

**MASSEY CANCER CENTER**  
**Protocol Review and Monitoring Committee**  
**Protocol Submission Form**

**DIRECTIONS**

**1. Title of protocol:** Enter the full title of the protocol.

**2. Principal Investigator:** Enter the name of the Principal Investigator at Virginia Commonwealth University. Do not list the national or coordinating chair if they are not a Massey principal investigator.

**3. Study Contact:** List the individual who will be the point of contact for the study. Make sure to list a VCU employee, not the national or coordinating study contact. This individual will be contacted, in addition to the principal investigator, about all issues regarding the study. If no study contact is named, enter the principal investigator's name in this space. Please update [MasseyPRMS@vcu.edu](mailto:MasseyPRMS@vcu.edu) if a study site contact is hired and the principal investigator is no longer the study site contact.

**4. Sub-Investigator(s):** List all other researchers or clinicians interested in participating in the study. Be mindful that VCUHS Investigational Pharmacy will not fill prescriptions written by clinicians who are not on the study team.

**5. Biostatistician:** Please list the VCU/Massey affiliated biostatistician who is involved in the study design and data analysis. When listing a biostatistician as a member of a study team, please be sure to provide documentation that biostatistician has reviewed and approved the protocol as submitted to PRMC (acceptable documentation includes e-mail confirmation from the biostatistician). The Massey Cancer Center requires biostatistical input in the protocol design for all interventional clinical trials.

**6. Student project:** Student projects may require more careful review of the study design by reviewers.

**7. Do you already have external funding for this study?**

This question is being asked for two reasons: to determine the funding source and to determine the type of review required.

Funding Sources: This information must be reported to the National Cancer Institute (NCI) for all studies. If your funding is received subsequently, as in a "Just In Time" (JIT) grant approval situation, please notify [masseyprms@vcu.edu](mailto:masseyprms@vcu.edu). This could include money from NCI, an NCI Cooperative Group, a SPOR, a non-profit group, pharmaceutical company, biotechnology company, etc. Please indicate if the cost of the study is being split between two different sponsors.

Review Type: NCI Cooperative Group studies and externally peer reviewed studies (those that have already been scientifically peer reviewed by another organization) do not require full scientific review by the PRMC. The funding source will determine the extent of the review. Studies that have already been NCI or otherwise externally scientifically peer reviewed and approved receive an abbreviated review for patient recruitment competition with other open studies at VCU. A list of externally peer reviewed funding agencies can be found here: <http://cancercenters.cancer.gov/documents/fundorg.pdf>

**Are you seeking outside funding for this study?** Please indicate if the study is being submitted for "Just In Time" (JIT) funding, or if a funding application is pending.

**8. Is your study a retrospective chart review?** Retrospective Chart Reviews look at previously collected data, typically patient medical charts, to make connections and find common themes.

There is no need to answer questions 9 - 16 for studies involving secondary data analysis or retrospective chart reviews. If you are unsure of the designation of your study, please contact [masseyprms@vcu.edu](mailto:masseyprms@vcu.edu) for further clarification.

**9. Are you using TDAAC (Tissue and Data Acquisition and Analysis Core)?** TDAAC provides support for biomedical research by providing a bank of high quality human tissue samples and specialized processing abilities. TDAAC does its own scientific review of studies using its resources. In this instance, PRMC defers its scientific review to TDAAC, and upon TDAAC approval, the PRMC will review to ensure

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that the study does not conflict with existing studies.

**10. Where will the study be conducted?** This information is helpful to Massey Cancer Center's Regulatory Coordinators when they are facilitating regulatory submissions.

**11. For studies involving subject recruitment, how many patients are seen annually who meet the eligibility criteria?** This question is asking how many patients are seen at VCU HS who would be eligible to enroll in this study. Please note that the PRMC will make an independent assessment to determine if there are adequate subjects available to complete the study.

This data will be obtained from the Cancer Research Informatics and Services (CRIS) Core. For more information, visit: <http://www.massey.vcu.edu/cancer-research-informatics-and-service-core.htm>.

If the study is being conducted in the community, please approximate the number of people who would be eligible to participate.

**What is the expected enrollment duration?** List how long the study will be actively recruiting patients, or approximately how long the study will take to reach completion. Massey's expectation is that most studies will complete in 2 years.

**What is the expected annual local enrollment?** Enter the number of participants you hope to enroll on the study, keeping in mind the amount of patients who meet the eligibility criteria. Please also note that the PRMC monitors patient recruitment to interventional trials and expects all studies to accrue at least two subjects per year.

**12. Who will provide overall data and safety monitoring?** All clinical trials must have a data and safety monitoring plan. There are three different kinds of data monitoring plans. For most non-therapeutic/intervention studies, the investigator and study team have a data safety monitoring plan detailing their plan to review study data and recruitment for safety. Please see the NCI explanation here: [http://grants.nih.gov/grants/policy/hs/faqs\\_aps\\_dsm.htm](http://grants.nih.gov/grants/policy/hs/faqs_aps_dsm.htm). For examples of DSM Plans, visit: [http://grants.nih.gov/grants/policy/hs/data\\_safety.htm](http://grants.nih.gov/grants/policy/hs/data_safety.htm). For Massey investigator initiated studies that are greater than minimal risk to subjects, Massey has a Data Safety and Monitoring Board (DSMB) independent of the Principal Investigator and study team that monitors study safety. Lastly, most industry studies, NCI Cooperative Group studies, and some multi-center studies have an external data monitoring committee that performs its own review of data and safety outside Massey Cancer Center. If the latter applies, the plan must be submitted to PRMC for review (exception being NCI Cooperative Groups).

**13. Is this a multi-center trial?** This question is applicable to investigator initiated studies coordinated by the Massey Cancer Center or multi-institutional studies coordinated by a consortium of cancer centers.

**14. What other studies compete for a similar group of patients?** Massey is tasked with ensuring that trials complete accrual goals. Therefore, ongoing or planned trials that compete with the submitted study must be assessed to determine if there are sufficient numbers of potential subjects to complete the study.

**15. If you listed competing studies above, please provide a rationale for opening your study.** If there are studies that compete with the one you are submitting, please indicate why you feel it is still important to open this study. Common rationales include different study objectives, patients approached at different stages during treatment course, and recruitment done in community not in Massey clinic, etc. If the disease population is large enough to accommodate multiple studies enrolling simultaneously, the PRMC may still approve the study to open. It is helpful to provide your plan to manage enrollment of patients to specific studies for the same population. Do note that the PRMC looks at the Massey disease menu and identifies competing studies if they are not listed on this form. The complete list of Massey clinical trials can be found here: <http://www.massey.vcu.edu/find-a-clinical-trial.htm>.

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**16. When are you expecting to approach patients to participate in this study?** Please indicate when you plan to approach the patient about participating in the study. For example, this may be during a patient's course of treatment (pre or post surgery, before hormonal therapy, etc.), post therapy, during remission, or at relapse. The PRMC recognizes that multiple studies can be open for the same patient population if studies are targeting different stages in the patient's cancer treatment timeline.

**Where will you be approaching patients?** Please list where you will be discussing the trial and actively recruiting patients. This could be in the Dalton clinic, in the Bone Marrow Transplant Clinic, out in the community, different states, etc. This information helps the PRMC decide if this study competes with other open studies for the same patient population. Regarding recruitment of Massey patients: if a physician is not a member of the protocol staff, the investigator must provide documentation that he/she has discussed and received agreement to refer patients. Some evidence of this support is required. If you do not have a letter or an e-mail of support, your application will not move forward.

**Additional information:**

To ensure that advertisements or publicity about the trial best represent the mission of the Massey Cancer Center and the university, you may find it helpful to have someone from the Massey Public Relations and Communications Office review the materials. This should be done prior to your submission to the IRB to avoid having to resubmit materials after changes have been suggested by the Public Relations office. For assistance with such materials, please contact Jenny Owen ([jrowen2@vcu.edu](mailto:jrowen2@vcu.edu)), Director of Public Relations and Communications. (Please note that you should allow at least two weeks for review and approval of flyers, advertisements, or public service announcements.)

**If you have additional questions or need assistance with your submission, please contact [masseyprms@vcu.edu](mailto:masseyprms@vcu.edu).**