LAKE CHAMPLAIN CANCER RESEARCH ORGANIZATION, INC.

THE University of Vermont CANCER CENTER

2018 Pilot Project Awards

Program Description, Investigator Eligibility, Funding and Award Period, Allowable Expenses, Research Project Criteria, and Scoring Criteria

Program Description

Lake Champlain Cancer Research Organization (LCCRO) Pilot Projects are one-year awards supporting projects that pursue novel ideas in cancer research. Areas of supported research include basic, clinical, epidemiological, behavioral, and psychosocial cancer-related investigations. Translational collaborations (for example, a clinician and a basic scientist) are strongly encouraged.

LCCRO research grants support discrete, well-defined projects that can be completed in one year and require limited levels of funding. Projects proposing novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research are especially encouraged. Emphasis will be on investigation that credentials applicants for peer-reviewed extramural cancer research funding.

Because the research project is limited, the grant application may not contain extensive detail, discussion, background material or preliminary information. Accordingly, reviewers will focus their evaluation on the conceptual framework and general approach to the problem. The level of innovation and the potential for the proposed project to significantly advance our knowledge or understanding of the stated problem are additional areas that will be taken into consideration in evaluating the proposal. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required but may be included if available.

Investigator Eligibility

Applications are limited to investigators who are Full or Associate Members of the University of Vermont Cancer Center (UVMCC) who are eligible to apply for independent, peer-reviewed research funding, and whose research activities align with one of the three established UVMCC Programs:

- Cancer Control and Population Health Sciences (CCPHS)
- Host Factors and Tumor Progression (HFTP)
- Molecular Mechanisms of Malignancy (MMM)

Extramural collaborators are not required to be UVM Cancer Center members but at least one PI must be a Full Member. Proposals from investigators whose UVMCC Membership is pending can be accepted if the membership application has been submitted in advance of the Pilot Project application.

Please go to Intramural Funding Web Portal at
http://www.med.uvm.edu/uvmcancercenter/research/intramural-funding
to download Letter of Intent and Application Forms

Funding and Award Period

Pilot research projects will be supported at up to $75,000 for a one year, non-renewable period. The one-year award period will be January 1, 2018 to December 31, 2018.

Allowable Expenses:	Non-Allowable expenses:
Salaries & Benefits for *Research* Faculty & Staff (e.g. laboratory technicians, data managers, etc.)	Salaries for individuals occupying tenured/tenure track positions
Salaries & Benefits for Graduate and PostDoctoral *Research* Assistants	Salary support for teaching activities
Specialized Services (e.g., microscopy, animal care, etc.)	Secretarial or administrative salaries
Research Supplies	Equipment maintenance and service contracts
Research Patient Care Costs (tests & procedures done solely for research; prior approval required)	Therapeutic Equipment
Equipment (up to $5,000)	Speaker travel and honoraria
Domestic travel directly related to the aims of the project (up to $2,000)	Textbooks/course books and periodicals; binding of periodicals and books
Publication costs	Membership dues
	Rental of office or laboratory space
	Recruiting and relocation expenses
	Construction, renovation, or maintenance of buildings/laboratories
	Food costs associated with meetings or conferences held by investigative team

Research Project Criteria

Proposed projects should not fall within the specific aims of a currently funded project of any of the collaborating investigators.

The LCCRO Scientific Advisory Committee (SAC) reviews all applications and provides recommendations for funding to the LCCRO Board of Directors based on innovation, scientific merit, need, relevance to UVMCC programmatic initiatives and potential for future peer-reviewed funding. A major criterion will be the perceived probability that the research project will lead to the submission of a fundable research grant application to NCI, NIH or a

similar major source of peer-reviewed funding.

Previously supported research activities will be a factor in evaluating proposals and continuation projects will not be considered. However, proposals submitted by investigators who have previously received intramural funding that has led to extramural support and who are now applying for funding for new projects are eligible for consideration.

Areas of supported research include basic, clinical, epidemiological, behavioral, and psychosocial cancer-related investigations. Multi-disciplinary collaborations are strongly encouraged; similarly, collaborations among researchers representing different UVMCC programs (for example, CCPHS & HFTP) are strongly encouraged. Proposals that collaboratively engage multiple disciplines and program areas will be given preference over those which do not.

Preference will also be given to early career investigators or to projects with significant impact on UVM Cancer Center Program development or which are relevant to the UVMCC catchment area, the State of Vermont, or Northern New England.

Amended applications that address recommendations from a previous review are encouraged.

Investigators who are delinquent with reports on any previous awards are ineligible for new funding until they have satisfied reporting requirements.

Reviewers are instructed to look for:

- INNOVATION, first and foremost
- Investigator record of sustained productivity in cancer research and effectiveness of translational investigation
- Projects whose results are likely to generate extramural funding.
- Projects that are clearly cancer related
- Priority will be given to projects related to:
    - Aging and Rural Populations
    - Regional Collaboration
    - Translational Projects
    - Programmatic Themes

Scoring Criteria

- The table below provides a NIH Scoring System guide for reviewers in assigning overall impact scores and individual criterion scores.
- Overall impact, for a research project, is the project's likelihood to have a sustained, powerful influence on the research field(s) involved.
- Each review criterion should be assessed based on the strength of that criterion in the context of the work being proposed.
- As a result, a reviewer may give only moderate scores to some of the review criteria but still give a high overall impact score because the one review criterion critically important to the research is rated highly; or a reviewer could give mostly high criterion ratings but rate the overall impact score lower because the one criterion critically important to the research being proposed is not highly rated.
- An application does not need to be strong in all categories to be judged likely to have

major impact, e.g., a project that by its nature is not innovative may be essential to advance a field.

- A score of 5 is a good, medium-impact application. Applications to this program that have been approved for funding have historically achieved scores of 3.0 *and better*.
- The entire scale (1-9) should always be considered.

Overall Impact or Criterion Strength	Score	Descriptor
High	1	Exceptional
	2	Outstanding
	3	Excellent
Medium	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

1. Significance

Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

3. Multi-Disciplinary Collaboration

Do the PD/PIs, collaborators, and other researchers represent a stimulating cross-pollination of disciplines? Are diverse UVMCC Programs represented?

4. Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

5. Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?

6. Environment

Will the scientific environment in which the work should be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria:

Protections for Human Subjects.

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46.101b, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46.101b, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information, see the Guidelines for the Review of Inclusion in Clinical Research.

Inclusion of Women, Minorities, and Children.

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information, see the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals.

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the

Worksheet for Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Revision

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations:

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) should be used, 3) the procedures that should be used to monitor possession use and transfer of Select Agent (s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genomic Data Sharing Plan.

Budget and Period of Support

Reviewers will consider whether the budget and the period of support are fully justified and reasonable in relation to the proposed research.

Additional Comments to the Applicant

Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.

Applications must be consistent with NIH expectations for “rigor and reproducibility.”

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Mandatory Letter of Intent
Due by Noon on Monday September 11, 2017

Full Application
Due by Noon on Monday October 9, 2017