To: Members  
Virginia Commonwealth University  
Massey Cancer Center  

From: Robert Winn, MD, Director  
Harry D. Bear, MD, PhD, Interim Associate Director for Clinical Research  
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Date: January 4, 2021  

Subject: Request for Proposals for Translational Clinical Trial Concepts  

The Massey Cancer Center will provide support for development of innovative early phase clinical trials based on laboratory discoveries of MCC Scientific Program investigators. After initial approval by a Massey leadership group (the Clinical Trials Concept Review Committee), assistance will be available for development of the protocol. Following DWG, PRMC and IRB review and approval, Massey Cancer Center will also provide support for the conduct, analysis and reporting of the trial. All Massey members are eligible to apply for MCC support by developing and submitting translational concepts for review by the Clinical Trials Concept Review Committee. If you are not a member of the Massey Cancer Center, you may apply by going to the following link:  
https://www.massey.vcu.edu/research/members/application/  

Initial review of concepts by the CTCRC will consist of basic science review, clinical science and scientific feasibility review, and biostatistical review. Submitted concepts will be given either preliminary approval status or disapproval. Investigators receiving preliminary concept approval will be provided with support of a MCC Scientific Writer and other Clinical Trial Office staff to assist with development of an advanced protocol draft and budget for submission to potential external sponsors to obtain drug supply and identify possible funding support. Once drug supply and the level of external support have been identified, the protocol draft and the proposed budget will undergo a second review by the CTCRC to obtain final approval for final protocol development, submission to the DWG, PRMC and IRB, followed by trial activation and conduct.  

MCC is soliciting submissions of proposed concepts for translational trials, which are due on the following dates:  

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<th>Concept submissions due no later than</th>
<th>CTCRC review date</th>
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<tr>
<td>March 26, 2021</td>
<td>April 27, 2021</td>
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<td>September 24, 2021</td>
<td>October 26, 2021</td>
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Concepts should be submitted using the Translational Clinical Trial Concept Submission Form (see link below). Published manuscripts related to the science should be cited and a link provided to facilitate the review process. Accepted manuscripts related to the basic science behind the clinical trial concept that are in press or submitted for review should be provided as pdf attachments. Other relevant unpublished supporting data may be included in an Appendix, up to 3 pages in length. Important components of applications include:

- The research providing the scientific rationale and hypothesis for the concept should be sufficiently mature to support testing the hypothesis in the clinic. If additional preclinical work is required, consider submitting the preclinical project under the MCC Pilot Project program. Visit the MCC website for next funding cycle.
- A biostatistician must be involved in the concept design and named as a sub-investigator on the concept.
- Strong preference will be given to concepts backed by data published in peer-reviewed journals.
- Trials that address secondary outcomes that could interface with cancer prevention and control studies are encouraged.
- The proposed trial's potential impact on the Cancer Center catchment area and cancer disparities should be addressed in the proposal.

Ranking will be based on novelty, scientific merit, feasibility, the value of the trial to the cancer clinical research priorities of the Massey Cancer Center, and the projected time to trial activation. Collaborations between clinical investigators and basic laboratory researchers and/or investigators in social and behavioral health and other cancer control research are strongly encouraged.

Interested members should submit a completed Translational Clinical Trial Concept Submission Form to Julia Godek at jlgodek@vcu.edu. The Announcement and Submission Form are available on the MCC website at http://massey.vcu.edu/research/funding/clinical-trial-concept-program/