

Accelerated Translational Incubator Pilot (ATIP) Program

Frequently Asked Questions

NOTE:

Extension of Application Deadline to 4/1/24 issued 2/26/24

***Clarification of Eligibility Criteria for Submitted Proposals
and Extension of Application Deadline*** issued 02/12/24



ICTR Research Navigators
February 12, 2024
Version 14.0

TABLE OF CONTENTS

Section #	Title	Page
1.	ABOUT THE ATIP PROGRAM.....	4
1.1.	HOW MANY TIMES A YEAR ARE ATIP APPLICATIONS ACCEPTED, AND WHEN ARE THE SUBMISSION DEADLINES?.....	4
1.2.	HOW DOES ATIP DIFFER FROM OTHER TRADITIONAL FUNDING PROGRAMS?.....	4
1.3.	DO ELIGIBLE PROJECTS <i>REQUIRE</i> COLLABORATORS FROM HOPKINS CTSA PARTNERS?.....	4
1.4.	WHAT IS THE ROLE OF A RESEARCH NAVIGATOR?.....	5
1.5.	WHAT IS THE REVIEW PROCESS?.....	5
1.6.	WILL I GET “PINK SHEETS” (REVIEWER COMMENTS)?.....	5
1.7.	I SUBMITTED AN APPLICATION FOR CONSIDERATION THAT WAS NOT FUNDED. CAN I RESUBMIT THE SAME APPLICATION AT THE NEXT ROUND?.....	5
1.8.	AT THE LAST DEADLINE, I SUBMITTED AN APPLICATION THAT WAS NOT FUNDED, CAN I SUBMIT AN APPLICATION FOR A <i>DIFFERENT</i> PROJECT AT THE UPCOMING DEADLINE?.....	6
1.9.	ARE THERE EVER INSTANCES WHERE THE SUBMISSION DEADLINE IS EXTENDED?.....	6
2.	WHO MAY APPLY?.....	6
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?.....	6
2.2.	CAN A PI SUBMIT MORE THAN ONE ATIP APPLICATION IN THE SAME FUNDING ROUND?.....	6
2.3.	CAN AN ATIP APPLICATION HAVE MULTIPLE PIS?.....	6
2.4.	I AM A KL SCHOLAR AT JOHNS HOPKINS/UMB. MAY I SUBMIT AN ATIP APPLICATION FOR FUNDING CONSIDERATION?.....	6
3.	ATIP APPLICATION COMPONENTS.....	7
3.1.	WHY ARE PROJECT MILESTONES AND SCHEDULES NECESSARY?.....	7
3.2.	WHO SHOULD BE LISTED IN THE APPLICATION AS PROJECT TEAM MEMBERS?.....	7
3.3.	WHAT BIOGRAPHICAL INFORMATION SHOULD BE INCLUDED IN THE GRANT APPLICATION?.....	7
	BIOGRAPHICAL SKETCH INFORMATION:.....	7
	• IN NIH-FORMAT FOR THE PI AND ALL CO-INVESTIGATORS, (5-PAGE LIMIT EACH).....	7
	• IF NOT INCLUDED IN THE BIOSKETCH, PROVIDE SEPARATE “OTHER SUPPORT” INFORMATION FOR THE PI AND ALL CO-INVESTIGATORS (LIMITED TO 3-PAGES EACH).....	7
	• A BRIEF IDENTIFICATION AND BIOGRAPHICAL DESCRIPTION OF ALL OTHER STUDY TEAM PERSONNEL NAMED IN THE ATIP APPLICATION (4-PAGE LIMIT TOTAL).....	7
4.	REGULATORY APPROVALS AND DOCUMENTATION.....	7
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?.....	7

Section #	Title	Page
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?	11
4.3.	NCATS REVIEW AND FUNDING TIMELINE	12
4.4	IF MY PROJECT INVOLVES ONLY INVERTEBRATE ANIMAL RESEARCH OR IS DETERMINED BY THE IRB TO BE NHSR, AM I REQUIRED TO SUBMIT A DOCUMENTATION PACKAGE TO NCATS FOR PRIOR APPROVAL?.....	13
5.	FUNDING	13
5.1	DO NIH GRANT POLICIES AND GUIDELINES APPLY TO ATIP FUNDS?.....	13
5.2	IF AWARDED, WHEN WILL I HAVE ACCESS TO MY ATIP FUNDS?	13
5.3	ARE INVESTIGATORS ALLOWED TO USE ATIP FUNDS FOR FACULTY SALARY?	13
5.4	DO I NEED TO INCORPORATE JOHNS HOPKINS UNIVERSITY INDIRECT COSTS INTO MY BUDGET?.....	14
5.5	ARE INVESTIGATORS ALLOWED TO USE ATIP FUNDS FOR A SUBCONTRACT WITH AN OUTSIDE INSTITUTION?.....	14
5.6	CAN I LOSE ALL OR PART OF MY ATIP PROJECT FUNDING?.....	14
6	FUNDED PROJECTS.....	15
6.1	WHAT SHOULD I EXPECT IF MY PROJECT IS FUNDED?.....	15
7	COMPUTER SYSTEM & SUBMISSION CONCERNS	17
7.1	WHAT SHOULD I KNOW ABOUT SUBMITTING THE ONLINE APPLICATION? ...	17
8	ADDITIONAL CONSIDERATIONS	18
8.1	IF I SUBMIT AN ATIP APPLICATION, CAN I USE OTHER ICTR RESOURCES FOR THE PROJECT?.....	18
8.2	I STILL HAVE QUESTIONS ABOUT ATIP. WHO CAN I CONTACT FOR MORE INFORMATION?.....	18

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 milestone-driven focused funding program of the Johns Hopkins Institute for Clinical and Translational Research (ICTR). **This ATIP award cycle is seeking proposals focused on secondary data analysis of existing datasets to explore new approaches in one of the following areas:**

- Integrating “omics” and clinical data
- Integrating imaging and clinical data
- Drug discovery and development

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.

We are interested in learning more about *the process of integration of data* and not necessarily the analysis of the data. **Examples** might be around integration of data when data were not collected or classified uniformly, addressing approaches to data security, reducing risks of data identification, or easing using of data for research groups.

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.

Proposals given additional consideration will include those which:

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

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 PARTNERS?

Collaborative projects are not required. However, proposals for collaborative projects with teams comprised of translational scientists from our current CTSA Hub partners, including the University of Maryland, Baltimore, Morgan State University, and Johns Hopkins, are welcome and encouraged.

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 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.

Funding Decisions: The ICTR ATIP Selection 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.

However, 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.

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 there are extenuating circumstances to justify such a request, please contact the Research Navigators at: ICTR_Navigators@jhmi.edu.

2. WHO MAY APPLY?

All Johns Hopkins University, University of Maryland, and Morgan State University faculty with full-time appointments are eligible to apply.

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?

Only faculty can apply to the program as a PI, however, if you have documentation of an appointment to a faculty position that will go into effect prior to the ATIP award notification date, which is approximately two (2) months post submission deadline, **you may be allowed to apply**.

Please contact the Research Navigators at 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 KL SCHOLAR AT JOHNS HOPKINS/UMB. 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 if considering an ATIP application.**

3. ATIP APPLICATION COMPONENTS

3.1. WHY ARE PROJECT MILESTONES AND SCHEDULES NECESSARY?

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 faculty, post-docs, fellows, undergraduate and graduate students, and staff at your institution. This also includes co-investigators and/or collaborators from partner universities, institutions, companies, and/or facilities.

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

Biographical sketch information:

- In NIH-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)

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, [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
- Human Subjects Research protections training certifications for the PI and any key personnel directly involved in the study

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
- Current Human Subjects Research protections training certifications for the PI and any key personnel directly involved in the study

*(*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 Prior Approval 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
- 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 Prior Approval Request 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 steps in the sIRB process are to determine which IRB will be asked to serve as the sIRB of record, and whether or not the two or more institutions taking part in the research project have an established “reliance agreement” in place. A 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 is subject to the sIRB requirement and, if so, how to move forward, please contact the Research Navigators at ICTR_Navigators@jhmi.edu.

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.”*

NOTE: ATIP proposals that fail to convincingly exclude the involvement of a foreign component will be considered as non-responsive to the RFA and returned without review.

If uncertain as to whether or not your project may involve a foreign component, **please contact the ICTR Navigators at 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)

[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 NHSR, 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 4.1.1 or 4.1.2 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?

Yes. Funds may be used for faculty salary, fellow salaries, and stipends paid to undergraduate or graduate students. Funds may also be used for computational support, and data access fees. Requests for travel **essential to the conduct of research will be considered on a case-by-case basis and will require ATIP leadership approval;** Equipment purchases not exceeding 25% of the total award, will also be considered on a case-by-case basis, with final allocations subject to **ATIP leadership approval.**

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 may be permitted, but require authorization from either the [ICTR Financial Office](#) or the [Research Navigators](#) in advance of application submission.

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

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 two (2) 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.

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.
- See the ATIP webpage linked [here](#) for application materials and RFA
- 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 **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.

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 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.