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ABOUT THE PROGRAM

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

ATIP grant proposals are accepted two times a year, with submission deadlines announced one month in advance. The next round will be announced on 2/1/14.

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 at Johns Hopkins University. 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.

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 'project management' role throughout the course of the grant award period.

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: Research Navigators review applications for compliance with budgetary, content, eligibility, and other submission guidelines as described in the RFA and the ATIP Connection Request form. Incomplete or noncompliant applications are returned without scientific review.

First Round: Members of the ATIP Executive Committee assess applications in terms of the fit, feasibility, and translational nature of the proposed project. In addition, the ICTR Research Navigators will perform a preliminary feasibility review and assign a feasibility score that will be used in final calculation of the first round score.
Second Round: Applications that pass the first round of assessment are sent for scoring to a minimum of two external reviewers with expertise in fields relevant to the science in the proposal. These reviewers are asked to disclose any relationships to the grant applicant. If not conflicted, they will then be asked to provide written feedback addressing the merits of the application based on the five criteria listed above and scored accordingly. Reviewer comments from this round will be provided to applicants, but reviewer identities will be kept confidential.

Second Round Navigator Assessment: Due the accelerated nature of the program and the 12-month project timeline, an in-depth assessment of project readiness will be done on all applications in second-round. The Research Navigators will perform these assessments and may contact applicants for additional information as needed. The Navigator assessments will be provided to the ATIP Executive Committee prior to funding decisions being made.

Funding Decisions: The ATIP Executive Committee will evaluate all second-round feedback and in-depth Navigator Assessments and make final funding decisions. All applicants are notified of funding decisions approximately two months after the submission deadline. The start and end date of the 12-month grant will be included in the notification of the funding decision. Only those applicants who receive second-round reviews will be provided with feedback from the external review process. Resubmission is strongly discouraged except by invitation.

WILL I GET ‘PINK SHEETS’ (REVIEWER COMMENTS)?

Because of limited resources, feedback is not provided to those applicants who are eliminated from funding consideration in the first-round (internal) review. Applicants whose submissions score well enough to be sent for second-round (external) review are provided with feedback obtained during the external review process. The identity of external second-round reviewers will not be divulged.

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 strongly discouraged except by specific invitation from ATIP leadership.

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.

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.
WHO MAY APPLY?

Any faculty member at Johns Hopkins University is eligible to apply for an ATIP grant. Junior faculty in all schools, particularly those new to translational research, are encouraged to apply and will receive extra consideration. Undergraduates, graduate students, and postdoctoral fellows are not eligible to apply as Principal or Co-Investigators for pilot grants but can be incorporated as team members into any proposal.

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 PI?

According to the RFA, only faculty can apply to the program as a PI, however, if you have documentation of appointment to a faculty position which will go into effect prior to the ATIP award notification date, which is approximately eight weeks post 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.

CAN A PI SUBMIT MORE THAN ONE ATIP APPLICATION IN THE SAME FUNDING ROUND?

A PI may submit multiple ATIP applications in the same round, but it is not suggested and the projects cannot be related. If multiple applications are submitted by the same PI in the same round AND if more than one of those applications receives a fundable score, only one project will be funded. No exceptions will be granted in this regard.

CAN AN ATIP APPLICATION HAVE MULTIPLE PIs?

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

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

Yes, you may, but you must contact the Research Navigators at ICTR_Navigators@jhmi.edu prior to submitting the project the application.
ATIP FAQ\JAN2014

ATIP APPLICATION

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. More information on the construction of the project schedules can be found in the “ATIP Application: Development of Milestones and Project Schedules” document. This resource and the Project Schedule template can be found with the ATIP RFA and Project Readiness Checklist on the main ICTR ATIP page.

The form may also be downloaded from the online ATIP application, or you can email the Navigators to request a copy. Completed schedules must be uploaded to the online application under the ‘Project Schedule’ section.

Should your application be chosen for second round review, the Research Navigators will closely scrutinize the milestones and project schedule submitted with your application. If they determine that the identified milestones and schedule activities are not sufficiently detailed, they may contact you for additional information and/or work with you to revise the milestones and the project schedule.

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. If your project is selected for funding, you will be required to complete an “ATIP Project Team and Responsibility Roster” which the Navigators will keep on file with the ICTR. Providing a comprehensive list of project team members in the initial ATIP application will help to streamline this process.

WHAT BIOGRAPHICAL INFORMATION SHOULD BE INCLUDED IN THE GRANT APPLICATION?

We are looking for a two page NIH-style biographical sketch or CV for the PI. For the rest of the project team members, the PI can provide up to four (4) pages total providing brief identification and a biographical description of each team member and his or her role in the project.
REGULATORY APPROVALS AND DOCUMENTATION

IF AWARDED, DO I NEED TO HAVE CERTIFICATES OF HUMAN SUBJECTS RESEARCH COMPLIANCE AND/OR HIPAA TRAINING BEFORE I CAN RECEIVE MY ATIP FUNDS?

If your ATIP project involves a human subjects research protocol, you MUST complete human subjects research compliance and HIPAA training as specified on the JHM IRB “Training Requirements for Human Subjects Research” webpage.

In addition, all ATIP project team members MUST complete Research Compliance and HIPAA training as specified on the JHM IRB “Training Requirements for Human Subjects Research” webpage if they will be involved in collection of data, collection of specimens, or have access to Protected Health Information (PHI).

ALL human subjects research compliance training and/or HIPAA training certificates MUST be supplied to the Research Navigators before ATIP funds will be released.

IF MY APPLICATION IS SELECTED FOR FUNDING, DOES MY APPLICATION HAVE TO BE IRB APPROVED BEFORE I CAN RECEIVE MY ATIP FUNDS?

No, the application does not have to be IRB approved in order to receive your ATIP funds. However, before you can initiate any ATIP activities that involve human participates, the application must be IRB approved. The Research Navigators have ‘Read only’ access to the eIRB system and will download the necessary documents from the eIRB to maintain in your ATIP project file. If the application is being approved by another IRB (e.g., BSPH IRB, WIRB, etc…), however, then you will need to supply copies of the protocol, consent, application, and approval to the Navigators. Additionally, your milestones and project timeline/schedule must include the approval activities. Please note that those projects with IRB approvals or IRB applications under review at the time of submission will score better with regard to the Navigator Feasibility review which factors into the overall score and will impact whether or not a project may proceed to second round review. Therefore, it is in the best interest of all applicants to have regulatory approvals or have regulatory submissions under review as soon as possible in order to give their projects every advantage.

IF MY PROJECT INVOLVES ANIMAL RESEARCH, DOES MY ANIMAL PROTOCOL HAVE TO BE IACUC APPROVED BEFORE I CAN RECEIVE MY ATIP FUNDS?

No, the animal protocol does not need to be approved by the IACUC in order to receive your ATIP funds. However, before you can initiate any ATIP activities that involve animals, the animal protocol application, whether a new protocol or an amendment, must be approved. In addition, you must supply copies of all approvals, renewals, and the animal protocols to the Research Navigators throughout the course of the grant award period. Please note that those projects with IACUC approvals or IACUC applications under review at the time of submission will score better with regard to the Navigator Feasibility review which factors into the overall score and will impact whether or not a project may proceed to second round review.
Therefore, it is in the best interest of all applicants to have regulatory approvals or have regulatory submissions under review as soon as possible in order to give their projects every advantage.

**IF MY PROJECT REQUIRES AN IND(s) AND/OR IDE(s), AND IT IS SELECTED FOR FUNDING, DO I NEED TO HAVE APPROVAL FROM THE FDA BEFORE I CAN RECEIVE MY ATIP FUNDS?**

Because of the 12-month funding period and accelerated nature of this program, if you know your ATIP project requires an approved IND or IDE you MUST contact the Research Navigators to discuss this prior to submitting an ATIP application (ICTR_Navigators@jhmi.edu). Further, if you aren’t sure whether or not your project requires an IND/IDE, please contact the Navigators.
FUNDING

DO NIH GRANT POLICIES AND GUIDELINES APPLY TO ATIP FUNDS?

The ATIP program is the funded with NIH funds through the ICTR’s UL1 grant and therefore all ATIP awardees must comply with all applicable NIH grant polices and guidelines.

IF AWARDED, WHAT IS THE START DATE OF THE ATIP AWARD?

The usual grant start date is approximately 60 days post the submission due date. However, the grant start date may be revised as circumstances require. Awardees are notified of the exact start date in their award notification letter.

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

Historically, you will be given access to the ATIP funds within one to two weeks of the date the award is made. This delay is because an internal order (IO) number for the new account must be requested and assigned by Sponsored Shared Services. Barring any stipulations outlined in the award letter, study related charges incurred prior to the availability of the IO account may be moved to the account when it becomes available. As stated above, your award letter may include certain stipulations of the award that must be agreed upon or addressed prior to the release of funds. Once cited stipulations are resolved, and the IO number has been assigned, you will be able to access your ATIP funds.

ARE INVESTIGATORS ALLOWED TO USE ATIP FUNDS FOR FACULTY SALARY?

No. Funds may not be used for faculty salary. 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.

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.

If the ATIP project is funded, the ICTR will add indirect costs, at a rate of 26% of the funded direct costs, to the budget. Please see the next question concerning subcontracts for more information on the inclusion of subcontract indirect costs.

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

Subcontracts with outside institutions/facilities are permitted but should be no more than 50% of total requested budget. Subcontracts greater than 50% of the total requested budget may be considered with a strong justification.
Applicants with projects requiring subcontracts must provide a budget and justification detailing the total funds required for the sub-award, including total direct costs **AND** total indirect costs of the outside facility. Note that if the outside facility’s indirect costs rate changes, direct cost rates changes, and/or the requested budget are not calculated correctly, the applicant may not use more than the approved funded budget for the subcontract. For example, an ATIP applicant requests a total budget of $80,000. Included in that budget is a subcontract for $40,000, inclusive of the outside institution’s direct and indirect costs. After receiving ATIP funding, the applicant discovers that the subcontract is actually going to cost $60,000. If the applicant cannot negotiate with the outside institution to lower the costs to original amount of $40,000, then he/she will have to use $60,000 of the original $80,000 award for the subcontract costs leaving $20,000 to use for the research activities being conducted at Hopkins and the balance of any expenditures over $20,000 becomes the responsibility of the applicant.

If the budget includes a subcontract, the total requested funds for the subcontract must be listed in the overall project budget. The ICTR Financial Office can provide guidance on the subcontract process. Subcontract budgets for ATIP projects should be submitted on the NIH budget form used for grant submissions (PHS 2590 or PHS 398), along with a scope of work and budget justification. Subcontract issuance can take four weeks or longer depending on circumstances.

Contact the Research Navigators at ICTR_Navigators@jhmi.edu if you have additional questions about subcontracts.

**CAN I LOSE MY ATIP PROJECT FUNDING?**

Yes, it is possible to lose award funding. The 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 meet self-set project milestones and timeline,
- Failure to attend (or send a designee to attend) 2/3rd of the ATIP PI meetings, and
- 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.

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.
FUNDED PROJECTS

WHAT SHOULD I EXPECT IF MY PROJECT IS FUNDED?

1. You will receive an award letter detailing the terms and conditions of the ATIP award as well as the start date of the funding period approximately 60 days post the grant submission deadline.
   - 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, funds may be withheld until resolution is achieved.

2. 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. Please see Appendix II for a copy of the Supplemental Information Request form.

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.

   Normally the meetings 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.
4. Progress Reports

If awarded, you will be asked to complete a progress report form on a bi-monthly basis. The form will be sent via email to you by the Research Navigators and is essentially comprised of:

- a section for a brief summary regarding progress made to date,
- a table of your project’s milestones and activities timeline with start and completion dates,
- a section for information regarding the use of other ICTR resources,
- a section for documentation of publications/abstracts/presentations resulting from the project, and
- a section for any additional comments from the PI

These reports are relatively straightforward and the task of completion may be delegated to another project team member at the discretion of the PI.

5. ATIP PI Studio Consultations (NEW REQUIREMENT)

All funded awarded PIs will be given the opportunity to participate in an ICTR Studio consultation once during their funding period. The ICTR Studio is a new multidisciplinary service center created to help investigators improve the quality and impact of their translational research and is available to other JHU faculty by invitation only. 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. Assistance is provided by consultants who are acknowledged authorities in their fields, and who possess a broad spectrum of expertise ranging from content experts to help formulate the most relevant research questions, to methodological and technical specialists available to address issues related to the use of institutional and CTSA resources for pre-clinical and clinical studies.

Timing of each awardee’s Studio consultation will be encouraged 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 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 the project involves one of several previously identified areas of study including the Johns Hopkins Institute for Computational Medicine (ICM), Statistical Methods and Applications for Research in Technology (SMART), Institute for NanoBioTechnology,
and Center for Clinical Trials – Prediction of Individual Treatment Outcomes in Patients, 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.

While participation in the Studio Program is a condition of award, ICTR leadership believes that it will be a very rewarding process for ATIP grant recipients. For more information about the ATIP Studio consultation opportunity, please contact the Research Navigators at ICTR_Navigators@jhmi.edu.

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.

7. Post-Project Funding 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 obligated to collect data on the outcomes of ATIP projects. Therefore, if awarded, you as the project PI will receive requests to complete surveys at 6-months, 1, 2, and 3 years after your ATIP funding ends 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. Additionally, the Research Navigators may contact you regarding information required for the ICTR annual report.
COMPUTER SYSTEM & CONNECTION REQUEST SUBMISSION CONCERNS

WHAT SHOULD I KNOW ABOUT SUBMITTING THE ONLINE APPLICATION?

- The online system will be open to submit applications approximately 30 days prior to the submission deadline.

- Applications are submitted via the Connection Request system. Go to the following link (http://ictrweb.johnshopkins.edu/ictr/connection/) and log in using your JHED ID, then select the Accelerated Translational Incubator Pilot (ATIP) Program Application

- The system allows you to start an application and save it so that you can complete it over time. The system has an automatic time out mechanism, so we strongly suggest you save your application as often as possible to ensure no information is lost.

- Within each section of the application you may upload more than one document.

- References may be included at the end of the ‘Research Plan’ document, uploaded as a separate document in the ‘Research Plan’ section, or uploaded to the ‘Supplemental Materials’ section of the application.

- The application does not have to be submitted by the PI. Study staff or co-investigators may complete and submit the application, but need to be sure that the Principal Investigator is identified.

- Before you submit your application, double check to make sure that it is complete with all correct documents uploaded.

- 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 any issues related to submission of your ATIP application that have not been addressed here, please contact the ICTR Navigators at ICTR_Navigators@jhmi.edu.

*If included in the Research Plan, references will NOT be counted toward the 5-page limit.
ADDITIONAL CONSIDERATIONS

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 found at the ICTR webpage under Clinical Resources (http://ictr.johnshopkins.edu/home/equipment-clinical-resources/) or by requesting list of resources from the ICTR Research Navigators (ICTR_Navigators@jhmi.edu).

I STILL HAVE QUESTIONS ABOUT ATIP. WHOM CAN I CONTACT FOR MORE INFORMATION?

If you have any questions or issues related to ATIP application that have not been addressed here, please submit a Connection Request via the “Ask a Navigator: Help with Research Problems” link located on the left-hand menu of the ICTR homepage or contact the ICTR Navigators at ICTR_Navigators@jhmi.edu.
Glossary of Terms

Activity: A component of work performed during the course of a project.

Decompose (decomposition): A planning technique that subdivides the project scope [overall purpose] and project deliverables into smaller, more manageable components, until the project work associated with accomplishing the project scope and providing the deliverables is defined in sufficient detail to support executing, monitoring, and controlling of work.

Deliverable: Any unique and verifiable product, result, or capability to perform a service that must be produced to complete a process, phase, or project.

Event: Something that happens, an occurrence, an outcome.

Milestone: A significant point or event in the project.

Objective: Something toward which work is to be directed, a strategic position to be attained, or a purpose to be achieved, a result to be obtained, a product to be produced, or a service to be performed.

Project Schedule: The planned dates for performing a scheduled activity and the planned dates for meeting schedule milestones.

Project Scope: The work that must be performed to deliver a product, service, or result with the specified features and functions.

Reference: