

Pulmonary Fibrosis

FOUNDATION

Pulmonary Fibrosis Foundation

Research Fund to Cure Pulmonary Fibrosis

Guidelines

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OVERVIEW AND OBJECTIVES

One of the primary missions of the Pulmonary Fibrosis Foundation (PFF) is to fund research that will ultimately lead to successful therapies to improve care and quality of life for those affected by pulmonary fibrosis (PF). As part of this commitment, the Foundation will support new research through its own grant award program and through partnership grants with other patient advocacy organizations.

The Research Fund to Cure Pulmonary Fibrosis was established with the primary goal of funding innovative grants that offer a high likelihood of advancing research that improves the understanding of pulmonary fibrosis and/or that could translate into successful therapies in the following areas:

- Basic Science
- Translational Research
- Clinical Research
- Epidemiological Research
- Health Services Research

RESEARCH GRANTS: DESCRIPTIONS AND PRIMARY OBJECTIVES

PFF Scholars Program: The PFF Scholars Program is designed to support early stage researchers and provide career development opportunities to future leaders in the field of pulmonary fibrosis. An award of up to \$50,000 USD to be given over a two-year period to encourage early stage investigators (individuals must be post-doctoral trainees, instructors, or Assistant professors) to support them as they seek “K” or “R”-level funding. Those who have held a faculty appointment for more than 5 years are not eligible. The PFF will support additional scholarly activities, including supplementary mentorship by a PFF Scholar Advisor, participation in PFF Scholar activities throughout the year and at the PFF Summit and Volunteer meetings, and the opportunity to invite a PFF Visiting Professor to their home institution. The PFF allows no more than 8% of indirect costs for these awards, which is already included in the total award amount.

PFF Patient Registry and Biorepository – Research Opportunities: The PFF strives to support pulmonary fibrosis research toward a better understanding of the disease and the development of more effective treatments.

We encourage, but do not require, the use of the PFF Patient Registry and Biorepository for all kinds of research into interstitial lung diseases and PF. The resources may be used exclusively to conduct retrospective research or incorporated into a prospective study design.

To determine if the Registry resources are appropriate for your research, you may visit <http://www.pulmonaryfibrosis.org/medical-community/pff-patient-registry>

to download the Registry protocol and casebook describing the data elements collected. The PFF Ancillary Studies Policy can also be reviewed through the above link.

The PFF Registry Ancillary Study Proposals will open three (3) times per year. Please check proposalCENTRAL for open proposal opportunities. Once the application window closes, studies will be reviewed by the appropriate committee and the statistical team at the Data Coordinating Center, and the results of the review will be provided to the submitting investigator within four weeks.

Note: Investigators who are not affiliated with a PFF Patient Registry site are welcome to propose ancillary studies, but are required to work with at least one PFF Patient Registry site investigator. A list of primary investigators can be found on the above referenced link.

Foundation Awards: Awards of up to \$15,000 USD are intended to provide funds to investigators and institutions where unique circumstances exist and additional funding will help advance an exceptional research effort. These awards are not usual practice and are awarded at the discretion of the Chief Medical Officer with advisement of the Scientific Advisory Committee.

Foster increased funding opportunities for PF research: The Foundation will seek to increase research funding through partnerships with industry, governmental agencies, and other foundations.

Partnership Grants: Fund emerging PF research through partnership grants with organizations such as the American Thoracic Society (ATS) or the American College of Chest Physicians (CHEST). This unique partnership allows the PFF, in collaboration with other organizations, to jointly award grants focusing on PF.

THE ROLE OF PEER-REVIEW IN FUNDING RESEARCH

The Foundation's Research Fund operates its grant making initiatives with the understanding that approval for funding must rest in the hands of a credible, peer-review committee of experts. Members of the Research Advisory Committee will review all accepted applications. Funding decisions will be made on the basis of scientific merit, originality, and responsiveness to the purpose of the specific grant award. A complete list of the Scientific Advisory Committee is available at:

<http://www.pulmonaryfibrosis.org/our-role/leadership/scientific-advisory-committee>

RESEARCH FUND GRANT DEFINITIONS

International Applicants: United States tax laws restrict the ability of the PFF, a not for profit foundation certified by the Internal Revenue Service as a tax exempt organization pursuant to Section 501(c)(3) of the Internal Revenue Code, to make grants to international

applicants. International applicants will be required to certify that grant funds will be used solely for the types of charitable, educational, and scientific purposes permitted to be performed by domestic Section 501(c)(3) organizations, and that the grant funds will not benefit private interests, as opposed to the public at large. The determination whether such certification is satisfactory will be made by the PFF in its sole discretion.

For an informational description of the types of organizations to which the PFF is permitted to award grants, see Exemption Requirements – 501(c)(3) Organizations, at <https://www.irs.gov/charities-non-profits/charitable-organizations/exemption-requirements-section-501-c-3-organizations>

PFF Scholars: The PFF Scholars are talented and promising early stage researchers conducting mentored research that will ultimately lead to independent funding. The awards are intended to enable investigators to be competitive for K or R awards from the NIH, other federal agencies, private foundations, or other sources.

Who is eligible to become a PFF Scholar? The following criteria must be met to be eligible to be a PFF Scholar:

1. Must have an MD, DO, RN, PhD, or other doctoral level or professional degree
2. Must have an appointment at an academic institution as a post-doctoral fellow, Instructor, or Assistant Professor. Those who have held a faculty appointment for more than 5 years are not eligible.
3. For those with a clinical degree (MD, DO, RN, etc.), candidates must have completed their clinical (e.g., ACGME) fellowship training as of the beginning of the Award period. Although designed for fellows and Instructors, early Assistant Professors within 5 years of completing their fellowship are also eligible.
4. For those without a clinical degree, candidates must have received their PhD (or equivalent) as of the beginning of the Award period and be within at least 5 years of receiving their PhD.
5. Must have demonstrated a commitment to becoming an independent investigator in an interstitial lung disease-related field
6. Must not be the PI of another career development award (e.g., K Award) or independent grant (e.g., R01). Other awards no greater than \$50k direct costs per year are allowable.

Budgetary or scientific overlap with other awards is only permitted when the other award has an annual direct cost less than \$50,000. In the event that an individual receives a “K” or “R” award between the time of application and the end of the PFF Scholar award, the awardee must notify the PFF within one month of the notice of grant award. The Scientific Advisory Committee, PFF Scholar Steering Committee, and Foundation leadership will carefully review for scientific and budgetary overlap. Proposals that overlap will render the Scholar ineligible for ongoing PFF grant funding, but participation in the PFF Scholars Program may continue.

Applicants must have a strong link with one or more senior investigators, and be pursuing a career as an independent investigator. A signed letter from the investigator’s supervisor will be acceptable documentation. The intent of the PFF Scholars Program is to allow the investigator to generate data to be competitive for a major independent research award within three years. Applications from individuals who do not meet the eligibility criteria will not be reviewed.

If there are any questions regarding eligibility, please contact Zoe Bubany, VP of Board and External Relations, at 888.733.6741 or by email at grants@pulmonaryfibrosis.org prior to submitting an application.

GRANT APPLICATION INSTRUCTIONS AND REQUIREMENTS

Submitting a Letter of Intent (LOI): Individuals interested in applying to the Research Fund are required to submit an LOI prior to submission of a full application. The Scientific Advisory Committee will review all LOIs. All successful applicants will be notified if approved and subsequently requested to complete a full application. Information regarding general LOI and application procedures can be found at proposalCENTRAL at <https://proposalcentral.altum.com/>

PFF Scholar Award Application: Individuals interested in applying for a PFF Scholar Award are required to submit an LOI according to the instructions available at proposalCENTRAL at <https://proposalcentral.altum.com/> Accepted applicants will be required to complete a full application on the proposalCENTRAL website.

PFF Patient Registry or Ancillary Studies Proposals: All submissions must be made through proposalCENTRAL. There is currently no LOI process required to submit a proposal to utilize Registry resources.

Utilizing proposalCENTRAL: LOI and Full Application Process: The PFF utilizes proposalCENTRAL for the administration of the Research Fund. Applications will not be accepted in any other format. Instructions are provided for both completion of an LOI and full grant application. If invited to submit a full grant application using proposalCENTRAL, care should be taken to ensure that the application is completed properly and without error. In particular, please note the following:

- All required information must be supplied (required fields are marked with an asterisk). If a field is not required but it is applicable to the specific grant, please provide the information.
- Please remember to click “Save” for each section that is completed.
- Please remember that the applicant is responsible for providing and uploading two letters of support for the full proposal (this is not required to submit an LOI). Letters sent directly to the Foundation office will NOT be accepted.
- Biosketches are required only for individuals that are essential to the completion of the project.
- Applicants must submit the LOI or full proposal before the deadline! Please note that no exceptions will be made for applications submitted after the deadline. All deadlines are set for Eastern Time.
- If at any point the applicant encounters any technical problems, please contact proposalCENTRAL technical support at pcsupport@altum.com or by phone at 800.875.2562

Please address any questions regarding content and eligibility to: Zoe Bubany, VP of Board and External Relations, at 888-733-6741 or by email at grants@pulmonaryfibrosis.org.

Review Process for Letters-of-Intent (LOI): The Scientific Advisory Committee will review and rank all Letters of Intent to identify research applications that are the most meritorious in purpose and scope to the goals of the Research Fund. Two important considerations are:

- Does the LOI describe an initiative that has a high probability of providing new and important information?
- Does the applicant have the ability to undertake the project if funded?

The highest ranked LOIs will receive a notification of invitation to submit a full application through proposalCENTRAL.

Full application review process for PFF Scholars. All applications will be reviewed and scored by at least two members of the Scientific Advisory Committee. Applicants who already have existing support can submit their funded application and scientific reviews. Those applying for PFF grant support should submit the following:

Research Plan (Aims page + a 4 page Research Strategy)

- **Significance:** Does this project address an important problem? How will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on

the concepts, knowledge, treatments, and interventions in this field?

- **Approach:** Are the design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- **Innovation:** Is the project original and innovative? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
- Clear next steps to K or R level funding

Career Development Plan

- Candidate Background (1/2 page)
- Propose Career Development Plan (1-2 pages)
 - o Long-term Goals
 - o Current skills and knowledge
 - o The skill and knowledge gap to be filled by the proposed career development activities
 - o The specific activities the candidate will engage in to gain new skills and knowledge. This section must provide concrete specific detail.
 - o Examples of activities might include (but are not limited to)
 - Meeting with mentors
 - Didactic classwork, Master's or Doctoral program, seminars, workshops, etc.
 - Short-term immersive training experiences
 - Mentored research methods and activities

Mentor and Institutional letters

- (1) Primary mentor's letter
 - o The primary mentor must have demonstrated a successful track record of mentorship. The letter must include a Table listing their prior and current mentees including: (1) mentees' names, (2) mentees' position during mentoring, (3) mentor's role in mentorship (primary, secondary, advisor, etc.), (4) Number of co-publications with the mentee, (5) mentees current position

- The mentor must have sufficient funding to support the candidate and their research (beyond the PFF Award)
- (2) Institutional letter
 - The candidate's Department Chair or Division Director should provide a signed letter that lists the support and resources the Department is providing to the candidate, and the resources (in its broadest sense) committed to the candidate's career development
- (3) Additional letters of support (up to 2) may be submitted.

Review Process of Other Full Applications (excludes PFF Scholar and Registry proposals): All applications will be reviewed and scored by at least two members of the Scientific Advisory Committee. Important considerations include:

- **Significance:** Does this project address an important problem? How will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, knowledge, treatments, and interventions in this field?
- **Approach:** Are the design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- **Innovation:** Is the project original and innovative? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
- **Investigators:** Are the PI and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PI and other researchers? Is the PI likely to become successful as an independent investigator?
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment(s), or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support? In the review of Junior Investigator awards, the strength of the scientific mentoring team will be considered.

PFF SCHOLARS SCORING PROCESS

Reviewers will score each application on a scale of 1-9 using the system established by the NIH with one (1) being exceptionally strong with essentially no weaknesses, and nine (9) being exceptionally weak with very few strengths and numerous major weaknesses.

If there is a significant disparity between reviewers, at the discretion of the Chair of the Scientific Advisory Committee, an additional review may be performed.

The applicants will be ranked according to their average scores and recommendations for funding will be made by the Scientific Advisory Committee. Final approval for all grants will rest with PFF Scholars Steering Committee, Chief Medical Officer, and executive management of the Foundation.

CONFLICT OF INTEREST

Each reviewer is required to identify whether there is a real, potential, or apparent conflict of interest with respect to an application. The following would constitute potential conflict of interest:

- Reviewer is from the same institution as the applicant.
- Reviewer has a direct relationship with the applicant such as:
 - A partner in practice;
 - A colleague working on a combined project which involves the research being proposed;
 - An active or potential faculty member in the applicant's institution.
- Reviewer has fiscal involvement within the project or as a consequence of the project.
- Reviewer has a significant relationship with a corporate entity that is partnering with the Foundation and/or the Institution in the grant for which the applicant has applied.
- Reviewer has a personal relationship with the applicant, either positive or negative, that could influence the reviewer's ability to maintain objectivity about the applicant or the project.

Reviewers with conflicts of interest regarding certain applications will not be assigned those applications to review and will be asked to recuse themselves from discussion and voting.

POLICY ON ADDITIONAL GRANT FUNDING – SCIENTIFIC OVERLAP

Simultaneous submission of grants with scientific overlap is allowed, but if multiple applications are funded, then the applicant must notify the PFF within one month of formal notification of award. The Scientific Advisory Committee will assess the degree of overlap. In case of significant scientific overlap the applicant will have to choose between the PFF research grant and the other grant award. Budgetary overlap is NOT allowed.

APPLICATION DEADLINES

The annual calendar presented below displays the anticipated events throughout the year. Please note that PFF Patient Registry and Biorepository awards/study opportunities have its own application schedule. Specific dates will be provided by the PFF each year as a new funding cycle begins.

Announcement of Program – Call for Letters of Intent (LOIs)	October
Deadline for submission of LOIs	November

Scientific Advisory Committee Review and Ranking of LOIs	November - December
Investigator notification of LOI acceptance	January
Full application submission deadline	February/March
Review of Grant Applications	February-April
Investigator notification	May/June
Announcement of Approved Grants	After contracting is complete
Award Funds Available	October
Annual Reports due for Awards Approved in the Previous Calendar Year	October