



RESEARCH GRANT APPLICATION

APPLICATIONS ARE REVIEWED THREE TIMES ANNUALLY

Submission deadlines*: March 1, July 1, November 1

(* See “Application Categories and Award Terms” for exceptions)

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General Guidelines and Policies for Grant Submission

Introduction

The Fibrolamellar Cancer Foundation (FCF) is a public, nonprofit organization established to drive and support research related to Fibrolamellar Carcinoma. FCF is also committed to raising awareness of this disease, as well as fostering a global community of patients and caregivers impacted by this rare liver cancer. More information about FCF is available at www.fibrofoundation.org.

FCF Research Philosophy

It is important for all applicants to fully understand our research philosophy to guide preparation of proposals. **Exhibit 1** delineates the key tenets of that philosophy, which we encourage applicants to review.

Eligibility

Applicants must be employed by an institution engaged in health-related research. Applicants must agree to always be supervised by the institution while conducting research supported by FCF. If a change in institution is made while applying for, or utilizing funds from FCF, applicants must notify FCF. Continuation of the grant award will be subject to review based upon the change in circumstances.

The research must focus on Fibrolamellar Carcinoma (FLC) [also known as Fibrolamellar Hepatocellular Carcinoma (FL-HCC)]. Studies should be intended to advance the understanding, diagnosis, epidemiology, or treatment of FLC. Of particular interest are applications showing a clear path towards novel therapies / clinical trials with the eventual goal of achieving a cure for FLC. FCF will accept grant applications to support innovative and promising research projects towards the above goals.

Collaboration and open sourcing are a requirement for funding by FCF and will be specified in any grant agreement. FCF believes that collaboration among multiple teams and institutions, together with early sharing of data and resources, often accelerates the path to a cure for rare cancers.

Application Categories and Award Terms

Scope and Budget. There is no fixed “magic number” for the scope and funding of a worthy project. Rather, researchers are asked to submit a proposal with appropriate budget as needed to support clear specific aims and/or milestones (general guidelines are indicated below). In all cases the potential significance of the proposed work and resulting impact on FLC patient care should be clearly indicated. FCF generally considers applications in the following three categories:

A. Resource, Preliminary, or Proof-of-Concept Study

- Designed to achieve well-defined, near-term deliverable(s) or milestone(s) and/or to demonstrate feasibility of a concept or approach
- Budget up to \$49,500 for a period of up to one year
- Accelerated review process

B. Full Research Study

- Basic or translational study to achieve well-defined Specific Aims and/or Milestones
- Up to 2 years with an annual budget generally not exceeding \$200,000; interim progress review required for year 2 funding
- Proposals for projects over longer time periods and/or with larger budgets will be considered, but should be discussed with FCF prior to submission

C. Clinical Study

- Study with human subjects, approved by an appropriately constituted Institutional Review Board (IRB)
- In a study involving more than one type of cancer, generally, FCF will cover only those costs directly associated with subjects with FLC
- Applicants should submit a complete research grant application with the Study Protocol appended
- No general limit with respect to time frame or annual budget
- Applicants are advised to consult with the FCF prior to submission

Covered Costs. Funding will cover direct costs only, and all costs should be reflected in the budget.

Multi-year Grants and Extensions. If a multi-year grant is awarded, FCF will make a firm commitment to fund the first year of the effort. FCF reserves the right not to continue funding for subsequent years if insufficient progress has been made and/or the reporting protocol is not followed.

Any requests for no-cost extensions must be approved in advance by FCF.

Letter of Agreement. A formal Letter of Agreement (LOA) with the Principal Investigator's institution must be signed to finalize any grant that has been provisionally approved by FCF. The payment schedule and all specific terms will be outlined in the LOA.

The LOA for the funding will clearly state that collaboration, data sharing and co-ownership/revenue sharing between the applicants' institution and FCF of data and discoveries that are directly related to FCF funding through the institution are mandatory.

Questions. If clarification of any specific award terms is needed prior to applying for a grant, please contact Kurt Losert, CEO, at klosert@fibrofoundation.org. For questions about proposal scope or research content, please contact Payal Ray, Research Program Director, at pray@fibrofoundation.org and Mark Furth, Chief Science Officer, at mfurth@fibrofoundation.org.

Nonprofit Statement

FCF is a nonprofit organization under Section 501 (c)(3) of the Internal Revenue Code.

Preparation and Submission of Application

Preparation

Applicants should follow the format given below. Please submit the application by email as a single electronic file (Adobe PDF format preferred; MS Word documents accepted). Margins should not be less than 3/4" (top, bottom, left, and right). Figures and Tables should be numbered, and large enough to be readable. They should be referred to by number in the text. Please number all pages. Rules for fonts follow NIH guidelines:

- 11-point font size or larger (Arial, Georgia, Helvetica, or Palatino Linotype preferred; 10 point may be used for Figure or Table legends)
- No more than 15 characters per linear inch (including spaces)
- No more than 6 lines per vertical inch

Please use the following application format, with sections clearly labeled:

- **Title, Principal Investigator(s), Institution(s)**
- **Lay Abstract:** limited to 300 words in plain English, i.e., “layman’s” terms. This portion of the application should contain enough information to adequately explain the project and its relevance to FLC, suitable for communication with FCF’s executive staff and Board of Directors, other stakeholders, and the patient and caregiver community.
- **Technical Abstract:** Limited to 300 words, primarily for scientific/medical reviewers.
- **Specific Aims and/or Milestones:** Maximum of one (1) page with a clear description of the rationale, hypotheses being tested, research approach, and deliverables to be achieved.
- **Background and Significance:** Maximum of two (2) pages for category A (resource / preliminary / or proof-of-concept study); maximum of three (3) pages for categories B & C (full research study or clinical study). Section should clearly delineate innovative aspects and relevance to understanding, diagnosis, epidemiology, and/or treatment of FLC. Must include citations of literature pertinent to the area under investigation.
- **Preliminary Data:** Relevant data from the applicant(s) with a clear indication of how it applies to the rationale and the likelihood of achieving Specific Aims and/or Milestones. If this application represents a renewal or resubmission, significant new information or data since the prior grant submission should be clearly noted. Maximum of two (2) pages for category A application; maximum of three (3) pages for categories B & C.
- **Proposed Studies and Methods:** Clear indication of workplan by which Specific Aims/Milestones are to be achieved. Standard methods can be incorporated by citation. Anticipated results and potential pitfalls should be addressed. Note availability of special institutional or external facilities / resources if required to achieve the workplan. Maximum of three (3) pages for category A application; maximum of four (4) pages for categories B & C.
- **Clinical protocol:** Add as an Appendix the draft or approved protocol for any proposed clinical study. Indicate status of Institutional Review Board submission and (if required) review by appropriate regulatory agency (e.g., US Food and Drug Administration, FDA).
- **Literature cited:** Please include article title and names of at least the first and last authors. No page limit.
- **Biosketch and Other Support:** Maximum of 3 pages per investigator. Should be submitted in NIH format for the Principal Investigator(s) and other investigators listed in the application. Potential overlap with other funding should be clearly detailed.

For the following sections, please use EXHIBIT 2 (pp. 8–11), adding extra lines if required

- **Signatures:** The Principal Investigator and the Institutional Representative must sign the application using the template provided in Exhibit 2 before it will be accepted for review.
- **Budget:** One page generally will suffice. Indicate salaries and percent effort for personnel; materials/consumables (major categories, any unusual costs); services/contracts; animal costs; equipment. Justification for salary support and supplies and equipment listed on the budget page should be stated. Specific justification is needed for any equipment purchase over \$500.00. Full disclosure will be required of any other sources covering the same costs noted in the proposal, e.g., salary, benefits. The budget should be inclusive and for direct costs only. **FCF does not pay indirect costs, as it represents that 100% of donated funds are used for research.**
- **Attestation Statement:** must be read and signed by the Principal Investigator.

Additional Documents

- If the application includes the use of an investigational compound or agent supplied by a pharmaceutical or biotechnology company, a letter of support from the company must be provided as part of the submission.
- In the event the proposal is recommended for funding, FCF reserves the right to contact the company and conduct due diligence to ensure the sustained availability of the agent for the duration of the study and beyond, if applicable.

Use of Artificial Intelligence (AI) for Grant Applications

- Grant applicants are permitted to use AI tools in the development of their proposals. However, applicants are fully responsible for the accuracy of the content of their proposals. All use of AI, and details about how it was used, must be disclosed in the application.
- While the use of AI in a grant application will not influence scoring, applicants are cautioned against its use due to the possibility of the tools incorporating mistakes, fabricated information, or copyrighted content. Applicants should carefully review any content generated by AI and edit the results for accuracy.

Submission

- The application should be submitted as a single file in Adobe PDF format (preferred) or as a Microsoft Word document and should be received by FCF before midnight of an announced application deadline, or another date agreed in advance with FCF.
- Submissions should be sent via email to Payal Ray at pray@fibrofoundation.org with copies sent to Kurt Losert at klosert@fibrofoundation.org and Mark Furth at mfurth@fibrofoundation.org. If an application file is too large for submission by email, please contact us.
- If receipt of a grant application is not acknowledged within 10 days of submission, please contact us to confirm delivery.

Notification

The notification of the decision of FCF to approve funding of the application will be sent to the Principal Investigator and the Institutional Representative.

Grant Application Review Criteria

Proposals are scored by reviewers on a three-level scale, as 1, 2 or 3 (no fractional scores), as follows:

1. Proposed project is well-designed and has strong potential to advance the understanding, diagnosis, epidemiology, and/or therapy of FLC. Should be funded; no major flaws, but some specific modifications may be recommended.
2. Proposed project has strong potential to advance the understanding, diagnosis, epidemiology, and/or therapy of FLC, but should not be funded without correction of significant weaknesses in rationale, supporting data, or experimental design / feasibility. Applicants should be encouraged to address these weaknesses and to resubmit the application after making appropriate modifications.
3. Proposed project as described does not have strong potential to advance the understanding, diagnosis, epidemiology, and/or therapy of FLC, and/or has major flaw(s) that may not be correctable or would require substantial time to address.

Specific Evaluation Points

Objectives / Rationale

Do the applicants provide well-defined objectives with concrete Specific Aims and/or Milestones? Is the rationale for the proposed work scientifically sound, based on the literature cited and any preliminary data?

Impact / Innovation

If successful, is the project likely to advance the understanding, diagnosis, epidemiology, treatment and/or prevention of FLC in an important way? Is the proposal innovative or relatively redundant with ongoing work in the field?

Experimental Design / Feasibility

Is the proposed work well-designed to meet the Objectives? Is it likely that the studies can be carried out successfully, in a timely manner, with the proposed resources?

Investigators / Environment

Is the study team well qualified to carry out the proposed work, and does it have an established track record in the field of the proposal? Are institutional and/or external facilities and support adequate?

Critical Improvements

What changes should be made in the proposed workplan to correct minor or major flaws?

Budget

Is the budget appropriate for the proposed work?

EXHIBIT 1

Fibrolamellar Cancer Foundation's Research Philosophy

Our objective is to find a cure for FLC. This gives us a unique perspective and informs our approaches. We believe a cure relies on:

- Research that provides essential resources and knowledge for the field (e.g. model systems, understanding genetic underpinnings, annotated patient specimens)
- Innovative research that opens new pathways for diagnosis, sophisticated treatments, and drug discovery.

We want our research dollars to **make a difference**. We support promising projects that are less likely to get traditional funding, including:

- **Seed funding of promising early-stage efforts** that could yield breakthrough benefits for patients
- High quality projects proposed by **investigators** with demonstrated commitment to fibrolamellar cancer research
- Foundational projects with the potential to offer important and **long-term payoffs**.

Our research dollars should never substitute or displace other funding. We prefer to fund **new projects** over existing well-funded efforts.

We prioritize proposals that aim to find **life extending therapies, and a potential cure**.

We believe we can find such life extending therapies, and a potential cure, **together**:

- We value research that involves and catalyzes collaboration
- We value open-access research (rapid sharing of data, reagents and models with FCF and the research community)
- We embrace researchers that can secure **matching grants**.

Our goal is a **rigorous, yet efficient**, process to find and fund high quality projects:

- For rigor, proposals must undergo a comprehensive peer-review
- For efficiency, proposals need only provide sufficient detail to facilitate a peer review.

Collaboration and cooperation are essential to the success of any research program. The Fibrolamellar Cancer Foundation chooses grant recipients carefully to ensure they will build working relationships among researchers, institutions, and industry and will share information, materials, and expertise with us and others in the field.

EXHIBIT 2

APPLICATIONS SHOULD BE RECEIVED BY MARCH 1, JULY 1, or NOVEMBER 1

Date: _____

Title of Project: _____

Total Amount Requested: \$ _____

Planned Study Duration (months): _____

Principal Investigator:

Last Name First Name MI Degree(s)

Title Name of Institution Department

Institution Physical Address

Institution Mailing Address

Principal Investigator Telephone Number Principal Investigator Fax Number

Principal Investigator Email Address

Principal Investigator Signature Date

Official of Institution:

Last Name

First Name

MI

Degree

Title

Name of Institution

Department

Institution Physical Address

Institution Mailing Address

Official of Institution Telephone Number

Official of Institution Fax Number

Official of Institution Email Address

Official of Institution Signature

Date

Budget Detail

Personnel

Salaries: \$ _____

Benefits: \$ _____

Equipment

\$ _____

Supplies (group in categories) _____

Miscellaneous (list specifics)

Total Amount Requested
(MUST match amount on page one)

\$ _____

Award Conditions and Principal Investigator Attestation Statement

1. By affixing my signature below, I attest that I have read and will follow the following principles about funding supplied to me by the Fibrolamellar Cancer Foundation (FCF).
2. The funds that I have applied for will be used to fund only the direct costs of the proposed research for which I am applying. I understand that no funds are available for indirect costs.
3. I further understand that if duplicate funding for this project is obtained at any time, I will immediately inform FCF and withdraw my request for funding. If any portion of the project is now being funded by, or in the future is funded, by another source, I will fully disclose that to FCF.
4. This application is in the format outlined by the Foundation. If my institution is a research organization, such organization must be exempt from federal taxation under Section 501(c)(3) of the Internal Revenue Code and must provide FCF a copy of the determination letter issued by the Internal Revenue Service granting such exempt status.
5. The proposed investigation focuses on Fibrolamellar Carcinoma, and the proposed project shall serve to advance existing Fibrolamellar Carcinoma research in accordance with Section 501(c)(3) of the Internal Revenue Code.
6. My institution will be responsible for certifying to the Foundation that the research is conducted in accordance with current medical research standards and that it complies with the current guidelines of the U.S. Department of Health and Human Resources regarding Vertebrate Animals, Recombinant DNA, Research Misconduct, and Financial Conflict of Interest. The institution will further verify that any research involving human subjects or vertebrate animals has been approved by the necessary review boards and committees, in accordance with existing laws and regulations.
7. The budget submitted with the application includes justification for any budgetary items exceeding \$500.00.
8. I, as Principal Investigator, shall provide detailed scientific updates to FCF at least every six months and submit formal annual reports for grants exceeding one year. I will also submit a final report summarizing research results and listing all publications, including conference abstracts, in which the findings have been reported. That final report will be submitted no later than 60 days after the grant end date.

Principal Investigator Signature

Date

Name