

# Accelerated Translational Incubator Pilot (ATIP) Program

## Frequently Asked Questions

ICTR Research Navigators  
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## **1. ABOUT THE ATIP PROGRAM**

### **1.1. HOW MANY TIMES A YEAR ARE ATIP APPLICATIONS ACCEPTED, AND WHEN ARE THE SUBMISSION DEADLINES?**

A Request for Applications (RFA) for ATIP grant proposals is issued once annually. Historically, the announcement is made in either the fall or late winter.

### **1.2. HOW DOES ATIP DIFFER FROM OTHER TRADITIONAL FUNDING PROGRAMS?**

The Accelerated Translation Incubator Program (ATIP) is a focused funding program of the Johns Hopkins Institute for Clinical and Translational Research (ICTR) designed to start or facilitate new, translationally oriented research projects by clinical and non-clinical faculty. It provides reasonable funds to initiate, implement, and complete early or mid-stage projects designed to aid in the development of new therapies, devices, or approaches to clinical research. The program employs a milestone-driven approach that requires collaboration among the clinicians and scientists necessary to complete projects. This program anticipates that funded projects will, within the strict 12-month funding period, produce tangible results that will lead to the next stage of development. Research Navigators are assigned to each ATIP grant awardee to provide a wide range of support and guidance as needed.

### **1.3. DO ELIGIBLE PROJECTS REQUIRE COLLABORATORS FROM HOPKINS CTSA PARTNER UMB?**

Though not a requirement, proposals for collaborative projects that include UMB and JHU translational scientists will be prioritized

### **1.4. WHAT IS THE ROLE OF A RESEARCH NAVIGATOR?**

The Research Navigators serve as the primary link between the ATIP Investigator and ICTR by providing their expertise to the study team and monitoring study progress and milestone achievements as representatives of the ATIP leadership. The Navigators maintain an active presence throughout the course of the grant award period.

### **1.5. WHAT IS THE REVIEW PROCESS?**

Only complete applications received by the submission deadline are considered for funding. The review process is 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.

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

## 1.6. WILL I GET “PINK SHEETS” (REVIEWER COMMENTS)?

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.

## 1.7. I SUBMITTED AN APPLICATION FOR CONSIDERATION THAT WAS NOT FUNDED. CAN I RESUBMIT THE SAME APPLICATION AT THE NEXT ROUND?

Resubmission of a previously reviewed grant is not permitted. Investigators whose ATIP applications were not funded 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](mailto:ckobrin1@jhmi.edu) or [ICTR\\_Navigators@jhmi.edu](mailto:ICTR_Navigators@jhmi.edu).

## 1.8. AT THE LAST DEADLINE, I SUBMITTED AN APPLICATION THAT WAS NOT FUNDED, CAN I SUBMIT AN APPLICATION FOR A *DIFFERENT* PROJECT AT THE UPCOMING DEADLINE?

Yes.

## 1.9. ARE THERE EVER INSTANCES WHERE THE SUBMISSION DEADLINE IS EXTENDED?

Historically, no extensions have been granted. However, if you wish to make such a request, please contact the Research Navigators at: [ICTR\\_Navigators@jhmi.edu](mailto:ICTR_Navigators@jhmi.edu).

## 2. WHO MAY APPLY?

**Any JH faculty member with a proposal that has not been previously submitted to another ICTR funding program within the last 12-months**, including 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.

**Previously awarded ATIP PIs are not eligible to apply with a new project within the twenty-four-month period following the receipt of their initial ATIP award funds.**

Junior faculty in all schools, particularly those new to translational research, are encouraged to apply and will receive extra consideration.

### 2.1. I AM NOT CURRENTLY ON FACULTY BUT HAVE BEEN OFFERED A FACULTY POSITION THAT WILL GO INTO EFFECT BY THE ATIP DEADLINE DATE. CAN I APPLY TO ATIP AS PROJECT PI?

According to the RFA, **only faculty can apply to the program as a PI**, however, if you have documentation of an appointment to a faculty position which will go into effect

**prior to the ATIP award notification date**, which is approximately four months post submission deadline, **you may be allowed to apply**. Please contact the Research Navigators at [ICTR\\_Navigators@jhmi.edu](mailto:ICTR_Navigators@jhmi.edu) prior to submitting the application to discuss this situation.

## **2.2. CAN A PI SUBMIT MORE THAN ONE ATIP APPLICATION IN THE SAME FUNDING ROUND?**

Applicants may submit **one** ATIP application in response to this RFA. If multiple applications are submitted by the same PI in the same round, only one will be arbitrarily selected for review. No exceptions will be granted in this regard.

## **2.3. CAN AN ATIP APPLICATION HAVE MULTIPLE PIS?**

No. The ATIP application system is set up to recognize only one PI per application.

## **2.4. I AM A JOHNS HOPKINS KL SCHOLAR. MAY I SUBMIT AN ATIP APPLICATION FOR FUNDING CONSIDERATION?**

Yes, you may apply but you **must** first demonstrate that you have maximized use of available KL funds before doing so. **Please contact the Research Navigators at [ICTR\\_Navigators@jhmi.edu](mailto:ICTR_Navigators@jhmi.edu) if considering an ATIP application.**

# **3. ATIP APPLICATION COMPONENTS**

## **3.1. WHY ARE PROJECT MILESTONES AND SCHEDULES NECESSARY?**

Completed project schedules are a required component of the ATIP application and must be uploaded to the online application in the 'project schedule' section.

The ATIP program is designed to fund projects that can be completed within 12 months. Therefore, project milestones and schedules are needed in order to assess the feasibility of project completion within the funding period. For this reason, it is important to be meticulous when developing milestones and project schedules.

Additionally, a well-constructed project schedule allows the PI and study team to monitor progress and make adjustments in response to obstacles. It can also be used to accurately estimate the amount of money and other resources required to complete the project at any point in the project.

**All applicants are required to submit a project schedule as part of the application** and the Project Schedule template can be found with the ATIP RFA on the main ICTR ATIP page.

The milestones and project schedule will be closely scrutinized and if the information supplied for either of these sections is not sufficiently detailed, you may be contacted to provide additional clarification.

### 3.2. WHO SHOULD BE LISTED IN THE APPLICATION AS PROJECT TEAM MEMBERS?

Anyone who will contribute in ANY way to the science, conduct of the research, collection of the data, and/or preparation of reports/publications must be listed as a project team member in the ATIP application. This includes Hopkins faculty, post-docs, fellows, undergraduate and graduate students, and staff. This also includes co-investigators and/or collaborators from outside universities, institutions, companies, and/or facilities. Those investigators at institutions other than JHU (i.e. without JHED IDs) who are participating in this project should be listed in the application interface under "Outside investigators" with name, degree(s), rank, affiliated institution, email address, and role provided.

### 3.3. WHAT BIOGRAPHICAL INFORMATION SHOULD BE INCLUDED IN THE GRANT APPLICATION?

Biographical sketch information should:

- a. Be in NIH-format for the PI and ALL co-investigators (5-page limit)
- b. Include full NIH "[Other support](#)" information for PI and ALL co-investigators (5-page limit each) [NOTE: If not included in the Biosketch itself, provide separate "Other support" information for the PI and all co-investigators, (limited to 3-pages each)]
- c. Include a brief identification and biographical description of all other study team personnel named in the ATIP application (4-page limit total)

## 4. REGULATORY APPROVALS AND DOCUMENTATION

### 4.1. IF MY PROPOSAL INVOLVING HUMAN SUBJECTS RESEARCH IS SELECTED FOR FUNDING, DOES MY APPLICATION HAVE TO BE IRB APPROVED BEFORE I CAN RECEIVE MY ATIP FUNDS?

Yes, IRB approval is required as is satisfying all other applicable institutional requirements (e.g. [Biosafety registrations](#), [HSR compliance and HIPAA certification](#) of staff, [Clinical Engineering clearance](#) of devices, [ISCRO approval](#) for stem cell research, [Radiation Safety registration](#), etc.). In addition, all applicants with projects involving [human subjects research as defined by NIH](#) must also obtain approval from the National Center for Advancing Translational Science' (NCATS) before the study can be initiated. Research with human cell lines or tissue repositories that meet the definition of [human subjects research](#) require prior approval as well.

**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 sometimes take up to several months, the applicant must then submit a Request for Prior Approval to NCATS before being permitted to access their grant and begin working.** Detailed instructions for preparation of the document package, required file naming conventions, and submission of the materials will be provided by the ICTR Navigators with the notification of selection of the project for award.

#### **4.1.1. IF MY PROJECT INVOLVES HUMAN SUBJECTS RESEARCH THAT IS DEEMED TO MEET CRITERIA FOR *EXEMPTION CATEGORY 4* BY THE IRB, MUST I STILL SUBMIT A DOCUMENT PACKAGE TO NCATS FOR PRIOR APPROVAL?**

If the JHM IRB determines that a human subjects research project meets criteria for exemption 4 (NCATS Category 2), an abbreviated NCATS submission is required including:

- Brief summary of the overall project and aims, as well as the specific aspects of the proposed study to be supported by NCATS funds with a line item budget for each (e.g. list supplies, services, and personnel costs, etc.)
- IRB approval of the proposed project with the institutional exemption determination citing [45 CFR 46.104 \(4\)](#)
- 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.
- 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

#### **4.1.2 IF MY PROJECT INVOLVES HUMAN SUBJECTS RESEARCH THAT IS DEEMED TO BE EXEMPT (EXEMPTION CATEGORIES 1,2,3,5, OR 6) OR MINIMAL RISK BY THE IRB, MUST I STILL SUBMIT A DOCUMENT PACKAGE TO NCATS FOR PRIOR APPROVAL?**

If the JHM IRB determines that a project meets criteria for exempt human subjects research (Categories 1, 2, 3, 5, or 6) or is minimal risk\* research, (NCATS Category 2) an abbreviated NCATS submission is required including:

- 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.)
- IRB approval of the proposed project or institutional exemption determination
- 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
- Inclusion Enrollment Report(s)
- 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

*(\*If the project is determined by the IRB to be minimal risk, but meets the NIH definition of a clinical trial (NCATS Category 1), see 4.1.4 below.)*

**4.1.3 IF MY PROJECT IS DEEMED GREATER THAN MINIMAL RISK BUT DOES NOT MEET NIH'S DEFINITION OF A CLINICAL TRIAL (NCATS CATEGORY 1) WHAT DOCUMENTATION IS SUBMITTED TO NCATS FOR PRIOR APPROVAL?**

The NCATS Human Subjects Research Prior Approval (HSRPA) documentation package is required and will consist of all materials in 4.1.2 as well as the following, which are either already part of the eIRB application, or which should be readily available from the applicant including:

- 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) (*optional if applicable*)
- Overall structure of the study team (*optional*)

**4.1.4 IF MY PROJECT MEETS NIH'S DEFINITION OF A CLINICAL TRIAL (NCATS CATEGORY 1) WHAT DOCUMENTATION IS SUBMITTED TO NCATS FOR PRIOR APPROVAL?**

The NCATS HUMAN SUBJECTS RESEARCH PRIOR APPROVAL (HSRPA) documentation package is submitted and will consist of all materials in 4.1.2 and 4.1.3 as well as the following, which are either already part of the eIRB application, or which should be readily available from the applicant including:

- 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

**4.1.5 Is my project subject to the NIH SINGLE IRB REQUIREMENT FOR MULTI-SITE STUDIES?**

As the source of ATIP awarded funds is the NIH-NCATS, funded projects that involve [non-exempt human subjects research](#) which is being conducted using the same protocol at multiple U.S. sites, are subject to the NIH single IRB (sIRB) review requirement. This requirement applies even if the study is partially funded

by the NIH, but is waived if the source of the NIH funding is a career development, research training or fellowship award, or if prohibited by a federal, tribal, or state law, regulation, or policy.

- a. **If an ATIP proposal meets the requirements for sIRB review, how is that arranged with the JHM IRB?**

**The first step in the sIRB review process is to determine whether or not the JHM IRB is being asked to serve as the sIRB of record, or to rely on an external IRB by delegating institutional review board review responsibilities to the IRB of another institution.** Reliance Agreement is the formal, document that provides the mechanism for sIRB review arrangements between institutions. The terms of the Reliance Agreement must be agreed to by the participating institutions before research can begin.

**For questions about whether your proposal may require a reliance agreement and/or to initiate an agreement, please contact the JHM IRB Reliance Office at [jhmirbreliance@jhmi.edu](mailto:jhmirbreliance@jhmi.edu) for assistance.**

**NOTE: THAT [sIRB REVIEW FEES APPLY](#) WHEN THE JHM IRB WILL BE THE IRB OF RECORD, and sIRB review fees MAY be included in the ATIP budget.**

#### **4.1.6 Does my project contain a FOREIGN COMPONENT?**

NIH defines a “Foreign Component” as the ***“performance of any significant element or segment of the project outside the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended.”***

***Activities that would meet this definition include, but are not limited to, the following:***

- *The involvement of human subjects or vertebrate animals at a foreign site;*
- *Extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling and similar activities; and/or*
- *Any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.”*

**Per the [NIH Grants Policy Statement](#), projects with a foreign component require:**

- Preparation of an application that requires Additional information and documentation beyond the contents of the NCATS prior approval package
- Review AND approval from NCATS, followed by
- **Review AND approval from the NIH Fogarty International Center (FIC) and/or the US State Department (USSD)** (\*Award recipients should **anticipate significant delays** due to the additional required “foreign component” reviews.)
- **That no awarded funds may be used to support ANY project activities** until prior approval has been issued/received

To avoid lengthy regulatory processes that may delay considerably the start of the project, investigators should avoid proposing any activities that meet the NIH's definition of a [foreign component](#). If uncertain as to whether or not a project may involve a foreign component, please contact the ICTR Navigators at [ICTR\\_Navigators@jhmi.edu](mailto:ICTR_Navigators@jhmi.edu) for assistance with this matter.

#### 4.2. IF MY PROPOSAL INVOLVING LIVE VERTEBRATE ANIMALS IS SELECTED FOR FUNDING, DOES MY APPLICATION HAVE TO BE IACUC APPROVED BEFORE I CAN RECEIVE MY ATIP FUNDS?

Yes, IACUC approval is required as is all other applicable institutional requirement approvals (e.g. [Biosafety registrations](#), [Radiation Safety registration](#), etc.). In addition, all applicants with projects involving live [vertebrate](#) animals must now obtain approval from the National Center for Advancing Translational Science' (NCATS) before the study can be started.

**If notified by the ICTR that the ATIP submission has been selected for funding, then the applicant must immediately start working to obtain all institutional regulatory approvals and submit their study for ACUC review. Upon receipt of IACUC approval, which can take several months, the applicant must then prepare a document package to be submitted for NCATS' review.** Detailed instructions for preparation of the document package, required file naming conventions, and submission of the materials will be provided by the ICTR Navigators with the notification of selection of the project for award.

##### 4.2.1 WHAT DOCUMENTATION IS SUBMITTED TO NCATS TO REQUEST PRIOR APPROVAL FOR VERTEBRATE ANIMAL RESEARCH?

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:

- Animal Welfare Assurance #
- IACUC Approval letter
- If the proposed research is ancillary to another research protocol, the title and PI of the parent protocol
- Total budget for activities to be supported with ATIP funding with justification
- 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.

### 4.3. NCATS REVIEW AND FUNDING TIMELINE

#### 4.3.1 NCATS Category 2 (Exempt Human Subjects Research and Projects Deemed to be Minimal Risk)

Most Category 2 Human subjects research studies may access their ATIP funding 14 days following the formal submission of the documentation package and email notification to NCATS. However, while conducting their review, NCATS may submit questions back to the institution and/or require the site to stop HSR activities if the submitted documentation does not support Category 2 criteria.

#### 4.3.3 NCATS Category 1 Review (NIH Defined Clinical Trials and Human Studies Deemed Greater than Minimal Risk; All studies with a Foreign Component including Category 2 studies)

[NCATS](#) has up to 30 days from the date of **receipt of a complete packet**, to review the materials and respond. **Until approval has been received from NCATS, ATIP funding will not be issued.** 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. If there are any uncertainties in how to respond the ICTR Navigators should be contacted immediately for assistance. Based upon experience in the last ATIP funding cycle, these reviews were completed within 30 days.

##### 4.3.3.1 NCATS Approval

**If the requirement to receive prior approval by NCATS for use of the ATIP pilot funds has been satisfied, the start date of the ATIP grant will be determined upon:**

1. Submission of both the documentation package and notifying institutional email for Category 2 studies
2. Receipt from NCATS of their approval notification for Category 1 studies.

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:** Despite being selected for funding, should a project NOT satisfy NCATS' requirements for approval, and the issue cannot be readily resolved, the pilot award will have to be modified subject to the approval of the ICTR ATIP Leadership Committee or disallowed.

#### **4.4 IF MY PROJECT INVOLVES ONLY INVERTEBRATE ANIMAL RESEARCH OR IS DETERMINED BY THE IRB TO BE NHR, AM I REQUIRED TO SUBMIT A DOCUMENTATION PACKAGE TO NCATS FOR PRIOR APPROVAL?**

No. Only projects involving human subjects and/or vertebrate animals are currently subject to this requirement.

## **5. FUNDING**

### **5.1 DO NIH GRANT POLICIES AND GUIDELINES APPLY TO ATIP FUNDS?**

Yes. All ATIP awardees must comply with all applicable NIH grant policies and guidelines.

### **5.2 IF AWARDED, WHEN WILL I HAVE ACCESS TO MY ATIP FUNDS?**

If your project requires NCATS prior approval, your funding start date will be determined and IO number issued only after all requirements for NCATS approval have been satisfied for your category of study. Briefly, for HSR *Category 2* studies that is 14 days after the submission to NCATS of both the documentation package described in 6.1.1 or 6.1.2 and the institutional email formally notifying them of this action. For HSR *Category 1* studies and Live Vertebrate Animal Studies, it is receipt of the NCATS approval letter.

At the time that you are notified of your IO number, you will be able to access your ATIP funds. If your project does *not* require NCATS prior approval, upon resolution of any stipulations in your award letter, your grant funding period will be determined and IO number assigned. Upon receipt of that notification from the ICTR, you will be able to access your ATIP funds.

### **5.3 ARE INVESTIGATORS ALLOWED TO USE ATIP FUNDS FOR FACULTY SALARY?**

No. Funds may not be used for faculty salary with the exception of support for Research Associates or comparable non-tenure track faculty appointments. ATIP funds *may* be used for fellow and staff salary support, as well as for stipends paid to undergraduate or graduate students at Johns Hopkins.

### **5.4 DO I NEED TO INCORPORATE JOHNS HOPKINS UNIVERSITY INDIRECT COSTS INTO MY BUDGET?**

No, you do not need to include indirect costs to the ATIP proposal budget. The only possible exception is in the case of a subcontract. **If your project may involve a subcontract, please see 5.5 below.**

## 5.5 ARE INVESTIGATORS ALLOWED TO USE ATIP FUNDS FOR A SUBCONTRACT WITH AN OUTSIDE INSTITUTION?

Subcontracts with outside institutions/facilities *may* be permitted and are considered on a case-by-case basis.

If allowed, the subcontract may be subject to certain restrictions (e.g. inclusion of IDC from subcontracted institution, subcontract budget is no more than 50% of total requested ATIP funds, etc.). **For this reason, applicants must obtain authorization from the ICTR Sponsored Projects Office to include a subcontract in their proposal in advance of submission.** Proposals requiring a subcontract for which authorization was not obtained from the ICTR in advance of submission may be declined.

**Applicants with projects requiring a subcontract, or questions as to whether or not a project may require a subcontract, should contact the ICTR Sponsored Projects Office at [ICTRSponsored@jhmi.edu](mailto:ICTRSponsored@jhmi.edu) or the [Research Navigators](#) as soon as possible prior to submission of the proposal.**

## 5.6 CAN I LOSE ALL OR PART OF MY ATIP PROJECT FUNDING?

Yes, it is possible to lose award funding for several reasons.

- 1) Should a project NOT satisfy NCATS' requirements for approval, and the issue cannot be readily resolved, the pilot award will be disallowed despite being selected for funding by the Johns Hopkins ICTR ATIP program.
- 2) The ATIP award letter states the terms and conditions of the award. Noncompliance with any those terms or conditions could result in the loss of funding. Some of the things that may result in the loss of funding include but are not limited to:
  - Failure to secure all necessary regulatory approvals within a timeframe that is compatible with the project being completed within 12 months
  - Failure to meet self-set project milestones and timeline,
  - Failure to inform Research Navigators and/or ATIP leadership of changes (e.g., research plan, financial, etc.) to the original ATIP project prior to implementation.
  - Failure to comply with all reporting requirements and/or respond in a timely fashion to the Research Navigators' requests for any additional information which may be needed, throughout the funding period.
- 3) An awardee may lose a portion of the award if they have not satisfactorily addressed the requirement for a Studio consultation by the beginning of the fourth quarter of the funding period. This can be accomplished either by having already initiated a Studio for the project or by submitting 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 of awarded ATIP funds** which will be held in reserve at the outset of the funding period.

There may be circumstances beyond the control of the PI that have a negative impact on a project. Good communication with the Research Navigators is essential to help maintain good standing with the ATIP program.

## **6 FUNDED PROJECTS**

### **6.1 WHAT SHOULD I EXPECT IF MY PROJECT IS FUNDED?**

**6.1.1 You will receive an award letter detailing the terms and conditions of the ATIP award approximately four (4) months post the grant submission deadline.**

If your project **requires NCATS prior approval for human subjects or vertebrate animal research**, you will receive an additional, separate notification from the Research Navigators detailing preparation of your NCATS prior approval review package. Navigators will work with you to address any questions that arise as you prepare the required documentation for submission and review. Upon receipt of your NCATS review and approval, see 6.1.2 below.

**6.1.2 If your project does not require NCATS prior review or has received approval from NCATS to proceed:**

After award notification letters are sent, the Research Navigators will send a letter of introduction requesting an initial meeting to be held within the first six (6) weeks of the grant period if possible.

- Included with the introduction letter will be the “Project Team Role and Responsibility Roster”, which you will be asked to complete and return to the Navigators prior to the introductory meeting. On the roster, you will be required to indicate whether you or any of the project team members have a conflict of interest and, if so, how the conflict is being managed.
- The introduction packet may also include a ‘Supplemental Information Request’ form. If you were not asked by the Research Navigators to complete this form previously, you will be asked to complete and return it prior to the introductory meeting.

#### **6.1.3 Introductory Meeting**

The purpose of this initial meeting is:

- To discuss the expectations of the ATIP program in more detail,
- To review the role of the Research Navigators,
- To discuss the ATIP project and clarify any questions that the Navigators have, and
- To address any questions that the PI or project team may have concerning the ATIP program or the ICTR.
- If potential project management concerns were brought to your attention by the Research Navigators during the Navigator Assessment process, which could not be fully resolved prior to notification of award, they will be discussed at this time.

Normally the meetings can be conducted virtually and take between 30 minutes and an hour, depending on the number of attendees and issues to be discussed.

You may invite as many members of the ATIP project team to this meeting as you like, but there is no set requirement for attendance. Financial and administrative personnel are welcome to attend.

#### **6.1.4 Progress Reports**

If awarded, you will be asked to complete a progress report form on a regular basis. The reporting intervals will be established to optimize the management of each awarded project. The progress report form will be in REDCap. Notifications will be sent via email to you by the Research Navigators. The reports are designed to both help us recognize any difficulties that might be delaying the study as well as reporting on the research accomplished. The information requested in these reports will consist of the following:

- a brief summary regarding progress made to date,
- a table of your project's milestones and activities timeline where you would update the actual start and completion dates for each milestone and activity against the planned scheduling of these events
- any topics or questions for an ICTR Studio consultation
- information about any new funding sources obtained
- information regarding the use of other ICTR resources,
- documentation of any publications/abstracts/presentations resulting from the project
- information about any IP developed resulting from the project, and
- and any additional relevant information from the PI

#### **6.1.5 ATIP PI Studio Consultations**

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 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:

- 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.
- 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.
- 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 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](mailto:ICTR_Navigators@jhmi.edu).

#### **6.1.6 Project Communication**

If awarded, good communication between you as PI, your project team, and the Research Navigators is of paramount importance. Whether via email, telephone, or individual meetings, the expectation of ATIP leadership is that you and your study team will inform the Research Navigators of ALL problems and obstacles encountered in real-time. The role of the Research Navigator is to help facilitate resolution of obstacles, so if you or members of your project team encounter issues or have questions, the Research Navigators should be the first people you contact. If they cannot answer the question themselves, they will find the answer for you.

#### **6.1.7 Post-Project Surveys and Requests for Information**

As the primary objective of the ATIP program is to provide pilot funding sufficient to move projects in early development forward for expeditious translation and dissemination into the community, we are committed to collecting data on the outcomes of ATIP projects. Therefore, if awarded, you as the project PI will receive requests for information about the status of your project and any headway made with regard to outcomes such as acquisition of subsequent development funding, identification of corporate sponsors, or publications, after completion of your award and yearly, thereafter, for a minimum of five (5) years. Additionally, the Research Navigators may contact you regarding information required for ICTR annual reporting.

## 7 COMPUTER SYSTEM & SUBMISSION CONCERNS

### 7.1 WHAT SHOULD I KNOW ABOUT SUBMITTING THE ONLINE APPLICATION?

- Applicants should be sure to review all instructions and allot themselves adequate time to prepare and submit their application.
- The online system will be open for submission of applications from the date of RFA announcement until the submission deadline. The system will be closed at the time of the submission deadline.
- Applications are submitted via an online system located here: <https://redcap.link/ATIP2023>
- The application does not have to be submitted by the PI, though the PI has primary responsibility for the content in all sections of this submission.
- Before you submit your application, double check to make sure that it is complete with all correct documents uploaded and sections completed.
- If you accidentally submit your application before it is complete, please contact the ICTR Navigators at [ICTR\\_Navigators@jhmi.edu](mailto:ICTR_Navigators@jhmi.edu) **BEFORE 5PM on the date of the submission deadline.**
- If you have issues related to submission of your ATIP application that have not been addressed here, please contact the ICTR Navigators at [ICTR\\_Navigators@jhmi.edu](mailto:ICTR_Navigators@jhmi.edu).

## 8 ADDITIONAL CONSIDERATIONS

### 8.1 IF I SUBMIT AN ATIP APPLICATION, CAN I USE OTHER ICTR RESOURCES FOR THE PROJECT?

Yes, you may. We encourage ATIP applicants to utilize any of the ICTR sponsored resources in their research. The entire listing of available resources may be at the [ICTR home page](#). Please contact the ICTR Navigators at [ICTR\\_Navigators@jhmi.edu](mailto:ICTR_Navigators@jhmi.edu) if you have or have questions about a specific resource.

### 8.2 I STILL HAVE QUESTIONS ABOUT ATIP. WHO CAN I CONTACT FOR MORE INFORMATION?

If you have any questions or issues related to ATIP application that have not been addressed here, please contact the ICTR Navigators at [ICTR\\_Navigators@jhmi.edu](mailto:ICTR_Navigators@jhmi.edu).