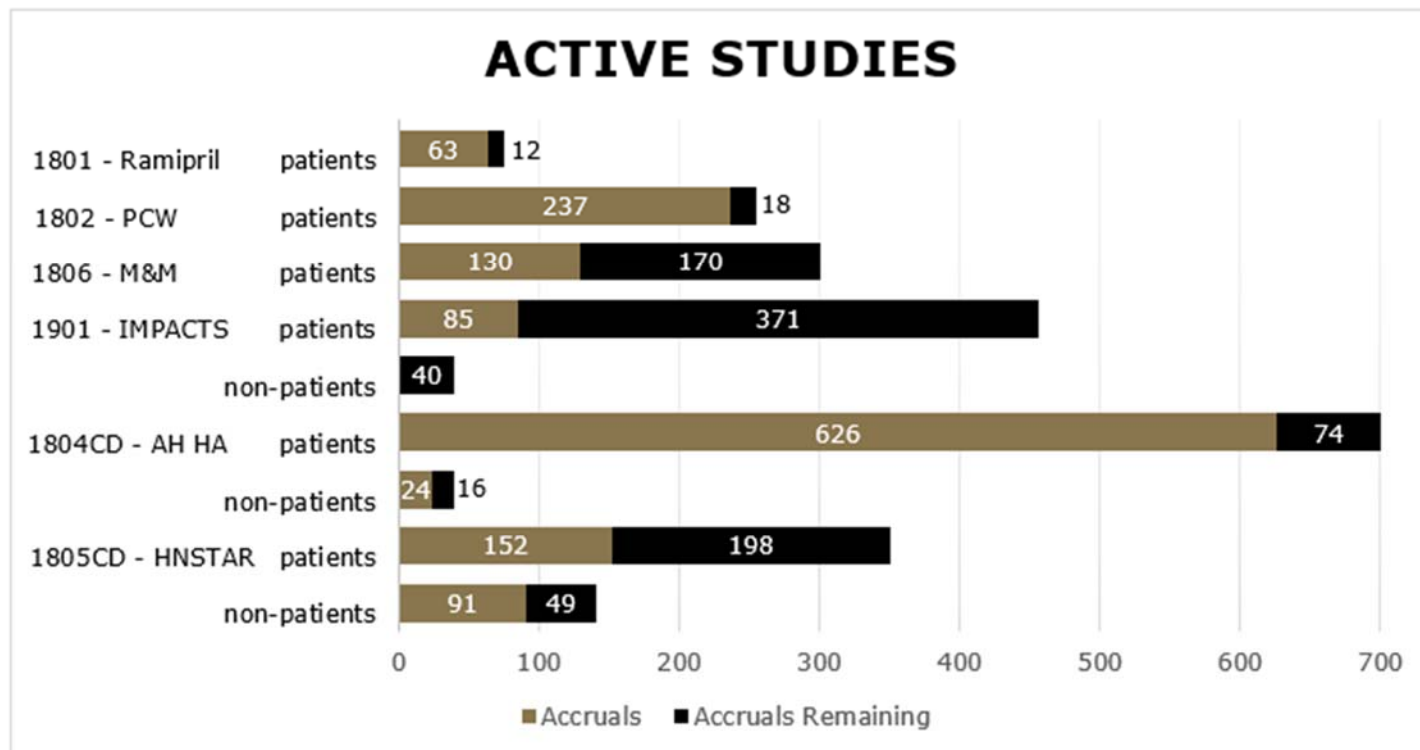




COMMUNITY CONNECTION

Quarterly Newsletter
February 2023



* Data through 02/12/2023

Study Highlight

WF-1805CD- HN-STAR – Implementation and Effectiveness Trial of HN-STAR



It tailors recommendations from the American Cancer Society guidelines based on each survivor's treatment history and self-reported concerns.

HN-STAR streamlines care for head and neck cancer survivors.

HN-STAR presents recommendations in 3 ways:

1. During the clinic visit, as an online guidance to the provider
2. In an initial survivorship care plan, which summarizes decisions made in clinic for the survivor and PCP
3. In updated survivorship care plans over the course of the year, based on updated symptom reports

Brief Overview

Local Staff Activities

- Check survivor eligibility, consent, enroll survivors.
- Assist survivors with surveys if needed.
- Upload survivorship care plans into EMR and send to PCP (HN-STAR arm).
- Abstract oncology and primary care medical records.

Practice Eligibility

- Treated ≥ 12 new cases of head and neck cancer in the prior year.
- Has ≥ 1 designated clinician to use HN-STAR or provide usual care.

Participant Eligibility

- ≥ 18 years old
- Diagnosed with head and neck squamous cell carcinoma
- Deemed free of disease and finished chemotherapy and/or radiation therapy (+/- surgery) ≤ 24 months prior to enrollment.
- English speaking and able to complete surveys.
- Plans to attend clinic visit with a designated clinician.
- Does not need to have a PCP.

SCHEMA

Study Population: 350 Head and neck cancer (HNC) survivors presenting to ≥ 30 NCORP practices for post-treatment follow up care



Randomization: 1:1 practice level randomization (≥ 15 intervention, ≥ 15 usual care) stratified by number of incident head and neck cancer cases treated in past year (12 to 39 vs. ≥ 40)



Intervention: Implementation of the Head and Neck Survivorship Tool: Assessment and Recommendations (HN-STAR).



Data collection from survivors: Baseline Health Assessment (pre-visit), Post-Visit Survey, and Follow-up (1 year) Health Assessment evaluating patient-centered outcomes, receipt of survivorship care, and implementation outcomes. Online Quarterly Health Assessments (3, 6 & 9 mo) if at an HN-STAR practice. A subset of survivors ($n=30$ from HN-STAR arm, $n=10$ from usual care arm) will complete two in-depth phone interviews (post-visit and follow-up) to assess implementation outcomes.

Data collection from designated clinicians: At least one designated clinician per practice ($n \geq 30$) will complete a brief post-visit survey for each survivor regarding delivery of survivorship care. Two surveys & one interview to characterize practice patterns and implementation of HNC survivorship care - (1) prior to first enrolled patient and (2) after the 10th survivor at their practice has completed the study or the completion of study enrollment at their site.

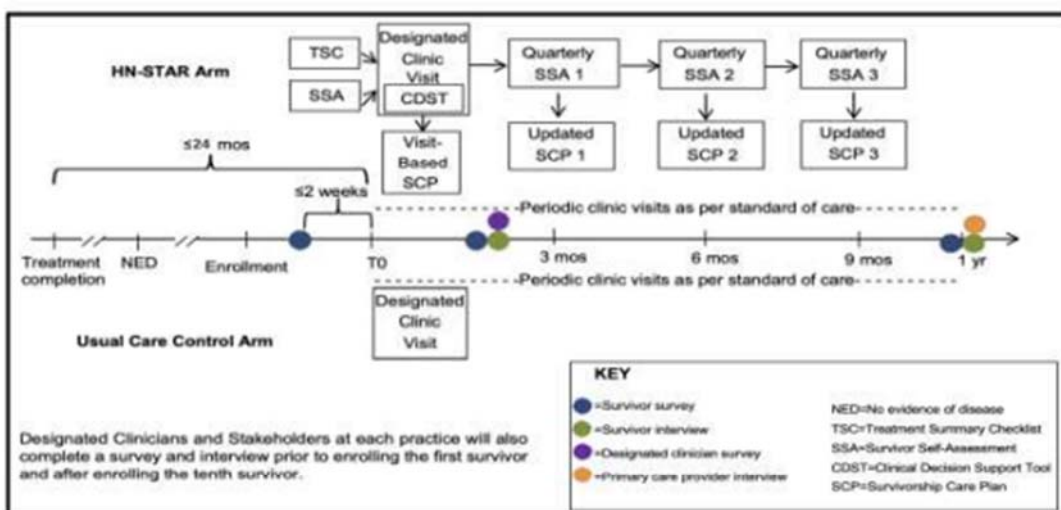
Data collection from stakeholders (including site leaders): 1-3 stakeholders per practice ($n=30-50$) will complete two surveys & one phone interview to characterize practice patterns and implementation of HNC survivorship care - (1) prior to first enrolled patient and (2) after the 10th survivor at their practice has completed the study or the completion of study enrollment at their site.

Data collection from primary care providers: A subset of primary care providers ($n=30$ from HN-STAR arm, $n=10$ from usual care arm) will complete interviews regarding care provided to HNC survivors.



Primary endpoint: Head and neck cancer-specific quality of life, as measured by the Trial Outcome Index of the Functional Assessment of Cancer Therapy - Head and Neck Cancer.

Figure 1: Schema



Study sample: n=350 survivors of head and neck cancer (for surveys, including n=40 who will complete two interviews), ≥30 designated clinicians (at least 1 per site), 30-50 stakeholders (1-3 per site), 40 primary care providers.

Study duration: 3 years

Brief eligibility criteria:

Practices: 1) Treated ≥12 incident head and neck cancer cases in the prior 12 months, 2) have at least 1 clinician willing to complete study trainings, visits, surveys, and an interview.

Survivors: 1) ≥18 years of age, 2) completed treatment for HNC including radiation and/or chemotherapy (with or without surgery) ≤24 months prior to the designated clinician visit, 3) deemed free of disease at last assessment, 4) speaks and reads English, 5) is cognitively and physically able to complete study surveys.

Designated Clinicians: Clinicians (at least 1 per site) will be MD, DO, NP, or PA, English-speaking and reading, and providing clinical care for cancer patients or survivors.

Stakeholders: Stakeholders (1-3 per site) will be English speaking and reading, employed at the practice for at least one month, and involved in provision of care for HNC survivors, including IT support.

Primary Care Provider: Provider will be MD, DO, NP, or PA to a survivor in this study and providing general preventive care only.

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

Top 3 Accruing CC Affiliates*

Rank	Affiliates	Accruals
1	HI012 - Kapiolani Medical Ctr for Women & Children (Hawaii MU)	6
2	AL002 - University of Alabama at Birmingham Cancer Center	5
3	PA136 - Community Medical Center (Geisinger)	2
	MO056 - Heartland Regional Medical Center (Ozarks)	
	IL042 - John H Stroger Jr Hospital of Cook County (Stroger MU)	
	IA072 - Mission Cancer and Blood - Des Moines (IWORC)	

* Data from 10/01/2022 - 12/31/2022

Top 5 Accruing CCDR Affiliates*

Rank	Affiliates	Accruals
1	OK010 - Mercy Hospital Oklahoma City (Ozarks)	19
2	WI212 - ThedaCare Regional Cancer Center (WINCORP)	17
3	IA024 - Oncology Associates at Mercy Medical Ctr (IWORC)	12
4	SC024 - Spartanburg Medical Center (Upstate)	8
5	MO021 - Mercy Hospital Saint Louis (Ozarks)	6

* Data from 10/01/2022 - 12/31/2022

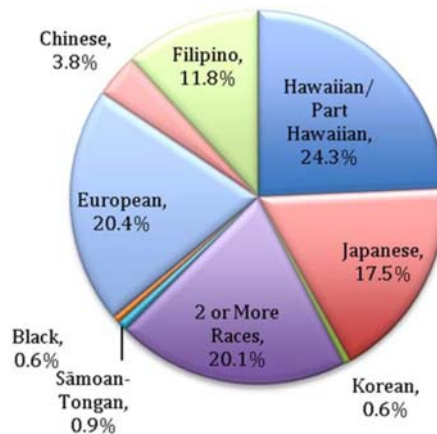
Site Highlight: Hawaii MU NCORP



UNIVERSITY OF HAWAII
CANCER CENTER



The University of Hawaii Cancer Center – Hawaii Minority/Underserved (M/U) NCORP is located on the island of Oahu, the most populated island in the Hawaiian Island chain. Our mission is to reduce the burden of cancer for the people of Hawaii and the Pacific by providing access to innovative clinical trials. We have a unique opportunity in Hawaii to enroll racial minorities and individuals living in rural areas on neighboring islands. These populations are often underrepresented in clinical trials. The state of Hawaii is composed of mostly racial minorities with ~20% of individuals identifying as two or more races. There is no majority race and we are often times referred to as a “melting pot” of backgrounds.

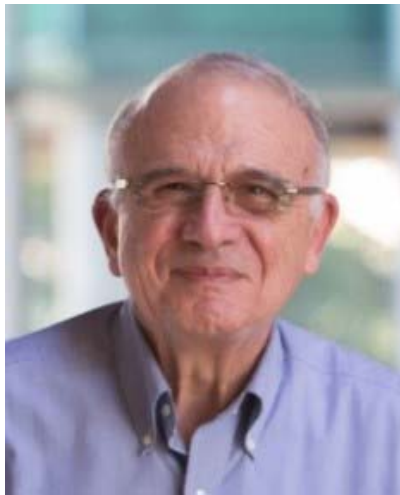


2021 State of Hawaii Racial Demographic Distribution

Hawaii M/U NCORP network currently includes 11 participating affiliates, 10 participating sub-affiliates throughout the state and also includes FHP Health Center in Tamuning, Guam. We have about 62 MD/DO investigators and 8 APRN investigators. Although most of our sites are located on Oahu, we hope to increase access to trials for communities on neighboring islands and across our broad catchment area of the Pacific. To accomplish this goal, we have developed a close partnership with the Community Outreach and Engagement Department at our cancer center. Together, we hope to educate our community and breakdown cultural, socio-economic, and language barriers to ensure oncology clinical trials are available to all.

The Hawaii M/U NCORP is led by **Jeffrey Berenberg, MD (below, left), Jared Acoba, MD (below, center), and Christa Braun-Inglis, DNP, APRN-Rx, FNP-BC, AOCNP (below, right).**

Like many others across the country, our clinical trials office has been affected by high staff turnover, losing ~60% of our staff in early 2022. Although this presented tough challenges for our NCORP, we are using it as an opportunity to re-build and refine our processes for protocol selection/opening, staff on-boarding and education, plus much more. We look forward to everything to come in 2023.



University of Hawaii Cancer Center team members

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

Research Staff Spotlight: Lori Francar, MLIS, BSN, RN



Lori joined St. Vincent Hospital's Clinical Research department in 2011 and has supported her team in various different areas. Her most significant role has been serving as the Cancer Care Delivery Research (CCDR) Champion since 2019. When she started in this role, NCORP sites were still trying to learn the best ways to successfully implement and operationalize CCDR trials. Since that time, Lori has been integral with spearheading and successfully participating in at least nine CCDR trials and extensively evaluating many other CCDR trials. She has built relationships across multiple departments within HSHS St. Vincent Hospital and its sub-affiliates which has positively impacted the research department outside of CCDR. This is evident in her most recent success by fostering relationships with new radiation oncology practitioners and engaging their participation in WF-1805CD.

Her dedicated and relentless support for CCDR trials (concept development to enrollment) truly makes Lori a "shining star" in our program.

****Nominated by:** Sally Luehring, Director St. Vincent Clinical Research Institute and Amy Koffarnus, Research Administrator CROWN Consortium.

Do you have a site or study staff member that should be recognized? Please submit recommendations to NCORP@wakehealth.edu with "Quarterly Newsletter Site/Staff Highlight" in the subject line.

Top Accruing Investigators by Study

(from 10/1/2022 - 12/31/2022)

WF-1801

1. William Edenfield, MD (1) – SC060, Prisma Health
1. Michael Haughton, MD (1) – SC053, Prisma Health
1. Zachary Vaslow, MD (1) – NC004, SCOR

WF-1802

No accruals during this time period.

WF-1804CD

1. Lindsey Kulbacki, PA-C (8) - WI212, WINCORP
1. Sonia Varghese, MD (8) - OK010, Ozarks
2. Christopher Thompson, MD (7) - OK010, Ozarks

WF-1805CD

1. Rafi Kabarriti, MD (5) - NY045 & NY313, Montefiore MU
1. Jeremy Kilburn, MD (5) - SC024, Upstate
2. Nathan Munson, MD (4) - WI212, WINCORP

WF-1806

1. Grant Williams, MD (5) - AL002, UAB
2. Sorab Gupta, MD (3), PA138 & PA136, Geisinger

WF-1901

1. Christa Braun-Inglis, NP (5) - HI012, Hawaii MU
2. Gopichand Pendurti, MD (2) - MO056, Ozarks

Top CC Accruing Investigators

(from 10/01/2022 - 12/31/2022)



Christa Braun-Inglis, NP
HI012, Hawaii MU (5)



Grant Williams, MD
AL002, UAB (5)

Top CCDD Accruing Investigators

(from 10/01/2022 - 12/31/2022)



Lindsey Kulbacki, PA-C
WI212, WINCORP (8)



Sonia Varghese, MD
OK010, Ozarks (8)

Meet Wake Forest NCORP Research Base Staff: Cristel Castelo



Cristel joined our team in September 2022 working with the regulatory group. She assists with all regulatory aspects related to studies including NCI, CIRB, local IRB submissions and the update of federal agencies such as CT.gov. Currently, she is the regulatory lead for Ramipril (WF-1801), Prostate (WF-1802), M&M (WF-1806) and AH-HA (WF-1804CD).

Cristel relocated from Seattle to North Carolina in 2020 and has been in the clinical trial arena for about 5 years. She spent most of those years working for the biotech sector on the patient operations side of the clinical trials.

When Cristel is not working, she spends most of her spare time with her children; her “little 1 year old tornado” and her teenage daughter. She enjoys cooking, traveling, and spending time with friends/family. Sightseeing is also a favorite and she is on a journey to find the best restaurants around town.

WF-1802 - PCW - Influence of Primary Treatment for Prostate Cancer on Work Experience

We have re-opened previously closed strata's for WF-1802

In order to obtain an ideal number of participants in each strata, we will be replacing patients who were enrolled and did not complete baseline prior to treatment or completed baseline with no additional follow-up. Please screen and approach potential participants for all strata's.

We have the following slots available:

Higher Income, AA- 10 slots available

Lower Income, AA- 1 slot available

Lower Income, White – 33 slots available

We have added the additional slot availability in OPEN for each strata. You can determine the remaining slots left for any stratum by going to **CTSU-OPEN>Slot Reservation>Report.**

2023 Wake Forest NCORP Boot Camp

The first NCORP Boot Camp was held from February 6-8, 2023 in Winston-Salem, NC. We invited 6 early career investigators to participate in this program and work on developing new study ideas for the Wake Forest NCORP Research Base. The trainees for this year were:

Todd Adams, MD -- VCU Massey Cancer Center, Richmond, VA

Hannah Arem, PhD -- MedStar Health Research Institute at Georgetown, Washington DC

Dori Beeler, PhD -- Levine Cancer Institute, Charlotte, NC

Traci Bethea, PhD, MPA -- Georgetown Lombardi Comprehensive Cancer Center, Washington DC

Shelley Bluethmann, PhD, MPH -- Wake Forest University School of Medicine, Winston-Salem, NC

Christa Braun-Inglis, DNP -- University of Hawaii Cancer Center, Honolulu, HI



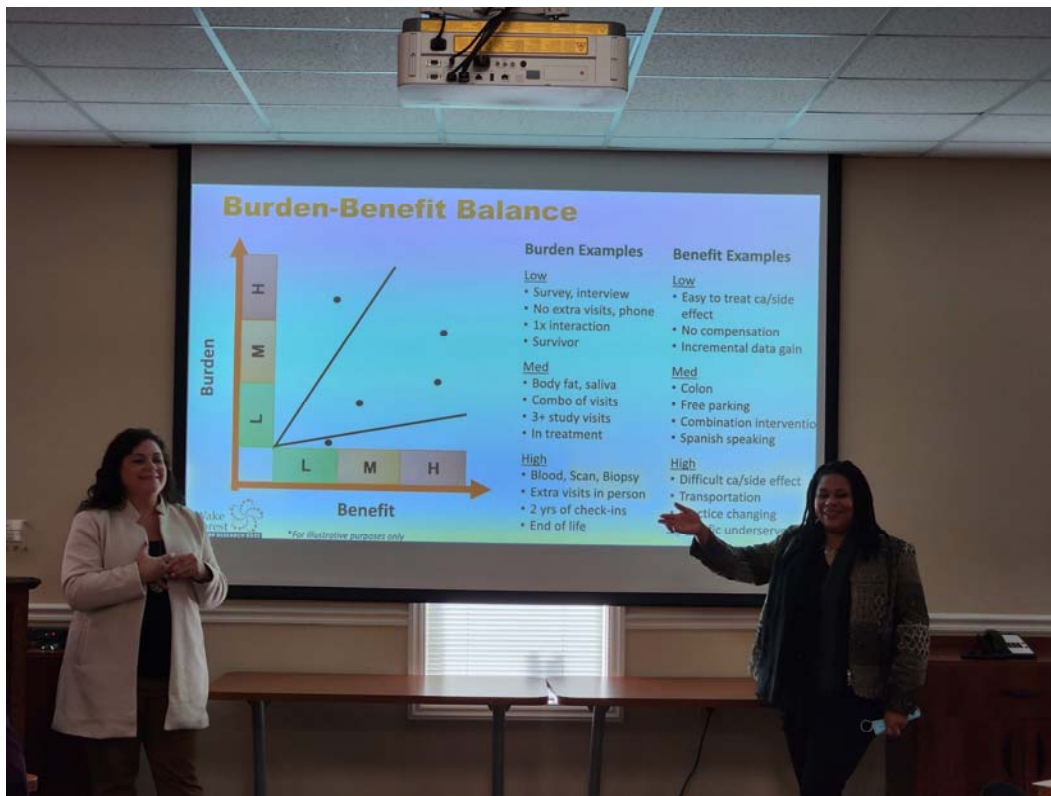


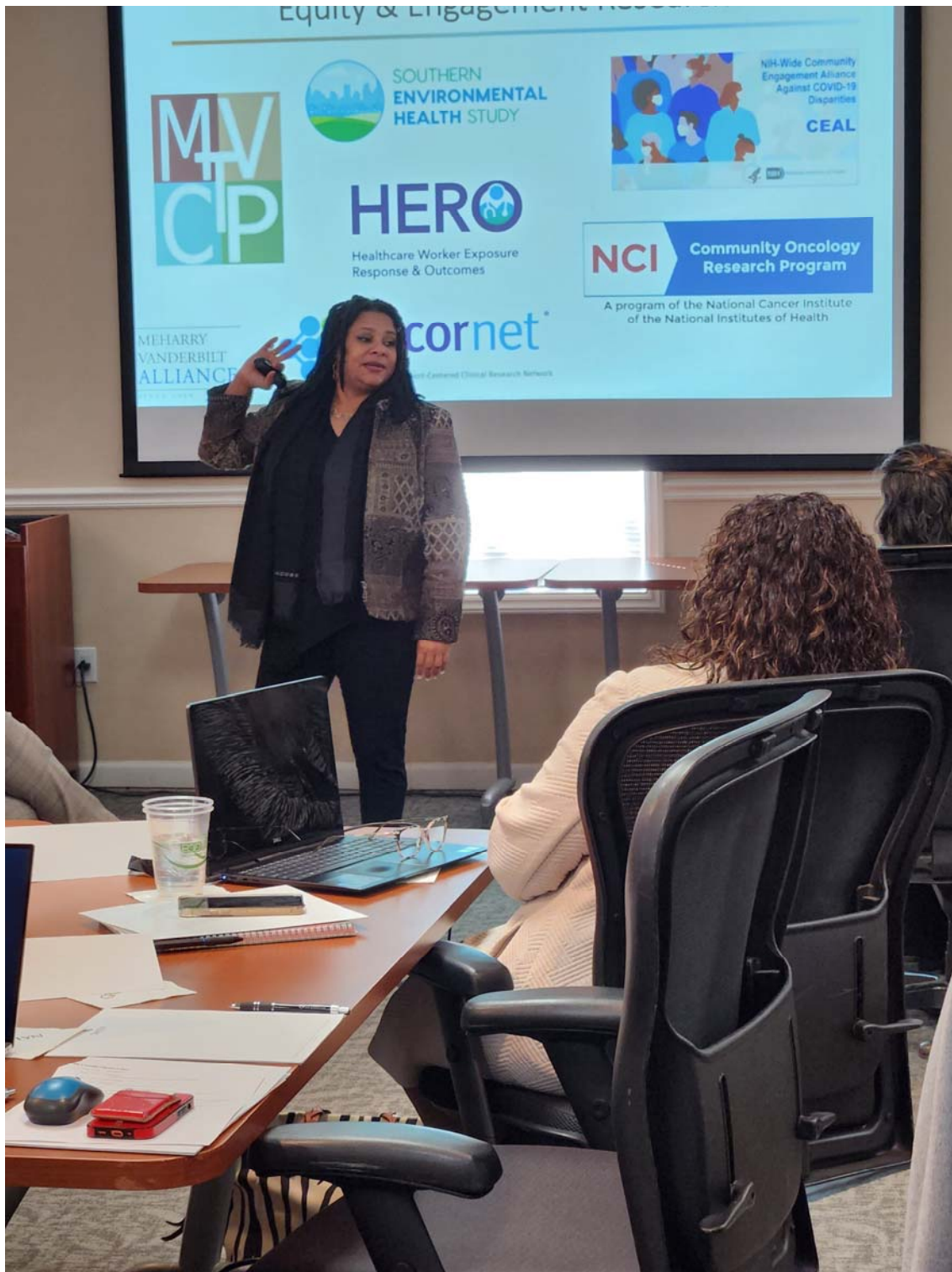
New Publications & Presentations

Study	Abstract Title	Authors	Conference	Acceptance & Format	Conference Date	Conference location
UPBEAT WF97415	Declines in Social Support during Breast Cancer Treatment and their Association with Exercise Capacity Reductions in Breast Cancer Survivors (WF-97415)	Nguyen J, Reding KW, D'Agostino R, Ladd A, Szewczyk W, Lucas AR, Mihalko S, Weaver KE< Lesser GJ, Hundley WG	Western Institute of Nursing Conference	Poster Presentation: Friday, April 21, 2023 from 1:00 PM - 5:00 PM.	April 19-22, 2013	Tucson, AZ
PREVENT WF98213	Changes in abdominal muscle composition are related to cardiac function and inflammation during cancer therapy (PREVENT WF-98213)	Moriah P. Bellissimo, Kerry W. Reding, Susan Workman, Leila Mabudian, Nathaniel S. O'Connell, Emily Heiston, Amy Ladd, Ralph D'Agostino Jr, Kathryn E. Weaver, Glenn J. Lesser, Bernard Fuemmeler, W. Gregory Hundley	American College of Cardiology Conference	Moderated Poster	March 4-6, 2023	New Orleans, LA
PREVENT WF98213	Accelerated vascular stiffening in premenopausal women undergoing breast cancer treatment: Insights from the PREVENT Trial (WF-98213)	JH Jordan, RB D'Agostino, Jr, CJ Park, S Dent, AR Lucas, GJ Lesser, KE Weaver, WG Hundley, A Thomas	Society for Cardiovascular Magnetic Resonance Conference	Poster Session: Rapid Fire 1-2PM January 26, 2023	January 25-28, 2023	San Diego, CA

Health Equity Core Updates

Dr. Karen Winkfield and Carla Strom from the WF NCORP Health Equity Core recently participated in the WF NCORP Boot Camp workshop. This workshop awarded 6 early career investigators with attendance to a workshop which guided these early career investigators with their innovative ideas to develop a 2 page proposal which will then be developed into a concept. Dr. Winkfield and Carla presented a session on Health Equity, Diversity, and Inclusion in Trials. They covered topics on unconscious bias and under-representation in Clinical Trials as well as the importance of including patient advocates in trial development.





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 Update



CHANGE IN DATE: Due to a scheduling conflict, the 2023 Wake Forest NCORP Annual Meeting dates have been changed to **October 16-17, 2023**. This will still be a Monday/Tuesday meeting.

The location will still be The Renaissance in Asheville, NC.

Please make this adjustment on your calendar.

WF NCORP RB Quarterly Calls

The January 11, 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/788428057>

Our next quarterly call is scheduled for April 12, 2023 at 3pm EDT.

Recipe: Lasagna-Stuffed Spaghetti Squash



Ingredients

- 2 small spaghetti squash (about 1 lb 10 oz each)
- 1 c. no-salt-added small-curd cottage cheese
- 1/4 c. grated Romano cheese
- Kosher salt and pepper
- 8 oz. frozen broccoli florets, thawed, squeezed of excess moisture and chopped
- 3/4 c. low-sodium marinara or tomato sauce
- 3 oz. part-skim mozzarella, grated
- Green salad, for serving

Directions

STEP 1: Using a large serrated knife, cut the spaghetti squash in half lengthwise. Use a spoon to scrape out and discard the seeds.

STEP 2: Place all 4 squash halves, cut side down, on a large piece of parchment paper in the microwave. Cook on high power until just tender, 9 to 11 minutes.

STEP 3: Meanwhile, heat broiler and lower the rack to the middle position of the oven. In a bowl, combine the cottage cheese, Romano and . tsp pepper; fold in the broccoli.

STEP 4: Season the squash halves with . tsp each salt and pepper, then use a fork to scrape up most of the squash strands, leaving them in the squash. Divide the cheese mixture among the squash and top with the sauce, then the mozzarella. Broil until the filling is heated through and the top is golden brown, 2 to 3 minutes. Serve with a green salad, if desired.



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CANCER CLINICAL TRIALS

<https://mncanceralliance.org>

I joined a clinical trial because...

"I was diagnosed with cancer at 27, and everyone was shocked. I wanted to be part of a team focusing on my age group and the impacts of treatment. I'm so glad I took part." - Raya




FOR MORE INFORMATION, CALL 1-800-CANCER (1-800-422-6237) OR VISIT [HTTPS://WWW.CANCER.GOV/CONTACT](https://www.cancer.gov/contact)



minnesota cancer alliance
working together to eliminate the burden of cancer

CANCER CLINICAL TRIALS

<https://mncanceralliance.org>

I joined a clinical trial because...

"I wanted to show my community that being part of a clinical trial is nothing to fear. The more of us that participate, the more we are represented in research. The choice to be part of the trial was mine... and I am proud for it."

- Nevada




FOR MORE INFORMATION, CALL 1-800-CANCER (1-800-422-6237) OR VISIT [HTTPS://WWW.CANCER.GOV/CONTACT](https://www.cancer.gov/contact)

SketchQuotes by Nelle Rhicard at www.reframeideas.com [reframeideas.com]



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