THE University of Vermont CANCER CENTER

2019 Pilot Project Awards

Guidelines for Applicants & Reviewers

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

Program Description

The University of Vermont Cancer Center (UVMCC) Pilot Projects Awards support pilot projects that pursue novel ideas in cancer research at a funding level of up to $50,000 for a period of up to 24 months. 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.

UVMCC research grants support discrete, well-defined projects that can be completed within two-years and require limited levels of funding. Projects proposing novel scientific ideas or new models, 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 these are pilot projects, 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, letters of collaboration, 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) and at least one project PI or co-PI must be a Full Member. Only investigators who are eligible to apply for independent, peer-reviewed research funding, and whose research activities align with one of the established UVMCC Programs will be considered:

- 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 UVMCC members. 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.

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/ideas are eligible for consideration.

PIs or Co-PIs with currently-funded pilot projects are not eligible to apply.

Applications where a researcher is PI or Co-PI on more than one project will be accepted, but only one can be funded, based on highest score.

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

Funding and Award Period

Pilot research projects will be supported at up to $50,000 for up to 24 months. The award start date will be January 1, 2019, subject to administrative considerations.

Allowable Expenses

Allowable Expenses:	Non-Allowable expenses:
Salaries & Benefits for Research Staff (e.g. laboratory technicians, data managers, etc.)	Salary support for any Key Personnel on this project.
Salaries & Benefits for Graduate and Postdoctoral Research Assistants	Salary support for teaching, secretarial or administrative activities
Specialized Services (e.g., microscopy, animal care, etc.)	Consultants, sub-contracts or consortium agreements that call for payments outside UVMCC, UVM or UVMMC
UVMCC Core Facilities: Biobank, Biostatistics, Cancer Translational Research Lab (CTRL), Clinical Trials Office (CTO), Vermont Integrative Genomics Resource (VIGR)	Any external services when the services provided are available using UVMCC resources.
Research Supplies	Office supplies, unless directly related to the aims of the project
Patient Care Costs related to Clinical Trials. (e.g., stipends, procedures, lab tests done solely for research). *Corresponding salary support for UVMCC Clinical Trials Office personnel must also be budgeted to support these activities.*	Therapeutic Equipment
Equipment (up to $10,000)	Equipment maintenance and service contracts
Domestic travel directly related to the aims of the project (up to $2,000)	Speaker travel and honoraria
Publication costs	Membership dues, textbooks/course books and periodicals; binding of periodicals and books
Costs associated with IRB approval	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 UVMCC Pilot Project Committee reviews all applications and provides recommendations for funding based on innovation, scientific merit, need, relevance to UVMCC programmatic initiatives and potential for future peer-reviewed funding. A major criterion will be the probability that the research project will lead to the submission of a credentialed research grant application to NCI, NIH or a similar major source of peer-reviewed funding.

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.

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

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:**
    - **Translational or bi-directional research**
    - **Rural populations or other research relevant to the catchment area**
    - **Inter- and intra-programmatic projects, and inter-institutional collaborations**
    - **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. Pilot project applications 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

Please note there are three groups of review criteria that follow:

A. **Review Criteria for all Projects:**

B. ***Additional* Review Criteria for Projects that include Clinical Trials**

C. ***Additional* Review Criteria for all projects**

***Additional* criteria (B & C) are not scored individually but will be considered in the overall impact score.**

A. Review Criteria for all Projects:

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).

Reviewers should consider how this study contributes to establishing a strong scientific foundation or premise to support an extramurally funded research application.

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?

B. ***Additional*** Review Criteria for Projects that include Clinical Trials:

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

1. Significance

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

2. Investigator(s)

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

3. Innovation

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

4. Approach

Does the application adequately address the following, if applicable?

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

5. Environment

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

6. Study Timeline

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate? Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

C. *Additional* Review Criteria for all projects:

1. 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 additional information, see the Guidelines for the Review of Inclusion in Clinical Research.

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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).

8. 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.

9. 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.

10. 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."

APPLICATIONS ARE DUE BY NOON ON MONDAY, OCTOBER 15, 2018

Please go to Intramural Funding Web Page to download Application.