The Johns Hopkins Institute for Clinical and Translational Research

ICTR Request for Applications

***NOTE:** Revised Application Submission Instructions (01.16.2025)*

ACCELERATED TRANSLATIONAL INCUBATOR PILOT (ATIP) PROGRAM

Eligible:	All Johns Hopkins University, University of Maryland, and Morgan State University faculty with full-time appointments
Budget:	Awards will range in size from **$25,000 to $50,000 in direct costs only**
Grant Period:	12 months
Invited Application Deadline:	**Midnight on Sunday, February 2, 2025**
Award Notification:	Thursday, March 13, 2025 *(Anticipated)*

Program Overview

This ATIP award cycle is seeking proposals focused on exploring innovative products or approaches that can be generalized across different diseases and settings to overcome identified barriers to translational *science*. Eligible projects will involve one of the following areas:

- **How does use of wearable technology in research improve measurement of important health parameters?**

  We are particularly interested in assessing the added value beyond more traditional measures like self-report, how to increase adherence to collection of data, how to engage diverse populations in use of wearables, how to assess and improve data quality, and novel approaches to analysis of the data.

- **Support for research teams who are utilizing and assessing alternatives to the use of animals in translational research**

Projects are intended to: (1) explore possible innovative new leads or new directions for established investigators; (2) stimulate investigators from other areas to lend their expertise in research in clinical and translational science and (3) provide initial support to establish proof of concept.

The goal of this grant is to support research **in addition to** learning about the successes or failures of the approach taken, for the ultimate purpose of helping other teams make informed choices when planning their research. The ICTR pilot program under the direction of NCATS is moving to support translational science projects. Such projects provide information on how to help multiple research teams identify and address common and impactful barriers to translational research.

Proposals given additional consideration will include those which:

- Enhance diversity in the translational research pipeline; addresses health inequities, **and/or** the social determinants of health
- Contribute towards improving the health in the state of Maryland across all communities

The ATIP grant program will employ a milestone driven approach to pilot funding that is:

- Designed to start or facilitate new, translationally oriented research projects by clinical and non-clinical faculty.
- Intended to promote innovative translational research and cross-disciplinary collaborations
- Planned to facilitate the progress and completion of all projects through focused project management support provided by the Research Navigators.

Program Details Eligibility

A. Proposals considered for funding must:

1. Be focused on overcoming identified barriers to translational *science*

a. **Translational *science*** projects lead to generalizable scientific and operational principles and/or approaches, that other research teams can use to successfully address longstanding challenges to accelerating the rate at which observations made in the laboratory, clinic and community can be developed into real world interventions and applications.

- **Translational *science* projects DO NOT** focus on progressing between particular steps along the **Translational Science Spectrum** (i.e., between the Basic to Preclinical Research stages; between the Preclinical to Clinical Research stages; etc.) for a **specific disease or target. The latter are accomplished by translational research studies, which are not eligible for funding.**

- A short video further clarifying the concept of **translational *science*** can be seen **here**.

2. Involve one of the following areas:

a. Wearable technologies to measure health parameters
b. Alternatives to animal testing

Ideas for eligible research projects that involve one of the areas listed above, may include but are not limited to:

a. Increasing adherence to data collection by addressing issues that may result in the inconsistent use of a wearable device
b. Improving data quality by addressing issues that may result in the incorrect use and/or maintenance of the device
c. Assessing if the device is "fit-for-purpose" in the intended population and setting:
   - Are the device's performance characteristics acceptable?
   - Is the device measuring the parameter of interest?
   - Does the device yield the desired data?
d. Novel approaches for analyzing data in problematic situations such as in the setting of heterogeneity that may result from:
   - Software updates
   - Changes in algorithms
   - Hardware issues
e. Engaging diverse populations in the use of wearables:
   - Underserved populations to improve health equity
   - Underrepresented populations with respect to wearable technology who may also require special accommodations such as the elderly and pediatric populations

d. Identifying non-animal methods and approaches for developing new drugs that are cost-effective, robust and more consistent as well as reliable predictors of human safety. Acceptable systems include those that have either fully replaced the use of animals (i.e., organs on chips, in silico models, tissues, cells and human volunteers) or are still using invertebrates such as *Drosophila* and immature forms of vertebrates like zebrafish larvae.

4. **Unequivocally exclude elements that would satisfy the NIH's definition of a foreign component**

   Note: Applications that fail to convincingly exclude either of these possibilities will be considered as non-responsive to the RFA and returned without review. **The ICTR Navigators should be contacted at ICTR_Navigators@jhmi.edu in advance of submitting the Letter of Intent and the invited application for any questions regarding foreign components**.

5. **Have clear endpoints that can be completed within a twelve-month funding period[1].**

Conflicts of Interest

Beginning at the time of application, and continuing throughout the funding period for awarded projects, the awardee and all members of the study team are responsible for reporting any financial or fiduciary interests that might appear to present a **conflict of interest (COI)[2].** The presence of a conflict of interest does not necessarily disqualify investigators from receiving this award and/or participating in the funded research. However, **failure of any member of the study team to disclose any such issues could result in the termination of this award and the disallowance of all study costs.**

Funding Restrictions

1. **Requests for less than $25,000 or exceeding $50,000 will not be reviewed.**

2. **Budget requests:**

   a. Should focus on the support needed to conduct the proposed study
   b. may include personnel salaries for participating faculty, fellows and stipends for undergraduate or graduate students.
   c. For equipment purchases not exceeding 25% of the total award, will be considered on a case-by-case basis, with final allocations subject to ATIP leadership approval.
   d. For travel essential to the conduct of the research will be considered on a case-by-case basis. And will require ATIP leadership approval.

3. **Expenditures that are deemed to be inappropriate for this funding mechanism, per the terms of this RFA or applicable NIH regulations for pilot funding grants, will be disallowed.** Approval for awarded projects requiring budgetary modifications to address such issues, will be conditional on resubmitting for ICTR Leadership Committee review, the appropriately revised versions of all affected components of the ATIP application.

4. **Subcontracts may be permitted, but require authorization from either the ICTR Financial Office (ICTRSponsored@jhmi.edu) or the Research Navigators in advance of application submission.** [3]

5. **No changes may be implemented to the approved budget (or research plan that does not affect the budget) for awarded projects, prior to submitting the request to the Research Navigators for review and approval by the ATIP leadership.**

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[1] **Appendix 1** for information regarding project **feasibility**

[2] **Appendix 2** for details on managing **conflicts of interest**

[3] **Appendix 3** for additional application requirements for **budgets with subcontracts**

Application Process

Please note that unlike years past, this Accelerated Translational Incubator Pilot program call for applications will be managed in two stages as follows:

Stage I: Letter of Intent Submission

Letters of Intent are being solicited from eligible faculty, and will be subjected to a competitive review for responsiveness to the RFA, including an obvious focus on translational science.

Stage II: Application Submission by invitation ONLY (Deadline: 12MN on Sunday, February 2, 2025)

Once a subset of projects has been selected to advance to the application stage, ONLY those investigators will be invited to submit full proposals

A. Stage I: LETTER OF INTENT Submission PROCESS

1. **The mandatory LOI is limited to 2-pages and must include responses to all of the following at the time of submission to be reviewed for possible advancement to Stage II:**

   a. Project title
   b. Name, rank, affiliation, and email of PI applicant and key personnel
   c. Research Objectives/Specific Aims
   d. Project overview including **concise description of:**
      - Proposed experiments/steps to achieve **A.1.c.** above
      - Preliminary data
   e. Identification of the specific barrier or barriers to translational science and description of the how the proposal will address it/them
   f. List of all applicable **and executed** regulatory approvals and agreements that are required for the project

   Note: References are **optional** and should be included on no more than 1 page that will not be counted in the 2-page LOI limit

B. Stage II: Invited APPLICATION Submission PROCESS

Only those investigators who are notified that their project was selected to advance to Stage II of the application process will be invited to submit a complete proposal via email to ICTR_Navigators@jhmi.edu.

The grant application is comprised of the following mandatory components, which must all be completed at the time of submission in order for the proposal to be accepted for review:

1. **ATIP Project Information Form**[4] (must use provided template)
2. **Research plan**[5] (5-page limit, containing the following: Brief Introduction; Project Milestones and Timeline; Background (including Preliminary Results, if available) and Significance; Experimental Design; and Anticipated Problems and Possible Solutions.
3. **Reference list** of up to 30 references

[4] **Appendix 4** for the requirements for this **form**

[5] **Appendix 5** for **Research Plan** guidelines

4. **Comprehensive budget**[6] using the provided template AND itemizing all costs to $1000
5. **Detailed budget justification for all requested expenses**
6. **Biographical sketch information:**
   - In NIH-Biosketch format **for the PI and all co-investigators**, (5-page limit each)
   - If not included in the Biosketch, provide separate "Other support" information for the PI and all co-investigators (limited to 3-pages each)
   - A brief identification and biographical description of all other study team personnel named in the ATIP application (4-page limit total)
7. **Project readiness checklist** (must use provided template)
8. **Project schedule** to include discrete research milestones and the logical steps needed to attain each of those achievements (must use provided template)

Application component numbers 1-8 are created as individual files which should be named using the following naming convention: *"PI Last Name_Component*_DDMMMYY".*

*__Component designations__ are: Project Information, ResearchPlan, Reference, Budget, Justification, Bio, Checklist, and Schedule.

All named files are then saved in a **zip file**[7] that is itself named *PI Last name_ATIP_DDMMMYY*. This single zip file should then be submitted **to the Johns Hopkins ICTR Research Navigators by email to ICTR_Navigators@jhmi.edu.**

ATIP Application Review Criteria and Process

Only complete applications from invited applicants that are received by the February 2, 2025 midnight deadline will be considered for review.

Applications will be evaluated and scored using the following criteria:

1. Scientific merit, novelty, impact and appropriateness of design
2. Project feasibility for completion within 12-months
3. Relevance to and contribution towards helping to develop principles for overcoming acknowledged barriers to translational science; How well principles can be applied to other health-related areas
4. Addresses health inequities, and/or the social determinants of health
5. Contributes to a goal of improving health in the state of Maryland across all communities
6. New collaborative and/or interdisciplinary research team
7. Jr. PI OR a new area of research for an established investigator

The review process will be conducted as follows:

- **Administrative Review:** ICTR Research Navigators will review applications for compliance with budgetary, content, eligibility, and other submission guidelines.
- **Triage:** A triage process may be employed in order to identify those proposals that best represent the type of project that this RFA seeks and prioritize the review of submitted proposals.
- **Review Process:** ATIP Selection Committee comprised of faculty from JHU and our current CTSA Hub partners (University of Maryland Baltimore, Morgan State University), ICTR Deputy Directors, ICTR Core Management, and other faculty, including those suggested by applicants with expertise in fields relevant to the science in the proposal, will be asked to assess the applications. **Only those who have declared that they have no possible conflicts with the proposal they are being asked to evaluate will be asked to review.**

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[6] Appendix 6 for guidelines for the grant **Budget**

[7] Appendix 7 for instructions on creating a **zip file**

Funding Decisions: The ICTR ATIP Selection Committee will make all funding decisions.

Notification and Feedback: All applicants will be notified of funding decisions approximately 2 months after the submission deadline.

1. No teams will be granted access to awarded funds until all institutional and external (i.e., NCATS prior approval) regulatory approvals[8] and requirements have been satisfied

2. Only those applicants whose projects are deemed to be more closely aligned with the goals of the ATIP funding mechanism, will be able to request anonymized feedback from the review process.

3. Investigators whose ATIP applications were not selected for funding are eligible to request the ICTR Research Studio's assistance with creating a more competitive grant application for eventual submission to other funding programs. Additional information about the Research Studio can be obtained by contacting Carol Kobrin at ckobrin1@jhmi.edu or ICTR_Navigators@jhmi.edu

For information regarding the following, please refer to the indicated appendices in this RFA:

1. PI responsibilities for awarded projects[9]
2. The availability of a certificate of confidentiality for applicable awarded studies[10]

Appendices

[8] **Appendix 8** for more detailed discussion of these **regulatory requirements**

[9] **Appendix 9** for additional information about PI responsibilities

[10] **Appendix 10** for information about Certificates of Confidentiality

Appendix 1: Project Feasibility Within 12 Months

The requirement for showing a high degree of feasibility to yield results within 12 months, includes the feasibility of recruiting the required complement of human subjects during the 12month study for those proposals that include patient populations.

The time needed to secure all applicable **regulatory approvals** for the project, as well as to address any outstanding needs (i.e., staffing) will also be considered when determining the feasibility of completing the research in 12 months. Projects which have ALL internal and applicable external regulatory approvals in place or underway at the time of submission, staffing matters in order, etc. will be deemed more likely to be able to begin **within 2 months of notification of award** will receive additional consideration.

Projects will not be considered for funding if:

1. The research plan appears to be overly ambitious for this timeframe.

2. Delays with starting the study are anticipated due to factors which include but are not limited to: securing regulatory approvals; acquiring all required materials, equipment and animals; and the availabilities of all proposed study personnel.

3. The research team does not demonstrate a clear plan to secure all required internal and external regulatory requirements that must be satisfied before award funds will be released, if selected for funding.

Appendix 2: Conflict of Interest Management

Morgan State University Faculty and Study Staff

In addition to reporting to the ICTR, faculty, staff, and other employees of Morgan State University are required to report outside activities and potential conflicts of interest or commitment in accordance with the MSU Policies on Conflicts of Interest in Research or Development and Professional Commitment of Faculty.

More information about the disclosure process is available at the MSU Office of Research Administration website or via email at ask.ora@morgan.edu.

University of Maryland, Baltimore Faculty and Study Staff

In addition to reporting to the ICTR, faculty, staff, and other employees of the University of Maryland Baltimore (UMB) are required to report outside activities and potential conflicts of interest or commitment in accordance with the UMB Institutional COI Policy.

More information including FAQs is available at the UMB Conflict of Interest Office website. You can also contact a member of the COI Team or email the COI Office at for assistance at disclosure@umaryland.edu.

JHU Faculty and Study Staff

Individuals who have a COI are expected to report those **interests not only to the ICTR, but more importantly to the Johns Hopkins University Office of Policy Coordination (SOM, KKI) or designated school COI office (KSAS, WSE, JHSON, JHBSPH).** The latter is essential because a plan for managing the conflict that has been developed by the Committee on Outside Interests, is required for the individual to remain associated with the awarded project.

More information about the University's Conflict of Interest Policy, including examples of what constitutes an outside interest, may be found at the **JH Office of Policy Coordination website.**

Appendix 3: Application Requirements for Budgets Including Subcontracts

A. Applicants may be asked to provide:

1. A second budget and corresponding justification for the sub-award, that contains **BOTH the total direct costs** AND **total indirect costs of the outside facility.**

2. A scope of work for the outside facility

   Subcontracts with outside institutions/facilities should account for no more than 50% of the total requested budget, unless strong justification is provided.

B. Using ATIP Funding to Present Results at Meetings

Though generally not permitted, such requests will be considered if a strong justification is provided. The latter is included in the budget justification document and contains detailed meeting information (e.g., location, approximate date(s)), travel costs being requested, study team attending, etc.).

Appendix 4: ATIP Project Information Form

A. Abstract Requirements

1. **DOES NOT** exceed 500 **words** OR **contain proprietary or otherwise confidential information**.
2. **Includes:**
   - A brief background of the project and introduction;
   - Specific aims and objectives with hypothesis being tested;
   - The proposed methodology (action steps) to be used in each aim/objective;
   - The significance of the proposed research
   - Any other information that may be relevant to your project and was not already included in any of the above

B. Additional Considerations

Additional consideration will be given to ATIP applicants whose project addresses enhancement of diversity in the translational pipeline, health inequities and/or social determinants of health (SDOH), and/or contributes towards improving health within the state of Maryland across all communities. If any of these are applicable to your project, you may provide a brief statement(s) of up to 250-words within this section of the form.

C. ATIP Project Specific IRB Information

In this section, applicants are asked to provide information regarding IRB review(s) and other regulatory approvals needed in order to perform the specific work as proposed within the ATIP application.

E. Reviewer Recommendations

In this section of the form, applicants **MUST** provide suggestions for **at least** (**2) potential non-conflicted reviewers *internal* to the institution where they hold a faculty position** and (**2) non-conflicted reviewers *external* to the institution where they hold a faculty position.** Potential external reviewers who are either faculty at one of our CTSA grant partner institutions (i.e., University of Maryland at Baltimore, Morgan State University, Johns Hopkins) or another **NIH CTSA hub** are preferred.

F. Other Study Personnel

All study team members, co-Investigators, consultants, and collaborators, **whether supported by grant funds or not**, must be identified in the personnel list within this section.

G. Other Contact Information

If the PI has an Administrative Assistant, finance team, or any other staff who are not part of the study team, but who should be copied on correspondence, contacted for scheduling meetings, etc., their contact information is requested in this section.

Appendix 5: Research Plan Guidelines

A. 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.** A bibliography containing up to 30 citations may be included 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.

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

1. **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. Any new collaborations or highly innovative aspects should be succinctly noted.

2. **Project Milestones and Timeline**: A **summary** of specific milestones and a 12month timeline of the project 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: *The milestone/timeline summary information presented in this Research Plan section is distinct from the content that should be provided in the* ***Project Schedule component of the application****. The latter* ***MUST*** *include the milestones described in the research plan* ***AND*** *a breakdown of all activities necessary to complete the milestone, as well as the time required for each named activity.*

C. Background and Significance:
Include here the scientific background of the project including preliminary results, if available.

D. **Experimental 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. 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, as are details for outside contractual services.

E. **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 ATIP budget as well as the 12month 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.

Appendix 6: Comprehensive Budget Guidelines

Applicants **MUST** use the budget template provided in the ATIP application, but may customize it as their project requires.

A. The budget will itemize:

1. To $1000 all items with a unit cost that is less than $1,000.
2. Supplies, only where the requested amount exceeds $1000. They should be listed **in separate categories**, such as glassware, drugs, chemicals, radioisotopes, etc.
3. Each component of a piece of equipment, with the corresponding amount requested separately listed and justified

B. The budget **MUST include:**

1. An explanation of other funding sources that will be used to cover costs not covered by ATIP
2. The name and email address of the applicant's financial contact
3. All additional documentation requested by the **ICTR Sponsored Projects team** for proposals authorized to include a subcontract, as described in greater detail in Appendix 3.

Appendix 7: Creating a Zip File

To create a zip folder, select all individual document files to be included, then right click the folder file and select "Send to", then select "Compressed (zipped) folder". A new zipped folder with the same name is then created in the same location.

Appendix 8: Common Regulatory Approvals and Requirements Associated with ATIP Supported Studies

Regulatory approvals are not required for ATIP application submission. **However, all applicable institutional (i.e., Institutional Review Board), and external (i.e., FDA IND or IDE, NCATS Prior Approval Requests for Pilot Funding Awards) approvals must be obtained before the awarded grant can be used for the project. The Navigators can assist with filing IND and/or IDE applications.**

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.

For awarded projects, copies of all applicable approvals, renewals, certifications, protocols and amendments must be made available to the Research Navigators throughout the course of the grant award period upon request.

A. Institutional Regulatory Approval Requirements

1. 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.

2. Human Subjects Research

Proposals that involve human subjects research which per 45 CFR Part 46, require Institutional Review Board (IRB) review, may also be required to satisfy other institutional requirements such as HSR compliance and HIPAA certification (*JHU personnel only*) of staff.

B. NIH NCATS Requirement for Prior Approval for Pilot Funding Awards

All proposals involving human subjects research (i.e. as defined by NIH, 45CFR 46) must also be submitted to the NIH (i.e. National Center for Advancing Translational Science [NCATS]) for their review and approval. The corresponding approval(s) from the reviewing IRB must accompany all NCATS submissions.

The NCATS Prior Approval submission process can be a lengthy one and has the potential to delay the start of a study for up to several months (ATIP FUNDING CANNOT BE USED WITHOUT FIRST SATISFYING THE NCATS REQUIREMENT FOR PRIOR APPROVAL). Therefore, if a submission has been selected for ATIP funding that involves human subjects, IT IS CRITICAL that the applicant immediately start working to obtain all institutional (i.e., IRB reviews) and applicable external regulatory approvals, if they have not done so already.

Detailed instructions for preparation of the document packages for requesting prior approval for human subject studies will be provided by the ICTR Navigators with the notification of selection of the project for award. While the associated institutional approvals are required to complete this submission, it is possible and strongly advised to begin preparing select portions of this filing while awaiting IRB approvals.

1. Specific Requirements for Human Subjects Research

All applicants with projects involving human subjects research as defined by NIH, including applicable studies with human cell lines or tissue repositories, are all required to obtain this approval.

If notified by the ICTR that the submission has been selected for ATIP 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, which can take between 3-5 months, the applicant must then prepare a document package to be submitted for NCATS' review.

The NCATS Human Subjects Research Prior Approval Request package will consist of applicable materials that are either already part of the eIRB application, or should be readily available from the applicant.

The following materials are required for all human subjects research, including minimal risk and exempt human subjects research projects[11]:

a. Brief summary of the specific aspects of the proposed study that will be supported by NCATS funds with a line-item budget for each (e.g., list supplies, services, and personnel costs, etc.)
b. IRB approval of the proposed project or institutional exemption determination, and parent project (if applicable)
c. If the proposed clinical research protocol is considered an amendment to a parent protocol, a summary of the parent protocol with an explanation of how the proposed study connects to it.
    - Recruitment/retention plan and recruitment status
    - Study timeline
    - Inclusion plans for individuals across the lifespan, and women and minorities
    - Human Subjects Research protections training certifications for the PI and named key personnel
    - Inclusion Enrollment Report(s) [12]
    - A new or revised "Protection of Human Subjects" section for the pilot that clearly identifies the information relevant to the pilot project and describes the risks, adequacy of protections against risks, potential benefits, and importance of the knowledge to be gained by the revised or new activities

Only those projects meeting the NIH definition of a clinical trial and/or which are determined by the IRB to be greater than minimal risk, will be required to provide the following additional documentation[13],[14] :

- NIH Biosketch for the PI and for each Key Personnel involved in the proposed human subjects research study
- Complete clinical research protocol
- Informed consent document o and assent document (if applicable)
- Data and safety monitoring plan (DSMP) or Board (DSMB) (as applicable)
- Overall structure of the study team
- Protocol synopsis including narrative description, primary purpose, interventions, study phase, intervention model, masking, allocation, outcome measures, statistical power and design, subject participation duration, etc.
- Documentation that an IND or IDE has been obtained, or letter from the FDA that the study is IND-exempt or the IDE has been waived (if applicable) o Product information such as the clinical investigator brochure, package insert, or description of the device, if a clinical trial is proposed (if applicable)
- Dissemination plan

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[11] Instructions for content are detailed in the Forms I-**RESEARCH INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES**

[12] Unless using an Existing dataset

[13] Instructions for content are detailed in the Forms I- **RESEARCH INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES**

[14] As per the NCATS New Projects with Human Subjects Research Addendum & Instructions (See pages 3-11)

2. **NCATS Review and Funding Timeline**

Depending on the type of study being performed (e.g., minimal risk, exempt HSR, greater than minimal risk, or NIH defined clinical trial), after formal submission of the NCATS Prior Approval request to NCATS, there will be either:

a. a mandatory 14 day wait period before funds may be released (minimal risk or exempt HSR)
b. up to a 30-day review period from the date of **receipt of a complete packet,** for NCATS to review and respond, during which funding may not be released (greater than minimal risk/NIH defined clinical trials). Every effort is made by NCATS to expedite the process and grantees are asked to respond promptly to any requests for additional information or clarifying questions. Based upon experience in the last ATIP funding cycle, uncomplicated reviews were completed within 30 days. Funding is only released upon receipt of NCATS' approval.

If approved by NCATS, the date that ATIP funding starts will be determined upon receipt of the approval notification. Please note that ATIP remains a 12-month award, where all spending of grant money must be completed at the end of the grant period, regardless of when NCATS' approval was obtained. Copies of all approvals, renewals, certifications, protocols and amendments must be made available to the Research Navigators 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 ICTR is not permitted to use the funding to support the project in question and the pilot award will have to be modified subject to the approval of the ICTR ATIP Leadership Committee or disallowed.

Appendix 9: PI Responsibilities for Awarded Projects

A. Reporting Responsibilities

All funded PIs will be required to submit regular written progress reports, including supporting data, to the ICTR Navigators. Progress reports are reviewed by Navigators to ensure that projects are meeting their milestones and progressing according to the timelines submitted by the awardees. The progress reports are a means for identifying those groups who might benefit from Navigator/ATIP leadership intervention. The Navigators may query awardees and/or request additional information and/or data from study teams after review of information provided so that they may fully investigate specific issues related to overall project progress. Every effort is made to assist investigators and their teams in overcoming unforeseen obstacles encountered during the award period. For these reasons, due to the accelerated nature of the program, failure to submit progress reports in a timely manner can have significant implications for a project and, as such, may result in termination of funding.

B. Studio Requirement

As a condition of accepting an ATIP grant, all awarded PIs will be asked to present their ATIP awarded project for discussion in an ICTR Studio consultation. The ICTR Studio is a multidisciplinary service center that was created to help investigators improve the quality and impact of their translational research. This ICTR initiative is operated as a Master class, where sessions are organized with a panel of expert consultants specially selected to accommodate the specific needs of each project. Consultants are acknowledged authorities in their fields, who possess a broad spectrum of knowledge ranging from scientific and medical expertise to help the work focus on the most relevant research questions in the field,

to methodological and technical specialists to address issues related to the use of institutional and CTSA resources for pre-clinical and clinical studies.

Timing and organization of each awardee's Studio consultation will be based on the needs of the investigator and study team, the progress of the research with regard to the originally approved timeline, and input from ATIP leadership.

For example:

I. If the project is progressing well, the Studio may be scheduled late in the award period or immediately following the end of the grant in order to assist the PI with development of the next steps in the translational pathway.
II. If the project has met with an unforeseen obstacle affecting the original timeline and additional expertise or assistance is needed, a Studio can be scheduled immediately in order to help the PI address and move past the issue.
III. If the project focuses on development of a new methodology, technology, or approach that may be of interest to the research community at large, a Studio may be scheduled at the convenience of the PI during the award period with the JHU research community invited to attend as IP considerations allow.

If a Studio consultation has not been initiated for the project by the beginning of the fourth quarter of the funding period, the PI will be required to submit to ATIP leadership a brief Studio consultation plan outlining issues to be addressed in the Research Studio. **Failure to submit a plan will result in forfeiture of ten percent (10%) of awarded ATIP funds which will be held in reserve at the outset of the funding period.** For more information about the ATIP Studio consultation opportunity, please contact Carol Kobrin at **ICTR_Navigators@jhmi.edu.**

Appendix 10: Certificate of Confidentiality

Applicable ATIP projects that subject research participants to the potential risk of being identified during the course of the study, are covered by the protections of an NIH Certificate of Confidentiality (CoC). This CoC was issued to the Johns Hopkins ICTR by NIH-NCATS, as a condition of our CTSA award. The latter is being used to fund ATIP. It protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other types of health-related research that collect or use identifiable, sensitive information. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information to anyone not connected to the research. The Certificate prohibits disclosure in response to legal demands, such as a subpoena. Additional details about Certificates of Confidentiality are availability from the NIH webpage **Certificates of Confidentiality (CoC) - Human Subjects.** If you have any questions regarding the provisions of this Certificate, please contact the Research Navigators at ICTR_Navigators@jhmi.edu.