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- Deadlines:** ATIP Application – Friday, November 13, 2020, 5 pm (Eastern Time)
- Eligibility:** Faculty at the level of Assistant Professor, Associate Professor, or Professor from the University of Maryland, Baltimore (UMB) and University of Maryland, Baltimore County (UMBC)
- Budget:** Up to \$50,000 in direct costs
- Grant period:** May 1, 2021 – April 30, 2022; Awardees Announced End of January 2021
- Application:** Form templates and electronic submission instructions are available at <https://www.umaryland.edu/ictr/funding/atip-grant-program-foa/>

ATIP GRANT PROGRAM REQUEST FOR PROPOSALS

The University of Maryland, Baltimore (UMB) Institute for Clinical and Translational Research (ICTR) is pleased to announce the **fifth 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 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** or through the UMB ICTR internal funding mechanism.

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 period and final, approved budget.
- 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 the application deadline. Incomplete applications will not be reviewed.

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

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ATIP GRANT PROGRAM GUIDELINES

A. UMB ICTR ATIP Funding Opportunity Categories

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.

• **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 Lead Principal (PI) must name a UMB Co-PI.
- Multiple PI applications are allowed – limit to 1 Lead PI (the applicant) and 1 Co-PI. A Multiple PI Leadership Plan describing the respective roles must be included with the application. In multi-PI applications, the Lead PI will serve as the point of contact for communications. New or junior investigators are encouraged to apply and will receive extra consideration.
- An investigator may submit only one proposal in response to this funding opportunity announcement. Also, an investigator can only serve as a Lead PI or Co-PI on one proposal; however, the PI may serve as a non-PI collaborator on other proposals.
- Undergraduates, graduate students, postdoctoral fellows, and Research Associates/Instructors are not eligible to apply and cannot be listed as Co-PIs or Co-Investigators. However, they may be listed as in other roles in the 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 a timeline of one or more milestones for each Specific Aim with clear outcome endpoints. The timeline must be realistic for completion within the

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funding period and with the approved final budget.

- 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.
- PIs with previously funded ATIP awards may not apply for another ATIP grant as a Lead PI or Co-PI. They may, however, be involved as Co-Investigators or 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 and Training Certificates

- **Human Subjects Research**

Awarded projects that propose research that involves human specimens and/or data must provide a Letter of Determination or Approval from the Institutional Review Board (IRB). If the IRB determines that the project is Human Subjects Research (HSR), you will need to provide current CITI human subjects research and HIPAA certifications for all team members. If the HSR project is also a clinical trial (ClinicalTrials.gov), all team members are required to have current Good Clinical Practice (GCP) training as well. More information about training can be found on the [UMB IRB website](#). Additional institutional requirements may include: Data Use Agreements, Biosafety registrations, Clinical Engineering clearance of devices, Radiation Safety registration, etc.

Although the IRB Letter of Determination/Approval and other documents are not required at the time of the pilot grant application submission, **applicants are strongly encouraged to begin the submission process early.**

All required documents and approvals must be received prior to the release of grant funds. In addition, awarded projects selected for the NIH NCATS funding mechanism must have all documents and approvals reviewed by NIH NCATS before funding can be released. After receipt of the required documents and approvals, the NIH NCATS may take up to 30 days to review and approve funding release for a project.

See **Additional NIH NCATS Approval Requirements** below.

- **Animal Studies**

Awarded projects proposing research that involves live vertebrate animals must have the research approved by their [Institutional Animal Care and Use Committee \(IACUC\)](#). All other required institutional registrations/approvals (e.g. [Biosafety, Radiation Safety, 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.**

All required documents and approvals must be received prior to the release of grant funds. In addition, awarded projects selected for the NIH NCATS funding mechanism must have all

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documents and approvals reviewed by NIH NCATS before funding can be released. After receipt of the required documents and approvals, the NIH NCATS may take up to 30 days to review and approve funding release for a project.

See **Additional NIH NCATS Approval Requirements** below.

- **IMPORTANT! NIH NCATS APPROVAL REQUIREMENTS**

Awarded projects designated for the NIH NCATS funding mechanism have document requirements in addition to the IRB Determination Letters, IACUC approval letters, training certificates and biosketches/resumes of all study team members. The UMB ATIP Navigator will contact you regarding the additional documents. After receipt of the required documents and approvals, the NIH NCATS may take up to 30 days to review and approve funding release for the project. Delays will shorten the funding period correspondingly.

D. 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 automatically 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/>

E. 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

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- **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.

F. 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-level team members listed on the grant cannot exceed \$7,500 of the **total** budget. The \$7,500 allowance is inclusive of fringe benefits.
- Official quotes from the provider of services, supplies, and/or equipment are required.
- **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.
- Travel: 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, 2021 – April 30, 2022 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 the previous section C) – and NIH NCATS approval, if applicable –**must be obtained** prior to disbursement of funds.
- Funds will be disbursed in two installments, with the second installment contingent upon submission of a satisfactory progress report at 6 months.

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G. Reporting Requirements

- All funded projects are required to have a **milestone telephone update** three, six, and nine months from the May 1, 2021 start date. A **written report** on the progress of the milestones and budget expenditures will be required at the sixth-month time period and a final, written progress report will be due within 90 days of the end of the award (12-month time period). Failure to attend milestone telephone updates and submit progress reports in a timely manner can have significant implications for the project and may result in termination of funding.
- Additional, semi-annual reports will be requested for up to 10 years to track grant applications/awards, 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, 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.

APPLICATION REQUEST FORM (UMBC applicants)

For UMBC applicants, please provide the following information via this [link](#) or paste in browser <https://rs.igs.umaryland.edu/surveys/?s=TFXHYDRCPF> (created in REDCap)

- Name
- 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

Once your request is submitted, you will receive an ICTR-Navigator@umaryland.edu email with a link to the application. Please email the ICTR Navigator if you do not receive the application link within 3 business days. Please make sure to request application in time to allow for a complete application submission. Incomplete application will not be reviewed.

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ATIP APPLICATION PROCESS

UMB applicants: Please access the ATIP Application directly through the [UMB ICTR website, FOA page](#). You will be prompted to enter your UMID username and password.

UMBC applicants: See above for APPLICATION REQUEST FORM (UMBC applicants).

Prepare each of the following sections and submit electronically via the ATIP Application link. Information about **formatting is found in Section M**. The application is maintained in the UMB REDCap system. See the [required budget and milestones templates](#) available on the [UMB ICTR website](#).

A. Cover Letter (Limited to one page)

- Title of ATIP Innovative Collaboration Pilot Grant, Artificial Intelligence /Cybersecurity/Machine Learning Pilot Grant or Community-Engaged Research Pilot Grant
- State whether application is for the ATIP Innovative Collaboration Pilot Grant, Artificial Intelligence/Cybersecurity/Machine Learning Pilot Grant or Community- Engaged Research Pilot Grant
- Names, academic ranks, and appointments of the designated primary (Lead) PI and one Co-PI if applicable.
- 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. See section M below for formatting)

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 improving the health of patients within the next 3-5 years

C. Specific aims, objectives, or hypotheses (Limited to one page. See section M below for formatting)

D. Research plan (Limited to five pages. See section M below for formatting). The abstract, specific aims, and references are separate from the research plan.

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

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should also be indicated.

- **Project Milestones and Timeline:** Submissions must include a timeline of one or more milestones for each Specific Aim with clear outcome endpoints. The timeline must be realistic for completion within the funding period and approved final budget. This summary may be presented as a chart, a paragraph, or incorporated throughout the experimental design. Milestones should highlight specific goals to be attained relative to the specific aims 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 section G below).***
- **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, recruitment site(s), 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.

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- **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 must use the budget template available on the [ICTR website](#)
- The school of team members must be noted on the budget template, including the school location of the to-be-determined team members.
- 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 for the conduct of the research, and any other expenses required to complete the study. For individuals receiving salary support, provide a brief paragraph in the budget justification about the role of each support staff and their qualifications
- Recent, official quotes for budgeted services, supplies, and equipment

F. Biographical sketch information

- A biographical sketch in NIH-format for the PI(s) and other faculty level study team members and resumes for non-faculty (5-page limit each).
- Full “Other support” pages from PI(s)

G. Project Milestone Timeline

- Applicants **MUST** use template provided on [ICTR website](#).
- The project timeline must include one or more milestones for each Specific Aim described in the research plan and the time required for each activity.
- The timeline **must** be realistic for completion within the funding period and final approved budget.
- Please note that IRB/IACUC submissions/approvals or subsequent grant applications/planned publications **should not** be included in this milestones’ timeline.

H. Reference list of up to 30 references

I. Internal and External Reviewers

You are required to submit the contact information of two internal reviewers and two external reviewers. Please ensure that no conflict of interest (COI) exists between the reviewers and you, the Co-PI and Co-Investigator(s) (if applicable) or any other person with a major professional role in your application. The peer review system relies on the professionalism of the applicant and reviewers to identify any COI that may affect or appear to affect the integrity of the peer review process.

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Examples of a reviewer COI:

- The reviewer is planning a collaboration with anyone with a major professional role on your application or another application in this round.
- Within the past three years, the reviewer has published with, has collaborated with, or has been in a mentoring relationship with any person on the application who has a major professional role.
- The application includes a letter of support or reference letter from the reviewer.
- The reviewer is an advisor for the proposal under review or for a grant held by anyone playing a major professional role on the application.
- The reviewer has an indirect financial interest: The reviewer will have received more than \$10,000 (in the form of honoraria, stocks, or fees) from you over the period from one year ago through the end of the proposed project.

Not considered a COI:

- The reviewer has an indirect financial interest of less than \$10,000.
- The reviewer freely donates reagents or other materials to the proposed project, and these reagents or materials would also be available to other researchers.
- The reviewer, you, as well as a person with a major role on the proposed project, contribute data, reagents, specimens, etc., to the same repository or database.
- The reviewer is a member of a research network that involves a person with a major role on the proposed project.
- The reviewer is a co-author of a non-research publication (e.g., review, commentary) or a mega multi-authored publication with a person with a major role on the proposed project.

J. *ATIP Key Personnel Information*

You are required to complete a brief ATIP Key Personnel Information form in the electronic application for each person on your proposal's team. Please use the template provided on the ICTR website as a guide only. For the Lead PI and Co-PI (if applicable), you will also need to provide additional NIH information requirements on gender, race, etc. as well as an NIH eRA Commons Username and an ORCID 16-digit ID as noted on the template.

K. *Regulatory Approvals*

If already available. Do not upload regulatory documents that are not specific to this application.

L. *Multiple PI Leadership Plan*

Only for multi-PI applications (limit to 1 Lead PI (the applicant) and 1 Co-PI). A Multiple PI Leadership Plan describing the respective roles must be included with the application. In multi-PI applications, the Lead PI will serve as the point of contact for communications.

M. *Formatting Guidelines*

- **Font size:** Must be 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%. If you are converting to PDF, some PDF conversion software reduces font size. It is important to confirm that the final PDF document complies with the font requirements.
- **Font types:** Arial, Georgia, or Helvetica

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- **Type density:** Must be no more than 15 characters per linear inch (including characters and spaces).
- **Line spacing:** Must be no more than six lines per vertical inch.
- **Text color: black**
- **Name of the applicant** (Last name, First name) should appear in the top right-hand corner of each page.
- **Page numbers** should appear on the bottom right-hand corner of each page.
- **Paper Size and Margins**
 - *Standard letter paper size (8 ½" x 11").*
 - Provide at least one-half inch margins (½") - top, bottom, left, and right - for all pages.

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/CTSA

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 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.