



Molecules to Medicines: Novel Agents Pilot Funding Award (Biologics)

Funding Opportunity Announcement

Funding Opportunity Purpose

The intent of this award is to promote cancer research collaborations between a basic researcher and an investigator focused on translational research in the areas of cancer biology, cancer immunology, or cancer immunotherapy with the goal of developing biological agents to treat cancer. The focus should be on 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, or other approaches with translational potential. The application requires a multi-principal investigator (MPI) collaboration with both basic and translational researchers serving as PIs. The focus of the award must be on:

- Designing novel biologics using the knowledge gained from cancer biology and immunology
- Establishing and optimizing the biological processes for preparing or purifying biologic agents
- Investigating the mechanism by which tumor-targeting biologics affect proliferation, survival, invasion, and other hallmarks of cancer in cell culture or patient-derived organoids
- Studying the mechanism of action of biologics (eg, immunotherapeutic agents) using established experimental culture systems
- Validating antitumor activity as demonstrated in efficacy studies using relevant animal models such as patient-derived xenografts, transplantation, or transgenic cancer models

IND-guided advanced preclinical studies are not supported through this award mechanism and should not be included in the proposal.

Key Dates

FOA Release:	July 7, 2023
LOI Due Date:	July 28, 2023
Selected applicants invited to submit full application:	August 11, 2023
Full Applications Due Date:	September 8, 2023
Earliest Start Date:	October 1, 2023

Anticipated Number of Awards

It is anticipated that 1 award will be made.

Award Budget and Project Period

Projects will be funded at up to \$100,000 and are limited to a 1-year period.

Eligibility

The project must be submitted as an MPI project with at least 2 PIs, each of whom makes a substantial contribution to the research. Each PI must be a full-time VCU faculty member, and at least one of the PIs must be a Massey Cancer Center member. The PIs must have the necessary training and expertise to conduct and supervise the proposed research. 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.

Pre-submission Guideline for the Novel Agents Pilot Funding Award

Submission of the Letter of Intent (LOI) form is required. Novel Agents LOIs are due by 5:00pm EST on (7/28/2023). The LOIs will be reviewed by the M2M steering committee and selected applicants will be invited to submit a full application by (8/11/2023). No feedback will be provided on the LOIs.

Application Components

Formatting: Use a standard 8 ½ x 11-inch page with at least ½-inch margins on all sides. Fonts (Arial is recommended) must be 11 points or larger with a type density of no more than 15 characters (spaces included) per inch and line spacing of no more than 6 lines per inch.

The application components, in the following order, should be submitted as a single PDF file.

Cover Page (use provided template): The provided cover page template, including MPI and co-investigator contact information, project title, and lay abstract, should be completed.

Research Plan (3-page limit excluding references): The research plan should be divided into 4 sections: (1) Specific Aims, (2) Research Strategy, (3) MPI Justification, and (4) Future Plans.

The Specific Aims section should list the broad, long-term objectives of the proposed project (eg, to test a hypothesis, create a novel design, solves a specific problem, address a critical barrier to progress in the field,). The individual specific aims should be stated along with a summary of the expected outcomes and the impact the results of the research will have on the research field involved.

The Research Strategy should address the significance, innovation, and approach for each specific aim individually or for all of the specific aims collectively. The significance discussion should explain the importance of the problem, describe the strengths and weakness of prior research in the area, and explain how the proposed project will advance scientific knowledge or technical capability. The innovation discussion should explain how the research challenges or shifts current research paradigms; describe any novel theoretical concepts, approaches or methodologies to be developed or used, and any advantage over existing methodologies, or interventions; and explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, or interventions. The approach discussion should describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims. The experimental design and methods should be discussed. As appropriate, potential problems and alternative strategies to overcome them should be addressed.

The MPI Justification section should briefly discuss the expertise that each PI brings to the application.

The Future Plans section should briefly discuss as appropriate plans for publication, applying for extramural support including NCI NEXT support, and next steps for IND application development.

A Reference List section should be included at the end of the Research Plan, but the references are not included in the 3-page limit for the Research Plan.

Budget (PHS 398 Form Page 4): Provide a budget and budget justification in accordance with the allowable and non-allowable expenses as indicated below.

Biographical Sketch (PHS 398 format): Include biographical sketches for all key personnel (PI and co-investigators).

Other Support (PHS 398 format): Include other support for all key personnel (PI and co-investigators).

Optional Letters of Support: Include letters of support as needed (eg, collaborators, shared resource support, reagent or animal model sharing).

*PHS 398 forms and samples can be found at <http://grants1.nih.gov/grants/funding/phs398/phs398.html>.

Allowable and Unallowable Expenses

Allowable expenses:

- Research and laboratory supplies
- Shared resource charges
- Technical or laboratory staff salaries (including fringe benefits)
- Stipends (including fringe benefits where applicable)
- Animal costs
- Patient care costs and stipends
- Research-related contractual agreements
- Software (prior approval required)
- Publication costs

Non-allowable expenses:

- Faculty salaries
- Equipment (including computers)
- Equipment maintenance and service contracts
- Secretarial and administrative salaries
- Graduate and undergraduate student tuition and student fees
- Textbooks, coursebooks, and periodicals (including subscription fees)
- Membership dues
- Rental of office or laboratory space
- Recruiting and relocation expenses
- Construction, renovation, or maintenance of buildings or laboratories
- Routine printing costs
- Food costs associated with meetings or conferences held by the investigative team
- Conference registration fees and travel costs

Review Criteria

Applications will undergo NIH-style peer review and will be scored using the following criteria.

- Cancer relevance
- Significance
- Investigator(s) and Multi-PI justification
- Innovation
- Approach
- Environment

Award Conditions

- Awardees are responsible for obtaining any required regulatory approvals from the Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), Institutional Review Board (IRB), Laboratory Safety Committee (LSC), Radiation Safety Committee, other regulatory body as required.
- An award is made for a one-year period as designated in the issued notice-of-award letter. Unexpended funds may not be used beyond the award period unless a no-costs extension (NCE) has been requested at least 30 days prior to the project end-date and the NCE is approved. If an NCE is approved, a revised notice-of-award letter will be issued, which will specify the additional project period and any further restrictions or requirements. Expenses incurred outside of the approved project period are the responsibility of the PI.
- Awarded funds are to be used in accordance with the budget submitted in the application. Awardees must obtain prior approval for any changes in the budget.
- The award will be administered through MCC.

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- The pilot award funding index will not be released until the awardee provides an alternate index (2-ledger or 6-ledger index) to which over-expenditures on the funding index can be charged.
 - A progress report is required 30 days after the end of the project period.
 - Awardees agree to providing periodic updates (eg, resulting publications, extramural awards, patents) for up to 5 years following the completion of the project.
 - Awardees agree to meet with the donor to discuss the research project.
 - If requested by MCC leadership, the PI of the award is expected to assist in the review of future grant applications.
 - It is expected that data generated from basic research projects supported by this award will lead to the submission of grant applications to national funding agencies or foundations.
 - All publications and presentations that arise from work conducted under this award must acknowledge the support of the VCU Massey Cancer Center.

Submission Instructions

The complete application as a single PDF file should be emailed to Alex Haynes haynesa4@vcu.edu with "M2M Novel Agents Pilot Funding Award" in the subject line. All submissions will be acknowledged within 48 hours of receipt. If acknowledge is not received within that time frame, please email **BOTH** Alex Haynes and Anita Harrison at harrisona7@vcu.edu to confirm receipt of the application.

Application Questions

Please direct any questions to Alex Haynes at haynesa4@vcu.edu or 305-915-4200.