UNIVERSITY *of* WASHINGTON

SEATTLE TUBERCULOSIS RESEARCH AND ADVANCEMENT CENTER

NEW INVESTIGATOR AWARDS

2024 REQUEST FOR APPLICATIONS (RFA)

NEW INVESTIGATOR AWARDS (NIAS)

AUGUST 21, 2024

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SEATTLE TB RESEARCH ADVANCE MENT CENTER (SEATRAC)

OVERVIEW

NEW INVESTIGATOR AWARDS

Purpose To support promising New Investigators (NIs) to conduct TB research by providing financial support to acquire pilot data to increase likelihood of future successful external funding.

Types of Projects Supported: TB-related research is defined broadly and includes basic science, clinical, epidemiological, behavioral, and implementation science research.

ALLOWED BUDGET

Amount: $50,000 per year for up to two years of funding.

Funds can be used for both salary support and research/experimental costs. Approximately two NIAs will be given annually with a goal to fund one in basic/translational/data science and one in clinical/epidemiology/implementation science.

DEADLINES

RFA RELEASE DATE	**AUGUST 21, 2024**
KEY PRE-SUBMISSION ITEMS: ***REQUIRED*** **NON-BINDING LETTER OF INTENT FORM**	**NOVEMBER 10, 2024**
RECOMMENDED **EMAIL REQUESTS FOR SYNCHRONOUS NIA CORE CONSULTATION APPOINTMENTS:**	**AUGUST to NOVEMBER, 2024**
CORE FEEDBACK WINDOW ENDS	**NOVEMBER 18, 2024**
APPLICATION DEADLINE	**DECEMBER 19, 2024**
REVIEW DATE	**JANUARY – FEBRUARY 2025**
ESTIMATED EARLIEST AWARD DATE	**MARCH 2025**

PLEASE READ THE ENTIRE RFA FOR DETAILED APPLICATION INSTRUCTIONS.
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ELGIBILITY CRITERIA

1. **MD or PhD** or equivalent terminal degree (including an MBChB plus a Master's Degree). New or Early-Stage Investigators as defined by the NIH are eligible to apply. This includes post-doctoral and clinical fellows, and early-stage faculty (Assistant Professor and earlier). Only individual Principal Investigators (PIs) are eligible to apply; we do not allow Co-PIs to apply.
2. **NIH K-awardees** are allowed to apply as long as there is a clear differentiation in the scope of work between the K-award and NIA
3. Our primary mission is to support Seattle-based TB researchers; all applicants must have a pre-established primary mentor at a Seattle-based TRAC affiliated institution
4. Enroll as a SEATRAC member
5. SEATRAC is committed to ensure a diverse workforce and encourages applications from individuals that are historically underrepresented defined by the NIH.
6. Applicants may submit only one application to this program per cycle. We accept applicant resubmissions of prior-year NIA proposals that have been revised to address previous NIA reviewer critiques.

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APPLICATION INSTRUCTIONS

RECOMMENDED: Pre–Submission Process

>**Online NIA Letter of Intent Form:** We will use this information to solicit reviewers with appropriate expertise. Please prepare the following information for online submission.

- Principal Investigator Name, Title, and Contact Details
- Draft Project Title
- Topic Key Words (5-10 words)
- Draft Project Summary in Lay Language (1-2 sentences)
- Scientific Category (e.g., Basic Science, Clinical Epidemiology, Implementation Science, Mixed Methods)
- Name(s)/Institution(s) of Project Mentor(s)
- Name(s)/Institution(s) of Project Collaborator(s)/Consultants
- Demographic Information

>**SEATRAC Membership:** Applicants are required to become SEATRAC members prior to submission. Join here: https://redcap.iths.org/surveys/?s=P4HYM3KEFWWHCA43

Note: All applicants are strongly encouraged to review our Applicant Eligibility requirements closely. Ineligible applicants are disqualified automatically. Please refer to the Applicant Eligibility section above for details, and contact *seatrac@uw.edu* with any questions, prior to requesting pre-submission consultations.

> After fulfilling all pre-submission requirements, please submit your application package in one PDF **by December 19, 2024 11:59 pm PDT to seatrac@uw.edu.**

REQUIRED: The Full Written Proposal must be written in English and include:

- 1.First Page (PHS 398 Form page 1). Download: MS Word or PDF).

  - **UW-based applicants do not need to submit an eGC-1 and institutional signature on their NIA application.**
  - *Non*-**UW applicants are required to submit a PHS 398 Form - page 1 with institutional signature as part of their NIA application.**
- 2. Detailed budget for first 12 month period: (PHS 398 Form page 4 - Download: MS Word or PDF)

  3. Complete 2-year budget and justification: (PHS 398 Form page 5 - Download: MS Word or PDF)

☐ 4. NIH Biographical Sketch for the NIA applicant (Download: [MS Word](#))

☐ **In section A, include an answer the question:** *How will the SEATRAC NIA prepare you for a career as an independent TB investigator?*

☐ 5. NIH Biographical Sketch for the primary NIA mentor.

☐ 6. Resubmission Information (if applicable; maximum **1** page) Use PHS 398 Continuation Format pages (Download: [MS Word](#) or [PDF](#)).

☐ Your response to the reviewers' comments from your prior submission (1 page maximum)

☐ 7. Research Plan (Maximum 4 pages for sections a-d below). Use PHS 398 Continuation Format pages (Download: [MS Word](#) or [PDF](#)).

☐ Specific Aims (suggested length **½** page)

☐ Significance (suggested length **½** pages).

☐ Innovation (suggested length **½** page)

☐ Approach (suggested length **2½** pages)

☐ 8. Bibliography and References cited (as needed)

☐ 9. Plan for Protection of Human Participants (if applicable; maximum **1** page). Please note that international projects, especially those involving human participants, can take several months to obtain all required approvals and therefore applicants should incorporate this into their study timeline.

☐ Address whether your research plan is part of an ongoing IRB approved project. Address any logistical issues related to obtaining IRB approval and your expected timeline.

☐ 10. Plan for Care and Ethical Treatment of Animal Subjects (if applicable; maximum **1** page)

☐ 11. Mentor's Letter of Support (should include the statement, "**I have read and discussed this application with [applicant name] and am supportive of its submission**.")

☐ 12. Letters of support (restricted to **mentor(s)** and any **collaborators** for the proposed project).

☐ 13. No appendices are allowed.

RECOMMENDED:

> **Core Consultation:** All applicants are encouraged to discuss their proposal with a Core faculty member during the preparation of their proposal. These consultations are best done early in the pre-submission process. Feedback may include recommendations to confer with additional SEATRAC experts on the proposal. The Data Science, Basic Science and Clinical and Translational Science Cores offer consultations. Visit the [Cores page](#) for more information, and contact seatrac@uw.edu to schedule a consultation.

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BUDGET DEVELOPMENT GUIDELINES

1. Applicants from UW, Fred Hutch, and Seattle Children's should not include indirect costs in their project budget, <u>unless</u> there is a foreign or domestic subcontract. Applicants from all other SEATRAC-affiliated institutions (e.g. Institute of Systems Biology) should include indirect costs in their project budget.

2. If the proposal requires a subcontract to an international institution, the *maximum allowable indirect cost (F&A) rate is 8%*. Subcontract budgets should include subcontractor F&A costs. A detailed and complete budget and budget justification must be provided for all subcontracts. Applicants should confirm that their home department will take administrative responsibility for processing and implementing subcontracts (international or domestic).

3. Requested support for project collaborators who are NOT at the same institution as the awardee should be listed as consultant costs. If the collaborator cannot accept consultancy fees, a subcontract must be issued to their institution. These costs must be listed in the detailed budget as consortium costs with applicable indirect costs included, which will count towards the direct costs limit.

4. Requested support for equipment and technology, including computers, must be fully justified in the budget justification with a clear connection to the scientific aspects of the project and not for general office use. General office supplies are not allowed.

5. Tuition, fees and stipends for graduate students are allowable within the following guidelines: (**NOT-OD-21-049**)

6. Costs associated with Institutional Review Board (IRB) review of human research protocols, or Institutional Animal Care and Use Committee (IACUC) review of animal research protocols, are not allowable as direct costs.

7. All costs must conform to the NIH Grants Policy Statement (GPS) and applicable U.S. Office of Management and Budget OMB circulars for necessity and reasonability, allocability, conformance and consistency, as well as allowability. Please follow the link below to section 7.2 cost principles section of the **NIH Grants Policy Statement** for more information.

8. For those requesting a two-year project, second year funding is contingent upon demonstration of satisfactory progress during year-one.

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REVIEW CRITERIA

Significance

- Does the study address an important problem consistent with the objective to advance our understanding of TB prevention, treatment, and/or cure? How will impacted communities benefit directly via advancement of TB prevention, treatment and/or cure?
- If the Aims are achieved, how will scientific knowledge be advanced?
- What will be the effect of these studies on the concepts or methods that drive the field of TB research?

Investigator

- Are the PI, mentor(s), collaborators, and other researchers well suited to the project (e.g. have complementary expertise)?
- Does the applicant have appropriate experience and training?

Approach

- Are the conceptual framework, design, methods, and analyses adequately developed, well integrated and appropriate to the Aims of the project?
- Does the proposed work satisfy NIH Guidelines on Rigor & Reproducibility?
- Does the applicant acknowledge potential problem areas and consider alternative approaches?
- Successful applicants usually have some preliminary data to support their application, but preliminary data is not a requirement.

Innovation

- Does the project employ novel concepts, approaches, or methods?
- Are the Aims original and innovative? Does the project challenge existing paradigms?

Impact of Project on Pathway to Independence

- Will the project help prepare the applicant for a career as an independent TB researcher **(we recommend that this be described in Section A of the applicant's biosketch)**?
- Will the proposed mentorship aid in the investigator's career development **(We recommend that this be described in Section A of the Mentor's Biosketch)?**
- Does the project take the NIH guidelines on rigor and reproducibility into consideration? (Please also refer to the NIH's Rigor and Reproducibility Guidelines).
- Will the proposed experiments generate pilot data that will lead to a future application for independent funding?

POST AWARD INSTRUCTIONS

Prior Approvals

- <u>Use of human participants or animal subjects, international sites.</u> Prior to funding, a copy of all Institutional Biohazard, Animal Subject and Institutional Review Board (IRB) approvals (if applicable) must be forwarded to <u>seatrac@uw.edu</u>. If the project involves human participants and falls under a category that requires additional NIH review, the awardee must submit their protocol and consent forms to SEATRAC for NIH clinical clearance.
- Proposals involving either international sites and/or clinical research above minimal risk will require additional clearance from NIH prior to receipt of funding, which requires documenting IRB approval from all participating sites, human participants training certification for all key personnel, and providing the approved protocol/consent form(s).
- Please note that international projects, especially those involving human participants, can take several months to obtain all required approvals and therefore applicants should incorporate this into their study timeline.
- No human participant work may be initiated until IRB approval is received.

Budget

- Disbursement of funds is contingent upon review by SEATRAC Admin and Fiscal teams. <u>Overlapping Support:</u> In the event that other pending support is funded which overlaps with or reduces your effort on this SEATRAC project, you must email seatrac@uw.edu immediately. Your application aims and budget will be reviewed and if it is determined that you are unable to meet the specific aims of your SEATRAC proposal, the SEATRAC award will be revoked.

Reporting and Presentation Requirements

- Awardees will be required to submit yearly progress reports to the SEATRAC and, after their project is finished, make an oral presentation either at the monthly TRTC seminar series or annual TRTC Symposium.
- Additionally, we expect awardees to disseminate the results from NIA projects to the communities relevant to the research, ideally both through scientific and community forums, and where appropriate, shared with public health decision makers.
- Awardees will submit a mid-year progress report reviewed by the mentor, a Development Core Director, and appropriate other Core Director (Data, Clinical, or Basic Science).
- At activity completion, awardees will provide a report detailing outcomes of the award including contribution to their career development plans, development of abstract/manuscript with the pilot data, and next steps for application for independent funding with the pilot data generated.

- Previous NIA awardees will be contacted annually to provide information regarding their current position, TB research activities, subsequent abstracts and publications, and TB-related funding.

TB Leadership Program (TBLP)

- NIA awardees will participate in the TBLP which is designed to provide additional resources and mentoring for career success.
- The TBLP structure is being developed and will include items such as a Mock Study Section, support for conference attendance to present publications, and a manuscript writing workshop.

Acknowledgment of SEATRAC Support

- SEATRAC support (P30AI168034) must be acknowledged in all publications and presentations derived from SEATRAC funding, including NIAs.
- Publications supported by this award must have PMCID numbers in order to comply with the NIH Public Access Policy.

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