The Johns Hopkins Institute for Clinical and Translational Research (ICTR)

REQUEST FOR APPLICATIONS

ACCELERATED TRANSLATIONAL INCUBATOR PILOT (ATIP) PROGRAM

Deadline: **Monday, December 13, 2021 at 5:00 PM**

Eligible: All Johns Hopkins University faculty

Budget: Up to $50,000 in direct costs; No faculty salary with exception of Research Associate or equivalent (i.e. non-tenure track ranks)

Grant Period: Twelve months

Application: Online at **https://redcap.link/jhuatip2022**

Program Overview

The Accelerated Translational Incubator Pilot (ATIP) grant program employs 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 at Johns Hopkins University.
- Intended to promote innovative translational research and cross-disciplinary collaborations by supporting projects focused on the development of new therapies (medications, devices, nutrition, behavioral interventions, etc.), diagnostics, approaches to prevention or translation of knowledge through the health care system.
- Planned to facilitate the progress and completion of all projects through focused project management support provided by the Research Navigators.

Program Details

Eligibility

1. Proposals which:
   a. Focus on the translation of laboratory and/or clinical research projects that can be brought to patients within 3 to 5 years[1] **AND** have clear endpoints that can be completed within a twelve-month funding period[2].
   b. **Have NOT** been previously submitted to any ICTR funding program[3] within the last 12 months regardless of their funding status
   c. Are **NOT** resubmissions of previously unfunded ATIP grant applications

2. Investigators who have **NOT** been the PI of an awarded ATIP project within the past 24 months

[1] See **Appendix 1** for factors used to evaluate
[2] See **Appendix 2** for considerations to assess
[3] See **Appendix 3** for a list

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).[4] 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

- **Requests exceeding $50,000 will not be reviewed.**
- **Budget requests for 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.**
- **No-cost extensions may be granted on a case-by-case basis with strong justification. Subcontracts may be permitted on a case-by-case basis, but require authorization from either the ICTR Financial Office (ICTRSponsored@jhmi.edu) or the Research Navigators in advance of application submission.**[5]
- Funding may be used for: fellow salaries; stipends paid to undergraduate or graduate students at Johns Hopkins; travel **essential to the conduct of research[6] with ATIP leadership approval; and** equipment purchases limited to 50% of the total award;
- 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 Executive Committee.

The submission deadline for ATIP applications is 5:00 PM on Monday, December 13, 2021. All application materials must be received by this deadline to be considered. No exceptions will be granted.

APPLICATION PROCESS

Only one grant application may be submitted and that application must be made through the **ATIP ICTR REDCap Application form**, located on the ICTR web site at:

The grant application is comprised of the following eight 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, Study Personnel and Suggested Reviewers REDCap Survey**

[4] See **Appendix 4** for details on managing Conflicts of Interest
[5] See **Appendix 5** for additional application requirements for budgets with subcontracts
[6] See **Appendix 6** for details on requesting travel expenses

Page[7]
Research plan[8] (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.
Reference list of up to 30 references
Comprehensive budget using the provided template AND itemizing all costs to $1000 [9]
Detailed budget justification for all requested expenses
Biographical sketch information:
- In NIH-format to include full NIH "Other support" information (5 page limit)
- A brief identification and biographical description of all other study team personnel named in the ATIP application **(4-page limit total)**

Project readiness checklist using the provided template
Project schedule to include discrete research milestones and the logical steps needed to attain each of those achievements

Application component numbers 2-8 are created as individual files which should be named using the following naming convention: *"PI Last Name_Component*_DDMMMYY".*

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

All named files are then saved in a **zip file**[10] that is itself named *PI Last name_ATIP_DDMMMYY*. This single zip file is then uploaded into the REDCap application.

ATIP Review Criteria and Process

Only complete applications received by the deadline will be considered for review.

Applications will be evaluated and scored using the following five criteria:
1. **Relevance to translation**, including plans to move a 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 a 12-month period**
4. **Creating collaborations** or the potential for such, between investigators[11]
5. Whether or not the project's PI is a **junior investigato**r and/or a **junior or senior investigator moving into a new research area**

The review process will be conducted as follows:
- **Administrative Triage:** ICTR Research Navigators will review applications for compliance with budgetary, content, eligibility, and other submission guidelines.
- **Review Process:** ICTR Deputy Directors, ICTR Core Management, and other JH faculty reviewers, including those suggested by applicants with expertise in fields relevant to the science in the proposal, **who have previously declared no possible conflicts with the proposal they are being asked to review,** will be asked to assess the applications.

[7] See **Appendix 7** for the requirements for this REDCap section
[8] See **Appendix 8** for detailed guidelines for the Research Plan
[9] See **Appendix 9** for detailed guidelines for the grant Budget
[10] See **Appendix 10** for information on creating a zip file
[11] See **Appendix 11** for guidance on collaborative projects

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

Notification and Feedback: All applicants will be notified of funding decisions approximately 4 months after the submission deadline.

1. No teams will be granted access to awarded funds until all institutional and external regulatory approvals and requirements have been satisfied (please see **Appendix 12** for a more detailed discussion of these requirements)

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 **(Appendix 13**)
2. The availability of a certificate of confidentiality for applicable awarded studies (**Appendix 14**)
3. Potential research areas **(Appendix 15)**

Questions about the ATIP application process should be directed to the ICTR Research Navigators at ICTR_Navigators@jhmi.edu.

Appendices

Appendix 1: **Feasibility of Translating the Research into New Patient Interventions Within 3-5 Years**

Projects will not be considered for funding if they lack a rigorous demonstration of:

a. The scientific principles underlying the proposal
b. The competency of any novel methodology or technology to achieve their intended purpose in the proposal

Proposals consisting solely of preclinical experiments in murine models are discouraged.

Appendix 2: **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 12-month study for those proposal that include patient populations.

The time needed to secure all applicable regulatory approvals for the project (please see **Appendix 12** for a more detailed discussion of these requirements), 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:

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

Appendix 3: **Other ICTR Funding Programs**

These include the ICTR Translational Research Communities Nexus Awards, Boost/Propel grants; the ICTR Community Partnership and Collaboration Core Pilot grant program; the Doris Duke Early Clinician Investigator Awards; the JHCRN Research Accelerator and Mentorship Program (RAMP); JH and Kaiser Permanente Research Collaboration Committee Pilot Awards; as well as unfunded ATIP proposals

Appendix 4: **Conflict of Interest Management**

Individuals who have a COI are expected to report those **interests not only to the ICTR, but more importantly to the 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 Office of Policy Coordination website (http://www.hopkinsmedicine.org/Research/OPC/Outside_Interests/).

Appendix 5: Application Requirements for Budgets Including Subcontracts

Applicants may be asked to provide:

a. 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.**
b. 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.

Appendix 6: 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 7: ATIP Project Information, Study Personnel, Suggested Reviewers REDCap Survey Page:

a. **Abstract Requirements**
   I. **DOES NOT** exceed 500 **words** OR **contain proprietary or otherwise confidential information**.
   II. **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. **Study Team Personnel**
   All study team members, co-Investigators, consultants, and collaborators, **whether supported by grant funds or not**, must be identified in the personnel list.

c. **Suggested Reviewers**
   Applicants **MUST** provide suggestions for **at least** (**2) potential non-conflicted reviewers *internal* to JHU** and (**1) non-conflicted reviewers *external* to JHU**. Potential reviewers external to JHU who are either faculty at our CTSA grant partner University of Maryland at Baltimore or other **NIH CTSA hub** are preferred.

Appendix 8: **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 must include the following components:

I. **Brief Introduction:** This section is intended to help orient the reviewer to better understand the scientific basis for the project; why the work is being proposed; as well as the suitability of the research for ATIP 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.

II. **Project Milestones and Timeline**: A **summary** of specific milestones and a 12-month 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.

Unlike traditional NIH grants, the majority of translational grants are designed to reach a specific, translationally oriented target (e.g. the preclinical [not basic] and/or clinical research associated with the screening of drugs, the generation of a diagnostic or assay). 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.*

III. **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). The response to demonstrating "Significance" should:
- o Indicate relevance to the overall target of clinical translation.
- o Clarify how the research will advance the field
- o **Discuss the project's potential for improving the health of patients within the next 3-5 years.**

IV. **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.g. chemical synthesis, structure activity analysis, pharmacokinetics, or toxicology).

V. **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 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.

Appendix 9: Comprehensive Budget Guidelines

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

The budget will itemize:

a. To $1000 all items with a unit cost that is less than $1,000.
b. Supplies, only where the requested amount exceeds $1000. They should be listed **in separate categories**, such as glassware, drugs, chemicals, radioisotopes, etc.
c. Each component of a piece of equipment, with the corresponding amount requested separately listed and justified
d. Animal purchases to include the species, number requested, and cost per animal.

The budget **MUST include:**

a. An explanation of other funding sources that will be used to cover costs not covered by ATIP
b. The name and email address of the applicant's financial contact
c. All additional documentation requested by the **ICTR Finance Office** for proposals authorized to include a subcontract, as described in greater detail in **Appendix 5.**

Appendix 10: Creating a Zip File

Right click the folder, select "*Send to*", then *"Compressed (zipped) folder*". A new zipped folder with the same name is then created in that location.

Appendix 11: Applications That Feature Collaborative Projects

Special attention will be paid to projects:

a. Promoting cross-disciplinary collaborations
b. Shared between Hopkins and other ICTR partners (i.e. UMB, Morgan State and Kaiser Permanente).

Note: For research projects involving human subjects that require Institutional Review Board (IRB) review per 45 CFR Part 46, **the NIH has mandated the use of a Single IRB [sIRB]** for NIH-funded multisite studies, where each site is using the same protocol to conduct human subjects research that is not exempt from federal regulations (i.e. the IRB review requirement). If this applies to your project, see the **JHM IRB sIRB policy** and **mandatory review fees**, **which are not being waived for investigator-initiated studies,** linked here**.**

For questions regarding the sIRB requirement, please contact the Research Navigators at **ICTR_Navigators@jhmi.edu.**

Appendix 12: 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 [IRB]), 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

I. 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.

II. 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 Biosafety registrations, HSR compliance and HIPAA certification of staff, Clinical Engineering clearance of devices, ISCRO approval for stem cell research, Radiation Safety registration, etc.

i. Considerations primarily for awarded studies

1. ClinicalTrials.gov Registration

PIs are expected to register clinical trials at ClinicalTrials.gov prior to submission of their NCATS Prior Approval Request and enrollment of the first study participant. This applies to studies meeting the **NIH definition of a clinical trial**. as well as those that are considered to be an **"applicable clinical trial" under FDAAA 801.** Resources and assistance with this process are available via the **JH ICTR ClinicalTrials.gov Program.** If you have any questions, please contact the Research Navigators at ICTR_Navigators@jhmi.edu.

2. **CRMS Registration and Use**
   ATIP pilot projects required to have a completed Prospective Reimbursement Analysis (PRA) (i.e. have the potential to generate a patient care charge) are expected to comply with all of the terms and conditions in the Vice Dean for Clinical Investigation's letter entitled ***"Registration of Participants in the Clinical Research Management System (CRMS) and Research Consent Form Availability"***. If you have any questions regarding access to or use of CRMS, please contact the Research Navigators at ICTR_Navigators@jhmi.edu.

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

All proposals involving either human subjects research (i.e. as defined by NIH, 45CFR 46) or **live vertebrate animals**, must also be submitted to the NIH (i.e. National Center for Advancing Translational Science [NCATS| for their review and approval. The corresponding approvals from the reviewing IRB or the JHM Animal Care and Use Committee (ACUC) 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 human subjects or vertebrate animal submission has been selected for ATIP funding, IT IS CRITICAL that the applicant immediately start working to obtain all institutional (i.e. IRB, IACUC reviews) and applicable external regulatory approvals, if they have not done so already.

Detailed instructions for preparation of the respective document packages for requesting prior approval for human subject or live vertebrate animal 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 or IACUC approvals.

I. Specific Requirements for Live Vertebrate Animal Studies

Upon receipt of IACUC approval, which can take several months, the applicant must then prepare a document package to be submitted for NCATS' review.

The NCATS review package will consist of applicable materials that are either already part of the ACUC application, or should be readily available from the applicant including:

a) Animal Welfare Assurance #
b) IACUC Approval letter
c) Vertebrate Animal Section

- *Description of Procedures*
  A concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the Research Strategy section. The species, strains, ages, sex, and total number of animals by species to be used in the proposed work must be identified. If dogs or cats are proposed, the source of the animals must also be provided.

- *Justification*
  Justification must be given that the species are appropriate for the proposed research, explaining why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

- *Minimization of Pain and Distress*
  Interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints to minimize discomfort, distress, pain, and injury must be described.

- *Method of Euthanasia*
  A description of the method of euthanasia must be provided. Justification for any methods of euthanasia that are not consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals will also be required.

d) If the proposed research is ancillary to another research protocol, the title and PI of the parent protocol
e) Total budget for activities to be supported with ATIP funding

II. 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 (HSRPA) review package will consist of applicable materials that are either already part of the eIRB application, or should be readily available from the applicant.

The following materials are required for all human subjects research, including minimal risk and exempt human subjects research projects[12]:

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
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.

[12] Instructions for content are detailed in the Forms F **RESEARCH INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES** (See pages R-98 thru R-117)

- Recruitment/retention plan and recruitment status
- Study timeline
- Inclusion plans for individuals across the lifespan, and women and minorities
- Inclusion Enrollment Report(s) [13]
  - 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[14,15]:

- NIH Biosketch for the PI and for each Key Personnel involved in the proposed human subjects research study
- Human Subjects Research protections training certifications for the PI and any key personnel directly involved in the study
- Complete clinical research protocol
- Informed consent document
  - 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)
  - 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

III. NCATS Review and Funding Timeline

For projects where submission to NCATS of the document packet is not by itself sufficient to satisfy the requirement for prior approval , NIH reviewers have up to 30 days from the date of **receipt of a complete packet,** to review and respond. Every effort is made to expedite the process and grantees are asked to respond promptly to any requests for additional information or clarifying questions. Based upon experience in the last ATIP funding cycle, uncomplicated reviews were completed within 30 days.

[13] Unless using an *Existing Data Set or Resource.*

[14] Instructions for content are detailed in the Forms F **RESEARCH INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES** (See pages R-98 thru R-117)

[15] As per the NCATS New Projects with Human Subjects Research Addendum & Instructions (See pages 4-9)

If approved by NCATS, the start date of a 12-month ATIP grant will be determined upon receipt of the approval notification. Copies of all approvals, renewals, certifications, protocols and amendments must be made available to the 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 13: 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 14: 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.

Appendix 15: Potential Research Areas

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

1. Pre-Clinical Translation
   a. Development of pre-clinical research tools
   b. Development of novel treatment platforms or therapies
   c. Drug screening assays
   d. Methods for generation of novel vaccines or peptides
   e. Animal models for drug selection
   f. Preclinical toxicology markers/assays
   g. Surrogate marker assays, including genomic, proteomic assays, and metabolic, imaging methods
2. Clinical Translation
   a. Development of clinically relevant tools
   b. Development and verification of surrogate marker assays
   c. Clinical trial design paradigms (e.g. computer simulation)
   d. Development or evaluation of diagnostic tests
   e. Clinical trials
      I. Pilot/Phase 0 or 1 trials
      II. Collection of pharmacokinetics/pharmacodynamics data
3. Post-Clinical Translation
   a. Comparative effectiveness research studies
   b. Knowledge transfer to providers or community
   c. Novel approaches to partnering with communities to enhance research