Request for Proposals: AST Research Network / Natera: Identification and Use of Novel Biomarkers for Transplant Injury

If you have any questions, please email research@myAST.org.

The application deadline is 11:59 pm Pacific Standard Time on February 25, 2022.

A. Overview
The American Society of Transplantation (AST) and Natera are collaborating to provide an individual research grant to support translational and/or clinical research in transplantation with a primary focus on the identification and use of novel biomarkers including plasma cell-free DNA to detect and monitor transplant injury in kidney, heart, or lung transplant patients.

About Natera
Natera is a global leader in cell-free DNA testing. The mission of the company is to change the management of disease worldwide with a focus on reproductive health, oncology, and organ transplantation. Natera operates an ISO 13485-certified and CAP-accredited laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) in San Carlos, Calif. It offers a host of proprietary genetic testing services to inform physicians who care for pregnant women, oncologists, and cancer researchers, including biopharmaceutical companies, and genetic laboratories through its cloud-based software platform.

B. General Information:
One grant will be awarded. The grant is for two years at $50,000 a year for a total of $100,000 per grant. In addition, up to 100 Prospera tests will be available from Natera at no cost to the budget to be used for research projects investigating the use of cell-free DNA biomarkers in transplant patients. In such cases, the applicant can make a request to Natera’s review process if additional tests are found to be needed for a successful project.

Please submit your proposal planning on two years of funding. Research must commence on July 1, 2022 and end on June 30, 2024. The research start date cannot be deferred for any reason.

The recipient will sign a letter of agreement with the AST Research Network. Payments will be issued to the recipient’s institution by the AST Research Network in annual installments. The recipient will report to the AST Research Network.

C. Research Focus
This funding mechanism is directed to supporting a two-year term of research in translational and/or clinical transplantation science that is focused on either the use of cell-free DNA as a tool to detect and monitor injury of kidney, heart, or lung transplants or the identification and use of alternative biomarkers for the same purpose.

Applicants should consider the following when preparing their proposal: Background of the proposed work and the specific question to be addressed followed by a specific hypothesis and one or two aims that will be performed to test the hypothesis and finally, a discussion of anticipated results and potential contribution and impact of the results to the field.
This RFA is not intended to support projects performing head-to-head comparison between the different cfDNA tests or other technologies to detect rejection.

D. Application and Review Process: Research Grant
1. Applications must be complete and submitted online through the AST Research Network submission website, www.myast.org/research-grants.
2. Funding decisions will be made by an expert review committee that will include members of AST.
3. Grants will be scored and awarded on the basis of novelty, research approach, feasibility of obtaining relevant data, and prior work, as well as other factors.
4. All applicants will receive comments on the strengths and weaknesses of their grant application.
5. All applicants will be notified of the status of their application in [NOTIFICATION MONTH].
6. Those awarded a grant will be notified with the amount and term length and will be asked to accept or decline the grant via email.
   a. Upon acceptance, the recipient will be asked to complete and return an official letter of agreement, signed by the applicant and the grants office.
7. Grant awards will be officially announced during the [FOLLOWING YEAR] American Transplant Congress (ATC), June 4-8, 2022 in Boston, MA. For the individual selected, the term of the grant will begin July 1, 2022.
   a. Recipients are expected to register for and attend ATC. Registration is not included as part of the AST grant.

E. Eligibility Criteria
1. Academic Appointment and Institutional Resources:
   a. Investigators with an academic appointment who are involved in the care of solid organ transplant patients are invited to submit proposals.
2. AST Membership
   a. The applicant must be an active member of the AST or have submitted a completed membership application by February 25, 2022.
3. Previous AST Funding/Funding from Other Sources
   a. The applicant may currently hold other independent research awards.
   b. Faculty may only hold one new AST grant per year: as a PI of a concurrent AST directed grant, as a PI of a Faculty Development Research Grant or Mid-Career Transition Research Grant, or as mentor/sponsor of a Fellowship Research Grant. If more than one grant from a given faculty member (as PI or mentor) is submitted and deemed competitive for funding, the AST will determine which grant to fund.
   c. If the applicant is currently receiving funding for a project similar to the topics described in this RFA, the applicant should explain how the funds of this grant would not overlap with the funds of the other research support.
4. Miscellaneous
   a. The proposed work is to be performed in a North American laboratory.
   b. Education: The applicant must have completed post-graduate training at the time of application.
   c. Applicants who have a substantial relationship with Natera that would present a real or perceived conflict of interest if awarded this grant must first contact the AST Research Network to declare the conflict before submitting an application.
   d. Citizenship: The applicant must be either a) a U.S., Canadian, or Mexican citizen; b) a lawfully admitted permanent resident foreign national of the U.S., Canada, or Mexico with a valid visa during the awarded period; or c) a foreign national admitted lawfully for
residence in the U.S., Canada, or Mexico during the awarded period. J1 and H1B visa holders are eligible to apply.

F. Application Process and Requirements:
Applications must be completed in full by February 25, 2022 in order to be reviewed. Applications that do not conform to these guidelines will be denied without review.

1. Name, title, and institution of principal investigator, co-investigator, and/or key co-collaborator(s).
2. Abstract of the proposed research plan: This document should concisely summarize the project in 400 words or less. The abstract should introduce the project and note its relevance to the identification and use of novel biomarkers to detect and monitor transplant injury. It should describe the long-term objectives and specific aims, research design, and methods for achieving these goals.
3. Applicant’s NIH biosketch (5-page format) to include all usual and pertinent information, particularly describing other past and current research funding and prior published work.
4. The biosketch of additional personnel to be named on the grant (i.e., whoever would ultimately be listed at publication).
5. Complete proposed research plan: The research plan should be a maximum of six pages, not including references. The following sections must be included:
   a. Aims: Include the key questions posed or hypotheses to be tested
   b. Introduction: Provide the rationale for the research
   c. Preliminary Results (if any): Show preliminary results supporting the research plan
   d. Research Plan: Explain how the questions or hypothesis will be studied, with emphasis on experimental design over the details of the specific methods to be used. Anticipated results and potential pitfalls and alternative approaches should be briefly discussed. Specific research (and, if applicable, training) goals to be reached at the end of the grant should also be provided.
      i. Research plan should include a description of relevant facilities/capabilities
   e. Outline of specific milestones / deliverables expected for the first year of the project.
6. Budget
   a. The grant is intended to provide: salary support for the researcher, technical assistance, supplies/materials, and a maximum of 5% institutional overhead. No other costs are permitted.

G. Funding Guidelines & Terms of Agreement
Please review these guidelines and terms prior to completing your application. If you are awarded a grant, you and your institution’s grants office will sign a formal letter of agreement (LOA) stating that you agree to these funding guidelines and terms.

1. Research must begin on July 1, 2022 and end by June 30, 2024; the research start date and end date cannot be deferred.
2. Funding in the amount of $50,000 will be provided for one year of research. A second year of funding in the same amount may be provided to the recipient if milestones in the first year are met. The second year of funding will be subject to approval by Natera and AST.
3. Funding will not be released until visa status is confirmed (if applicable).
4. The recipient must maintain AST membership throughout the term of the grant.
5. The grant is intended to provide only salary support for the researcher technical assistance, supplies/materials, and a maximum of 5% institutional overhead. No other costs are permitted.
6. The grant is paid in annual installments to the recipient’s institution.
7. Grant funding is not transferable from one recipient to another. If the grantee relocates, the AST will determine if the grant can be transferred to the recipient’s new location, or if the grant must
be surrendered and any remaining funds returned (if the grant is surrendered, a final report will still be required).

8. The applicant must acknowledge the grant as a funding source in all manuscripts and presentations derived from the funded research using the following statement: “This work was supported by a grant from the American Society of Transplantation Research Network and Natera.” Copies of such publications must be submitted to the AST National Office.

9. Pursuant to regulations of the federal Physician Payment Sunshine Act (included in the Affordable Care Act), NPI numbers will be collected from grant recipients (if applicable) and tax ID numbers collected from the recipients’ institutions (if applicable). All payments will be reported to the Centers for Medicare and Medicaid Services Open Payments system, as payments from AST represent indirect transfers of value from the funding pharmaceutical company.

10. Reports are required at the following intervals, and continuation of funding is contingent upon completion of these reports:
   d. Final report within 30 days of the conclusion of the grant term.
      i. A final report is required even if the grant is surrendered for any reason prior to the conclusion of the grant term.

Offering and administering a research grant with this partner does not represent an AST endorsement of the use of the partner’s products.