



Leadership Council Agenda

Tuesday, June 23, 2020 @ 4:30 -5:30 pm

Microsoft Teams Meeting

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Conference ID: 219 768 573#

Voting Members		Quorum Present (4 required) Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
P	Amarinthia L. Curtis, MD, PI Finance Chair Spartanburg Medical Center	P	Jeremy M. Kilburn, MD, PI Secretary Bon Secours St. Francis	P	Howland E. Crosswell, MD, AYA Lead Bon Secours St. Francis
E	Robert D. Siegel, MD, Affiliate Responsible Investigator Bon Secours St. Francis	P	Leander Cannick III, MD, Affiliate Responsible Investigator Anmed Health	E	John E. Doster, MD, Affiliate Responsible Investigator Anmed Health
Non-Voting Members					
P	James D. Bearden III, MD, FACP, PI, Chair Spartanburg Medical Center	P	Michael S. Humeniuk, MD, Precision Medicine Lead	P	Rhonda Ballew, RN Anmed Health
P	Kamara Mertz-Rivera, MA, CCRC, Administrator	P	Heather Farmer, MS UC-NCORP Regulatory	P	Samantha Carter, AVP AnMed Health
E	Melissa Beckman, RN, BSN Bon Secours St. Francis	P	Alex N. Akkary, MBA Grants Management	P	Alaina Kennedy, BS Grants Coordinator
P	Melyssa Foust, MSN UC-NCORP, CCDR Coordinator	P	Kelsey Bridges, MHA UC-NCORP Quality Assurance		

Agenda Item	Discussion	Follow-up/ Assignments
Welcome		
Dr. Bearden	Time called to order 4:32 pm Attendance & Quorum Confirmed Minutes of Leadership Council Meeting <ul style="list-style-type: none"> May 26, 2020 Minutes sent same day as meeting, no corrections and additions received. 	Motion: Dr. Kilburn 2 nd : Dr. Curtis
Financial Report		
Dr. Curtis	Review of Financial Dashboard <ul style="list-style-type: none"> May & YTD Actuals – 6 Accruals Current Balance inclusive of re-budget \$175k 	<i>Information Only</i>
	CCDR Time & Effort <ul style="list-style-type: none"> Balance of 2327/4809 remaining YTD May: SMC 229 hours, 144 AnMed hours, 0 hours BSSF (Furlough) 	

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Accruals & Biospecimen/Special Entries		
Dr. Kilburn	Progress towards accrual goal May YTD Accruals (goal annualized): TMIST: 122% of goal (243 accruals/ 200 goal) Base Intervention: 121% of goal (355 accruals/ 292 goal) Biospecimens & Special Entry: 147% of goal (643/438 goal)	<i>Information Only</i>
PI Update		
James D. Bearden III, MD	NCI Steering Committee & Task Force – Positions Available, Submission Deadline: Due July 1, 2020 <ul style="list-style-type: none"> • Dr Humeniuk: Symptom Management and Quality of Life Screening Steering Committee, Bladder Cancer & Renal Cancer Task Force • Dr. Kilburn: Brain Malignancies Steering Committee, Breast Oncology Localized Disease & Renal Cancer Task Force • Dr. Crosswell: Pediatric Adolescent and Solid Tumor Steering Committee (PASTSC) Wake Forest: Upstate Top Site for PCW & Telehealth (as of May 31,2020)	<i>Information Only</i>
Protocol Review Committee: <i>Trials Activated</i>		
Dr. Kilburn & Dr. Humeniuk	See PRC Agenda/Minutes emailed June 16, 2020 <ul style="list-style-type: none"> • TRC-10446: <i>“Tocilizumab in Hospitalized Cancer Patients with Coronavirus 2019 (SARS-CoV-2) and Severe Complications of Coronavirus Disease 19 (COVID-19)” – Not available to our sites</i> • S1823: <i>“A Prospective Observational Cohort Study to Assess miRNA 371 For Outcome Prediction in Patients With Newly Diagnosed Germ Cell Tumors” - OPEN</i> • A081801: <i>“Integration of Immunotherapy Into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO”-OPEN</i> • S1929: <i>“Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)”-OPEN</i> • S1933: <i>“A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status”-OPEN</i> 	<i>Information Only</i>
Administrators Report		
Kamara Mertz-Rivera	BSSF- Contract Fully Executed	<i>Information Only</i>

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	Re-Budget Request received and approved Pending Time & Effort for re-budget GY1 Q3	
Heather Famer	ECOG-ACRIN- Patient Registration now available <ul style="list-style-type: none"> • 25 credits for membership (TMIST will accomplish) • If credit given to ECOG-ACRIN sites could be audited by ECOG-ACRIN for that study 	<i>Information Only</i>
Kelsey Bridges	Upcoming Audits & Monitoring Confirmed Audits: SWOG Lung-Map, July 8, 2020 (AnMed- Remote) Alliance, July 28-29, 2020 (Remote) -Case list sent out on June 18 th , 2020	<i>Information Only</i>
Policies & Procedures		
	No Updates/Action	
Committee Report		
AYA Dr. Crosswell & Dr. Kilburn	AYA Workplan Update -AYA Research Council Working Group to resume in July -2 accruals in May to AYA studies	<i>Information Only</i>
Disparities Melyssa Foust	<ul style="list-style-type: none"> • Q4 Community Engagement <ul style="list-style-type: none"> ○ Russian Community Church ○ TBD based on COVID-19 restrictions ○ Attempting to set up virtual meeting • Rural enrollments- capturing accruals 	<i>Information Only</i>
CCDR Update		
<i>Information Only</i>	<ul style="list-style-type: none"> • No New Studies, awaiting WF-1805CD • NRG-CC007CD- Shout out to AnMed for enrollment! • A231602CD-Shout out to Spartanburg for enrollment! • Affiliate Coordinator Call BSSF- June 16th, 2020 • Melyssa Foust participating on NRG Financial Toxicity Sub-Committee (First call – June 23rd) 	<i>Information Only</i>
Publications		
	Reminder: Please submit all publications for inclusion in progress report	<i>Information Only</i>
Research Base Meetings & Travel		
Research Base Meetings & Travel	Wake Forest: October 29-30, 2020, <i>Virtual Meeting</i> NRG: July 16-18, 2020, <i>Virtual Meeting (Registration open until July 7th)</i> NCORP Annual Meeting: August 31-1, 2020, <i>Virtual Meeting</i> SWOG: Discussion of Virtual Fall Meeting	<i>Information Only</i>
Open Forum		



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Information Only- Updated Monthly and will form required progress report

UC-NCORP Specific Aims Progress Report	
Aim	
Aim 1	<p>Adopt Research Advances: Accelerate the adoption of Research Advances into community practices through participation of community oncologists, non-oncology specialists, and primary care physicians in NCI clinical trials.</p> <p>Progress</p> <ul style="list-style-type: none"> Research Base Publications are shared with members (Alliance & SWOG shared ASCO abstracts and presentations) Cancer Letter- Dr. Curtis 07/21/19 Duke Cancer Review- GU Malignancies- Dr. Humeniuk moderated, 07/18/2019 External Advisory Board Member for Wake Forest’s NCI funded “Implementation in Science in Cancer Control” grant
Aim 2	<p>CCDR: Conduct and support the design of Cancer Care Delivery Research that impacts patient outcomes, practitioners, and health care delivery systems and reduces health care disparities.</p> <p>Progress</p> <ul style="list-style-type: none"> Lucy has a concept pending at Alliance with Dr. Hopkins and Blake Loman: Elderly Population using chair base exercise to mitigate fatigue during active treatment (Spring 2018). NCI CCDR Launch Call on 10/22/2019 hosted by Brenda Adjei, PhD and Dusu Sesay, attended by Drs. Bearden & Kilburn, Kamara Mertz-Rivera, Lucy Gansauer, Melyssa Foust, and Alex Akkary. 10/23/2019- CCDR plan shared with NCI program Director Brenda Adjei, PhD 10/23/2019- CCDR Coordinator, Abdelmohsen Alqalam best practice, strategies for accruing to EAQ1612CD and will share information with CCDR program director (introductory email)
Aim 3	<p>AYA: Enhance screening and access to clinical trials among Adolescent and Young-Adult population in our catchment area.</p> <p>Progress</p> <ul style="list-style-type: none"> AYA leader, Dr. Hal Crosswell ASCO Abstract submitted 08/20/2019 “Complete Response to Dual Immunotherapy in a Young Adult with Metastatic Alveolar Soft Part Sarcoma Enabled by a Comprehensive Patient Assistance Program in a Community Practice” (BSSF) IIT: “A Comprehensive Review of Adolescent Young Adult (Ages 15-39) Cancer Patients' Demographic, Psychosocial and Clinical Outcomes as compared to Pediatric and Older Adult Cancer Patient” Study PI: Crosswell (BSSF & SMC) Monthly tracking of AYA accruals AYA awareness: Roger Daltrey of The Who visited Greenville for dedication of Teen Cancer America Center, September 18, 2019 AYA Workplan presented by Dr. Crosswell 10/22/2019 and approved by Leadership Council

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	<ul style="list-style-type: none"> • Dr. Crosswell hosted AYA unit tour on November 15, 2019 for attendees at Wake Forest Annual Meeting • CTSU WEBINAR: NCTN and NCORP Adolescent and Young Adult (AYA) Trials, Webinar Date: Tuesday, December 3, 2019 at 3pm-4pm EST (Attendees: Dr. Bearden, Kamara Mertz-Rivera, Lucy Gansauer, Amy Adams, Melissa Beckman, Rhonda Ballew, & Samantha Carter) • AYA Joint Meeting with UC-NCORP and SCOR, January 8, 2020 • AYA Registry Protocol IRB approved • AYA Joint Meeting with UC-NCORP and SCOR, May 12, 2020
Aim 4	<p>Precision Medicine: Ensure capacity to screen and enroll in NCI Precision Medicine trials through engagement and partnerships with pathologists, surgeons, and multidisciplinary providers.</p> <p>Progress</p> <ul style="list-style-type: none"> • Precision Medicine Lead, Dr. Michael Humeniuk • Precision Medicine Studies Open and accruals are monitored: • LUNGMAP (AnMed & SRHS), Alchemist A081105 (All sites), MATCH EAY131 (All sites), DART S1609 (BSSF & SMC) • Dr. Khomani & Elizabeth Hassen presented a Precision Medicine Poster in Barcelona, Spain titled: "Implementing Precision Medicine in a Community Cancer Center to Impact Outcomes in Lung Cancer"
Aim 5	<p>Disparities: Promote the participation of the African Americans and other underrepresented groups in our catchment area into NCI Clinical Trials through community engagement and patient support programs.</p> <p>Progress</p> <ul style="list-style-type: none"> • Disparities Leaders: Drs. Bearden & Griffin • Disparity Presentation at NCORP Annual Meeting- 8/22/2019, Lucy Gansauer • Disparities Integration Workplan completed: Submitted to Leadership Council 8/27/2019 and approved • Q1 Community engagement for Sickle Cell Foundation completed with 75 attendees: Presenter: Lucy Gansauer 09/17/2019 • Monthly accruals and goals presented to Leadership Council broken down by disparate populations and underrepresented groups 10/22/2019. • Wake Forest Panel Discussion "Accruing Diverse Participants to NCORP Trials" November 15th, 2019: Lucy Gansauer & Kamara Mertz-Rivera • Q2 Community engagement- AYA Clemson students, attendance 21, Health Equity and Structural Barriers in Clinical Research. Presenter: Lucy Gansauer 01/23/2020 • Q3 Community Engagement, Target Population: Older Adult Support Group, AnMed Health, Research Base Disparity Committee Participation. Presenter: Lucy Gansauer & Melyssa Foust 02/05/2020
Aim 6	<p>Community Provider Engagement: Engage community oncologists (Medical, Surgical, Radiation, and Gynecological) and other medical specialists including Primary Care, Gastroenterology, Urology, Emergency Medicine, Radiology and Pathology in NCI clinical research.</p> <p>Progress</p> <ul style="list-style-type: none"> • Scheduling time with GI providers to prepare for NRG CC005 FORTE "Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps" (SMC)

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	<ul style="list-style-type: none"> • Identifying Primary Care Physicians to participate in the Alliance A211701 “A Prospective Study to Establish a New Onset Diabetes (NOD) Cohort” (SMC) • Community Engagement Committee with SWOG • Dr. Kilburn Community Engagement Committee with SWOG, is collaborating with Nadine Housri, MD to facilitate the adoption of the MedNet as a clinical trial tool. 10/4/2019 • SMC site selected 11/26/2019, for Alliance A211701 “A Prospective Study to Establish a New Onset Diabetes (NOD) Cohort” that has facilitated engagement with multiple levels of primary care within SMC. • Attended virtual meeting- FORTE, May 15, 2020 (Dr. Curtis, Dr. Kilburn, M. Foust, K. Mertz-Rivera)
Aim 7	<p>Social Media: Adopt the use of Social Media (Facebook, Twitter) to increase awareness of NCI Clinical Trials among providers, the public, and utilize social media resources provided by the research bases.</p> <p>Progress</p> <ul style="list-style-type: none"> • Pending budget release NCORP press release (AnMed, BSSF, SMC) • Conference call/ Meeting with representative from site’s marketing clinical trials for accruals (11/2019) • Annual Meeting- Social Media Topic on Agenda (Spring 2020) <p>NCORP Press Release:</p> <ul style="list-style-type: none"> ○ The Greenville News “Upstate SC hospitals get \$14.4 million cancer institute grant for joint clinical trials” (Sept. 15, 2019), online, social media and print ○ Discover Health (Sept. 16, 2019) ○ Channel 4 (WYFF4) “Three Upstate health care systems up their fight against cancer” (Sept. 18, 2019) (TV and online) ○ News 7 (WSPA) “Upstate hospitals team up to continue Cancer research trials” (Sept. 25, 2019) ○ Healthlink Magazine article “Upstate Powerhouses Join Forces to Fight Cancer” on UC-NCORP Grant. Drs. Bearden, Curtis, Siegel, Cannick and Kilburn + Kamara Mertz-Rivera all quoted. (01/2/2020) ○ Inside AnMed Health article “Brighter outlook: Cancer trials, \$14/4 million grant help patients get cutting-edge treatment close to home. (Feb. 2020) <ul style="list-style-type: none"> • Channel 4 (WYFF4) aired “Gibbs Cancer Center at Pelham expanding by 191,000 square feet” Highlighted expansion and UC-NCORP, access to clinical trials, featured cancer survivor and clinical trial participant. 03/05/2020 • Tours, Gibbs Cancer Center & Research Institute, including information on UC-NCORP and Clinical Research. Approximately 600 visitors. 03/03/2020-03/12/2020 • Multiple press releases occurred highlighting UC-NCORP’s grant award and partnership with NCI. These press releases promoted clinical trial awareness on Facebook, LinkedIn, Twitter, and local news social media pages. UC-NCORP celebrated Clinical Trials Day, May 20, 2020, with postings to Facebook and LinkedIn. Links were provided to promote and increase awareness of available clinical trials.
Aim 8	<p>Accruals: Achieve over 400 unique annual accruals exceeding the NCI requirement evenly distributed across study types listed below.</p> <p>Progress</p>

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	-Accrual Dashboard shared monthly
Aim 9	Interact with the NCORP Research Bases 1. provide community insight into feasibility during concept development; 2. identify pragmatic questions from the community setting that are appropriate for research; and participate in protocol development and on the study team.
	Progress
	1. Community Insight- Feasibility during concept development: - URCC meeting- 9/2019 #PIs & CRPs attend - Tracking research base feasibility surveys 2. Pragmatic Questions from Community: - Lucy has a concept pending at Alliance with Dr. Hopkins and Blake Loman: Elderly Population using chair base exercise to mitigate fatigue during active treatment. 3. Participation in Study Teams: - Lucy Gansauer, NCORP Community co-chair: URCC 18004CD “Understanding the Impact of Drug Shortages on Oncology Care Delivery” (2/2019) - Dr. Curtis presented at NCORP Annual Meeting 8/23/2019 “Accrual Planning and Opportunities within NCORP”, TMIST focus - Lucy Gansauer presented at NCORP Annual Meeting 8/22/2019 “Setting Benchmarks for NCORP Disparity Integration”: Disparity Integration Work Plan - 9/6-7/2019 URCC: sent 1 PI, Administrator, CCDR Coordinator, 3 CRPs - 10/2-10/5/2020 SWOG: sent 2 PIs, Administrator, CCDR, 3 CRPs - 11/7-11/9/2020 Alliance: sent 3 PIs, Administrator, CCDR, 2 CRPs - 11/14-11/16/2020 Wake Forest: 4 PIs, Administrator, CCDR, 12 CRPs - 01/08-1/11/2020 NRG, 1 PI, Administrator, CCDR, 3 CRPs - Spring 2020 Virtual Meeting, Alliance, 15 attendees - Spring 2020 virtual meeting, SWOG, 15 UC-NCORP attendees - NRG CCDR Financial Toxicity Sub-Committee, Melyssa Foust
Aim 10	Succession plan: Train the next generation of community research leaders and investigators.
	Progress
	-Principal Investigator in Training: Dr. Michael Humeniuk, being mentored by Drs. Bearden and Kilburn

Publications & Presentations		
8/22/19	Amy Curtis, MD, PI	NCORP Annual Meeting-TMIST
8/23/19	Lucy Gansauer, MSN, RN, CCRP	NCORP Annual Meeting-Disparities Integration
8/20/19	Hal Crosswell, MD	ASCO Abstract “Complete Response to Dual Immunotherapy in a Young Adult with Metastatic Alveolar Soft Part Sarcoma Enabled by a Comprehensive Patient Assistance Program in a Community Practice”

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9/2019	Dr. Khomani & Elizabeth Hassen presented a Precision Medicine Poster in Barcelona, Spain	“Implementing Precision Medicine in a Community Cancer Center to Impact Outcomes in Lung Cancer”
9/2019	https://onlinelibrary.wiley.com/doi/epdf/10.1002/cncr.31925 Elizabeth J. Cathcart-Rake, MD; Tyler Zemla, MS; Aminah Jatoi, MD; Kathryn E. Weaver, PhD; Heather Neuman, MD; Anne E. Kazak, PhD, ABPP; Ruth Carlos, MD; Lucy Gansauer, MSN, RN ; Joseph M. Unger, PhD; Nicholas M. Pajewski, PhD; and Charles Kamen, PhD, MPH	“Acquisition of Sexual Orientation and Gender Identity Data Among NCI Community Oncology Research Program Practice Groups”
9/24/2019	Journal of Oncology Practice, Volume 15, Issue 7 Robert D. Siegel, MD1 ; Richard G. Slough1 ; Howland E. Crosswell, MD1 ; Theresa M. Standifer1 ; Michael E. Borron1 ; Dionne L. Pringle, MA1 ; Karen K. Hancock1 ; Lara H. Widener1 ; Erin B. Hill1 ; Terra F. Spann, RN1 ; and Kristina M. Stoeppler-Biege, RN1	“Drug Recovery and Copay Assistance Program in a Community Cancer Center: Charity and Challenges”
10/02/2019	Lucy Gansauer, MSN, RN, CCRP	SWOG NCORP Workshop “Serving Your Catchment Area: Developing a Plan to Enroll Underrepresented Populations”
10/03/2019	Lucy Gansauer, MSN, RN, CCRP	SWOG Recruitment & Retention Committee, Education Subcommittee “Serving Your Catchment Area: Developing a Plan to Enroll Underrepresented Populations”
11/15/2019	Lucy Gansauer, MSN, RN, CCRP & Kamara Mertz-Rivera, MA, CCRC	Wake Forest Panel Discussion “Accruing Diverse Participants to NCORP Trials”



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Audits		
NRG	November 12-13, 2019	Final Report Received: Jan. 3, 2020 CAPA Approved: Feb. 3, 2020
SWOG Lung Map	January 22-23, 2020	Final Report Received: Feb. 15, 2020 CAPA: Approved: Mar. 19, 2020
SWOG Lung Map	July 8, 2020 (AnMed- Remote)	Remote
Alliance	July 28-29, 2020	Remote
Website or other Internet Sites		
08/01/2019	https://upstatecarolinaincorp.org/	UC-NCORP Website, public and members only
08/01/2019	https://www.spartanburgregional.com/clinicaltrials	NCI NCORP badge on Affiliate, Spartanburg Regional Healthcare System Website