of the projects, and may provide guidance, resources, and feedback to ensure the proposed translational milestones are met.

LETTER OF INTENT (LOI)

Please provide the following information via this LOI [link] (*created in REDCap*) no later than Monday, December 23, 2019, 5 pm (EST)

- Name
- School
- Department/Section
- Campus email
- Best contact number
- ATIP funding opportunity you wish to apply for
 - ICTR Innovative Collaboration Pilot Grant, or
 - ICTR Artificial Intelligence/Cybersecurity/Machine Learning Pilot Grant, or
 - ICTR Community-Engaged Research Pilot Grant
- Very brief project description

Once your LOI is submitted, you will receive a pop-up message as well as an email with the ATIP Application link.

ATIP APPLICATION PROCESS

Prepare each of the following sections and submit electronically via the ATIP Application link provided to you at the time of your LOI submission. Form templates are available on the UMB ICTR website.

A. *Cover Letter (limited to one page)*

- Title of ATIP Innovative Collaboration Pilot Grant or Community-Engaged Research Grant
- State whether application is for the ATIP Innovative Collaboration Pilot Grant or Community-Engaged Research Grant
- Names, academic ranks, and appointments of the designated primary PI and all other PIs

- Salary support amounts requested for each faculty listed on the grant
- Signature of PI(s)
- Signature of School Dean (or designee [e.g., department chair]) indicating support for submission

B. Abstract (limited to one page)

The abstract is not included in the 5-page Research Plan. It must be no longer than 30 lines of text and follow the required font and margin specifications of the Research Plan (See Research Plan Guidelines to follow). **The abstract should not contain proprietary confidential information.**

The abstract should include:

- A brief background of the project;
- The significance of the proposed research;
- The unique features, new collaborations, and innovation of the project;
- The methodology (action steps) to be used;
- Expected results;
- Relevance to the translational nature of the ICTR ATIP Pilot Grant Program;
- and potential for improving the health of patients within the next 3-5 years

C. Specific Aims (1-page limit, specific aims, objectives, or hypotheses)

D. Research Plan (5-page limit, content and format described below in “Research Plan Guidelines”). The research plan should include the following sections:

- **Brief Introduction:** This section is intended to help orient the reviewers to better understand the scientific basis for the project, why the work is being proposed as well as the suitability of the research for ICTR ATIP Pilot Grant funding. Any new collaborations or highly innovative aspects should be succinctly noted. Relevance to the translational nature of the ATIP program should also be indicated.
- **Project Milestones and Timeline:** A **summary** of specific milestones and a 12-month timeline of the project must be included in the research plan. This summary may be presented as a chart, a paragraph, or incorporated throughout the experimental design. 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 techniques, new populations, or new collaborations 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.

NOTE: *In addition to the milestone/timeline summary presented in the research plan, you must include a **Project Milestone Timeline** document (see template). This document **MUST** include the milestones described in the research plan AND a breakdown of all activities necessary to complete the milestone and the time required for each activity.*

- **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 translation (e.g. from lab to clinic). For Community-Engaged Projects, describe the community health concern that will be addressed through the academic-community partnership. The material on Significance should indicate relevance to the overall target of clinical translation. It should also clarify how the research will advance the field and **should also discuss the project’s potential for improving the health of patients within the next 3-5 years.**
- **Research Design:** Method description should be sufficiently detailed to convince reviewers of feasibility and validity. Details should focus on the novel aspects of the project rather than published or standard techniques. If obtaining data from human subjects, provide inclusion/

exclusion criteria for study group(s), and briefly outline recruitment, consenting, and compensation plan if applicable. Statistical approaches to data analysis should be outlined where applicable. Quantifiable goals for the completion of each milestone should be delineated. A brief section outlining any collaborative links to any other clinical or laboratory cores is necessary.

- **Statement of Collaborative Effort:** Include a specific statement as to how the collaboration between investigators from each school or community partner is necessary to further the goals of the proposal. Include processes for maintaining communication and interactions between the Schools and between UMB, UMBC, and/or community partners and monitoring equitable distribution of intellectual involvement. For Community-engaged research proposals, list all collaborating organizations and/or key individuals. Describe what will be the roles of each partner during project implementation and what are the expected contributions/benefits of the partnership for the academic and community partners.
- **Anticipated Problems and Possible Solutions:** Any anticipated experimental or interpretive 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 ICTR ATIP budget as well as 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.
- **External Funding Plan:** Identify future funding sources that will be applied for. Specifically identify NIH, NSF, DOD, or other external funding opportunities that the team will be prepared to apply for within 18 months of the start of the award.

E. Comprehensive Budget / Detailed Budget Justification

- Applicants **should** use the budget template available but may customize it as their project requires.
- The budget **should** be **itemized** to within \$1,000.
- List each component of equipment with amount requested separately and justify each purchase
- **Itemize supplies in separate categories**, such as glassware, drugs, chemicals, radioisotopes, etc. Categories in amounts less than \$1,000 do not have to be itemized.
- If animals are to be purchased, state the species, number to be used, and cost per animal.
- The budget **MUST** include an explanation of other funding sources that will be used to cover costs not covered by ICTR ATIP pilot grant funds.
- A **detailed** budget justification is required for salary, supplies, equipment, travel, and any other expenses required to complete the study.

F. Biographical Sketch Information

- A biographical sketch in NIH-format for the PI(s) (5-page limit) and key individuals/community collaborators. Biosketches are not needed for support staff, though you may include a brief paragraph about the role of each support staff and their qualifications.
- Full "Other support" pages from PI(s)

G. Project Milestone Timeline

- Applicants **MUST** use template provided on ICTR website

H. Reference List of up to 30 references

I. Regulatory Approvals (IRB and IACUC; state whether projects have been submitted for review or include the determination or approval letter).

RESEARCH PLAN GUIDELINES

- **Presentation and Formatting:** 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.

- **The abstract and references are not included in the five-page limit.**
- The name of the contact 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.

ICTR PILOT GRANT REVIEW CRITERIA AND PROCESS

Applications will be evaluated and scored using the following six criteria:

1. **Relevance to translation:** Are there plans to move the project through to the next step along the research pathway?
2. **Scientific impact, novelty, and merit, including experimental design**
3. **Feasibility of project completion within defined budget period**
4. The **creation or potential for creation of collaborations** between investigators and/or academic-community partnerships
5. Whether or not the project's PI is a **junior investigator** and/or will promote the development of new translational researchers by **moving junior or senior investigators into a new research area**
6. **The plans for submitting a grant application for external funding.**

ACKNOWLEDGING UMB ICTR

All publications, abstracts, poster presentations, grant applications, intellectual/technological developments and licensing resulting from research supported by the UMB ICTR ATIP Grant Program should cite the **University of Maryland, Baltimore, Institute for Clinical & Translational Research and the National Center for Advancing Translational Sciences (NCATS)** as a contributing source of support. Please include the following citation:

"We acknowledge the support of the University of Maryland, Baltimore, Institute for Clinical & Translational Research (ICTR) and the National Center for Advancing Translational Sciences (NCATS) Clinical Translational Science Award (CTSA) grant number 1UL1TR003098."

Thank you for your cooperation in acknowledging the UMB ICTR's and NCATS support in your research.