The Johns Hopkins Institute for Clinical and Translational Research

Accelerated Translational Incubator Pilot (ATIP) Program

Frequently Asked Questions

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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 in late January/early February with submission deadlines announced in mid-May. The funding period for awarded grants begins on or about July 1st.

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 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 milestonedriven 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. 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.

1.4. WHAT IS THE REVIEW PROCESS?

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

- 1. 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.
- 2. First Round: ICTR Deputy Directors and Core Management will assess the applications in terms of the fit, feasibility, and translational nature of the proposed project. These assessments will each be assigned a numerical score. In addition, the ICTR Research Navigators will perform a preliminary feasibility review and assign a feasibility score that will be added to all of the assessment scores to calculate a final round score.
- 3. Second Round: Applications that achieve a minimum first round score established by ATIP leadership will be sent for review to a minimum of two reviewers external to the ICTR with expertise in fields relevant to the science in the proposal. These reviewers will be 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.
- 4. 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 review. The Research Navigators will perform these assessments, during which PIs may be contacted for additional information.
- 5. **Funding Decisions:** The ICTR Leadership Committee will evaluate all second-round feedback and in-depth Navigator Assessments and make final funding decisions.

1.5. 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. Only applicants whose submissions are submitted for second-round (external) review will be provided with feedback obtained during the external review process. The identity of external second-round reviewers will not be divulged.

1.6. 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 without specific invitation from leadership. 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 <u>ckobrin1@jhmi.edu</u> or ICTR Navigators@jhmi.edu.

1.7. 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.

1.8. 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.

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

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 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.

2.2. 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.

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 <u>must</u> contact the Research Navigators at ICTR_Navigators@jhmi.edu prior to submitting your 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 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 on the main ICTR ATIP page.

Should your application be chosen for second round review, the Research Navigators will closely scrutinize the milestones and project schedule submitted with your ATIP 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.

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?

- A biographical sketch in in NIH-format for the PI (5-page limit)
- A biographical sketch in NIH-format for the co-Investigator (5-page limit)
- <u>A brief</u> 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 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 need to complete human subjects research compliance and HIPAA training as specified on the <u>JHM IRB</u> <u>"Training Requirements for Human Subjects Research" webpage</u>.

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

ALL team members must complete all required compliance training prior to engaging in human subjects research activities. Training dates and certificates must also be made available to the Research Navigators upon request.

4.2. IF MY PROPOSAL 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 participants, 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., JHSPH IRB, WIRB), 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 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.

4.3. 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.

4.4. IF MY PROJECT REQUIRES OTHER INTERNAL/INSTITUTIONAL CERTIFICATIONS OR APPROVALS, DO I HAVE TO HAVE THESE AVAILABLE BEFORE I CAN RECEIVE MY ATIP FUNDS?

No, these approvals are not needed in order to receive your ATIP funds. <u>However</u>, investigators with regulatory approvals pending or in-hand <u>may receive</u> higher feasibility scores for their projects than those with regulatory submissions that have not been prepared or submitted for review. ATIP activities requiring these regulatory approvals/certifications may not be initiated until they are available and copies must be supplied to the Research Navigators upon request.

4.5. IF MY PROJECT REQUIRES AN IND/IDE FROM FDA AND/OR RAC APPROVAL FROM NIH, AND IT IS SELECTED FOR FUNDING, DO I NEED TO HAVE APPROVAL FROM FDA/NIH 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, IDE, or RAC submission, the filing must be made (immediately/ no later than 1 month after your award is announced) if this hasn't already been done. If you have questions about how to make this submission or if you aren't sure whether or not your project requires an IND/IDE or RAC approval, please contact the Navigators at ICTR_Navigators@jhmi.edu.

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 polices and guidelines.

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

The grant start date will be on or about July 1, 2016, however, this date may be revised as circumstances require. Awardees are notified of the exact start date in their award notification letter.

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

Historically, you will be given access to the ATIP funds within one week of the funding start date. 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.

5.4 ARE INVESTIGATORS ALLOWED TO USE ATIP FUNDS FOR FACULTY SALARY?

No. Funds may <u>not</u> be used for faculty salary with the exception of support for Research Associates. While technically faculty, Research Associate salary support is allowed. 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.

5.5 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, however, your project requires a subcontract, a second, separate budget including both directs and indirects will be required with the submission.

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.**

5.6 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 along with a scope of work and budget justification. Subcontract execution can take four weeks or longer depending on circumstances which should be considered in the project timeline given the accelerated nature of this program.

Contact the ICTR Financial Office at 443 287 ICTR (4287) if you have additional questions about subcontracts.

5.7 CAN I LOSE ALL OR PART OF 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 inform Research Navigators and/or ATIP leadership of changes (e.g., research plan, financial, etc...) to the original ATIP project prior to implementation.

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?

- 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
- a section regarding IP development resulting from the project, and
- a section for any additional relevant information 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

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 <u>ICTR Studio</u> 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 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.

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 <u>ICTR_Navigators@jhmi.edu</u>.

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 ICTR annual reporting.

7. COMPUTER SYSTEM & CONNECTION REQUEST SUBMISSION CONCERNS

7.1. 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 (<u>https://ictrweb.johnshopkins.edu/ictr/?RequestATIP</u>) and log in using your JHED ID, then select the Accelerated Translational Incubator Pilot (ATIP) Program Application
- While the system does not have an autosave feature, it will allow you to start an application and save it so that you can complete it over time. The system has an automatic time out mechanism after 20 minutes of inactivity, 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 should be uploaded in the Reference List section and will NOT be counted toward the 5-page limit
- The application does not have to be submitted by the PI. Study staff or coinvestigators 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.

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 found in the gold tabs across the <u>ICTR home page</u>. The Navigators will also be happy to perform a project specific assessment of the ICTR and institutional resources which you may find especially helpful in conducting the work proposed in your ATIP application. Please contact the ICTR Navigators at <u>ICTR Navigators@jhmi.edu</u> if you are interested in this resource.

8.2. 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 <u>"Ask a Navigator"</u> link provided here or contact the ICTR Navigators at ICTR_Navigators@jhmi.edu.