THE University of Vermont CANCER CENTER

Pilot Project Awards
Guidelines for Applicants & Reviewers

Program Description

The University of Vermont Cancer Center (UVMCC) Pilot Project Awards support pilot projects that pursue novel ideas in cancer research at a funding level of up to $40,000.

All applications must be related to some aspect of cancer including basic science, behavioral, bench, bidirectional, clinical, clinical trial, computational, data analytic, epidemiological, preventive, and translational studies. Applications should be identified as, and will be reviewed in one of three review areas: Basic Science, Clinical/Translational, and Population Science.

Projects not requiring regulatory approvals must be completed within one year; clinical trials or other projects requiring IRB approval may be permitted up to two years for completion.

Emphasis will be on investigations that prepare applicants for success in obtaining peer-reviewed extramural cancer research funding, ideally from NCI. Applicants are required to include in their proposals a clearly defined path to extramural funding by outlining which agencies and which funding programs they might target in subsequent extramural funding applications. The credibility of these plans will constitute a critical part of the review process.

Reviewers will also evaluate innovation and the potential for significant advances in understanding of the stated problem. Preliminary data may be included but are not essential.

Investigator Eligibility and Expectations

Applications are limited to investigators who are Full or Associate Members of the University of Vermont Cancer Center (UVMCC). Applicants should describe how the Research activities align with one of the 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 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.

Applicants who have received pilot awards in the prior three years or those with current awards are ineligible.

If a new extramural award for the same research is received, the UVMCC Pilot Project must be relinquished.

A PI or Co-PI can participate in only one project.

At the conclusion of their research, awardees are expected to report to their particular Cancer Center Program and may have the opportunity to report to the full membership concerning their project's challenges and successes. In addition, it is expected that awardees will maintain high levels of participation with the UVMCC Pilot Project Program in areas of future pilot review, presentations of study outcomes, and future progress reporting. Pilot award funding should be acknowledged on any resulting publications or abstracts.

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 $40,000. The award period will be up to 24 months for clinical trials and up to 12 months for all others.

Allowable Expenses

Allowable Expense:	Non-Allowable Expense:
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 outside UVM.
Research Supplies	Office supplies, unless directly related to the aims of the project.
UVMCC Core Facilities (Biobank, Biostatistics, Cancer Translational Research Lab (CTRL), Microscopy (MIC) Vermont Integrative Genomics Resource (VIGR)	Any external services when the same services are available using UVMCC resources.

Allowable Expense:	Non-Allowable Expense:
Patient Care Costs related to clinical trials (e.g., stipends, procedures, lab tests done solely for research). ***UVMCC Clinical Trials Office (CTO) personnel must be budgeted for clinical trial 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. Recruiting and relocation expenses
Publication costs	Membership dues, textbooks/course books and periodicals; binding of periodicals and books.
Costs associated with regulatory approvals (IRB, IACUC, IBC, etc.)	Rental of office or laboratory space; construction, renovation, or maintenance of buildings/laboratories

Research Project Criteria

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

One of the three UVMCC Pilot Project Selection Committees (Basic Science, Clinical/Translational, or Population Science) will review the relevant applications and provide recommendations for funding based on potential impact, 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 competive research grant application to NCI, NIH or a similar major source of peer-reviewed funding.

Collaboration among researchers representing multiple disciplines or program areas is encouraged.

Scoring Criteria

- All proposals should be held to the appropriate standards of scientific rigor for the discipline being evaluated.

- The table below provides an NIH Scoring System guide for reviewers in assigning overall impact scores and individual criterion scores.
- 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.
- Reviewers may not submit an Overall Impact Score that has no corresponding value for individual review criteria. For example, assigning an Overall Impact Score of 6 when the individual criteria scores are all 3s, 4s, or 5s isn't helpful to the applicant or to the review committee.
- Because constructive criticisms are an important heuristic for this program, reviewers will provide specific feedback on the strengths and weaknesses of each proposal as if the applicant were their own mentee.
- 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 or 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

Additional Review Criteria:

A. For projects not involving Clinical Trials

B. For Clinical Trials

C. Additional Review Criteria for all projects

A. Review Criteria for projects not involving Clinical Trials:

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 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 basis 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 investigators well suited to the project? If early stage 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)?

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 these standards being 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?

6. Study Timeline

Is the study timeline described in sufficient detail, taking into account start-up activities, the anticipated pace of research, and plans for project completion? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources to increase efficiency, as appropriate? Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of delays)?

7. Feasibility of Extramural Funding on completion

The project will be evaluated for the likelihood that, if the research is successful, it will lead to peer-reviewed extramural funding. Applicants are required to include in their proposals a clearly defined path to extramural funding by outlining which agencies and which funding programs they will target in subsequent extramural funding applications.

B. Review Criteria for 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 lead to new avenues of scientific investigation or may indicate that further clinical development of the intervention is unwarranted.

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 to support an extramurally funded research application.

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)

Do the investigators 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? Is there additional funding at any collaborating center to ensure success?

3. Multi-Disciplinary Collaboration

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

4. 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?

5. 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 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)?

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?

6. Study Timeline

Is the study timeline described in sufficient 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)?

7. Feasibility of Extramural Funding on completion

The project will be evaluated for the likelihood that, if the research is successful, it will lead to peer-reviewed extramural funding. Applicants are required to include in their proposals a clearly defined path to extramural funding by outlining which agencies and which funding programs they might target in subsequent extramural funding applications.

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. If appropriate, details pertaining to select agents should be evaluated.

5. 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.