



Fibrolamellar Cancer Foundation

RESEARCH GRANT APPLICATION

APPLICATIONS ARE REVIEWED THREE TIMES ANNUALLY

SUBMISSION DEADLINES*: FEBRUARY 15, JUNE 15,

OCTOBER 15

(* 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 primarily to support the funding of research related to **Fibrolamellar Carcinoma**. The FCF is also committed to raising awareness about this disease through education and marketing across all stakeholders, as well as fostering a global community of patients and caregivers for all suffering from, and caring for, this rare liver cancer. 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 further must agree to be supervised by the institution at all times while conducting research supported by the FCF. In cases of a change in institution while applying for, or utilizing funds from the FCF, applicants must notify the 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) [aka Fibrolamellar Hepatocellular Carcinoma (FL-HCC)]. Studies should be intended to advance knowledge relevant to the understanding, diagnosis, epidemiology, or treatment of FLC. Of particular interest are applications showing a clear path towards a novel therapy / clinical trials with the ultimate goal of achieving a cure for FLC. The FCF will accept grant applications to support innovative and promising research projects towards the above goals.

Collaboration and open sourcing. This is a requirement for funding by the FCF and will be so specified in any grant agreement. The FCF believes that collaboration engaging the best talent across 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” with respect to the maximum 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 (although general guidelines are indicated below). In all cases the Significance and potential contributions towards the benefit of FLC patients should be clearly indicated. The 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 1 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 the 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, the 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

Funding is to cover direct costs only, and costs should be reflected in the budget. If a multi-year grant is awarded, the FCF reserves the right not to continue funding after year one (1) 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 the FCF.

Letter of Agreement

A Letter of Agreement (LOA) with the Principal Investigator's institution must be signed prior to initiation of any grant approved by the FCF. The payment schedule will be outlined in the LOA.

The LOA to release funding will clearly state that collaboration, data sharing and co-ownership (between the applicants' institution and the FCF) of data and discoveries that are directly related to FCF funding through the institution are mandatory. If clarification is needed prior to applying for a grant, please contact Kurt Losert, CEO, at klosert@fibrofoundation.org. For questions on proposal scope or research content, please CC Mark Furth, Scientific Director at mfurth@fibrofoundation.org.

Nonprofit Statement

The 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 ¾" (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 to the 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). Should clearly delineate innovative aspects and relevance to understanding, diagnosis, epidemiology, and/or treatment of FLC. Should include citation 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, as well as any publications acknowledging funding from the FCF. 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 3 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 in the budget page should be stated. Specific justification is needed for any equipment purchases 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. **The 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.

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 the FCF before midnight of an announced application deadline, or another date agreed in advance with the FCF. Submissions should be sent by Email to: klosert@fibrofoundation.org, CC to mfurth@fibrofoundation.org. If an application file is too large for submission by Email, please contact us. Also, if receipt of an application is not acknowledged within 10 days after submission, please contact us to confirm it arrived.

Notification

The notification of the decision of the FCF regarding 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 with 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 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 I

Fibrolamellar Cancer Foundation Research Philosophy

Our objective is to find a cure. This gives us a different perspective and informs our philosophy. 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 such as:

- **Seed funding** that could yield breakthrough benefits for patients
- High quality projects proposed by **investigators** with demonstrated commitment to fibrolamellar cancer research
- Foundational projects with an important and **long-term payoff**

Our research dollars should never substitute for or displace other funding (i.e. preference for **new projects** over existing well-funded efforts)

We prioritize proposals that aim on **finding 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 the research community)
- We embrace researchers that have the ability to 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 that they will build working relationships among researchers, institutions, and industry and share information, materials, and expertise with others in the field.

EXHIBIT II

APPLICATIONS SHOULD BE RECEIVED BY FEBRUARY 15, JUNE 15, or OCTOBER 15

Date: _____

Title of Project: _____

Total Amount Requested: \$ _____

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: \$ _____

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 with regard to 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 at this time no funds are available for indirect costs.
3. I further understand that if duplicate funding for this project is obtained at any time, that I will immediately inform the FCF and withdraw my request for funding. In the event that 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 the FCF.
4. Application shall be in the format outlined by the Foundation. If the application is made by a research organization, such organization must be exempt from federal taxation under Section 501 (c) (3) of the Internal Revenue Code and must provide a copy of the determination letter issued by the Internal Revenue Service granting such exempt status.
5. The principal area of investigation shall be in the area of 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. The principal investigator's institution will be responsible for certifying to the Foundation that the research is conducted in accordance with current medical research standards and that it is in compliance 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 Principal investigator shall submit a budget with the application, with justification for budgetary items exceeding \$500.00.
8. The Principal Investigator (PI) shall submit annual reports for grants exceeding one year. The PI also shall submit a final report summarizing research results and listing all publications, including conference abstracts, in which the findings have been reported. The final report is to be submitted no later than 60 days after grant anniversary.

Principal Investigator Signature

Date

Name