UNIVERSITY of WASHINGTON

SEATTLE TUBERCULOSIS RESEARCH ADVANCEMENT CENTER

NEW to TB AWARDS (N2TB)

2023 REQUEST FOR APPLICATIONS (RFA)

NEW to TB AWARDS (N2TB)

August 21, 2024

BE BOUNDLESS

TABLE OF CONTENTS

OVERVIEW

ELIGIBILITY CRITERIA

APPLICATION INSTRUCTIONS

BUDGET DEVELOPMENT GUIDELINES

REVIEW CRITERIA

POST AWARD INSTRUCTIONS





NEW to TB (N2TB) AWARDS

Purpose To support **established investigators who are new to TB research** to conduct TB research by providing financial support to acquire and generate data that will increase the 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 one N2TB will be awarded annually.

DEADLINES

RFA RELEASE DATE	AUGUST 21, 2024
KEY PRE-SUBMISSION ITEMS:	
<i>REQUIRED</i> NON-BINDING LETTER OF INTENT FORM	JANUARY 29, 2025
RECOMMENDED EMAIL REQUESTS FOR <u>SYNCHRONOUS</u> N2TB CORE CONSULTATION APPOINTMENTS:	JANUARY – FEBRUARY, 2025
CORE FEEDBACK WINDOW ENDS	FEBRUARY 4, 2025
APPLICATION DEADLINE	FEBRUARY 11, 2025
REVIEW DATE	MARCH – APRIL 2025
ESTIMATED EARLIEST AWARD DATE	APRIL 2025

PLEASE READ THE ENTIRE RFA FOR DETAILED APPLICATION INSTRUCTIONS. Back to Table of Contents

ELGIBILITY CRITERIA

- 1. Faculty appointment with **MD or PhD** or equivalent terminal degree. Assistant, Associate, and Full Professors are eligible to apply.
- 2. No previous funding as Principal Investigator in **TB research**. Examples (not exhaustive) of grants include NIH R01, R21, R03, K08, K23, U or P level grants (including role as core or project leader). Please contact SEATRAC for questions about specific grants (including those from outside NIH) that may fall in this category.
- 3. Faculty member at a SEATRAC affiliated institution (UW, Fred Hutch, Seattle Children's).
- 4. Enrolled as a SEATRAC member
- 5. SEATRAC is committed to ensure a diverse workforce and encourages applications from individuals that are <u>historically underrepresented defined by the NIH</u>.
- 6. Applicants may submit only one application to this program per cycle. We accept applicant resubmissions of prior-year N2TB proposals that have been revised to address previous reviewer critiques.

APPLICATION INSTRUCTIONS

REQUIRED: Pre-Submission Process

><u>Online N2TB Letter of Intent Form</u>: We will use this information to confirm eligibility and 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)

>**SEATRAC Membership:** Applicants are required to enroll as SEATRAC members prior to submission.

Note: All applicants are strongly encouraged to review our Applicant Eligibility requirements closely and contact <u>seatrac@uw.edu</u> with any questions. Ineligible applicants will be disqualified automatically and notified.

After fulfilling all pre-submission requirements, please submit your required letter of intent **by February 11, 2025** 11:59 pm <u>here</u>.

REQUIRED: The Full Written Proposal

>Must be written in English and include:

- □ 1.First Page (PHS 398 Form page 1) Download: <u>MS Word</u> or <u>PDF</u>.
 - UW-based applicants do not need to submit an eGC-1 and institutional signature on their N2TB application.
 - Fred Hutch (FH) and Seattle Children's Research Institute (SCRI) applicants are required to submit a PHS 398 Form - page 1 with institutional signature as part of their N2TB application.
- 2. Detailed budget for first 12-month period (PHS 398 Form page 4) Download: <u>MS Word</u> or <u>PDF</u>
- 3. Complete 2-year budget and justification (PHS 398 Form page 5) Download: <u>MS Word</u> or <u>PDF</u>

- 4. NIH Biographical Sketch for the N2TB applicant, Download: MS Word
 - □ In section A, include an answer to the question: *How will the SEATRAC award prepare you for establishing an externally funded program in TB research?*
- 5. Resubmission Information (if applicable; maximum 1 page) Use PHS 398 Continuation Format pages, Download: <u>MS Word</u> or <u>PDF</u>.
 - Your response to the reviewers' comments from your prior submission (maximum 1 page)
- 6. Research Plan, including each of the four sections below (PHS 398 Continuation Format pages) Download: <u>MS Word</u> or <u>PDF</u>. (maximum **4** pages)
 - □ Specific Aims (suggested length ½ page)
 - □ Significance (suggested length ½ pages).
 - □ Innovation (suggested length ½ page)
 - □ Approach (suggested length **2½** pages)
 - □ 7. Bibliography and References cited (as needed)
 - 8. 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.
 - 9. Plan for Care and Ethical Treatment of Animal Subjects (if applicable; maximum 1 page)
 - □ 10. Letters of support from any **collaborators** for the proposed project.
 - □ 11. <u>No appendices are allowed</u>.

After fulfilling all requirements, please submit your full application package **by February 11, 2025** 11:59 pm PDT <u>here</u>.

RECOMMENDED:

Core Consultation: All applicants are <u>highly</u> encouraged to discuss their proposal with a Core faculty member during the preparation of their proposal. These consultations are best done early in the 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 <u>Cores page</u> for more information, and contact <u>seatrac@uw.edu</u> to schedule a consultation. Back to Table of Contents

BUDGET DEVELOPMENT GUIDELINES

- Applicants from UW, Fred Hutch, and Seattle Children's Hospital should not include indirect costs 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.
- 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.
- 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 <u>NIH Grants Policy Statement</u> for more information.
- 8. For those requesting a two-year project, second year funding is contingent upon demonstration of satisfactory progress during year-one.

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?
- 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?
- Will completion of the work contribute to the SEATRAC Mission to catalyze new avenues of scientific research that will impact the global TB epidemic?

Investigator

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

Innovation

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

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? (Please also refer to the_NIH's Rigor and Reproducibility Guidelines).
- 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.

Impact of Project on Establishing TB Research Portfolio

- Will the project help prepare the applicant for a career as a TB researcher (we recommend that this be described in Section A of the applicant's biosketch)?
- 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 certifications 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 <u>seatrac@uw.edu</u> 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, provide an oral presentation either at the monthly SEATRAC Seminar Series or Annual TB Symposium.
- Additionally, we expect awardees to disseminate the results from N2TB projects to the communities relevant to the research, ideally both through scientific and community forums, and where appropriate, shared with public health decision makers.
- 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 N2TB awardees will be contacted annually to provide information regarding their current position, TB research activities, subsequent abstracts and publications, and TB-related funding.

Acknowledgment of SEATRAC Support

- SEATRAC support (P30AI168034) must be acknowledged in all publications and presentations derived from SEATRAC funding, including N2TBs.
- Publications supported by this award must have PMCID numbers in order to comply with the NIH Public Access Policy.