AST Research Network
Career Development Grants: 2021 Fellowship Research Grant

The application deadline is 11:59 pm Pacific Standard Time on December 1, 2020. A limited number of grants are awarded each funding cycle, and the number and term of grants varies each funding cycle. To submit an application, visit www.myast.org/research-grants. If you have any questions, please email research@myAST.org.

The purpose of AST Research Network Fellowship Research Grants is to support the research of individuals who have spent two years or less performing research in the area of solid organ transplantation (and/or immunology relating to solid organ transplant) since obtaining their last doctoral degree (PhD, MD, PharmD, or equivalent). The grant rewards a project that provides a strong training vehicle for the applicant. The Fellowship Research Grant seeks to:

1. Foster training of early career investigators who have the potential to contribute to our understanding of transplant science/immunobiology and/or treatment of transplant recipients.
2. Foster research that is of high merit.
3. Encourage high quality applicants who want to develop a career in academic transplantation.

A. General Information: Fellowship Research Grant

Grants are generally awarded in the amount of $50,000 per year for either one year or two years, depending on AST Research Network funding levels. Please submit your research proposal planning on two years of funding. Research must commence on July 1, 2021 and cannot be deferred for any reason. Only grants supporting research related to solid organ transplantation will be considered.

Two grants from the same group or from the same institution with significant scientific overlap will not be funded regardless of score. The discretion as to which grant will be funded will be made by the AST Research Network Scientific Review Committee (SRC) at the time of review.

Fellowship Research Grant applications are submitted in one of three categories: basic, clinical, or translational science. The AST Research Network strives to support a Fellowship Research Grant in each category, provided funds are available.

- **Basic Science** is defined as anything in discovery science from molecules to cells to animal models.
- **Translational Science** is defined as anything from animal models designed specifically to translate basic research to clinical application, to work with clinical human samples with clear translational impact.
- **Clinical Science** is defined as research involving human patients, from data generation and mining to testing new protocols and therapies. Clinical science includes the following two types of research:
    - *Clinical Trials:* designed to answer specific question(s) about new therapies or new ways of using known treatments. Preference will be given to prospective studies.
    - *Clinical Outcomes or Observational Studies:* designed to better define the causes and/or consequences of pathological or biological processes in transplantation. Retrospective studies may be appropriate. However, proposals that analyze registry data (e.g. data collected by the United Network for Organ Sharing) are expected to test unique hypotheses or employ new data or methodologies. The analysis, including the statistics, should be performed by the applicant and not by the data registry staff.

B. Research Priorities: Fellowship Research Grant

The following research priorities were developed by the AST Research Network. These priorities are intended to provide applicants in the 2021 research grants cycle with a set of emphasis areas. However, it is important to note that we accept applications on *any* research topic related to solid organ transplant, as we recognize the importance of innovation in areas outside of these priorities.

Basic Science

I. Develop and validate biomarkers of graft dysfunction and immune activation
II. Validate animal modeling as relevant to current clinical challenges (graft injury, autoimmunuity, infectious disease, immunological memory) that validate specific mechanisms or therapies
III. Identify and study novel immune modifiers (i.e. cellular transplants including stem cells, regulatory cells, new drugs and biologics)
IV. Pursue systems biology approaches to study the impact of therapeutics on molecular pathways that reveal new mechanistic insights (note: purely descriptive profiling and mapping of molecular pathways by any set of technologies is not responsive to this area)
V. Develop new tools to study and/or visualize the human alloimmune response
VI. Develop regenerative medicine approaches for generating transplantable tissues

Translational Science

I. Studies to identify and validate surrogate markers for long-term outcomes including interventional studies designed to demonstrate the value of biomarkers in clinical transplantation
II. Studies to determine the effects of cell therapies on protective immunity (e.g. does infusion of Tregs or MSC alter patient defense against microbial pathogens or cancer?)
III. Studies to define predictors and/or mechanisms of disease after transplant (i.e. cardiovascular disease, recurrent GN, de novo HLA antibodies or chronic rejection)
IV. Identify specific molecules and/or molecular mechanisms that explain the roles of the microbiome in immunity and transplant outcomes (note: purely descriptive profiling of microbiomic changes is not responsive to this area)
V. The role of epigenetics in determining transplant outcomes

Clinical Science

I. Reducing post-transplant complications
II. Optimizing organ utilization (appropriate allocation and improving organ viability by interventions in the pre-transplant period including ex vivo conditioning)
III. Preventing or attenuating late graft failure – cellular and humoral chronic rejection, recurrent and de novo
IV. Improving the patient experience and addressing the challenges of therapy adherence
V. Research on transplant outcomes that test the value of transplantation for patients, transplant centers, payers and/or health care policy and costs at the State and Federal levels.
VI. Research on racial disparities in access to and outcomes of solid organ transplantation.

C. Application and Review Process: Fellowship Research Grant

1. Applications must be complete and submitted online through the AST Research Network submission website.
2. All complete applications received by the submission deadline are reviewed and scored by the AST Research Network Scientific Review Committee (SRC).
3. The review criteria include the quality of the applicant, scientific project, sponsor, and institution, with an emphasis on preparing the applicant for a career as an independent investigator.
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 March 2021.
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 recipients will be recognized during the 2021 American Transplant Congress June 5-9, 2021 in Seattle, WA. Recipients are expected to register for and attend ATC. Registration is not included as part of the AST grant.

D. Eligibility Criteria: Fellowship Research Grant

1. Applicant's Position
    a. The applicant (MD, PhD, PharmD, or equivalent degree) must be within the first two years of post-doctoral training (not including clinical training) by the grant application deadline (December 1). Applicants who have worked in other fields or taken a leave of absence are eligible beyond this two-year period, but this must be directly addressed in the sponsor's letter (see section E. 7).
    b. Throughout the period of the grant, the applicant must be at a "fellowship training" level and may not hold an independent faculty level position or a salaried senior staff position (or equivalent). The AST defines an independent faculty level position as: a) Assistant Professor or equivalent; or b) regardless of title, institutional support that includes independent lab space and/or start-up funds to allow independent research.
    c. The applicant's fellowship must commence prior to or on the start of the grant term (July 1, 2021).
    d. The minimum protected time for basic or translational grants is 50% and for clinical grants is 25%.
2. Applicant's Sponsor and Institutional Support
    a. The applicant must have a sponsor. Only one AST Research Network grant will be awarded per mentor/sponsor per year (e.g. as a recipient of a Faculty Development Research Grant, recipient of an AST directed grant, or as a sponsor of a Fellowship Research Grant). If more than one grant from a given faculty member is submitted and deemed competitive, the AST will determine which grant to fund.
    b. If the applicant's sponsor departs or is planning to depart the institution prior to the commencement of the grant (July 1, 2021), the following outcomes apply:
        i. If the sponsor's impending departure is known before the submission deadline, the applicant must notify the AST Research Network national office and the applicant will be allowed to revise their application accordingly.
        ii. If the departure occurs after the submission deadline, the applicant will not be eligible for funding and their grant withdrawn, as an evaluation of the sponsor is part of the scoring procedure.
        iii. If the departure occurs after a grant has been awarded and the grant has commenced, funding will be suspended. Reinstitution of the grant will be at the discretion of the AST Research Network Scientific Review Committee (SRC) Executive Committee, contingent upon satisfactory replacement of the sponsor and other factors.

3. AST Membership
    a. The applicant is not required to be an active AST member.
    b. The applicant's sponsor must be an active AST member or have submitted a completed membership application by December 1, 2020.
    c. If the applicant is awarded a grant, the sponsor's membership must be maintained throughout the term of the grant.
4. Other Funding
    a. Fellows who currently are PI on a K-series grant or hold other individual fellowships, career development awards, or other grants awarded in their name that support their salary are not eligible to apply for an AST Research Network Fellowship Research Grant.
    b. Candidates can apply for an AST Fellowship Research Grant at the same time as applying as primary investigator on a K-series, individual fellowships, career development awards, or other grants that support their salary, but may not retain AST funding if the other grant is awarded.
    c. Individuals who previously received an AST Fellowship Research Grant are not eligible to apply again. Applicants who previously applied for but *did not receive* an AST Fellowship Research Grant may apply if they meet other eligibility criteria.
5. Miscellaneous
    a. Location: The proposed work is to be performed in a North American research setting.
    b. Education: The applicant must have an MD, DO, PhD, DVM, PharmD or equivalent graduate degree at the time of the application.
    c. 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.

E. Specific Application Requirements: Fellowship Research Grant

1. Title
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 transplantation. It should describe the long-term objectives and specific aims, research design, and methods for achieving these goals.
3. Applicant's NIH-type biosketch: This document may not exceed five (5) pages.
4. Sponsor's NIH-type biosketch. This document may not exceed five (5) pages.
5. Statement of career goals: explaining the applicant's short- and long-term career goals and how the grant will enhance these plans. This document may not exceed one (1) page.
6. Complete proposed research plan: This document cannot exceed six (6) pages; the page limit does not include references. It should summarize the proposed research project as well as any simultaneous training that will be obtained during the period of grant support. The applicant and the sponsor may jointly write the proposed research plan, and the participation must be detailed in the separate sponsor narrative (section E.7.e). 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: 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. Include a description of the statistical methods. 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.
    e. For resubmissions only: provide a concise one-page summary of how the project has been modified in response to prior reviewer feedback. This summary is an additional page and is not counted toward the six-page limit.

7. Sponsor narrative: should not exceed three (3) pages and should include:
    a. A concise description of the overall research plan
    b. A description of the training program in addition to lab research (e.g., courses, conferences, outside interactions, etc.)
    c. A description of the sponsor's background in supervising the research and training of students and postdoctoral fellows
    d. The role of the applicant in the project
    e. A description of the role of the applicant vs. the sponsor in preparing this application. A significant role for the applicant in writing the application is highly encouraged, although input from the sponsor is expected. For international applicants not yet in the lab, it is understood that the PI will play a large role in writing the application.
    f. An evaluation by the sponsor of the applicant's experience and performance, future potential, and the degree of previous interaction with the applicant.
    g. An explanation of any mitigating or additional factors that need to be considered in terms of eligibility (e.g. account of extra years in education or a change in research field).
    h. The sponsor must specify whether he/she is a PI/recipient on an AST Research Network Faculty Development Research Grant or the sponsor of another AST Research Network Fellowship Research Grant.
    i. A guarantee of minimum protected time.
    j. For re-submissions only: provide a concise summary of how the applicant's proposal has been modified in response to prior reviewer feedback.
8. Overall project budget
9. Two (2) letters of recommendation: from two senior scientists other than the sponsor who are familiar with the applicant's potential as an investigator. Electronic copies with original signatures on institutional letterhead.

DISCLAIMER: The AST will not assume responsibility for any clinical study funded by the AST. Such proposals must be IRB-approved. Any responsibility will be assumed by the PI and the funded institution.

F. Funding Guidelines and Terms of Agreement: Fellowship Research Grant

Review these guidelines and terms prior to completing your application. If you are awarded a grant, you and your institution's grant office will sign a formal letter of agreement (LOA) agreeing to these funding guidelines and terms, and the LOA will be co-signed by your sponsor.

1. The grant is intended to support the applicant's salary and/or research costs. The following expenses are not permitted: institution overhead, capital equipment, or travel costs.
2. Funding will not be released until visa status is confirmed.
3. Research must begin on July 1, 2021; the research start date cannot be deferred.
4. The grant is paid in quarterly installments to the recipient's institution.
5. Prior to receiving each quarterly payment, the applicant is required to verify that he/she is still at the same institution, still meets the above-stated eligibility criteria, and continues to perform the research as outlined in the original application.
6. 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.
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; see item 9).
8. The applicant must acknowledge the grant as a funding source in all manuscripts and presentations derived from the funded research by using the following statement: "This work was supported by a grant from the American Society of Transplantation Research Network." Copies of such publications must be submitted to the AST National Office.
9. Reports from the recipient and letters from the sponsor are required at the following intervals, and continuation of current grant funding and eligibility for future AST funding is contingent upon completion of these items:
    a. Recipients must submit a status report on six-month intervals. One-year grants and two-year grants must submit a status report by December 31, 2021. Two-year grants must also submit a status report by December 31, 2022.
    b. Recipients of one-year grants and two-year grants must provide a final report within 30 days of the conclusion of the grant term. A letter from the sponsor must also be submitted summarizing their observations of the recipient during the term of the grant.
    c. Recipients of two-year grants must provide a mid-term progress report 11 months from the start of the grant term. The progress report will be due May 31, 2022. The AST Research Network SRC will review the progress report in June 2022 to determine if the second year of funding can proceed in July 2022. A letter from the sponsor must also be submitted indicating continued support of the recipient's activities.
    d. All grant recipients must submit a final report, even if the grant is surrendered for any reason prior to the conclusion of the grant term.
10. If the recipient's sponsor departs during the term of the grant, funding will be suspended and reinstitution of the grant will be at the discretion of the AST Research Network Scientific Review Committee (SRC) Executive Committee, contingent upon satisfactory replacement of the sponsor and other factors.
11. If the grantee accepts a faculty position during the term of the grant, he/she must notify the AST, surrender the grant, and return any remaining funds. A final report will still be required; see item 9.
12. During the term of the research grant, there can be no concurrent extramural funding.