THE University of Vermont CANCER CENTER

Protocol Review and Monitoring Committee (PRMC)

Quarterly Report Form

This form must be completed quarterly for all cancer protocols. Reports are due on the dates below for the following quarter periods. Check the three-month period* covered by this form:

☐ January 1 to March 31, *due April 15th*
☐ April 1 to June 30, *due July 15th*
☐ July 1 to September 30, *due October 15th*
☐ October 1 to December 31, *due January 15th*

*Note: If this is a first-time submission for a new protocol, the time period may be less than 3 months.

Protocol Information:

Protocol #: _____ CHRMS #: _____ Local PI: _____

Title: _____

Protocol on Commons (only applicable to for studies managed by the UVMCC CTO):

Open the UVMCC CTO Commons Study List, https://commons.med.uvm.edu/cp/uvmcc/cto/Lists/StudyList/OverallAccrual.aspx and open the link for the protocol document. Indicate below that this protocol document is up to date:

◯ Yes, the protocol linked is the most recently approved version. It is version #: _____ Version Date: _____

◯ No, it is not the most recently approved version. I have attached the recent version (# _____, dated _____)

Accrual Information:

Projected Local Accrual Targets for this protocol: Total Goal: _____ Annual Goal: _____

National Accrual Information: National Total Goal: _____ National Accrual To-Date: _____

LOCAL ACCRUAL	Total Number to Date (from date open through end of this reporting quarter)	Number in this Quarter (since last report)
Number of Patients Screened		
Number of Screen Fails		
Number of Subjects Accrued		
Number of Subjects Withdrawn		

See the last page for definitions of screened, screen fail, enrolled, and withdrawn.

Type of cancer:
List the cancer type and number of patients in this quarter that enrolled with that cancer type, for example: Lung, 2 patients; Breast, 3 patients. Choose the cancer type from the list on the third page of this form.

Type(s) of cancer these new patients have: _____

Demographics of Accrued Patients in this Quarter:

Make sure the total for each Category (i.e. Gender is one category) is the same *and* matches the Number of Subjects Accrued reported above.

Demo-graphic Category	Gender		Ethnicity			Race					
	Male	Female	Hispanic or Latino	Non-Hispanic or Latino	Unknown	White	African American	American Indian/ Alaskan Native	Asian	Hawaiian /Pacific Islander	Unknown/ Two Races/ Other
Number of Patients in this Quarter:											

Please email this form to Emily Harwood (emily.harwood@med.uvm.edu) at the UVM Cancer Center.

Additional Information: *(These next five questions are for Investigator-initiated studies only. Skip to bottom if NCTN or Industry study.)*

1. Is Outcome Data Available (for example, an interim analysis)? ◯ Yes ◯ No

   Please comment

2. If the protocol has sequential design (i.e. Phase I or II studies), was a decision point reached during this time period?

   ◯ Yes ◯ No

   If yes, please explain the situation:

3. Has any change/amendment been made in the protocol or consent during this time period?

   ◯ Yes ◯ No

   If yes, briefly explain change(s):

   If applicable, where these changes reviewed and approved by the IRB? ☐ Yes ☐ No

4. Have there been any serious adverse events during this time period? ◯ Yes ◯ No

   If yes, how many serious adverse events occurred?

   Please summarize the serious adverse events

5. Have there been any protocol deviations during this time period? ◯ Yes ◯ No

   If yes, how many protocol deviations occurred?

   Please summarize the protocol deviations

If the protocol is complete, please provide a lay summary, final study findings, future plans, and publications in preparation within 30 days by using the Final Study Report. Reprints and/or citations of all publications resulting from this study should be submitted when available. The Final Study Report form is found on the UVM Cancer Center website at the bottom under "Other Required Forms": http://www.med.uvm.edu/uvmcancercenter/members/protocol-review

Quarterly Report Completed:

Contact Person (coordinator): _____ Date completed: _____

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Primary Site Of Cancer
Anus
Bones and Joints
Brain & Nervous System
Breast
Cervix
Colon
Corpus Uteri (uterus)
Esophagus
Eye and Orbit
Hodgkin Lymphoma
Kaposi's Sarcoma
Kidney
Larynx
Leukemia: Lymphoid Leukemia
Leukemia: Myeloid and Monocytic Leukemia
Leukemia: other
Lip, Oral Cavity and Pharynx
Liver
Lung: other than NSCLC
Lung: Non-small cell lung cancer (NSCLC)
Melanoma, skin
Multiple Myeloma
Mycosis Fungoides
Non-Hodgkin Lymphoma
Other Digestive Organ
Other Endocrine System
Other Female Genital
Other Hematopoietic
Other Male Genital
Other Respiratory Intrathoracic Organs
Other skin
Other Urinary
Ovary
Pancreas
Prostate
Rectum
Small Intestine
Soft Tissue
Stomach
Thyroid
Urinary Bladder

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Definitions of terms:

Accrual. The number of subjects who have already enrolled (signed consent) and have started a study for treatment, or will be starting treatment, or completed treatment, or are actively in the process of completing a study at UVM Medical Center (UVMMC). This number does include dropouts or withdrawals, however this does not include screen failures.

Enrollment. Occurs when an eligible, informed, prospective subject undergoes the initial informed consent process and voluntarily agrees to participate in a research project at UVMMC or an affiliate. Some studies enroll a patient for screening purposes and then a patient screen-fails and that patient will not count towards accrual. Example: You enroll 100 to accrue 25.

Final report. A report that the principal investigator may elect to submit to the PRMC to serve as a final record of any pertinent activity since the last Quarterly Report and to record research project completion. The Final Report Form template is on the UVM Cancer Center Protocol Review website at the bottom of the page: http://www.med.uvm.edu/uvmcancercenter/members/protocol-review

Screening. For the purposes of this form, please consider the patients screened as those that are identified as potential participants regardless of whether they signed consent.
The screening process for eligible patients differs between studies. Some studies require screening tests to assess if prospective subjects are candidates for inclusion in studies. An investigator may discuss availability of studies with a prospective subject without first obtaining consent, however informed consent must be obtained before starting any clinical procedure that would be performed only for the purpose of determining eligibility for research, including withdrawal from medication. In those cases, screening assessments are done after the informed consent is obtained. Some studies refer to procedures that are performed as part of the patient's regular care. Such procedures are done whether or not study entry was considered, such as for diagnosis or treatment of a disease or medical condition. The results may be screened and used for determining study eligibility without first obtaining consent.
For more guidance regarding the definitions of screening, please see the FDA Information Sheet for Screening Tests Prior to Study Enrollment: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm

Screen failures. Subjects who consented to participate in research but who were disqualified during screening procedures. Screen failures signed the consent form and may have had screening procedures but did not undergo any other study procedure. Reasons for the participant to fail screening may include, but are not limited to, the participant not meeting inclusion criteria or meeting exclusion criteria (ineligibility).

Withdrawals. Subjects who signed the consent form, but later withdrew from the study, either before or after receiving a study drug, device or intervention. This does not include screen failures. Withdrawal indicates the patient stopped the study before completing the full schedule of study visits (including follow-up), or the patient transferred to another site not affiliated with UVMMC. Some protocols may have a variable number of visits and consider participants as completing, rather than withdrawing, in the case of disease progression or similar clinical outcome. In such cases, the protocol definition should be followed, with the withdrawal category reserved for participants who withdrew for other reasons.

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