

MASSEY CANCER CENTER
Protocol Review and Monitoring Committee
Protocol Submission Form

Please read the directions section before completing the form.

As a reminder, all investigators and sub-investigators listed on this form must have current CITI Training. Visit www.citiprogram.org for certification. Submit Completion reports to masseyprms@vcu.edu

1. Title of the Protocol:
2. Principal Investigator Name: E-mail:
3. Study Contact Name: E-mail:
4. Sub-Investigator(s) Name(s): E-mail(s):
5. Biostatistician – Required for investigator initiated clinical trials Name: E-mail:
6. Is this a study for a dissertation or student project? <input type="checkbox"/> Yes. <input type="checkbox"/> No.
7. Do you already have funding for this study? <input type="checkbox"/> Yes. If Yes, indicate source: <input type="checkbox"/> No. Are you seeking outside funding for this study? <input type="checkbox"/> Yes. If Yes, indicate source: <input type="checkbox"/> No.

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8. Is your study a retrospective chart review? (If so, please disregard sections 9 – 16)

Yes No

9. Is your study using TDAAC services (Tissue Data Acquisition and Analysis Core)?

Yes.
 No.

If Yes, disregard section 10.

10. Where will the study be conducted?

- VCU Health System
- Community Memorial Healthcenter
- Hematology-Oncology Associates of Fredericksburg
- Henrico Doctors Hospital
- Lynchburg Hematology-Oncology Clinic
- Mary Washington Hospital
- McGuire VAMC
- Riverside Medical Center
- Shenandoah Oncology, PC
- Virginia Cancer Institute
- Virginia Gynecologic Oncology
- Other _____

11. For studies involving subject recruitment, how many subjects are seen annually who meet the eligibility criteria? (If unsure, contact masseyprms@vcu.edu for this information.)

What is the expected enrollment duration?

What is the expected local enrollment?

12. Who will provide overall data and safety monitoring?

Investigator Massey DSMB External

13. Is this a multi-center trial?

Yes.
 No.

If Yes, is this a multi-center study being coordinated by VCU? Yes. No.

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14. What other VCU studies compete for a similar group of subjects? (For a complete list, visit <http://www.massey.vcu.edu/patient-care/clinical-trials/>.)

15. If you listed competing studies above, please provide a rationale for opening your study.

16. When are you expecting to approach subjects to participate in this study? (e.g. during the course of their treatment, after treatment, etc.)

Where will you be approaching subjects?

For Cancer Prevention and Control studies, have you included documentation of physician support for this study? (e.g. an e-mail or a signed letter from a physician confirming support)

- Yes.
 No.

**Please submit this form with a copy of the protocol and consent to
masseyprms@vcu.edu.**