

Request for Applications

The Johns Hopkins Tuberculosis Research Advancement Center (TRAC) provides pilot grants to faculty and senior postdoctoral fellows in the Schools of Public Health, Medicine, and Nursing to enable and support TB related research projects. Junior faculty in other JHU schools are eligible to apply if the proposal meets all other criteria. The primary purpose of these awards is to generate preliminary data to strengthen the individual's ability to secure independent extramural research funding with a focus on R- and K-series awards.

Funds Available

The budget for faculty grants is a maximum of \$50,000 in direct costs. The budget for grants awarded to senior postdoctoral fellows is a maximum of \$25,000. Indirect costs will be calculated by the TRAC and added at the time of funding. Awards will be for one year, with potential for carryover if progress is achieved. The number of grants awarded will depend on the budgets of approved applications. The earliest start date will be January 1, 2024.

Award Funding Tier	Maximum Award Amount
Faculty Award	\$50,000
Senior Postdoctoral Award	\$25,000

Important Dates

- Letter of Intent due date: Monday, September 11th by 8:00AM EDT
- Applicant feedback on LOI by: Monday, September 18th
- Application due date: Monday, October 16th by 8:00AM EDT
- Award announcement: Thursday, December 14th, 2023

Please carefully read the full application instructions prior to applying.

Also, if you need help from a TRAC mentor, please let us know ASAP so we can match you appropriately. Our Cores [Developmental Core, Clinical Core, Microbiology, Immunology, Animal Modeling and Imaging (MIAMI) Core, Pharmacology and Pharmacometrics Core, Bioinformatics, Modeling and Biostatistics Core] are also available to assist. Please let us know how we can help you succeed!

Request for Applications

JHU TRAC Scholar Grants for Faculty Development in Tuberculosis Research

Issued: June 28, 2023

I. Funding Opportunity Description

The Johns Hopkins Tuberculosis Research Advancement Center (TRAC) will provide pilot grants to faculty and senior postdoctoral fellows in the Schools of Public Health, Medicine, and Nursing to enable and support TB related research projects. Junior faculty in other JHU schools are eligible to apply if the proposal meets all other criteria. The primary purpose of these awards is to strengthen the individual's ability to secure independent NIH research funding with foci on R- and K-series awards.

This document describes the details of these pilot awards. Please read it in its entirety.

II. RFP Schedule

Due Date for Letter of Intent (LOI)	September 11, 2023, 8:00AM EDT
Applicant Feedback on LOI	On or before September 18, 2023
Due Date for Application	October 16, 2023, 8:00AM EDT
Applicant Notification of Outcome	On or before December 14, 2023

III. Award Information

Funds available

The budget for the faculty grants is a maximum of \$50,000 in direct costs. The budget for grants awarded to senior postdoctoral fellows is a maximum of \$25,000. The TRAC will calculate and add indirect costs at the time of funding. We plan to award three to five (3-5) 1-year grants with a start date of January 1st, 2024.

Award Funding Tier	Maximum Award Amount
Faculty Award	\$50,000
Senior Postdoctoral Award	\$25,000

IV. Eligibility Information

A. Eligible Applicants

 Applicants must be appointed full-time instructors; Research Associates; or Assistant Professors in the Schools of Public Health, Medicine, or Nursing; or Assistant Scientists or Assistant Lecturers in the School of Public Health at the time of the planned award. Junior faculty at other JHU schools are eligible to apply and strongly encouraged to do so as we are seeking people "new to TB."



- 2. Associate Professors in the field of TB are eligible to apply if there is no history of an R01 award or its equivalent and the criteria of an NIH New and Early Stage Investigator are met. Any Associate Professor new to TB research is eligible to apply. Those in other faculty titles/status are not eligible. Those in "visiting" or "adjunct" status are not eligible.
- 3. Senior Postodoctoral fellows are eligible to apply for funding at the \$25,000 tier for postdoctoral awards. Postdoctoral fellows with a letter from their department chair confirming a pending faculty appointment may apply at the \$50,000 faculty award tier. The faculty-tier award will not be granted until the faculty appointment is active. If a postdoc is on a T32, TRAC funds cannot pay for training and stipends that are already paid for by the T32.
- 4. K awardees: If you are a current recipient of an NIH K award, you are required to submit with your TRAC application NIH sponsor approval indicating that you are eligible to receive TRAC funding (an email from your project officer will suffice). K awardees can receive compensation on TRAC pilot studies for effort not directly committed to the K award, as long as the specific aims differ from those on the K award. Please see the NIH guide notice (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-094.html) for more details. K award policies vary by mechanism and may have specific levels of effort and salary restrictions. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section-12/12.1 general.htm)
- 5. Previous recipients of a TRAC Development award are able to apply for additional funding or funding for a new project if evidence of progress is demonstrated. Career trajectory should be evident. TRAC-funded awards are limited to 2 over a 5-year period. Eligibility and assessment of need will occur during review of the Letter of Intent, so please explain the rationale for an additional award.

B. Project information

1. The JHU TRAC has a specific focus on multidisciplinary and collaborative research, thus applications for collaborative projects, particularly those involving faculty in different disciplines and/or schools at JHU are strongly encouraged. If the proposal for the project is part of a larger grant, there should be an explanation of the larger idea, how this proposal fits into the parent grant and how the pilot funding will be used to help in the development of the larger grant proposal (e.g. to obtain preliminary data). Although the TRAC's process borrows heavily from NIH processes, future funding targets need not be limited to the NIH alone. The TRAC may not fund studies involving new drugs, treatments, or devices, or off-label use of a licensed drug (this includes healthy volunteer studies where drugs are administered). The TRAC may not fund clinical trials, such as studies that include prospective assignment to one or more intervention to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes of the participants. Use this NIH TOOL to make a quick determination of a Clinical Trial. Studies involving human subjects may be subject to additional NIH review prior to initiating the study, which may cause delays. Similarly, for studies with any foreign



- component, additional NIH review and approval is required prior to the initiation of any study procedures.
- 2. Funds must be used to support research projects in TB including, but not limited to, the areas of:
 - Clinical epidemiology
 - Molecular microbiology, immunology, and pathogenesis
 - Experimental therapeutics, vaccines, and biomarkers. Clinical trials are not permitted, but analysis of data or banked specimens from previous clinical trials may be allowed.
 - Implementation science

C. Designation of a Research Mentor

Both formal and informal mentoring processes are available and encouraged for TRAC Scholar Awardees. Investigators interested in developing an application may choose a mentor or request one from the TRAC in your letter of intent. Should this mentoring relationship be mutually welcome and successful, the mentor will assist the candidate through the application process, and if awarded, mentorship would continue through the completion of the award.

V. Indication of Intent

Interested applicants are required to complete an <u>online application</u> (https://www.surveymonkey.com/r/L7LVQMP) and attach a letter of intent to apply. Applications and letters are evaluated for eligibility and those deemed likely to lead to future funding will be invited to submit a complete proposal. The letter of intent should be limited to one page and should contain:

- A. Name of applicant
- B. Title of proposal
- C. Specific Aims
- D. Abstract, including how your study will lead to future funding.
- E. Discipline of study:
 - 1. Social, Prevention and Community-based research
 - 2. Clinical research
 - 3. Microbiology, Immunology and Molecular Biology
 - 4. Epidemiology/Biostatistics
 - 5. Implementation Science
- F. Name of mentor or request for TRAC to assign. If you are naming a mentor, we will assume that you have asked and they have agreed. If you are requesting that we assist with a mentor, please make this clear.

Please complete the online application (https://www.surveymonkey.com/r/L7LVQMP) and attach the Letter of Intent, no later than **September 11**th, **8:00AM EDT**. We will notify you by Monday, September 18th if your project has been selected to proceed to a full application.



VI. Proposal and Submission Information

A. Content and Form of Proposal Submission

Proposals should be concise, with the narrative of the application being no longer than six (6) pages, single-spaced. The required components of the application are as follows:

Component	Format and
Component	Notes
Project narrative	
Introduction	
Specific Aims	
Research Plan:	
Ø Significance [Must include how this work will lead to further grants and	
further career development in TB research]	Use Word Doc
Ø Innovation	
\emptyset Approach [Note: this section should include the names and affiliations	
of all collaborators including those at other institutions and must clearly	
indicate the location of the proposed work]	
Timeline for implementation of the project	
Proposed budget	
[Note #1: if your proposal includes a sub-site/subcontract, a budget page should	
be included for each site]	Use NIH Budget
[Note #2: Please consider budgeting for equipment maintenance, if appropriate]	Form
Figures and references, including letters of collaboration, especially for non-	FOITH
Hopkins mentors/Co-Is	
[This section should be used judiciously for the sake of reviewers.]	
Biosketches with Support of Principal Investigator only. You do not need to	Use NIH
submit a biosketch for mentors or co-investigators.	template

Please follow NIH guidelines on font and margins. (https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm)

The project narrative, budget, figures and references and biosketch should be merged into one PDF file for submission.

B. Submission Dates and Times

Application Receipt Date: 08:00 AM on October 16th

Award Announcement Date: On or before December 14th

C. Sending an Application

Please email your full proposal to jhuctb@jhmi.edu

A note regarding Office of Research Administration: This funding mechanism uses internal funding and does not require review or approval by an Office of Research Administration. Similarly, investigators should submit their application directly to the TRAC and not through ORA.

D. Application Processing

Applications must be received no later than the date and time listed on the announcement. Applications received after that date will not be reviewed. Upon receipt, applications will be evaluated for completeness and responsiveness. Incomplete and non-responsive applications will not be reviewed.

Institutional Review Board (IRB) approval of human subjects is not required prior to review of an application. However, initiation of IRB review, if necessary or applicable, will be required prior to the release of funds or the commencement of research.

E. Funding Use and Restrictions

Funds can be requested to support the research endeavors of the applicant, i.e. technical support, lab supplies, assays, computer time, and limited research equipment. Salary to support the applicant may be requested. For faculty-tier awards, although postdoctoral researchers may be involved in these pilot grants, it is not the purpose of these faculty grants to provide substantial support for postdoctoral researchers. A letter of permission from the division chair is required for all postdocs or fellows. Application budgets will be reviewed and the TRAC may elect, on a case-by case basis, to deny funding if the budget appears excessive for the proposed activities. Faculty awards are capped at a total of \$50,000 in direct costs and senior postdoctoral awards are capped at a total of \$25,000 in direct costs. Indirect costs will be added to the funding at the time of the award by the TRAC financial administrator. You do not need to concern yourself with this at the time of application. Depending on the nature of your proposal, the TRAC may choose to issue a partial award until project milestones have been met.

VII. Application Review Information

A. Triage

Letters of intent will be triaged and reviewed for compliance with faculty status eligibility criteria, to determine if they propose eligible research projects and meet NIH TB research priorities. Proposals not fitting eligibility criteria will not be advanced to full applications.

B. Primary Review Criteria

The primary criterion for evaluation of the application is scientific merit and the concomitant likelihood of future funding.

Please be innovative! This is an opportunity to explore new ideas and concepts. Innovation is a key review criterion.

C. Additional Review Considerations

Although scientific merit is the primary criterion, additional consideration is afforded to applications involving a collaboration of more than one Hopkins school or discipline. Specifically, this means that the proposal includes a co-investigator whose primary appointment is in a Johns Hopkins school or a discipline other than that of the applicant.



D. Review and Selection Process

Applications are evaluated by a study section, similar to an NIH review. Critique information is compiled and distributed, but applicants should not expect the same extensive commentary as contained in an NIH-type review.

Review criteria:

- Does the introduction provide a clear background regarding the problem to be studied, what has been done so far, and what questions need to be answered?
- Are the aims clear, concise, and measurable? Are they feasible given the small award?
- Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project?
- Does this study address an important TB problem?
- Does this investigator provide a sound and convincing plan for use of the data/outcomes from this study to seek additional research funding?
- If the aims of the application are achieved, what is the likelihood that the data will contribute to a high-quality application for subsequent funding?

E. Anticipated Announcement and Award Dates

Announcement of awardees is anticipated by December 14th with award notices to follow shortly thereafter.

VIII. Award Administrative Information

A. Award Notices

The Administrative Core of the TRAC will issue award notices. The TRAC Research Service Analyst will contact you with the award IO, once the TRAC project administrator clears your study. Indirect costs are added to the award at this time.

B. Conditions of Award:

- a. In the event that pending other support is funded which overlaps with or reduces your effort on this TRAC project, or you are awarded a K award, you must notify the TRAC Project Administrator. Your funding status will be reviewed, and, if it is determined that you are unable to meet the specific aims of your TRAC proposal or that you are ineligible for TRAC funding, you may be required to relinquish the TRAC award.
- b. Prior to funding, if applicable, you must forward a copy of all Institutional Biohazard, Animal Care and IRB approvals to the TRAC Project Administrator. If NIH clearance for a clinical or international study is required, funds may be withheld until these approvals are also in place.
- c. Faculty awarded funding will be required to provide annual reports of the progress of their study and a final report detailing the outcome of their project. Additionally, in order to evaluate the effectiveness of the program



following the completion of your study, faculty will also be required to file brief, non-narrative annual reports indicating:

- i. The number of subsequent grant applications
- ii. The funding outcome of these applications
- iii. Any publications or presentations that may have been based on the pilot grant

You are obligated to respond to TRAC requests for information for five years after your award project is completed.

d. Publicity: Information about grants awarded under this program, subsequent awards, and publications will be posted on the TRAC website. Applicants must agree to credit the TRAC in any publication or applications that result from awards.

IX. Core Consults

Applicants may, and are encouraged to, request consultation from any of the TRAC service cores to assist in the formation of proposals. These consults are free. You may request consultations here.

consultations <u>here</u> .	
Clinical Core Core Director: Maunank Shah	 Coordinate access to JHU associated clinics, patient cohorts and specimen repositories
Co-Directors: Amita Gupta, Christopher Hoffmann	 Assistance with implementation of clinical research for TRAC Awardees or early-stage career grants IRB, FDA, biosafety and other regulatory processes
	Facilitate collaboration and interdisciplinary clinical research through coordinated exchange of research methods and ideas
Bioinformatics, Modeling & Biostatistics Core Core Director: David Dowdy	 Statistical consultation on TB-related grant proposals Methodological assistance with computational modeling projects
Co-Directors: Joel Bader, B. Aletta Nonyane	 Linkage to high-performance computing facilities available at JHU, including ARCH (Advanced Research Computing at Hopkins)
	 Assistance with high-throughput data management and bioinformatics
	 Consultation on grants that might benefit from a modeling, bioinformatics, or statistical component
Pharmacology & Pharmacometrics	Pre-clinical study design
Core	Clinical trial design and protocols
Core Director: Eric Nuermberger	Analytical chemistry of specimens
Co-Director: Michelle Rudek	PK/PD data analysis and interpretation
Microbiology, Immunology, Animal	Standardization of experimental protocols
Modeling & Imaging (MIAMI) Core	 Support for animal models, cytokine analysis, scRNA-seq, and
Core Director: Bill Bishai	flow cytometry
Co-Director: Sanjay Jain	 Training and services in advanced whole-body live animal imaging (CET, PET, SPECT, new MRI)
	 Standardized methods for data sharing, analysis and training



 Analysis of high-throughput (e.g., transcriptomics, metabolomics) and imaging data
 Hands-on training for animal-related procedures/endpoints

X. Additional Information and Questions

Please direct requests for additional information and questions to:

Kate Boehner, RN, MSN

Program Coordinator, Tuberculosis Research Advancement Center

Kate.b@jhu.edu