To: Members and Associate Members  
Virginia Commonwealth University  
Massey Cancer Center

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Date: September 16, 2016

Subject: Call for Clinical Trial Concepts

While Translational Trial Concepts bringing Massey discoveries into the clinic receive the highest priority for activation, Massey leadership recognizes the importance of also supporting Clinical Trial concepts developed by our clinical investigators for career development and maintaining a robust IIT portfolio. Historically clinical trial concepts have been developed and submitted to potential sponsors without a structured review process. While this approach has been successful in developing trials, the process has been inefficient and challenging to manage from a resource utilization perspective.

To address these problems, Massey leadership is implementing a system for review of proposed Clinical Trial concepts by the Clinical Trial Concept Review Committee that currently reviews Translational Trial concepts. The criteria for review will be similar, but will not require the scientific basis for the trial to have been developed by Massey investigators. Concepts will initially be reviewed by the AD for Clinical Research to help investigators with development of a competitive concept prior to review by the CTCRC.

Approved concepts receive support of the MCC Scientific Writers and other Clinical Trial Office support to develop an approved concept into a preliminary protocol and budget for submission to external sponsors for drug supply and partial funding. Once drug supply and external support level have been identified, the preliminary concept and the proposed budget will undergo a second CTCRC review for final approval for full protocol development required for submission to PRMC. Protocols approved by PRMC for activation will receive the CTO support specified in the approved budget for conduct, analysis and reporting of the trial.

We are now soliciting submissions of proposed concepts for clinical trials, which are to be submitted no later than October 14, 2016 for review at the October 25th meeting of the CTCRC.
Clinical Trial Concepts
09/16/2016

- Strong scientific rationale for the study with peer reviewed references must be provided.
- Basic design with primary and secondary aims, endpoints and sample size in consultation with the Massey Biostatistical Core will be essential for review
- Trials that address non-traditional outcomes that interface with cancer prevention and control studies are encouraged.
- The proposed trial’s potential impact on the Cancer Center catchment area and cancer disparities must be addressed in the proposal.
- Concepts should be submitted using the Clinical Trial Concept Submission Form.
- Investigational products for these trials must be billable as routine care of provided by a sponsor for a trial to proceed. Preliminary approval can be obtained with drug supply commitment to obtain support for development of a formal LOI with preliminary budget if needed, but final approval will be contingent on drug supply.
- Funding for proposed correlative studies will need to be identified at time of submission for final approval. If Massey funds are requested, a budget should be included.

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 proximity to trial initiation. Collaborations between clinical investigators with basic laboratory and investigators in social and behavioral health and other cancer control research are strongly encouraged.

Clinical investigators are encouraged to continue interacting with contacts within the pharmaceutical industry in the early phases of concept development independently of this mechanism, as well as with their colleagues in the Multi-disciplinary conferences and Disease Focus Groups. When a point is reached that Massey resources are required for further development the concept should be submitted for review at that time. This is a new initiative and we welcome feedback and input on evolving the program so it is supportive and beneficial to investigators and

Interested members should submit a completed Clinical Trial Concept Submission Form to Martha Wellons at mwellons@vcu.edu by October 14, 2016 if the desire review on October 25th. The CTCRC will begin meeting quarterly and concepts can be submitted for review up to 4 weeks before a schedule meeting. The CTCRC meeting schedule, the Announcement and Submission Form are available on the MCC website at https://www.massey.vcu.edu/research/funding/mcc-clinical-trial-concept-program/