



## AST Research Network Career Development Grants: 2020 Faculty Development Research Grant

The application deadline is 11:59 pm Pacific Standard Time on Monday, December 2, 2019. 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](http://www.myast.org/research-grants). If you have any questions, please email [Research@myAST.org](mailto:Research@myAST.org).

The purpose of AST Research Network Faculty Development Research Grants is to promote the careers of young independent investigators within the first five (5) years of their first faculty appointment and whose research relates to the field of solid organ transplantation (and/or immunology relating to solid organ transplant). This grant allows the investigator to expand on preliminary research findings that will become the basis for individual research or career development awards from the NIH, VA, or equivalent agencies. The Faculty Development Research Grant seeks to:

1. Foster training of young 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 the continued commitment of high-quality applicants to their careers in academic transplantation.

### A. General Information: Faculty Development 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 budget allowances. Please submit your research proposal planning on two years of funding. Research must commence on July 1, 2020. The research start date cannot be deferred for any reason. Only grants supporting research directly 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.

Faculty Development Research Grant applications are submitted in one of three categories: basic, clinical, or translational science. The AST Research Network strives to support a Faculty Development 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: Faculty Development Research Grant**

The following research priorities were developed by the AST Research Network. These priorities are intended to provide applicants in the 2020 research grants cycle with a set of emphasis areas that will receive special consideration by reviewers. 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 (donor injury, autoimmunity, 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 immune 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 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.

### C. Eligibility Criteria: Faculty Development Research Grant

1. Academic Appointment and Institutional Resources:
  - a. The applicant (MD, PhD, PharmD, or equivalent) must have an academic appointment at an accredited institution of higher learning and be within five years of the initial academic faculty appointment by the grant application deadline (December 2). Regardless of academic title (including instructor, research associate, or equivalent), the AST defines initiation of faculty appointment as the date that the applicant obtained an institutional commitment towards an independent career which includes: a) an office distinct from lab space and/or independent lab space; and b) a start-up package or grant funds controlled by the applicant to work on projects that are independent from his/her mentor.
  - b. An applicant's faculty position must commence prior to or on the start of the grant term (July 1, 2020).
  - c. Failure to adequately document that the applicant is an independent faculty member with less than five years' experience will disqualify the application without further review.
  - d. Changing institutions once after having already become a faculty member does not restart the five-year period.
  - e. The five-year period may be extended if there are extenuating circumstances requiring a leave from relevant academic activities (e.g. child-bearing, armed services commitment). These will be considered on a case-by-case basis and must be accompanied by a letter of explanation by the applicant.
  - f. The minimum protected time for basic or translational grants is 50% and for clinical grants is 25%.
2. AST Membership
  - a. The applicant must be an active member of the AST or have submitted a completed membership application by December 2, 2019.
  - b. If awarded a grant, the applicant's membership must be maintained throughout the term of the grant.
3. Other Funding
  - a. Individuals who previously received a Faculty Development Research Grant or joint grant between AST and another society are not eligible to apply. However, a past recipient of an AST Fellowship Research Grant is eligible to apply for an AST Faculty Development Research Grant. Applicants who previously applied for but *did not* receive an AST faculty grant may apply if they meet other eligibility criteria.
  - b. Faculty may only hold one new AST grant per year: as a PI of a Faculty Development Research Grant, as mentor/sponsor of a Fellowship Research Grant, or as a PI of a concurrent AST directed 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. The AST Faculty Development Research Grant project must be distinct from that of any concurrent award. Moreover, this work should not directly overlap with funded projects of other faculty members within the same Section or Department.
  - d. Individuals are ineligible if they are a PI on a previous or current NIH grant to perform independent research (R01, project on a P01 grant, R21, VA Merit award or comparable non-mentored award).
  - e. Candidates can apply for an AST grant at the same time as applying for a K-series, NIH R01, P01 or any similar research award but may not retain AST funding if the other grant is awarded.
  - f. Applicants with concurrent K-series, R00, career development, or other similar awards at the time of application are not eligible to apply for an AST grant, even if the projects are distinct.
  - g. Applicants with concurrent smaller awards and prizes must report these awards, and the application will be adjudicated by the reviewers.
4. 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, and have completed post-graduate training (residencies, post-doctoral fellowships, etc.) 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.

#### **D. Specific Application Requirements: Faculty Development 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 bio-sketch: This document may not exceed five (5) pages and must include:
  - a. Applicant name
  - b. Position/title
  - c. Education/training: beginning with baccalaureate or other initial professional education, such as nursing, and include post-doctoral training; institution and location, degree, year(s) of completion, field(s) of study.
  - d. Positions and honors: list in chronological order all previous positions, concluding with your present position. List any honors including present membership on any Federal Government Public Advisory Committee.
  - e. Selected peer-reviewed publications (in chronological order). Do not include publications submitted or in preparation.
  - f. Research Support: list all research projects ongoing or completed during the last three years, supported by federal and non-federal funds. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project, total amount of grant, and amount of funding to be received in the year the AST grant may be awarded. The applicant should explain any specific or budgetary overlap with the grant and in the case of pending applications, how these will be resolved in the event the funding is received from more than one agency. The final resolution of any funding conflicts will be decided by the AST.
4. Statement of career goals (no more than one page): explaining the applicant's short- and long-term career goals and how the grant will enhance these plans.
5. 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 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. 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.
6. Letter from the Department Chair/administrative supervisor addressing the following:
  - a. The month/year of the first faculty appointment

- b. That the institutional commitment to the faculty member is sufficient to conduct independent research, including providing:
    - i. An office distinct from lab space, and/or independent lab space
    - ii. A start-up package or grant funds controlled by the applicant to work on projects that are independent from his or her mentor
  - c. Independence and protected research time
  - d. Note: If the applicant is still in training at the time of the application but has accepted a faculty position to begin on or before initiation of the grant, the letter must be from the Department Chair of the applicant's future department confirming the future appointment and providing the same details outlined above in this section.
7. Overall project budget
  8. Two (2) letters of recommendation: from two individuals who are familiar with the applicant's potential as an investigator. Electronic copies with original signatures on institutional letterhead.
  9. Additional letters of support that describe collaborations required for the project (if applicable).

***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.***

#### **E. Application and Review Process: Faculty Development Research Grant**

1. Applications must be complete and submitted online using 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 in a field of solid organ transplantation, by allowing them to expand on preliminary research findings that will become the basis for individual research or career development awards from the NIH, VA, or equivalent agencies.
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 2020.
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 2020 American Transplant Congress May 30-June 3, 2020 in Philadelphia, PA. Recipients are expected to register for and attend ATC. Registration is not included as part of the AST grant.

## **F. Funding Guidelines and Terms of Agreement: Faculty Development 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.*

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, 2020; 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 are required at the following intervals, and continuation of current grant funding is contingent upon completion of these reports:
  - 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, 2020. Two-year grants must also submit a status report by December 31, 2021.
  - 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.
  - 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, 2021. The AST Research Network SRC will review the progress report in June 2021 to determine if the second year of funding can proceed in July 2021.
  - 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. Applicants can apply for an NIH R01, P01, K-series, career development or any equivalent independent research award during the term of the AST grant, but may not retain AST funding if the other grant is awarded.