



## ALF 2024 PILOT RESEARCH AWARDS

**OPTIONAL LETTER OF INTENT (LOI) DEADLINE:** June 5<sup>th</sup>, 2024

**APPLICATION DEADLINE:** June 14, 2024

**AWARD PERIOD:** October 1, 2024 – September 30, 2025

### OBJECTIVE

The objective of the 2024 Pilot Research Awards is to provide funding for highly innovative projects that address novel and important questions related to Primary Biliary Cholangitis (PBC).

Pilot Research Awards provide funding during the pilot phase of research projects focused on new areas of investigation, innovative ideas, or “high-risk, high-reward” projects that have the potential to generate breakthrough findings and significantly advance the field. Pilot projects should address key outstanding questions in basic, translational, or clinical research on PBC.

Proposals do not require extensive preliminary data but need to articulate a clear, testable hypothesis and well-defined goals that are achievable within the timeframe and amount of the award. Funded projects are expected to result in acquisition of key preliminary data that will enable recipients to successfully compete for research awards from NIH and other national to support larger studies in these innovative research areas.

The following topics have been identified as areas of particular need in PBC research. ALF encourages proposals focused on these topics but also welcomes innovative projects focused on any other research area not listed below.

- Biomarkers
- Early and improved diagnosis
- Education and awareness gaps in medical providers
- Experimental models
- Fatigue, brain fog, and other symptoms
- Health inequities and other barriers to care
- Immunological mechanisms and dysregulation
- Microbiome
- Pathophysiology of disease
- Psychological burden/mental health issues
- Quality of life
- Relationship with other autoimmune diseases
- Therapeutic avenues

### PILOT RESEARCH AWARD AT-A-GLANCE

**Career Level:** All Faculty Levels

**Award Type:** Pilot Research Award

**Research Topic:** Primary Biliary Cholangitis (PBC)

**Research Type:** Basic, Translational, or Clinical Research

**Funding Amount:** \$50,000

**Award Duration:** 1 year

**Optional Letter of Intent Deadline:** June 5, 2024

**Application Deadline:** June 14, 2024

## ELIGIBILITY

In order to be eligible for a Pilot Research Award, all following eligibility criteria must be met:

- 1) Principal Investigator: The Principal Investigator (PI) must:
  - a) Be sponsored by a public or private non-profit institution accredited in the United States (U.S.) and engaged in health care and health-related research. Individuals employed at the NIH, FDA, and CDC are not eligible to apply.
  - b) Hold an MD and/or PhD (or equivalent degree), and a full-time faculty or equivalent position at an institution in the U.S. by the start date of this award.
    - i) If the applicant does not have a faculty appointment at the time of application, a letter signed by the department chair confirming that the applicant will have a faculty appointment no later than the Award start date must be submitted.
  - c) Be able to guarantee 50% protected research time overall.
- 2) Collaborators: Because the awards are focused on rare diseases, collaborators, including collaborators outside the U.S., are allowed if they are necessary for completion of the proposed research project (e.g., to reach adequate numbers of patients or biospecimens), with the following requirements:
  - a) The PI must be in the U.S.
  - b) The need for collaborators must be justified in the research plan
  - c) Collaborators must be included in Key Personnel and Budget Justification, and relevant documentation must be provided as indicated in the Required Documents section of the Application Instructions
- 3) Research project: The proposed research project must:
  - a) Be clearly different from existing research from the PI and collaborators. Established investigators who are applying for this award should state explicitly how the proposed research is different from their previous and current line(s) of investigation
  - b) Not be part of a larger project with alternate funding
  - c) Be hypothesis-based
  - d) Include specific aims that can be completed within the timeframe and amount of the award
  - e) Be primarily conducted at the PI's sponsoring institution in the U.S.
- 4) Funding Overlap: The PI and collaborators must:
  - a) Not hold or have held funding directly related to the proposed research from ALF or any other organization at the time of application.
    - i) The American Liver Foundation does not provide duplicate funding and must be notified immediately if the applicant receives funding on the same or comparable research project during the application process or during the award period.
  - b) Not apply for more than one award offered by the American Liver Foundation.

Applicants who are from groups identified by the NIH as underrepresented in the biomedical, clinical, behavioral, and social sciences are strongly encouraged to apply. This includes, but is not limited to, individuals from racial and ethnic groups underrepresented in health-related sciences (Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders, etc.), individuals with disabilities, and individuals from disadvantaged backgrounds. See NIH's [Notice of NIH's Interest in Diversity \(NOT-OD-20-031\)](#) for a complete list and additional details.

## AWARD DETAILS

An award of \$50,000 will be provided over one year in quarterly installments of \$12,500.

### Award terms:

- Recipients must acknowledge the award in all publications (abstracts, manuscripts, or other documents) resulting from research performed during the tenure of this award.
- Awards cannot be transferred to another institution without prior written approval from the American Liver Foundation.
- Recipients are directly responsible to the sponsoring institution.
- Unexpended funds at the end of the award period must be returned to the American Liver Foundation.
- If the award is relinquished prior to the specified end date of the award period, unexpended funds starting from the relinquishment date must be returned to the American Liver Foundation within 60 days.
- Final award payment will be held until receipt of all final reports.
- Recipient's personal and medical leaves of absence that last longer than 4 weeks must be communicated to the American Liver Foundation.
- Award recipients agree that their photograph and a brief summary of their research project will be featured in a press release and posted on the American Liver Foundation website and social media channels.

## OPTIONAL LETTER OF INTENT

A Letter of Intent to apply for funding is requested and strongly encouraged, but not required. The purpose of the Letter of Intent (LOI) is to allow ALF staff to estimate the number of, and plan for the review of, submitted applications.

The LOI should include at least the following information:

- Mandatory:
  - Applicant name
  - Applicant institution
  - Type of research (select one): Basic, Translational, or Clinical Research (see definitions below)
  - Disease focus: Primary Biliary Cholangitis (PBC)
- Optional: Research project's title or topic(s)

**Submit your optional letter of intent via email, no later than June 5, 2024, to:**

Helene Jordan, PhD  
American Liver Foundation  
National Director, Research Program Management  
[research@liverfoundation.org](mailto:research@liverfoundation.org)

## BUDGET AND JUSTIFICATION

Applicants must provide a budget using the budget template included in the Application Form. The budget justification should be listed on a separate page, after the budget template, with an explanation for each budget item (including a description of key personnel and their role in the project).

#### **Allowable costs:**

- Salary and benefits for graduate students, postdoctoral fellows, laboratory technicians or other key personnel necessary for completion of the proposed research project
- Laboratory supplies, animals, or other materials necessary for completion of the proposed research project
- Biostatistics, informatics, biobank, or other core facility costs necessary for completion of the proposed research project

#### **Non-allowable costs:**

- Salary and benefits for principal investigator (i.e., award recipient) or faculty collaborators
- Indirect costs (e.g., university overhead)
- Equipment
- Registration and travel costs to attend scientific conferences

## **SELECTION CRITERIA**

Proposals will be evaluated based on the scientific merit of the research project (innovation, significance, feasibility, approach, design and methods), the PI's background and commitment to a research career, and the environment in the project will be conducted

Applications will be reviewed based on the written materials submitted. **Incomplete applications and applications that fail to adhere strictly to the instructions (including the submission deadline and page limitations) will not be reviewed.** All decisions are final.

## **PROGRESS REPORT**

A scientific progress report, a progress report in lay language, and a financial report must be provided within 60 days of completion of the award.

Following the conclusion of the award, recipients must provide a report once a year for three (3) years that includes articles published or accepted for publication, new funding, patents, and any other relevant outcome that results from work funded by the pilot research award.

## **GLOSSARY**

**Basic Research:** Research focused on fundamental scientific investigations and usually conducted in controlled laboratory settings, with the primary goal of understanding basic biology or disease mechanisms. It aims to expand knowledge, discover new principles, and understand underlying mechanisms without specific applications towards processes or products in mind. However, the results of basic research form the foundation for translational and clinical research. This category can involve animal studies, cell culture and other in vitro studies, "omics" research, and studies using human biospecimens or human data that cannot be linked to a specific individual.

**Clinical Research:** Patient-oriented research with the primary goal of directly impacting the prevention, diagnosis, treatment, or outcome of liver disease in patients. Clinical research often involves direct contact with human subjects and aims to assess the safety, efficacy, and effectiveness of medical interventions, treatments, or diagnostics to inform clinical practice and improve patient care. Clinical trials are a common form of clinical research, and it can also include interventional, observational, epidemiological, or behavioral studies, outcomes research, and health services research studies.

**Collaborator:** An individual who works with the principal investigator in the scientific development or execution of the project. This individual would typically devote a specific percent of effort to the project and would be identified as key personnel. The collaborator may be employed by or affiliated with either the grantee organization or an organization participating in the project under a consortium or contractual agreement. See Eligibility Criteria section for specific considerations related to collaborators.

**Grant Administrator:** The staff member who oversees new grant agreements and grant payments; ensure that grants comply with relevant laws and regulations; guarantees that all required reports are submitted; and administers the grant after award.

**Indirect Costs:** Costs that are necessary to support a particular activity project or program but that cannot be easily or directly attributed to such activity, project or program. Examples of indirect costs are rent, utilities, and administrative personnel.

**Principal Investigator (PI):** The Principal Investigator or PI is the lead researcher for the grant project and has overall responsibility for the design, conduct, reporting and scientific integrity of the research. For ALF Pilot Research Awards, the applicant is considered the PI and the PI/applicant will be the award recipient.

**Public Health Service (PHS) 398 Forms and NIH Guidelines:** The PHS 398 Form is the application form used to obtain federal grant support. Go to [www.grants.nih.gov/grants/funding/phs398/phs398.html](http://www.grants.nih.gov/grants/funding/phs398/phs398.html) to access the PHS 398 “Biosketch” Form and PHS398 Instructions that have useful tips and directions for completing a Research Plan.

**Translational Research:** research that bridges the gap between basic research and clinical research, with the goal of translating observations from the laboratory, clinic, and community into potential interventions that improve health. Translational research can include converting basic research discoveries into practical medical interventions, therapies, or diagnostics that can then be tested in clinical research studies. For example, if basic research identifies a gene that could play a role in a certain disease, translational research could identify ways to target this gene and test their efficacy in the laboratory before moving to human testing. Translational research also investigates how results of successful clinical research studies can be translated into best practices and implemented by physicians in clinical care.

## APPLICATION INSTRUCTIONS

### Submission Deadline

The deadline for the optional [Letter of Intent](#) is June 5, 2024.

**The deadline for the [application](#) is June 14, 2024.** Applications received after the deadline will not be reviewed.

### Formatting Instructions

- 1) Download the Application Form and Application Guidelines from the [Pilot Research Award webpage](#).
- 2) Complete the Application Form by typing responses in the fillable pdf document, obtain requested signatures, and prepare all required documents as indicated below.
- 3) Use at least half-inch margins. Do not use lettering smaller than 10 point.
- 4) Include a header with your name (last name, first name) and the name of the award in the upper right-hand corner of each page in required documents not provided in the Application Form.

- 5) Be sure to adhere to page limits and complete all sections as indicated in these guidelines. Applications that do not meet the requirements, in content or format, will not be reviewed.
- 6) **Assemble the Application Package in the order listed in the Required Documents section** below.
- 7) The completed Application Form and all required documents must be combined into and submitted as one PDF document. This document is your Application Package. Name the PDF as follows: Last name\_First name\_Pilot Research Award. Your single PDF file must be no larger than 10MB (megabytes).

## Submission Instructions

- 1) Submit an optional Letter of Intent **via email** by June 5, 2024.
- 2) Submit your Application Package on the [Pilot Research Award webpage](#) by June 14, 2024.
- 3) Complete the Applicant Information in the submission form on the webpage.
- 4) Applicants must select a Primary Disease Focus and Primary Type of Research for their research proposal.
- 5) Upload your Application Package as one PDF document as indicated above.
- 6) Click the **“Submit” button** to submit your application.
- 7) You will receive an email confirmation that the PDF was received. Check your spam folder and **contact** [research@liverfoundation.org](mailto:research@liverfoundation.org) **if you did not receive an email confirmation**.

## Required Documents

Assemble the required documents in the order below:

- 1) **Title Page** – This is page 1 of the Application Form.
- 2) **Applicant Information and Required Signatures** – This is page 2 of the Application Form. It must be completed and signed by the appropriate individuals. Signatures may be digital, electronic, or “in ink”.
- 3) **Applicant Demographic Information** – This is page 3 of the Application Form.
- 4) **Lay Summary and Abstract** – This is page 4 of the Application Form. Provide a lay summary of your research along with your project’s abstract.
- 5) **Research Differentiation** – This is page 5 of the Application Form. PIs must explain how the proposed project differs from their existing research portfolio
- 6) **Institutional Review Board (IRB) and Animal Experimentation** – This is page 6 of the Application Form. All human and animal studies require IRB and Institutional Animal Care and Use Committee (IACUC) approval, respectively. Verification of IRB or IACUC approval of the proposed research in the applicant’s institution must be provided prior to the award being granted. If IRB or IACUC approval is not necessary or not attached, please state why.
- 7) **Budget** – Provide a detailed budget using the template form on page 7 of the Application Form. **Limit one page.**
- 8) **Key Personnel and Budget Justification** – Provide a description of key personnel (including their percent effort and role in the project) and an explanation for each budget item. All key personnel must be listed regardless of salary support in the budget (e.g., PI and faculty collaborators must be included as Key Personnel but their salary cannot be supported by this pilot research award). **Limit two pages.**
- 9) **Biosketch** – Provide biographical sketches for the applicant, collaborators, and any other key personnel using the [current NIH biosketch format](#). **Limit five pages each.**
- 10) **Other Support** – Provide a list of all other active and pending institutional, federal and non-federal support using the NIH [“Other Support” form](#) for the PI and Collaborator(s). See the NIH [“Other Support” webpage](#) for additional information and templates.

- 11) **Specific Aims** – State the proposed project’s overall research hypothesis, objectives, specific aims, and impact of the results. **Limit one page.**
- 12) **Research Plan** – The research plan must be prepared and assembled in the following order: Background and Significance, Innovation, Preliminary Results (optional), Research Design and Methods, and References. Results of unpublished observations may be summarized using text, tables or figures and they must be included in the five-page limit. **Limit five pages, not including references.**
- 13) **Research Facilities** – The research environment should be described, including, as applicable, laboratory space, access to patients’ materials or data, animals, core facilities, consultants and technical resources (including computer). **Limit one page.**