

# Innovation Pilot Awards Notice of Funding Opportunity (NOFO) – 2024

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.

## A. 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.

# B. Massey Comprehensive Cancer Center Priorities

- For 2024, Massey is placing a high priority on applications addressing health disparities within tobacco-related cancers (e.g., lung, head and neck, all GI, cervix, bladder, kidney, and AML); applications may include basic, translational, clinical, or population health approaches but should be translational in nature.
- 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.

# C. 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.

# D. 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.
- Projects are expected to be completed within the specific budget period. No cost extensions will only be granted in highly exceptional circumstances. 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.
- Projects must have compliance approvals (e.g., IRB, IACUC) in place within 90 days of receipt of the Notice of Award or funding may be rescinded. The official start date of the award and the release of funding will begin once the compliance approvals have been submitted.

# E. 2024 Innovation Pilot Opportunities

## INNOVATION PILOTS (One project per Massey research program will be selected)

## 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.

# F. 2024 Innovation Pilot Deadlines



NOFO release:	02/23/2024
Letter of Intent due by 5:00 pm EST:	3/15/2024
Selected applicants invited to submit full application:	3/25/2024
Full applications due by 5:00 pm EST:	4/29/2024
Earliest start date:	6/1/2024

# G. Submission Guidelines

## Pre-submission Guidelines for INNOVATION Pilots:

Submission of the Letter of Intent (LOI) form is required. Innovation LOIs are due by 5:00pm EST on (03/15/2024). The LOIs will be reviewed by Massey Senior Leadership or designated reviewers and select individuals will be invited to submit a full application by (04/29/2024). No feedback will be provided on the LOIs.

## Formatting:

• Use Arial 11pt. font for text and half inch margins.

## **Required Application Components:**

- 1. Massey Comprehensive Cancer Center Cover Sheet
- 2. **Project Summary** (limit to 30 lines)

## 3. Budget Form {Download from website}

- Facilities and Administrative (F&A)/Indirect Costs: These are not allowed.
- 4. NIH Biosketch for Principal Investigator(s) and all key personnel
- 5. Letter(s) of Support
  - **Innovation:** May include letters from supporting shared resources, mentors, collaborators, co-investors, etc. as appropriate for the application
- 6. Budget Pages (PHS 398 Form Page 4 and 5)
  - A detailed budget justification is required (See allowable/unallowable expenses below)
  - Applications involving a collaboration with a partner institution must complete budgets from each institution and they must be comparable.

## 7. Specific Aims and Research Strategy

- Specific Aims (1-page maximum)
  - State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that results from the proposed research will exert on teresearch field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
- Research Strategy: <u>6 pages maximum</u>

Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.

## A. Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

## B. Innovation

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

## C. Approach

- 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.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- 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.
- 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 <u>wagesn@vcu.edu</u> to schedule a consultation.

 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 <u>https://redcap.vcu.edu/surveys/?s=JW8EWLM8LTTKWKER</u> 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.

## 8. **Bibliography and References Cited**

- 9. 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.

## 10. Plans for 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. <u>This section is an important criterion for award selection.</u>

## 11. Massey Shared Resource Utilization (1-page maximum)

• Describe MCC 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

- 1. Bioinformatics
- 2. Biostatistics
- 3. Cancer Mouse Models
- 4. Flow Cytometry
- 5. Health Communication and Digital Information
- 6. Microscopy
- 7. Proteomics
- 8. Tissue and Data Acquisition and Analysis
- 9. Transgenic/Knockout Mouse
- 10. Lipidomics / Metabolomics
- 11. Heath Equity and Disparities Research

## 12. Compliance Document(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.

## **Budget Guidelines:**

Expenditures Allowed:

- 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

## Expenditures NOT Allowed:

- 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

# H. Terms of the 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 NOA and subsequently, an annual update for a five-year follow-up period. Awardees who do not reply to five-year follow up requests will jeopardize future Massey awards.
- Massey expects that the grantee will completely utilize the full amount of funding during the term of the award. No-cost extensions are highly discouraged and will only be considered under exceptional circumstances. All unspent funds at the end of the grant period will be returned to the Massey.
- All awards must have appropriate institutional compliance approvals (e.g., IRB, IACUC) within 90 days of receipt of the Notice of Awardand before funds will be allocated. The award will not receive a start date until the institutional approvals have been given. No aspect of the project can begin (including non-human subject research components) without documentation of all required approvals.

- Projects must start within 90 days of receipt of the Notice of Award or funding may be rescinded.
- 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.

# J. Questions

## For any questions, please contact:

Alex Haynes Manager for Membership and CCSG Data Analytics, Massey Comprehensive Cancer Center Email: <u>haynesa4@vcu.edu</u>