

Quarterly Report Form

This form must be completed quarterly for all cancer protocols. Reports are due to the UVMCC Compliance Specialist 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*

July 1 to September 30, *due October 15th*

April 1 to June 30, *due July 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 studies managed by the UVMCC Clinical Trials Office):

Open the UVMCC Commons Study List, <https://commons.med.uvm.edu/cp/uvmmc/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 local version. It is version #: _____ Version Date: _____

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

Accrual Information:

The UVMCC Protocol Review and Monitoring Committee (PRMC) monitors accrual progress of all cancer protocols. The PRMC has the authority to close studies that are not meeting 33% of their Annual Goal for accrual.

Definition of Accrual: Accrual is the total number of participants enrolled in the clinical trial. Enrolled means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process and final determination of eligibility has been made. Potential participants who sign consent and are screened for the purpose of determining eligibility for the study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.

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 <u>this</u> reporting quarter)	Number in this Quarter
Number of Subjects Accrued		

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:

The total for each Category (i.e. Gender is one category) must be the same and match "Number in this Quarter" above.

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

Protocol closed?

Did this study close-to-accrual during this reporting period or after? Yes No

If yes, provide the date this study closed-to-accrual at our site:

Additional comments regarding any data reported:

Note:

If this is an Investigator-Initiated Study, the Data and Safety Monitoring Committee (DSMC) also reviews your data.

If this is an Investigator-Initiated Study and you have been notified that your Data Safety and Monitoring Report is due for the next DSMC meeting, please attach the completed DSM Report (which asks for cumulative data, not just quarterly data) to this Quarterly Report Form.

Quarterly Report Completed:

Contact Person (coordinator):

Date completed:

Primary Site Of Cancer	Notes on Accrual for this Quarter
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	

Please email this form to UVMCC Compliance Specialist, Emily Harwood (emily.harwood@med.uvm.edu).