

**TRANSLATIONAL RESEARCH PROGRAM
FOR
CANCERS OF THE BILE DUCTS AND GALLBLADDER**

YOUNG INVESTIGATOR AWARDS

**2010 REQUEST FOR APPLICATIONS
Program Guidelines and Application Instructions**

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I. Program Summary

About CanLiv – The Hepatobiliary Cancers Foundation

CanLiv The Hepatobiliary Cancers Foundation is a tax-exempt, not-for-profit charitable organization incorporated in the State of New York. The mission of CanLiv is to improve the lives of individuals diagnosed with cancer of the bile ducts, gallbladder and liver by providing accurate, current information, calling public attention to these orphan tumors and fostering patient-focused translational and clinical research to improve patients' outcome.

Purpose of the CanLiv Patient-focused Research Grants

This award provides funding to promising new investigators to encourage and promote translational research in cancers of the gallbladder and/or bile ducts (cholangiocarcinoma).

CanLiv's definition of translational research is *hypothesis-driven research that seeks to expand understanding of carcinogenic mechanisms in cancers of the liver, gallbladder and/or bile ducts and has significant likelihood to imminently lead to new therapeutic options for patients.*

Funding Available

The total award amount is \$30,000.00 for one year payable on July 1 and January 1 in two equal installments. The number of Research Grants in each funding cycle is pre-determined by CanLiv. Awards are given based on individual merit and availability of funds.

Key Dates

Applications are to be submitted electronically to info@canliv.org

Online Applications Open: January 12, 2010 Full Application Due: March 5, 2010

Notification Date: April 23, 2010

Award Term: July 1, 2010 – June 30, 2011

Applicant Eligibility Criteria

1. Applicants must hold an M.D., D.O., PhD or D. Sci. degree, and be in their first to third year of a full-time, primary faculty appointment in a clinical, basic, or translational science department at an academic medical institution. For foreign-trained physicians or scientists, equivalency will be determined on a case-by-case basis.
2. Applicants must be tenure-track scientists at the level of Assistant Professor. Applicants cannot be tenured or under review for tenured academic positions at the time of application submission.
3. Have completed a productive period of postdoctoral research, with demonstrated ability to undertake independent investigator-initiated research.
4. Be able to commit at least 40% of full-time effort in research (applies to total research, not just the proposed project) during the award period.
5. Have a mentor from the Sponsoring Institution and provide an institutional Letter of Support.
6. Be planning a career in investigative clinical oncology focused on liver and biliary tract cancers.
7. There are no citizenship requirements. However, Applications from non-U.S. citizens who are ineligible to apply for NIH-funded research support will be closely reviewed with respect to the Applicant's potential to leverage CanLiv funding into other future research funding.
8. Employees or subcontractors of a government or for-profit private industry are not eligible.

9. Provide documentation of adequate support facilities to undertake and complete the proposed research.
10. Eligible investigators may submit only one application to CanLiv per year.

CanLiv - The Hepatobiliary Cancers Foundation Research Grant Review Committee reserves the right to evaluate and determine Applicants' eligibility based on the information and justifications included in the application materials.

II. Application Instructions

Applicant Information shall include:

- Applicant Name
- Contact information
- Institution
- Academic degrees, dates, awarding institutions
- Final subspecialty training completion date
- Faculty appointment start date

Biographical Sketch

Applicant should include an NIH-formatted Biographical Sketch.

Personal Statement (One page limit – font minimum size 11)

Submit a personal statement about the nature of your career's goals and research interests.

Budget

Using the NIH modular budget model, include personnel costs. Institutional indirect costs will not be allowed.

Supporting Documentation

Institution (Grants and Contracts Administrators) Contacts

Institution Letter of Support

- A Letter of Support from the Department Chair or Dean at the sponsoring institution where the applicant's research project will be conducted is required. The letter must include a description of the institutional support that will enable the applicant to perform the proposed research.

Mentor's Biosketch and Letter of Support:

- Mentors may provide their current NIH Biosketch.
- Confirmation that the Applicant is within the first three years of a full-time tenure-track faculty appointment, or is completing training and has commitment for a full-time faculty position.
- Confirmation of Applicant's eligibility for the award.
- The letter must critically evaluate the scientific merit and relevance to liver, bile duct and/or gallbladder cancer of the proposed research; the scientific independence demonstrated by the applicant in previous work; and the dedication of the applicant to cancer research. The letter should explain the applicant's relationship with the Institution, and the nature and extent of support for the proposed research available from the Institution.
- The role(s) or anticipated role(s) the Applicant holds or will hold at the Institution.

- A description of the Applicant's potential for a successful research career, and the Mentor's level of commitment to the applicant's career as an independent investigator.
- Assurance that the applicant's sponsoring institution will provide adequate facilities and support for performance of the proposed work.
- Intended structure of the mentor-investigator interaction during the proposed investigation.

Scientific Abstract

The Abstract (250 word maximum) should provide a clear and concise overview of the proposed research including the relevance to cancers of the liver, bile duct and/or gallbladder and the potential for translation of the outcome to therapeutic options for patients.

Research Plan

The research plan shall be **limited to 5 typewritten, single-spaced pages with one-inch margins and no smaller than 11-point typeface. All pertinent tables, graphics, and pictures must be included within the 5-page limit.**

The research plan must contain the following:

- **Specific Aims**

This section should state concisely and realistically what the research intends to accomplish and/or what hypothesis is to be tested, and should list measurable objectives for the proposed project.

- **Significance and Background**

This section should explain the proposal in terms of its significance, reviewing any previous work and current status of related research, should describe any preliminary work completed that led to the proposed research, should state the rationale behind the approach, and should include the long-term goals and implications of possible results.

- **Experimental Design/Brief Methods of Procedure/Statistical Analysis**

This section should provide condensed details of the proposal including nature of subject, sampling data collection procedures, experimental methods, type of data expected, procedures for data analysis and interpretation, and appropriate statistical considerations. A biostatistician will review all Applications.

This section should clearly state the applicant's role in the project (i.e. writing of protocol, performing the assays, etc.). When human subjects are involved, the precautions to ensure patient safety and confidentiality and the relevance or implications for patient care should be explained. In addition, a description of the facilities and resources available to conduct the study should be mentioned, including a description of industry support for any clinical trials.

Applicant's Resources

Describe the resources available to the applicant to carry out the research described in this proposal.

Budget and Justification

The award funds will be directed to the Sponsor and must be used towards salary support, supplies, equipment, and necessary for the pursuit of the recipient's research project. Award funds may not be applied to patient care costs that are reimbursable by a third-party payer, or to institutional overhead. Budget justification for the entire project period must be included for each line item requested. The budget guidelines are as follows: The total award amount is \$30,000 payable in two increments of \$15,000 each.

Cited References

Include a complete bibliography of the references cited in the proposal.

Required Attachments

- One to three recent publications authored by the applicant relevant to the proposed research
- Statement of Institutional Approval
- Human Subject Statement
- Laboratory Animal Statement
- Recombinant DNA Statement
- Biohazard Statement

Selection Process

The CanLiv Grants Selection Committee will select the recipient(s) based on the following Criteria:

- A focus on translational medical research in cancers of the liver, bile ducts and/or gallbladder.
- Significance and originality of the proposed study and hypothesis.
- Appropriateness, feasibility and adequacy of the proposed experimental design and methodology.
- Availability of institutional resources to support the proposed project.
- Prior research experience and accomplishments of the applicant during research training.
- Quality of the mentor and the plan for mentor interactions with applicant.
- Originality and level of innovation of the research project.
- Whether the study is designed appropriately to provide answers to the research questions posed.
- The contribution of the institutional environment to the probability of success of the proposed studies.
- The initiative, creativity, independence and previous accomplishments of the applicant.
- The likelihood of the Applicant's continued contributions to cancer research and their potential for obtaining additional research funding to extend the research supported by CanLiv.

III. General Summary of Award Terms and Conditions

Commencement

The Grantee must agree to commence the research project described in the Proposal on or about the time the Grantee's Institution receives the first Grant payment.

Use of Funds

The grant, provided to the recipient's sponsoring Institution, may be used for expenses attributable to the proposed research including the salary and benefits of the grant recipient and/or research assistants, laboratory supplies, and limited travel of the grant recipient. Up to 10% of the total budget may be allocated for equipment.

Payments

Twice-yearly installment payments will initiate on or around July 1, 2010. Although CanLiv intends to fund the grant through the end of the grant term, the Grantee and Institution acknowledge and accept that the subsequent grant payment is contingent upon the timely submission of interim progress and financial reports that are reviewed and found to be satisfactory by CanLiv.

Reporting Requirements

The Grantee must submit a final progress report to CanLiv at the end of the funding period. The progress report must be accompanied by a financial report. The final written report must be submitted no later than sixty (60) days after the ending date of the Grant term. Attendance at the 2011 CanLiv Research Symposium is also a requirement of the Award. The grant recipient is required give a presentation of their research in a mini symposium at the 2011 meeting.

Publications & Acknowledgement of Support

By accepting this grant, the Grantee gives CanLiv permission to include grant information (name, degrees, institution, project title, award amount, lay abstract) in publicly accessible databases of privately funded grants.

Any publications resulting from research funded in whole or in part by the Grant must be cited as follows, "Research Supported by the CanLiv-The Hepatobiliary Cancers Foundation Research Award". In addition, whether during the term of the grant or afterwards, the Grantee shall include this citation on any publicity or communications (external or internal) resulting from the Grant, including but not limited to press releases, media reports, interviews, conference talks and poster presentations of data. Copies of such publications must be forwarded to CanLiv.

Intellectual Property

The Award Contract will include specific requirements for management of any intellectual property that may results from CanLiv-supported research.

Notification of Changes

It is the responsibility of the Grantee to notify CanLiv immediately of any changes in the Grantee's position or Institution. CanLiv may not accept proposals to change the research project from that described in the application, and may terminate the Grant.

Organizational Assurances

For research involving human subjects or biospecimens, the Grantee shall certify that:

- a. The proposed research project has been reviewed and approved in writing by an accredited university or medical school Institutional Review Board (IRB) constituted in accordance with current regulations promulgated by the United States Department of Health and Human Services (HHS) and approved by HHS, or by the Association for the Accreditation of Human Research Protection Programs (in the absence of an HHS-approved university or medical school IRB).

b. The Grantee shall secure a legally acceptable informed consent from all human subjects taking part in any research funded in whole or in part by CanLiv in accordance with and to the extent required by current regulations promulgated by the United States Department of Health and Human Services and approved by HHS. If the applicant is chosen as a grant recipient, IRB certification must be documented by submitting a copy of the Institutional letter of approval which identifies the Grantee, project title, CanLiv as the funding agency and date of approval, and is signed by the IRB Chair or equivalent responsible Institutional official. Prior IRB certification for another project cannot be substituted, but can be officially amended to include the proposed project. Funds will NOT be released unless and until proof of IRB certification is received by Grantor. Grantees at non-US Institutions must adhere to ethical standards for the protection of human subjects that are at least equivalent to US standards, and to the legal requirements of the country of origin. If the applicant is chosen as a grant recipient, certification of ethical standards review and approval must be documented by submitting a letter, which cites all relevant approval and license numbers and dates required by the country of origin. In the absence of an official ethical review board (or equivalent) or legal requirements, the Grantee must agree in writing to adhere, at a minimum, to the World Medical Association Declaration of Helsinki: Ethical Principals for Medical Research Involving Human Subjects.

For research involving animals, the Institution shall ensure compliance with applicable chapters of the Public Health Service Animal Welfare Policy, the NIH Manual for Grants and Contracts, and any and all requirements of the Institution concerning animal welfare. If the applicant is chosen as a grant recipient, certification by the Institution Animal Care and Use Committee (IACUC) or equivalent must be documented by submitting a copy of the Institutional letter of approval, which identifies the Grantee, individual responsible for the project, project title, CanLiv as the funding agency, date of approval, and is signed by the IACUC Chair or equivalent Institution official. Prior IACUC certification for another project cannot be substituted, but can be officially amended to include the proposed project.

Grantees at non-US Institutions must adhere to ethical standards for the care of use of animals for research purposes that are at least equivalent to US standards and to the legal requirements of the country of origin.

Inquiries

Contact info@canliv.org or 877.751.5400