

June 2017 Enrolling Physicians for May 2017

Community Oncology

Research Program

A program of the National Cancer Institute of the National Institutes of Health



Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Tissue Procurement	Cancer Care Delivery Res.
Dr. Ali (Mercy Rolla)			0.3125	0.3125		
Dr. Bandi (Mercy St. Louis)	PALLAS					
Dr. Bonebrake (Cox)					2	
Dr. Bumberry (Mercy Spfld)					2	
Dr. Carlson (Mercy Spfld)	GOG-3005	0.3875	0.03125	0.41875		1
Dr. Ellis (OHA)	PALLAS					2
Dr. Finnie (Mercy St. Louis)	PALLAS					
Dr. Huq (Mercy St. Louis)	PALLAS					
Dr. Kosuri (Mercy St. Louis)	1	1.0375		1.0375		
Dr. Lobins (Cox)		0.325		0.325		
Dr. Nair (Mercy Spfld)			0.075	0.075		2
Dr. Nannapaneni (OHA)			0.3125	0.3125		
Dr. Rodgers (Mercy St. Louis)		0.275		0.275		
Dr. Snider (Mercy Spfld)			0.075	0.075		3
Dr. Tiriveedhi (Mercy Spfld)		1.06875	0.03125	1.1		
Dr. Williams-Wuch (Freeman)		0.25		0.25		
TOTALS		3.34375	0.8375	4.18125	4	8

As noted above May enrollments are not where we need them to be. We need to earn 13.33 credits each month to be on track to meet NCI's goal of 160 credits for our current grant year. In May, we earned 4.18125 credits. Reconciliation of CRO's credits earned with NCI's NCORP Sys documentation shows CRO having enrolled 52 patients, earning 67.68 treatment credits and 10.86 cancer control credits for the first 9-months of our grant year. This totals 78.54 credits places CRO at 65.45% towards reaching our 160 credit per year goal. CRO needs to see our enrollments and credits increase. With just two months, remaining in our current grant year everyone's efforts to increase our enrollments is greatly appreciated. At the end of May, CRO has submitted 30 of 36 needed Tissue + Blood Supplement 3v - 14 at Mercy Springfield and 16 obtained at CoxHealth.

DCP-001 Open to All Patients

DCP "Use of a Clinical Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP)" in a project of the NCI. The purpose of this project is to understand why patients do not participate in clinical trials. This information will help researchers design future studies. Also, to address the reasons why people do not participate, especially young adults and teenagers, older people and minorities. In addition, personal and medical information will be collected to help understand differences in treatment and treatment outcomes among these populations. The data collected will be used by: 1) NCI to evaluate the overall performance of the community program (NCORP); 2) The medical team to better understand reasons why patients don't participate, especially reasons related to the participating institution or the clinical trial itself; 3) Researchers to improve the design of current and future studies; 4) Researchers to develop research questions such as differences in access to care, treatment received and the outcome of the treatment received by different populations. This trial is now open to all patients enrolling to NCI trials. If the patient declines to participate staff must document the information in OPEN and CRO's CREDIT database. Enrollments are worth 0.03125 credits and declined enrollments are worth 0.0125 credits.

New CRO Components

Welcome to Heartland Regional Medical Center dba Mosaic Life Care, in St. Joseph, Missouri; Mercy Oklahoma in Oklahoma City, Oklahoma and Mercy Ft. Smith in Ft. Smith Arkansas. These new components are in process of transitioning care of their patients to CRO during the next month. This is an exciting event for CRO as we continue to grow.

NRG Off-Cycle Audit

NRG Oncology will be at CRO performing an off-cycle audit on July 6 -7, 2017. CRO is preparing our NRG charts for possible auditing. The off-cycle audit is being conducted due to the large volume of participants CRO has enrolled NRG Foundation trials.

Registration and Credential Repository (RCR)

A new online person registration **NCI Registration and Credential Repository** (RCR) process is under development at NCI and will activate on July 1, 2017. The new RCR application will require investigators, as well as other registration types of "non-physician investigator" and "associate plus", to submit their annual registration documents on line. All CRO Components will be doing their online registrations. In preparation for the transition, sites need to assure they have IAM accounts and updated Good Clinical Practice (GCP) Certificates for all investigators and staff. CRO Mercy Springfield and CoxHealth physicians will be receiving an email noting information needed and how to obtain the needed information. The first year with this transition will require additional efforts but once set up it will become easier.

SWOG S1416 Profile Study

SWOG1416 "Cisplatin With or Without Veliparib in Treating Patients With Metastatic Triple-Negative and/or BRCA Mutation-Associated Breast Cancer" is our profile study for June. This randomized phase II trial studies how well cisplatin works with or without veliparib in treating patients with metastatic triplenegative breast cancer and/or BRCA mutation-associated breast cancer. Patients must had had one prior cytotoxic regimen excluding cisplatin and PARP inhibitors for metastatic disease. Eligible participants must have completed any prior chemo, radiation therapy or hormonal therapy at least 14 days prior to registration.

ACTIVATION OF CIRB Protocols:

New Local Protocols:

None

CIRB Protocols:

Wake Forest WF97116 A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairment

NRG-GY003 - Phase II Randomized Trial of Nivolumab with or Without Ipilimumab in Patients with Persistent or Recurrent Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer – Reactivated 05/22/2017

Closure through CIRB:

GOG-0281 – closed to accrual 04/28/2017

SWOG S1609 – Cohort #3 temporarily closed to accrual effective 5/26/2017. Other cohorts still available ECOG-ACRIN EA8141 – Arm A closed to accrual; **ARM B still open to enrollment**

<u>Closure through Mercy IRB:</u>

None