UMB ICTR ATIP GRANT PROGRAM SPECIAL ANNOUNCEMENT: COVID-19 RESEARCH

Deadlines: **Accepted on a rolling basis through April 24th, 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: **One-year award to start as soon as regulatory approval is obtained**

Application: Form templates and electronic submission instructions are available at https://www.umaryland.edu/ictr/funding/atip-grant-program---covid-19---foa/

The UMB ICTR has partnered with the UMB Office of the President to launch a **COVID-19- specific** Accelerated Translational Incubator Pilot (ATIP) Grant competition to provide starter funds for projects specifically focused on **clinical and translational research related to COVID-19** that involve faculty from the UMB Schools of Dentistry, Law, Medicine, Nursing, Pharmacy, or Social Work; UMBC, and UMB-community partnerships.

We seek proposals that utilize UMB and UMBC's strengths to rapidly contribute to human health and related outcomes with respect to COVID-19 or the causal virus (SARS-CoV-2), including prevention, control, and response efforts. To that end, proposed research should accomplish one or both of the following:

1. Contribute to evidence-based responses to COVID-19 across a wide range of outcomes, including but not limited to:

    •   Clinical Trials involving novel vaccines; treatments using novel or repurposed drugs

    •   Screening, Detection, Prevention

    •   Psychological and socio-behavioral domains

    •   Digital Health and areas of Artificial Intelligence, Natural Language Processing, and Machine Learning

    •   Novel approaches for community monitoring and care delivery (e.g. surveillance apps, telehealth, etc.)

2. Establish preliminary research that will enable the Principal Investigator (PI)/team to leverage emergency or other research funding (announced or anticipated)

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

COVID-19 ATIP PROGRAM GUIDELINES

A.   *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 **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.

- PIs with previously funded ATIP awards may apply for this ATIP grant opportunity as a PI or co-PI.

B.   *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.

- *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

- *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 necessarily 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.

  UMB's COI Policy information, including examples of what constitutes an outside interest, may be found at https://www.umaryland.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/

C.   *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.
- 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.
- Funds will be disbursed in two installments, with the second installment contingent upon submission of a satisfactory progress report at 6 months.
- Additional, semi- 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.

ROLE OF THE ICTR NAVIGATOR

ICTR 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, ICTR 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.

ATIP APPLICATION PROCESS

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

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

- Title of ATIP Pilot 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. 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 significant impact of improving the health of patients across the spectrum of Covid-19 infection.

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 significant impact for improving the health of patients across the spectrum of Covid-19 infection.**

- **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.

- **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 12 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.
- Include recent, signed quotes for budgeted services and equipment

F. *Biographical sketch information*

- A biographical sketch in NIH-format for the PI(s) (5-page limit). Biosketches/resumes for community partners and individuals receiving salary support. Biosketches are not needed for support staff, but please provide 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).

J.

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.

REVIEW CRITERIA AND PROCESS

Applications will be evaluated and scored using the following criteria:

1. Impact: Does the proposal have the potential for significant impact on human health and related outcomes? If the potential is not immediate, is there a clear plan for securing external funding to enable such impact? Proposals that impact Maryland, specifically, are encouraged.
2. Scientific merit and novelty, including experimental design: Does the proposal have scientific rigor and clear, well-designed research objectives and questions?

3. Urgency: Is the project urgent and can it only be accomplished through this pilot funding?

4. Risks: Does the proposal outline and include plans for mitigating any risks to the research team and/or participants?

5. Dissemination: Does the proposal include plans to disseminate results?

6. Leverage: Can this proposal be leveraged to garner extramural support form specific funding agencies?

ACKNOWLEDGING UMB ICTR

All publications, abstracts, poster presentations, grant/funding 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** 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).**"*

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