

Grant Submission Guidelines

Grant submission process

Applicants should download the Grant Submission Form and Budget/Justification Form to their computer to complete. Please adhere to specific font type and size, margins, and page limitations as indicated below. All completed submissions must be uploaded to the ATS Early Career Investigator Award in Pulmonary Vascular Disease (Herein known as the Program) Web site in PDF format and submitted electronically, along with a Letter of Support from your Mentor, all necessary Biographical Sketches (PI, Mentor and Co-investigators, if applicable) and proof of citizenship or permanent residency.

Once your grant proposal is submitted, you will receive an email confirming your submission. The document can be modified up until the submission deadline. All changes occurring after award are subject to approval by the Steering Committee.

Guidelines

- The document can be modified up until the submission deadline
- No applications will be accepted after the submission deadline

Formatting

Font type and minimum type size: Arial, 11 point (for Windows users) or Helvetica, 12 point (for Macintosh users); no more than 16 characters per inch (CPI) for Windows or 14 CPI for Macintosh (CPI includes symbols, punctuation, and spaces)

- Maximum lines per page: 60 (average number of lines per page using the font and point size indicated above will be approximately 50-55 lines)
- PDF format only

Information Required for the Grant Submission

Grant Submission Form

The completed form should be uploaded to the program Web site in PDF format and submitted electronically. Click on “my application” and then edit to upload the completed grant, budget justification form and mentor letter. Completed applications must include the following documentation (please adhere to specific font type and size, margins, and page limitations as indicated below.)

- Project title and research focus
- Estimated start and completion dates - Research should begin no later than 6 months after approval of the grant unless an alternative date for commencement has been approved by the Steering Committee. Funded projects should be completed within 12 months of commencement.
- Institution and location where the project will be conducted (site of conduct)
- Is there a need for a drug transfer?
- Will your proposed research involve laboratory animals?
- Research abstract (No more than 325 words outlining your proposed research)

- The research proposal should be a clear and concise presentation of the applicant's proposed research. The applicant's mentor must review the proposal before it is submitted. **Proposal page limits: no more than 10 consecutively numbered pages.** The proposal must include:
 - Introduction (no more than 2 pages)
 - Specific objectives and hypothesis (no more than 1 page)
 - Background
 - Methods
 - Inclusion and exclusion criteria
 - Statistical analysis section (figures and tables should be included in the body of text, where applicable) (no more than 1000 words)
 - Preliminary data (no more than 2 pages but no limit to the number of figures, charts, tables, and diagrams)
- Literature Cited - All references (no limit on the number of literature references cited)

Budget/Justification Form

All completed applications must be re-uploaded to the Program site and submitted in PDF format electronically along with the documentation specified. Click on “my application” and then edit to upload the completed grant, budget justification form and mentor letter.

- Budget specifications, justification, and availability of other sources of funding
- Specify special resources, being careful to keep costs (eg, medications, devices, software, animals) within the limits specified below

Budgets are to be submitted in US dollars and should reflect realistic estimates of the funds required for the proposed research. Awards are made without assurance of continued support beyond the term designated.

The award is not necessarily designated to cover the total cost of the proposed research. The grantee institution is expected to provide the required physical facilities and administrative services normally available in a research institution.

The Program provides funds for the following items:

1. *NEW* research
2. Travel, related directly to the research project to communicate research findings, is allowable up to a maximum of \$1,500 (as a part of the submitted budget)
3. Maximum equipment: \$5,000

The Program does not provide funds for the following items:

1. Institutional overheads
2. Purchase of journals and books
3. Purchase of office furniture
4. Payments of dues and membership of professional societies
5. Recruitment and relocation expenses
6. Construction and maintenance of buildings
7. Payment of nonmedical or personal services to patients
8. Purchases of reprints/copies

The Program relies on the integrity of the applicants insofar as assessing overlap between the grants proposed and the other grants held or being requested by the applicant. The Program intends to fund independent research projects. Any overlap between grant proposals submitted and research already being conducted by the applicant must be specifically acknowledged by the applicant.

If a project designated for funding by the Program is also funded by another agency, the applicant must choose which grant to accept. If funding is awarded later by another institution, notification must be made to the Steering Committee, and the program will be entitled to withdraw the grant or the remaining part of it.

Letter of Support from the Mentor

Should detail the mentor's track record of productivity, funding and success with prior trainees; available lab facilities; and proposed training plan for the applicant, including the interaction between mentor and the applicant. The letter must also assess the applicant's research competence, clinical proficiency, originality, perseverance, and ability to exchange ideas and organize scientific data.

Note: Particular attention to the young investigator's career development must be addressed in the mentor letter. The young investigator must have **no more than 5 years** of experience beyond his/her faculty appointment at the start of the award (as of July 1st of the award year). Applicants who have received numerous advanced degrees with many years elapsing after graduate training may be less competitive than investigators seeking a research career early after training.

Mentors should also be aware that applicants must have completed their primary research training (PhD or sub-specialty fellowship training) by July 1st of award year. All young investigator applicants must fall into one of these categories:

Junior faculty member (up to and including the rank of assistant professor), Postdoctoral scholar, Doctoral candidate, or Fellow (Only if the scholar/doctoral candidate/fellow's training will be completed prior to the start of the grant **and** the applicant has a pending postdoctoral or faculty appointment). **The Mentor letter must be explicit in their commitment to the young investigator for their faculty appointment. Details of this commitment are appropriate for the mentor letter.**

Start and end dates

Research should commence no later than 6 months after approval of the grant, unless an alternative date for commencement has been approved by the Steering Committee. Failure to initiate the research within this period may result in a withdrawal of the grant.

Funded projects should be completed within 12 months of commencement. Clinical follow-up after the 12-month limit is allowed, however, if properly justified by the applicant and corroborated by the outcomes and data delivered. A report must be provided after 12 months and the follow-up must be evaluated and approved by the Steering Committee. No further funding will be provided after the 12-month limit.

Once your grant proposal is submitted, you will receive an email confirming your submission. The document can be modified up until the submission deadline. All changes occurring after award are subject to approval by the Steering Committee.

Submitted full grant proposals will be evaluated and extensively discussed by the Steering Committee and ranked according to the Steering Committee discussion outcomes.

The number of awards will be determined according to the funds available for grants. The top-ranked projects will be awarded. Based on budget requests and available funds for grants, the Steering Committee will also decide on the size of the grants awarded, which can differ from the amount requested by the applicant.

Grant review

Submitted full grant proposals will be evaluated and extensively discussed by the Steering Committee and ranked according to the Steering Committee discussion outcomes.

The number of awards will be determined according to the funds available for grants. The top-ranked projects will be awarded. Based on budget requests and available funds for grants, the Steering Committee will also decide on the size of the grants awarded, which can differ from the amount requested by the applicant.

Grant approval**Notification**

Applicants selected by the Steering Committee and those whose projects were not selected will be notified via email. The Program is under no obligation and is not obliged to provide details of the review process. In particular, ranking, qualitative and quantitative evaluations, names of reviewers and criteria for award or rejection will be communicated solely at the discretion of the Steering Committee.

The notification email may also include special terms or conditions that apply to all terms applicable.

Requested documents

If your proposal is approved for funding, you and your mentor will be responsible for all aspects of your research. You will be provided with a grant application agreement, which you must sign and return within 90 days of notification of the award, along with the requested documents.

- Institutional review/ethical committee approval for the submitted study (IRB)
- W-9 Form from the institution
- Study protocol
- Email and documentation sent to the site administrator documenting the commencement of your research
- Sample informed consent documents, if necessary
- Institution animal care and use document (IACUC), if necessary

Please note, no funds will be disbursed prior to complete submission of the documents listed above. Failure to submit requested documents within the given time frame may result in the withdrawal of funds. By signing and submitting the grant application agreement, the principal investigator agrees that experiments conducted with funds from the Program are compliant with the ethical conduct of research as expressed in the latest version of the World Medical Association Declaration of Helsinki.

Further conditions to funding

Only projects that meet the Eligibility Requirements for the Program, as outlined above, will be evaluated and considered for funding.

Applicants shall be deemed the “sponsor” of the research project, including without limitation for purposes of compliance with all legal or regulatory obligations imposed on study sponsors under applicable law. To the extent that the research project involves human subjects, the applicant will be responsible for obtaining from each study participant proper informed consent, which shall state that the applicant is the sponsor of the research project.

Drugs, if used in the submitted studies, must be approved in the country where the study will be conducted.

The Program is sponsored by Janssen Pharmaceutical Companies of Johnson & Johnson. All decisions to fund protocols are solely decided by the Steering Committee. Receipt of a grant in no way neither requires the recipient nor implies that the recipient, is obligated, to recommend or prescribe any products.

Any changes in the protocol will need to be reviewed and approved by the Steering Committee.

Award winners will be asked to provide supplementary documents, including but not limited to, the following: Institutional Review Board or ethical committee approvals for the submitted study; complete clinical study protocols; samples of informed consent documents; authorities' approvals to conduct animal trials (if applicable). Changes occurring after the grants are awarded are subject to approval by the Steering Committee.

Award winners and the institution where the study will be conducted must sign the Program Agreement for Grant Awards. A completed W-9 form from the institution will also be required to process funding. This must be completed within 90 days from the date of notification.

The signed agreement and requested documents are to be returned, as specified in the notification letter, no later than 90 days after communication of the award. Please do not begin your research until full execution of the agreement. No funds will be disbursed prior to complete submission of the requested documents. Failure to submit requested documents as specified and within the given deadline may result in a withdrawal of the award.

The Program relies on the integrity of the applicants insofar as assessing overlap between the grants proposed and the other grants held or being requested by the applicant. The Program intends to fund independent research projects. Any overlap between grant proposals submitted and research already being conducted by the applicant must be specifically acknowledged by the applicant.

If a project designated for funding by the Program is also funded by another agency, the applicant must choose which grant to accept. If funding is awarded later by another institution, notification must be made to the Steering Committee, and the Program will be entitled to withdraw the grant or the remaining part of it.

Progress and final reports

Startup of the Research Project - Within 90 days following the awards ceremony, an email supporting the startup of the research project with documentation should be sent to Jill Freeman, Program Director at jfreeman@medtelligence.net

Interim Progress Report - This report must be submitted 6 months from the startup of the research project. The completed report is to be uploaded to the Program Web site. The payment of the second installment is contingent upon approval of the Interim Progress Report by at least two Steering Committee members.

Comprehensive Final Scientific Report/Final Reconciliation - At the end of the grant period, a comprehensive final scientific report summarizing the project's accomplishments as well as a final reconciliation must be submitted to the Steering Committee. This report must include copies of any reprints, abstracts, and/or manuscripts submitted, published or in press as a result of the research. The payment of the final grant installment is contingent upon approval of the final report by at least two Steering Committee members. All final reports must be submitted within 90 days of the termination date of the grant. Final reports are essential to the function of the award. Failure to submit final reports may affect eligibility for future funding. The completed report is to be uploaded to the Program Web site.

Funds disbursement

Funds allocated to each competition cycle will be distributed to successful applicants. Every project awarded will receive up to \$100,000.

The Steering Committee will decide the manner in which an award will be disbursed. The research project must be initiated within 90 days of the Awards Ceremony in which the grant term commences and funds are to be disbursed.

Award winners must submit all requested documentation. Funds are scheduled to be distributed in the following three installments:

- One-third (1/3) upon complete submission of paperwork (grant application agreement, IRB, W-9 Form from the institution, sample informed consent documents, if necessary, and IACUC, if necessary) and receipt of an invoice
- One-third (1/3) upon satisfactory receipt of an interim report and receipt of an invoice
- One-third (1/3) after completion of the research and upon satisfactory receipt of the final report and approval by at least two Steering Committee members and receipt of a final invoice.

If more than three installments will be paid, further progress reports may be requested before proceeding with payment.

PLEASE NOTE: Complete reconciliation of the grant will be required by the ATS and any remaining funds are to be returned within 30 days of the accepted final report.

The Program is a 12-month mentored grant. If unforeseen circumstances lead to delays in completing the project in the specified timeframe, a request for additional project completion time must be submitted by the young investigator, mentor, and institution, explaining the reason(s) for the delay. In addition, a plan for completing the project successfully within a newly specified timeframe must be provided and approved by the Steering Committee in order to receive funding.

Special consideration will be given by the Steering Committee to allow an additional period of time (maximum 12 months) to conduct research, but not to supply additional funding. Extensions will be considered on an individual basis only and are subject to final approval of the Steering Committee.

All funds are disbursed in US dollars.

Study conduct and ethics

The Program is bound by its objectives to maintain and promulgate the highest ethical standards in clinical research and to maintain the highest standards in the conduct and assessment of such research. All research involving human subjects should be performed in accordance with the latest version of the World Medical Association Declaration of Helsinki at the time of submission, as well as generally recognized standards of Good Clinical Practice in the United States of America. Research proposals for human cloning will not be considered.

Publication data: a) upon request: Sponsor-Investigator and Researcher (i) shall inform Janssen Pharmaceutical Companies of Johnson & Johnson of any Research Project results in a timely manner, and (ii) agree to use best efforts to make all Research Project related results available to the scientific community through presentations.

(b) Researcher may publish and make presentations of the Research Project results to the extent such publications or presentations are consistent with academic standards, are not false or misleading and are not for commercial purposes, subject to the following:

- (i) Sponsor-Investigator and Researcher will provide Janssen Pharmaceutical Companies of Johnson & Johnson with copies of unpublished manuscripts (including abstracts) and summaries of presentations relating to the Research Project at least sixty (60) days before submission to a journal or publication (for a manuscript or abstract) and twenty-one (21) days before any presentation. Sponsor-Investigator and Researcher will remove any of Janssen Pharmaceutical Companies of Johnson & Johnson. Confidential Information or proprietary information identified by Janssen Pharmaceutical Companies of Johnson & Johnson in Janssen Pharmaceutical Companies of Johnson & Johnson sole discretion, and will consider in good faith any other comments and changes Janssen Pharmaceutical Companies of Johnson & Johnson provides.

At the end of such review period, Sponsor-Investigator and Researcher shall have the right to submit such disclosure without further delay.

- (ii) If Sponsor-Investigator and/or Researcher publish Research Project results, Janssen Pharmaceutical Companies of Johnson & Johnson is hereby granted a perpetual, fully-paid, royalty-free, worldwide right and license to make and distribute copies of such publication. After the date of first publication or presentation of Research Project results, or the date ninety (90) days after completion or termination of the Research Project, whichever is earlier, Janssen Pharmaceutical Companies of Johnson & Johnson shall have the right to independently publish the Research Project results. If applicable, Researcher must list the Research project on clinicaltrials.gov.
- (iii) The following language must be included when submitting the Research Project results to meetings and for submission and included in all presentations, meetings, publications and the like: "This research was sponsored by Janssen Pharmaceutical Companies of Johnson & Johnson ATS Early Career Investigator Award in Pulmonary Vascular Disease Program." This language must also appear on all posters, within all abstracts and as an acknowledgement in all manuscripts and presentations, as well as in any financial disclosure information.

Data and intellectual property

Upon notification of the award grant; the applicant and Janssen Pharmaceutical Companies of Johnson & Johnson will resolve issues in regard to ownership of data and intellectual property.

The grant-holder is required to make available to Janssen Pharmaceutical Companies of Johnson & Johnson and the Steering Committee any and all data and the results of his/her work through a final study report, if performed through his/her Program grant.

Equipment

All equipment covered by the program funds must be used for the purposes of the funded research. Applicants must give a full description of all equipment, including cost and technical data. The equipment will become the property of the host institution. The host institution will be responsible for related maintenance and accommodation, service and operation, and insurance costs.

Appropriate use of funds

The Steering Committee may demand reimbursement for funds that have been used in a manner contrary to the aims of the Program or in contravention of the agreed-upon conditions.

Forms

All forms mentioned above are available on the website.