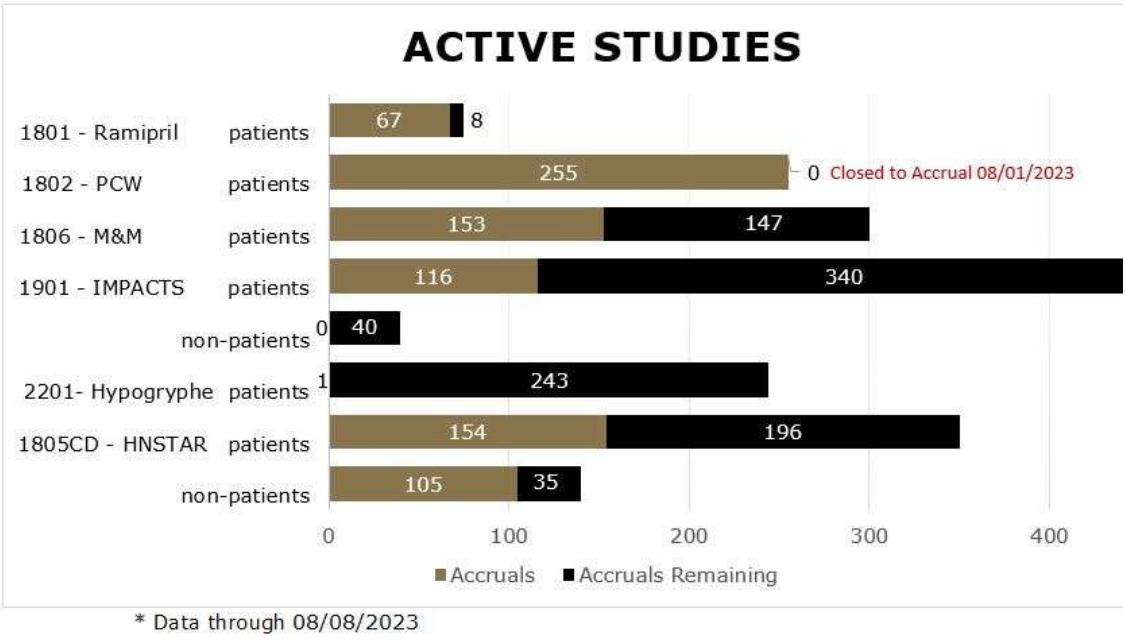
COMMUNITY CONNECTION

Quarterly Newsletter

August 2023

Study Accruals



* Data through 08/08/2023

Study Highlight: WF-2202 - Optimizing Psychosocial Intervention for Breast Cancer-related Sexual Morbidity: The Sexual Health and Intimacy Education (SHINE) Trial

(**Please note, this protocol is still pending final DCP and CIRB approval; anticipated to open Q1 2024)

Principal Investigator: Kelly Shaffer, PhD at University of Virginia School of Medicine, funded via R37

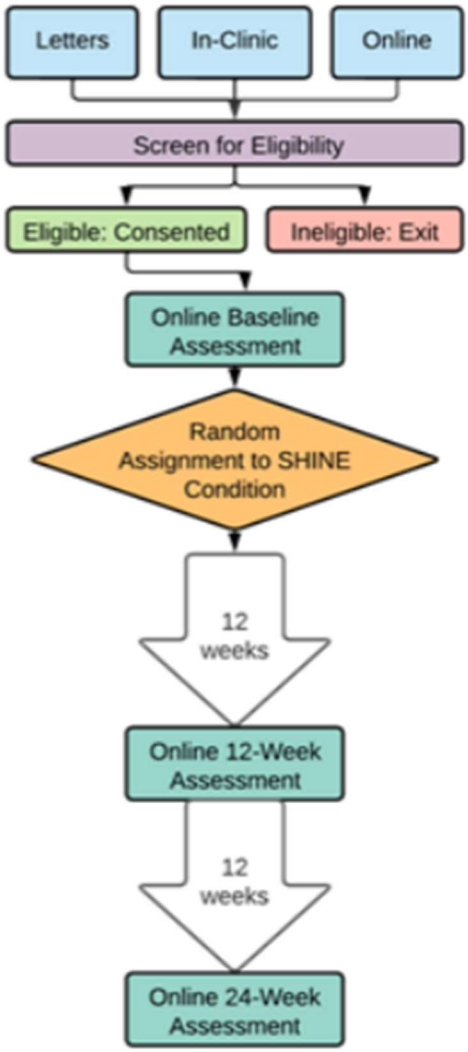
Study Goal: Using the multiphase optimization strategy (MOST) framework, we will identify a sexual morbidity intervention that has been optimized for greatest impact by returning the greatest improvement in sexual morbidity for the least intervention burden. Participants will be randomized to one of 16 conditions to receive access to a combination of one to four SHINE components. The four SHINE intervention components are: (1) psychoeducation about cancer-related sexual morbidity ("Psychoeducation"), (2) training for communication with clinicians ("Communication with clinicians"), (3) training for communication with partners ("Communication with partner"), and (4) physical intimacy promotion ("Intimacy").

The SHINE intervention and all study related assessments are internet-based and completed electronically.

Study Population: Partnered adult women status post treatment of Stage 0-III breast cancer experiencing sexual
concerns. n=320 (20 participants randomized into each of the 16 conditions)

Eligibility Criteria:

- History of Stage 0 -III breast cancer diagnosis.
- ≥12 weeks following last primary cancer treatment (defined for this protocol as chemotherapy, radiation, and surgical procedures intended to remove malignant tissue). Ongoing adjuvant endocrine therapy (e.g., tamoxifen, aromatase inhibitors), HER2-based immunotherapies (e.g., Herceptin), and/or pending breast reconstructive surgery are allowed.
- Age ≥18 years at the time of study enrollment.
- Following are self-reported on the Self-reported Eligibility Screener:
    - Cisgender female (i.e., assigned female at birth, female gender identity);
    - Currently in an intimate relationship, as reported on the PROMIS SexFS screener (this relationship may be with an individual of any sex and gender identity)
    - Endorse being at least “somewhat” bothered by ≥1 of the following during the last 30 days: (lack of) interest in sexual activity, vaginal dryness, pain during sexual activity, or (in)ability to orgasm, as reported on the PROMIS SexFS Bother Regarding Sexual Function1 screener
    - Endorse that ≥1 of the bothersome sexual symptoms, from the PROMIS SexFS Bother Regarding Sexual Function1 screener is related to their breast cancer;
- Has reliable access to the Internet or is willing to participate in the study tablet lending program.
- Has a working email address (or willing to create one) and receive emails from the study.



If you would like to be involved in this study, please contact us at NCORP@wakehealth.edu for more information.

Top Accruing CCDR Affiliates*

Rank	Affiliates	Accruals
1	OH122 - Licking Memorial Hospital (Columbus)	4
2	SC024 - Spartanburg Medical Center (Upstate)	3
2	NY045 - Montefiore Medical Ctr - Moses (Montefiore MU)	3
2	GA020 - Augusta Univ Med Ctr (GACARES MU)	3

* Data from 04/01/2023 - 06/30/2023

Top Accruing CC Affiliates*

Rank	Affiliates	Accruals
1	SC024 - Spartanburg Medical Center (Upstate)	3
1	MO056 - Heartland Regional Medical Center (OZARKS)	3
1	IL042 - John H Stroger Jr Hospital of Cook County (Stroger MU)	3
1	IA024 - Oncology Associates at Mercy Medical Ctr (IWORC)	3
1	HI012 - Kapiolani Med Ctr for Women & Children (Hawaii MU)	3
2	SC101 - Gibbs Cancer Center-Pelham (UPSTATE)	2
2	SC060 - Prisma Health Cancer Institute - Faris (Prisma)	2
2	OH245 - Southern Ohio Medical Center (Columbus)	2

* Data from 04/01/2023 - 06/30/2023

Site Highlight: Southeast Clinical Oncology Research Consortium NCORP

SCOR is one of the largest of the NCORPs, with 77 affiliates and sub-affiliates in 22 communities across six states throughout the southeast US – Florida, Georgia, North Carolina, South Carolina, Tennessee, and Virginia. SCOR's mission is to provide NCI clinical trials to improve the lives of cancer patients by bringing practice-changing clinical trials to the communities where patients live and work.

In each of these 22 communities, a community responsible investigator (CRI) and a study coordinator manage participation in NCORP activities and oversee accrual to NCI trials. These affiliates and sub-affiliates are home institutions to over 200 investigators -- medical oncologists, surgeons, radiation oncologists, gynecologic oncologists, and palliative care – and to more than 150 other research professionals involved directly or indirectly in the clinical research endeavor. SCOR has over 150 NCI clinical trials open for enrollment and have accrued more than 1,500 patients to NCI clinical trials and almost 300 enrollments to CCDR trials since August 1, 2019.

Dr. William J. Irvin, Jr., (pictured below on the far left) is the contact (main) Principal Investigator (PI) for SCOR, having stepped into that role on August 1, 2022, replacing Dr. Judith Owen Hopkins (pictured below second from left), who remains a SCOR PI. Both are medical oncologist. Dr. J. Daniel Pennington (pictured below second from right), a radiation oncologist, is the third SCOR PI. SCOR's Administrator is Michele Harmon, RN, BSN (pictured below on the far right). These leaders are aided by a staff of seven who oversee day-to-day operations of the NCORP from an operations center in Winston-Salem, NC.




SCOR was previously known as the Southeast Cancer Control Consortium, Inc., CCOP before NCI changed funding to NCORP. When the funding opportunity announcement for the new NCORP program was posted in 2013, SCCC based in Winston-Salem, NC, submitted an joint application with Upstate CCOP from Spartanburg, SC. When the NCORP grant was awarded in 2014, the combined group became “SCOR.”

In their first years, SCOR formed a cancer care delivery research (CCDR) committee to identify strengths, interests, and strategies for conducting and participating in CCDR studies. They also convened a Disparities Committee (now their Health Equity Committee) to increase the participation of minority, rural, and underserved populations, as well as Adolescent and Young Adults (AYAs) in their studies, and in the current grant year they’ve been particularly successful in accruing larger percentages of rural (31%) and minority (21 %) participants to NCI clinical trials. The catchment area for the six states has a population of over 17 million with over 40,000 cancer cases diagnosed each year.

SCOR also maintains its own cancer advocacy advisory board (called CAAB), to integrate the voices of cancer patients, survivors, and caregivers in the NCORP’s activities.

A particularly notable initiative is SCOR’s Young Investigators (YIs) program, which identifies early to mid-career oncologists with an interest in becoming SCOR leaders. These future leaders submit a letter of interest and their CV to the SCOR PIs. Those who are selected as good candidates for the program are integrated into the SCOR leadership structure, and each is paired with one of the SCOR PIs as a mentor. They’re also educated in SCOR history, policies, and procedures. Currently there are five YIs in the program with three former YIs actively involved in leadership roles.

SCOR is proud of all the hard work the community research staff and investigators devote to ensure successful accrual to NCI clinical trials.

Do you have site or staff that should be recognized? Please submit recommendations to NCORP@wakehealth.edu [wakehealth.us19.list-manage.com] with "Quarterly Newsletter Site/Staff Highlight" in the subject line.

Top Accruing Investigators by Study

(from 04/01/2023 - 06/30/2023)

WF-1801

1. Justin Shaya, MD (1) – MI017, MCRC

WF-1802

1. Daniel Fried, MD (2) – SC101, UPSTATE
1. Michael Humeniuk, MD (2) – SC024, UPSTATE
2. 4 other investigators accrued 1 each

WF-1805CD

1. Rafi Kabarriti, MD (4) - NY045 & NY313, Montefiore MU
2. Amarinthia (Amy) Curtis, MD (2) - SC024, Upstate
2. Achuta Kumar Guddati, MD, PhD (2) - GA020, GACARES MU
2. D'Anna Nicole Mullins, MD, PhD (2) - OH122, Columbus

WF-1806

1. Jasmine Sabah Nabi, MD (3) - IA024, IWORC
2. Kumar Kunnal Batra, MD (2) - IL042, Stroger MU

WF-1901

1. Christa Braun-Inglis, DNP (3) - HI012, Hawaii MU
1. Gopichand Pendurti, MD (3) - MO056, Ozarks
2. 9 other investigators accrued 1 each

Top CC Accruing Investigators

(from 04/01/2023 - 06/30/2023)

Christa Braun-Inglis, DNP
HI012, Hawaii MU (3)

Jasmine Sabah Nabi, MD
IA024, IWORC (3)

Gopichand Pendurti, MD
MO056, Ozarks (3)

Top CCDR Accruing Investigators

(from 04/01/2023 - 06/30/2023)

Rafi Kabarriti, MD
NY045& NY313,
Montefiore MU (4)

Amy Curtis, MD
SC024 Upstate (2)

Achuta Guddati, MD, PhD
GA020, GACARES MU (2)

D'Anna Mullins, MD, PhD
OH122, Columbus (2)

Research Staff Highlight: April Barrett

Bon Secours St. Francis Cancer Center

April began her research career in December, 2008 at a standalone research facility conducting therapeutic trials, mostly focused on COPD and Asthma. She joined Bon Secours St. Francis Cancer Center as a Research Coordinator in August, 2018. It was there that she was promoted to a newly created role of CCDR/Cancer Control Champion in November, 2021. She has since helped coordinate five different CCDR/Cancer Control trials. April has been one of the top accruers for the Wake Forest NCORP Research Base's WF-1805CD HN-STAR study, which was her first CCDR trial and is her only Wake Forest study. April enjoys spending time with her 10 year old son, husband, and three dogs. She enjoys dance and performing arts and loves being outside in nature both at the ocean and mountains and feels like she lives in the perfect location to get to both of those anytime of the year. She always looks forward to attending our annual meetings since they cover both areas!

Many thanks to April for her dedication, hard work, and commitment to research and her patients.

Meet Wake Forest NCORP Research Base Staff: Bill Stanfield

Bill Stanfield has been with the Wake Forest NCORP RB since early 2018 and has served as the Data Management Program Manager. Bill has over 20 years of experience in clinical research. He is primarily responsible for REDCap development, data & auditing, and technical support for current and new studies. He is currently working on the UPBEAT study (WF-97415), IMPACTS (WF-1901), HN-STAR (WF-1805CD) and Hypogryphe (WF-2201) Bill grew up in Buffalo, NY but now calls Winston Salem home. He enjoys travel with family, camping, and movies.

New Publications & Presentations

Publications

- DeMari JA, Dressler EV, Foraker RE, et al. Endometrial cancer survivors' perceptions of their cardiovascular disease risk (results from WF-1804CD AH-HA). Gynecologic Oncology. 2023;174:208-212.

Upcoming Presentations & Abstracts

- Foley K, Kittel C, Sutfin E, Chiles C, Weaver K, Miller D, Bellinger C, Stone R, Dressler E. Concordance among Patients, Lung Cancer Screening Staff, and Key Informants on Tobacco Use Treatment during Lung Cancer Screening: The OaSiS Trial (WF-20817CD). Society for Research on Nicotine and Tobacco European Chapter (SRNT-E). 2023, Sept 11-13.

- Danhauer SC, Lesser GJ, Dressler EV, Rosenthal DI, Chambers M, Garcia K, Cusimano A, Brown WM, Ochoa J, Yang P, Chiang J, Gordon O, Crutcher R, Kim JK, Russin MP, Lukenbill J, Porosnicu M, Yost KJ, Weaver KE, Cohen L. The Effects of Acupuncture on Treatment- Related Symptoms & Symptom Interference in Patients with Head and Neck Cancer Experiencing Chronic Radiation-Induced Xerostomia (RIX): Wake Forest NCI Community Oncology Research Program Research Base (WF NCORP RB) Randomized, Sham-controlled Trial WF-97115. 2nd World Congress Integrative Medicine and Health. 2023, Sept 20-23.

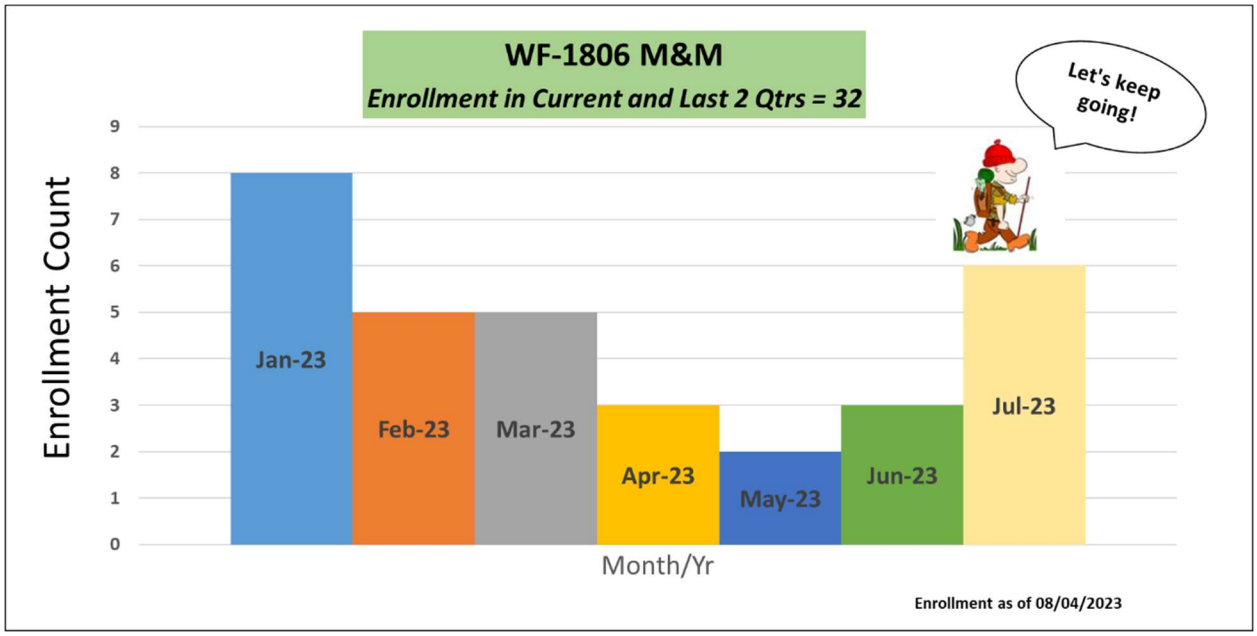
WF-1806 M&M: Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer

m & m Study
Myopenia & Mechanisms of Chemotherapy Toxicity

We need your help to get to our target of 300 patients – We are over halfway there with 153 participants enrolled thus far.

Does Muscle Matter?

This observational study looks at whether or not low muscle mass in older patients plays a role in their side effects from cancer treatment.



Our study team is happy to provide a study refresher for your site. Send an email to NCORP@wakehealth.edu.

Please help us enroll patients on this valuable study!

Health Equity Core Updates

The Health Equity Core (HEC) Committee would like to share information about their participation in the upcoming Wake Forest NCORP Research Base Annual Meeting (Oct 16 – 17, 2023).

- We are pleased to announce that Dr. Ruben Mesa will be our Keynote Speaker on Day 1. Dr. Mesa is the Executive Director of the Wake Forest Comprehensive Cancer Center. He co-leads the Health Equity Task Force for the American Society of Hematology (ASH) among many other areas of interest and leadership positions.
- The HEC will once again host a panelist discussion on Day 2 of the meeting, focusing on “Doing More with Less”.
- Immediately following the panelist discussion, the HEC will host a luncheon for all HEC members and interested parties. You will have the opportunity to register for this luncheon on the registration link for the annual meeting, which we hope to post soon.

The Wake Forest NCORP Research Base Health Equity Core focuses on recruitment & retention of minority/underserved populations. This group meets quarterly to share best practices, influence study design, discuss community engagement strategies and share resources and tools. If you are interested in joining this group, please contact us at NCORP@wakehealth.edu

Wake Forest NCORP Research Base Annual Meeting

The 2023 Wake Forest NCORP Annual Meeting dates will be **October 16-17, 2023**. This will be a Monday/Tuesday meeting.

A block of rooms has been reserved with a group rate of $269 per night beginning October 15 – October 18 at the Renaissance Hotel in Asheville, NC. You will need to book your rooms by 09/24/2023.
Hotel Registration Link [wakehealth.us19.list-manage.com]

The meeting registration link will be available soon.

WF NCORP RB Quarterly Calls

The July 26, 2023 quarterly call Webex has been added to the Wake NCORP website. If you missed it -
Use this link to access the
recording: https://vimeo.com/848861270 [vimeo.com]

*The 2023 Annual meeting will be held in place of the next quarterly call. A meeting invite will be sent at a later time for the first call of 2024.

Cancer Care Delivery Workshop at the Wake Forest NCORP Research Base Annual Meeting

(Deadline to submit interest 8/15/23)

Implementing change with Context-Driven Co-Design (CD2)

10/18/2023, 8:30-11:30 am

Change is the only constant in health care. NCORP settings, in particular, are often tasked with implementing new interventions, protocols, workflows, or other change efforts. In this workshop, we will summarize a process to support implementation: Context-Driven Co-Design (CD2). CD2, developed by Drs. Haines, Birken, and Morris at Wake Forest University School of Medicine, is a state-of-the-science approach to developing and tailoring strategies to support the implementation of evidence-based interventions and other innovations. CD2, which combines elements of user-centered design and implementation science, includes two components: (1) a detailed assessment of the setting in which an intervention will be implemented (i.e., context assessment) and (2) co-design sessions with intervention end users (e.g., patients and providers) to identify intervention adaptations and implementation strategies to improve intervention-context fit. This workshop will provide an in-depth understanding of the CD2 process through both didactic lecture and group discussion activities and equip participants with CD2 templates (e.g., interview guides, co-design materials) and the opportunity for participants to apply the steps of CD2 to a past, present, or future change effort relevant to their own setting.

Space is limited for this workshop. Interested participants should complete this REDCap form [wakehealth.us19.list-manage.com] by **8/15** for greatest consideration (others may be allowed as space permits). We strongly encourage (but do not require) participants to engage in a workshop evaluation (e.g., focus group; survey) to be conducted directly following the workshop. Selected attendees will be notified by 8/23.

Recipe: Cheater's Skillet Lasagna with Corn and Cherry Tomatoes

Ingredients:

- 3 ears of corn on the cob
- 2 tablespoons melted butter
- 1 pound lasagna noodles, roughly broken
- 4 tablespoons extra-virgin olive oil, divided
- 1 pint cherry tomatoes
- Kosher salt and freshly ground black pepper
- 2 large zucchini, peeled into ribbons with a vegetable peeler
- 1 bunch asparagus, peeled into ribbons with a vegetable peeler
- ½ cup grated Parmesan cheese
- ¼ cup capers
- 3 tablespoons chopped fresh basil

Directions:

1. Heat a large skillet over medium heat. Brush the corn with the melted butter and add to the skillet. Sear until well charred, about 4 minutes per side. Cool slightly, then cut the kernels from the cob.

2. Bring a large pot of salted water to a boil and cook the lasagna noodles until al dente, 7 to 9 minutes.

3. Drain the noodles and toss with 2 tablespoons of the olive oil. Heat the remaining olive oil in the same skillet you used to cook the corn.

4. Add the tomatoes to the skillet; season with salt and pepper. Cook until the tomatoes are blistered, 6 to 7 minutes. Add the zucchini and asparagus; cook until tender, about 4 minutes.

5. Add the noodles and corn to the skillet; toss to combine. Add the Parmesan, capers and basil; toss to combine. Serve immediately.

Recipe from: https://www.purewow.com/recipes/cheaters-skillet-lasagna_[wakehealth.us19.list-manage.com]

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