



Innovation Pilot Awards Notice of Funding Opportunity (NOFO)

The purpose of the Innovation Pilot Award is to identify and support the early development of and new directions in high-quality, innovative cancer research from all areas of science, including basic, translation, clinical, and population sciences.

Purpose

- Provide pilot funding for new concepts in cancer-related research, including but not limited to: discovery, diagnosis, treatment, prevention and control, and survivorship.
- Produce preliminary data to provide a basis for future applications to the NCI, other NIH institutes, or other peer-reviewing agencies or foundations.

Massey Comprehensive Cancer Center Priorities

- Massey will continue to prioritize application addressing the 2021-2025 research strategic plan focal areas – breast, prostate, lung and GI cancers; the lifestyle factors of tobacco and obesity and survivorship.
- In addition, the Massey leadership would like to encourage applications focused on the role of Artificial intelligence and data sciences in cancer-related sciences.
- Projects that genuinely demonstrate transdisciplinary, interdisciplinary, or translational approaches to addressing cancer-related research question(s).
- Proposals that represent collaborative, team science approaches, particularly those that involve investigators from more than one Massey research program in meaningful ways.
- Projects that utilize Massey-supported shared resources, especially those applicants who have collaborated with one or more Massey-supported shared resource directors to optimize the full capabilities or innovative capabilities of a shared resource.

Investigator Eligibility

- Both single and Multiple Principal Investigators (PI or MPIs) may apply. For MPIs, at least one PI must have a full-time faculty appointment at Virginia Commonwealth University (VCU) and is required to be an NCI Cancer Center Support Grant (CCSG)-eligible member (verify with Massey Administration before applying by contacting Alex Haynes, haynesa4@vcu.edu). The contact PI submitting the application must be an NCI CCSG-eligible Massey member.
- Effort between MPIs must be comparable, and both MPIs must contribute to the overall project in similar magnitude.
- An individual may submit only one application as PI or MPI per year. An individual is allowed to be a co-investigator, consultant, or mentor on multiple submissions
- Projects must directly engage the community in the design, implementation, and/or evaluation of the proposed research. Applicants are strongly encouraged to contact the Office of Community Outreach and Engagement to discuss the incorporation of Massey Community Champions into their projects.
- A project submitted on a TEAM SCIENCE application will not be considered for funding as a separate INNOVATION PILOT application in the same year.
- A Massey investigator may only hold one active pilot research award at a time. Exceptions may be granted for an NCI Catalyst award when the research focus is completely different from other funded Massey pilot awards.

Award Information

- Total awards are dependent upon available funding. The number of awards and the award amount may increase or decrease each year dependent upon the Massey budget and philanthropic funding available in any given year.
- The number of awards and the award amount may increase or decrease each year dependent upon scientific merit of the projects submitted for review and the priorities established for any released NOFO.
- It is expected that all proposals will consult and include a biostatistician from the Massey-supported Biostatistics Shared Resource as part of the proposal. Their role is to assist with design and statistical methods. Please contact Dr. Nolan Wages (wagesn@vcu.edu), director of the Massey Biostatistics Shared Resource, as soon as possible or visit the Biostatistics Shared Resource.

Funding Limits

- An applicant PI can request up to \$100,000.

Award Period

- The proposed award period for the Innovation Pilot is up to 18 months.

Innovation Pilot Opportunities

1. Cancer Prevention & Control

- Projects should be focused on addressing cancer prevention and control, including but not limited to: identifying cancer risks, testing novel interventions, health policy research, implementation and dissemination research, supportive care, and cancer survivorship research.
- Total project period may not exceed 18 months.
- Budget may not exceed \$100,000.
- Applicants may request up to the full amount and there is no minimum amount required.

2. Developmental Therapeutics

- Projects should address the development of innovative strategies for cancer treatment (including but not limited to): identifying and developing novel compounds to probe therapeutic targets and/or corresponding aberrant signal transduction pathways; validating compounds in vivo in preparation for clinical implementation; investigating mechanisms of actions of and resistance to both novel and existing targeted or immunologic agents.
- Studies focusing on a) design and synthesis of novel compounds using structure-based drug design or HTS, b) performing hit-to-lead optimization and structure activity relationship studies, c) using the compounds to probe aberrant cellular pathways in tumor cells, and d) studying mechanism by which these chemical probes affect proliferation, survival, invasion and other hallmarks of cancer in cell culture, patient-derived organoids and xenografts are highly encouraged.
- Similarly, Studies focusing on cancer immunology, or cancer immunotherapy with the goal of a) developing novel biologics to treat cancer, a) identifying essential pathways for survival, invasion or metastasis and tumor interactions with stromal cells or on immune cells leading to the development of biologic agents including, but not limited to, antibodies, anticancer peptides or vaccines, CAR-T and other cell therapies, therapeutic viruses, immunomodulators, are highly encouraged.
- Total project period may not exceed 18 months.
- Budget may not exceed \$100,000.
- Applicants may request up to the full amount and there is no minimum amount required.

3. Cancer Biology

- Projects should be focused on the development of new insights across the hallmarks of cancer biology (including but not limited to): identifying and characterizing the alterations in key signaling networks that drive cancer development and progression; deciphering the genetic and epigenetic mechanisms involved in cancer formation and progression; investigating the molecular mechanisms governing the complex interactions between cancer cells and their immune and stromal microenvironment.
- Total project period may not exceed 18 months.
- Budget may not exceed \$100,000.
- Applicants may request up to the full amount and there is no minimum amount required.

Submission Guidelines

- All applications must include the items below, in order as listed.
- All applications must be submitted using the Submittable platform.
- The application PDF uploads should be formatted in 11 pt. Arial font (main text); 9pt. Arial font (figures, legends and tables).

1. **Biosketches**— Use NIH Biosketch. Include any present or recently completed research support. Include biosketches of collaborators and mentors. Guidelines can be found on the NIH website (<http://grants.nih.gov/grants/forms/biosketch.htm>) - uploaded as a PDF to Submittable

2. Research Strategy

a. Specific Aims—*Limit 1 Page (Uploaded as a PDF to Submittable)*

b. Research Strategy—*Limit 6 Pages (Uploaded as a PDF to Submittable)*

i. Significance

1. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
2. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
3. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

ii. Innovation

1. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
2. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
3. Explain any refinements, improvements, or new applications of theoretical concepts, approaches/methodologies, instrumentation, or interventions.

iii. Approach

1. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted.
2. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
3. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.

4. All applicants are expected to seek the support of the Massey Biostatistics Shared Resource in the design and statistics methods to be employed. Please indicate who will be providing biostatistical support. Contact Dr. Nolan Wages at wagesn@vcu.edu to schedule a consultation.
5. Massey's Office of Community Outreach and Engagement (COE) is available to assist all applicant teams with identifying and facilitating the involvement of a Community Champion with their project, if desired. If you would like assistance from the Office of COE, please submit a request in a timely manner at the following website <https://redcap.vcu.edu/surveys/?s=JW8EWLM8LTTKWKER> or you may also contact via email at CancerChamps@vcu.edu Please allow 24-48 hours for a response and at least 2-5 business days to identify a Community Champion.

c. Literature Citations (*Uploaded as a PDF to Submittable*)

3. Multi-PI Leadership Plan (if applicable; 1-page maximum)

For applications designating multiple PIs, a leadership plan is required. The rationale for choosing a multiple PI approach should be described, including the added benefit of this approach. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. Each PI must bring key scientific knowledge and responsibilities. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PIs, including responsibilities for human or live vertebrate animal subject studies as appropriate.

4. Plan of Subsequent Funding (1-page maximum)

Discuss how the findings from your pilot will be used to write a proposal for subsequent NCI/NIH funding. In this regard, applicants should list potential aims for a NIH proposal. This section is an important criterion for award selection.

5. Massey Shared Resource Utilization (1-page maximum)

Describe Massey shared resource usage. Project(s) are highly encouraged to use at least one Massey Shared Resource. If no shared resources are utilized for the project, please include a page stating not applicable.

Massey Supported Shared Resources:

- Bioinformatics
- Biostatistics
- Cancer Mouse Models
- Flow Cytometry
- Microscopy
- Proteomics
- Tissue and Data Acquisition and Analysis
- Transgenic/Knockout Mouse
- Lipidomics / Metabolomics

6. Compliance Documents(s)

Include all applicable compliance approvals need on the cover sheet (e.g., animal, IRB). Funds will not be allocated and no aspect of the project can begin (including non-human subject research components) without documentation of required approvals.

Note: Appendix materials are not allowed unless specifically requested above.

7. Budget and Budget Justification— The applicant should use the budget table provided on the

submittable platform. Please include a separate budget justification PDF document with written justification for each category of expenses. (See Allowable and Non-allowable expenditures below). Budget Justifications can be uploaded as a PDF to Submittable.

<u>Allowable expenditures include:</u>	<u>Non-allowable expenditures include:</u>
▪ Salary support for research staff ▪ Research supplies ▪ Per diem charges for patients if part of a clinical study, not reimbursable by standard payment terms ▪ Stipends for community champion/advocate participation ▪ Technical assistance ▪ Graduate student/postdoctoral stipends if relevant to the project with a detailed justification ▪ Domestic/foreign travel necessary to carry out proposed project based on institutional travel policies ▪ Computational services ▪ Other expenses such as laboratory and shared resource fees, pathology, imaging, etc. ▪ Consultant costs ▪ Equipment/technology with the intent to design, test, or facilitate a new device and non-office equipment necessary to carry out the proposed project. Requests over \$5,000 must include a detailed justification. ▪ Publications costs not to exceed \$4,000 across the total project period	▪ PI or other faculty salary expenses ▪ Secretarial/administrative personnel salary support ▪ Office equipment and supplies ▪ Computer and equipment maintenance fees ▪ Tuition ▪ Travel and/or registration/related fees for conferences ▪ Travel not essential to carrying out the proposed research ▪ Purchasing and binding of periodicals and books ▪ Dues and membership fees in scientific societies ▪ Faculty recruiting and relocation expenses ▪ Administrative or institutional charges for services normally considered overhead (e.g. space rental, utilities, building maintenance) ▪ Non-medical or personnel services to patients ▪ Sub-contracts to institutions not affiliated with Massey Comprehensive Cancer Center ▪ Pre-award costs

Terms of Award

- Acceptance of funds implies a firm commitment to provide a brief verbal/email check-in progress report quarterly (financial and scientific) by the deadline outlined in the Notice of Award (NOA) and subsequently, a written annual update for a five-year follow-up period. Awardees who do not reply to the five-year follow-up requests will jeopardize their eligibility for future Massey awards.
- MPIs must spend on their Massey assigned index within 60 days of receipt of the Notice of Award or funding may be rescinded and will require a written explanation for the delays addressed to Massey Senior Leadership.
- All awards must have appropriate institutional compliance approvals (e.g., IRB, IACUC) within 90 days of receipt of the NOA and before funds will be allocated. Restrictions may be applied for expenditures prior to receiving compliance approvals.
- Following the initial 60-days Massey expects that the grantee will completely utilize the full amount of funding during the term of the award and are required to meet regularly with the Massey Post-Award and Administrative Teams.
- Projects are expected to be completed within the specific budget period. Projects will be monitored quarterly for scientific progress and expenditures, and the PI will be expected to account for any inactivity in any given quarter.
- A No Cost Extension is highly discouraged and will only be considered under exceptional circumstances and **must be requested no later than 60-day before the end of the project period**. All unspent funds at the end of the grant period will be returned to the Massey.
- All awards, publications, and presentations must acknowledge Massey Comprehensive Cancer Center as specified in the NOA.
- Acceptance of funds implies a firm commitment to provide the Massey leaders access to meet the team, give talks to the public, and tours of your facilities. Access to your laboratory will be facilitated by Massey Administration.

Review Process

Applications will be evaluated and scored according to:

- Scientific merit using NIH guidelines for scoring. Please note that the Massey review is run similar to an NIH study section and while its score drivers are similar, there is an important distinction: the Massey exists to support projects that need vital data to become competitive for an R01 or similar award. For this reason, an IMPORTANT score driver in the Massey review is the potential for future funding. It is the PI's job to lay out how the Massey funds will ensure a competitive future application. One page is dedicated to this purpose and that page is carefully evaluated during the Study Section meeting and by Massey Senior Leadership when making funding decisions.
- Potential for achieving high-impact results on an accelerated timeline when compared to the traditional pace of cancer research.
- Alignment with Massey priorities outlined in each year's NOFO.

Questions

Questions can be addressed to **Alex Haynes, Manager of Membership and Research Data Analyst**, at haynesa4@vcu.edu or 305-915-4200.