



STUDY MATTERS

October 12, 2023

Wake NCORP Website: <https://wakencorp.phs.wakehealth.edu/>

Wake Forest NCORP RB Annual Meeting

The 2023 Wake Forest NCORP RB Annual Meeting will be held **October 16-17, 2023** at the Renaissance Hotel in Asheville, NC.

[Click here to register](#)

****Registration for in person closes on October 13 and registration for virtual will close on October 15.****

If you plan on attending virtually, you must register as Virtual in order to receive the WebEx invite link to join the Annual Meeting.

Once you click on the registration link, you will land on the Northwest AHEC face page.

- If you do not have an account, you will need to create one at this time using the "Create Account" located in the banner at the top right.
- Once you have created an account, go back to the home page of the Meeting.
- A gray "Register" button is located on the left side of the page. Click on this button and you will be asked to sign in.

If you plan to attend the Health Equity Core Committee Luncheon, please register for that as well.

The Annual Meeting Packet can be found here:

<https://wakencorp.phs.wakehealth.edu/meetings-committees/annual-meeting/>

Our keynote speaker this year will be **Ruben Mesa, MD, FACP** who is the Executive Director of the NCI Comprehensive Cancer Center based at Wake Forest Baptist. Dr. Mesa is an international expert in hematologic cancers, who has dedicated his life's work to research and drug development for myeloproliferative neoplasms (MPN). He is a funded investigator of the NCI on several projects in MPN and has been appointed to the NCI Clinical Trial Advisory Committee. In addition to Dr. Mesa's extensive MPN research and clinical practice, he is passionate about advancing cancer health equity and increasing minority patients' participation in cancer clinical trials. He will be speaking on "Diverse Cancer Clinical Trials: Good Care – Good Science."

The group hotel rate is no longer available, but you may still be able to reserve a room.

[Book your hotel for the Wake Forest NCORP Research Base Annual Meeting](#)



Mariana Rodriguez-Pardy, MPH

Hispanics and Latine Americans routinely experience disparities in cancer-related care that and are significantly underrepresented in behavioral medicine and cancer supportive care. The majority of behavioral/psychosocial oncology research continues to focus on non-Hispanic whites.

As we celebrate Hispanic Heritage month, our team would like to shed light on some of these disparities while recognizing positive contributions to increase participation of Hispanic and Latine individuals in cancer research.

Patients with limited English proficiency routinely report sub-optimal communication with providers, poorer pain outcomes, and barriers to pain management (Zhao F, 2014). Given that Spanish is the most common non-English language spoken in the U.S. and approximately half of Spanish speakers have limited English proficiency, it is imperative that care services and research initiatives include opportunities for this growing segment of the population.

With an administrative supplement from the WF NCORP RB IMPACTS trial, our team aims to bridge this gap by leveraging our prior work in Pain Coping Skills Training (PCST) and create the Spanish-language linguistic adaptation of an evidence-based online PCST program, painTRAINER. Using a community engaged approach, our team is developing a **Culturally Appropriate, Non-opioid, Pain Coping Skills Training Intervention for Spanish-speaking Hispanic/Latine Patients with Cancer-related Pain.**

By developing a culturally and linguistically appropriate Spanish-language version of the painTRAINER program (*painTRAINER en Español*) our work will address the unmet but growing need for cancer-related pain management services among historically and traditionally marginalized populations—Spanish-speaking Hispanic and Latine patients.

Funding provided by NIH HEAL Grant (3UG1CA189824-08S2) and Wake Forest NCORP Research Base (2UG1CA189824)

References

Zhao F, Chang VT, Cleeland C, et al. Determinants of pain severity changes in ambulatory patients with cancer: an analysis from Eastern Cooperative Oncology Group trial E2Z02. J Clin Oncol 32:312-9, 2014



UPDATED - Roster Management in RUMS

****You may now have up to two RUMS Managers and up to three Administrators for each site for the WAKE roster.******

As a reminder, a **RUMS Manager** and **ADMINISTRATOR** should be assigned on the WAKE roster for each site with a CTEP ID. Individuals with the Administrator or RUMS Manager role on the WAKE roster may add and withdraw person roles at their site(s).

Individuals requiring access to the WAKE roster will need to request the Administrator or RUMS Manager roles by emailing NCORP@wakehealth.edu, or using the request primary role action icon in RUMS prior to making other roster updates. Instructions for making roster updates are available under the Help Topics on the RUMS toolbar. Please note that the RUMS Manager or Administrator will need to assign the appropriate roles to each site's staff member and make sure the role of "Registrar" is assigned for the WAKE roster to any staff who is planning to register patients in CTSU-OPEN.



OPEN CALL for Committee Members

- The Wake Forest NCORP Research Base is soliciting applications for NCORP Community/MU Community Site representatives for the following committees:
 - Cancer Control Scientific Committee
 - Cancer Care Delivery Research (CCDR) Scientific Committee
 - Health Equity Core Committee
- We are looking for committee members who bring diversity with regards to their expertise, service within NCORP (PIs, scientific leaders, CRAs, research RNs and Administrator) and background and populations engaged.
- **The due date to apply is October 31, 2023.** Selection of committee members will take place in November and committees will begin meetings in January 2024.
- **Link to apply (due to some changes to the survey settings, if you completed this survey last week, please re-apply):** <https://redcap.wakehealth.edu/redcapccc/surveys/?s=8A3F7YX8PADPEYJM>



**Wake Forest NCI Community Oncology Research Program (NCORP) Research Base
New Investigator Workshop - Call for Applications**

Deadline: Friday, December 1, 2023, by 11:59pm EST



Overview: This 3 day, in-person, Wake Forest NCI Community Oncology Research Program Research Base (WF NCORP RB) New Investigator Workshop will be held Monday, February 26, 2024, through Wednesday evening, February 28, 2024, at Graylyn Conference Center (<https://graylyn.com/>) in Winston-Salem, NC. Each applicant will submit a basic proposal (2-page max) for a Cancer Control or Cancer Care Delivery Research (CCDR) study suitable for community oncology sites to be fully developed during the workshop. Protocols that are largely written before the new investigator workshop are likely not appropriate. Modeled after the AACR/ASCO Methods in Cancer Clinical Research workshop and Atrium Health Wake Forest Baptist Comprehensive Cancer Center (AHWFBCCC) boot camp for therapeutic oncology trials, the program will offer didactics related to clinical trial design, NCORP operations, feasibility and approval processes, recruitment of diverse populations, and statistical considerations. Lectures and discussions on how to develop protocols for inclusive and broad patient representation and participation will be led by WF NCORP RB Health Equity Core leadership. Workshop lectures are mixed with intensive mentoring and feedback sessions from experienced NCORP investigators; active group participation through questions and feedback to others is expected of all participants. Additional information about the WF NCORP RB is available at <https://wakencorp.phs.wakehealth.edu>.

Accepted applicants will work with a mentoring team comprised of boot camp faculty with expertise in clinical care, cancer care delivery and implementation science, biostatistics and study design, and research and patient advocate perspectives. Additional mentors will be incorporated as needed to meet trainee needs, i.e., radiation or surgical oncology, hematology, adolescent and young adult (AYA) research, etc. WF NCORP RB research staff will provide additional perspectives on feasibility and multi-site implementation.

The desired outcome of the 3-day in-person workshop is a final study proposal ready for development into a grant submission (with NCI approval), a full NCORP concept to submit to the NCI Symptom Management and Quality of Life (SxQoL) or NCI Cancer Care Delivery Research Steering Committee for approval, or a pilot study to prepare for an eventual NCORP grant/concept. Participating mentors have extensive experience developing NCI concepts and NIH grants for NCORP studies and will work with each participant to decide if additional pilot data may be needed to support the concept. If so, mentors will assist in developing a plan and budget for pilot activities.

Following the workshop, participants will meet monthly with mentors and peers to develop the desired final product. Participants will attend and present their concepts at the WF NCORP RB Annual Meeting October 21 - 22, 2024 in Myrtle Beach, SC as the culminating experience. At the annual meeting, workshop participants will network with national NCORP leaders, receive feedback on their study concept from NCORP investigators, clinical research staff, and clinicians, and learn more about additional career development opportunities through this national research network.

Eligibility:

1. Doctorally trained in any oncology specialty, including medical, surgical, radiation, gynecologic, and pediatric oncology, or faculty from other departments conducting cancer clinical research. Senior fellows may also apply (letter of support from current faculty mentor for fellow applicants strongly encouraged).

*Prioritization will be given to those new investigators (i.e., have not previously been a PI (Principal Investigator) or study chair for a WF NCORP RB study) who self-identify as members of groups underrepresented in the biomedical research enterprise (e.g., certain racial/ethnic groups, persons with disabilities, students from disadvantaged backgrounds, women, and other groups as described in the NIH Notice of Interest in Diversity) from academic institutions and/or NCORP Community and M/U Community sites.

2. The proposal must focus on Cancer Control or Cancer Care Delivery Research; oncology treatment trials will not be responsive. Proposals of an interventional trial well-aligned with WF NCORP priorities that are feasible to open within the NCORP community oncology network (<https://ncorp.cancer.gov/about/>) are strongly encouraged. When appropriate, proposals are encouraged to include biological mechanisms, correlative science, and a focus on underserved patient populations. Priorities include:

Cancer Control

- Cardiovascular complications of cancer therapy
- Neurocognitive complications of cancer therapy
- Additional cancer and treatment-related symptoms (e.g., fatigue, pain) and related outcomes and supportive care interventions

Cancer Care Delivery Research

- Delivery of comprehensive survivorship care
- Integrating informal or familial caregivers into cancer care
- Integration of evidence-based care in cancer care settings

Funding: WF NCORP RB will pay for participant expenses and travel to the workshop in Winston-Salem, provide pilot funds to collect needed pilot feasibility data (where applicable), and to attend and present their concepts at the WF NCORP RB Annual Meeting in Myrtle Beach, SC.

Additional Information: Please contact WF NCORP RB at NCORP@wakehealth.edu for more information.

Deadline: Please complete application and upload CV using this link: <https://redcap.wakehealth.edu/redcapccc/surveys/?s=NMANY9PEHTHNY9LK> by 11:59pm EST on Friday, December 1, 2023.

Wake Forest NCORP Research Base Website

*****If you have already registered, please update your roles on the website*****

We use this information for targeting email communications and surveys.

If you have not registered, go to:

<https://wakencorp.phs.wakehealth.edu/>

Registering for an account will allow you to:

- Join site calls and other meetings from the Upcoming Events or Calendar sections
- Access study training materials
- View previous study meetings
- Download important study documents including training videos, study guides, and neurocognitive CRFs

Once registered, you must update your user profile to sign up for study-specific mailing lists and meeting announcements, indicate your NCORP Community site, add your user roles, and update your GCP for database access.

If you have any questions or need assistance with registration, please email NCORP@wakehealth.edu

Upcoming Site Calls

You can join site calls from our [Wake NCORP website](#). Click the call in the "Upcoming Events" section on the Home page or through the Calendar. You must be a registered user to join from the website.

If you are having trouble joining a call or have any other issues please email NCORP@wakehealth.edu

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

October 24, 2023 at 2:30pm ET. Please update your calendars

December Site Call Time Change Alert

The WF-1806 M&M Site Call scheduled for **December 26th (2:30 pm ET)** has been moved please delete this from your calendar.

The new meeting time is **December 12th at 3:00pm ET**. Use the meeting link below to add this meeting to your calendar.

WF-1901- IMPACTS- Internet-delivered Management of Pain Among Cancer Treatment Survivors

November 8, 2023 at 2:30pm ET. Please update your calendars.

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

November 15, 2023 at 3:00pm ET. Please update your calendars.

Please email 7NCORP@wakehealth.edu when shipping biospecimen samples to the NCORP Research Base Biospecimens lab (Studies WF-97415, WF-1801, WF-1901, and WF-2201). Include the FEDEX tracking number in your email so that misplaced samples can be tracked before they spoil. Please ship by "FedEx Priority Overnight" (please change this on the pre-printed shipping label if this is not selected).

WF-1801 - Ramipril - A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy

We need your help!

We really appreciate your participation in this trial and your efforts to help reach our goal of 75 participants. We only have 4 more to go!

If you have potentially eligible participants at your site, please consider recruiting them to this study.

The study is open to any patient with newly diagnosed Glioblastoma(GBM) scheduled to receive partial brain radiotherapy and temozolomide.

If there are any questions regarding WF-1801, please contact NCORP@wakehealth.edu

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



TRAVEL AWARDS

Congratulations to April Barrett (SC108), Luvdisa Glover (OH122) and each of their teams for earning the HN-STAR Travel Award to the Wake Forest NCORP Research Base Annual Meeting in October!

FAQs

The FAQ document has been updated and posted on our website at <https://wakencorp.phs.wakehealth.edu/>. Click on Studies/HN-STAR/FAQs.

WF-1901 - IMPACTS - Internet-delivered Management of Pain Among Cancer Treatment Survivors



MPACTS Site to Site Mentorship Initiative

This initiative gives sites the opportunity to connect with other sites who have been successful with recruitment in IMPACTS.

- **Goal:** To promote communication that supports a positive mentorship relationship between NCORP sites.
- **Objective:** To explore potential strategies to assist sites in building confidence, recruitment awareness, and providing tips for success with IMPACTS.

Site Mentor: University of Hawaii Cancer Center

Christa Braun-Inglis, DNP, APRN, FNP-BC, AOCNP is the champion Contact for **providers** with questions on getting IMPACTS out to your patients. Contact is cbrauninglis@cc.hawaii.edu

Courtney Chunn, Clinical Research Specialist III, is the champion contact for **study team members** assisting with recruitment. Contact is cchun@cc.hawaii.edu

TRAVEL AWARD

Congratulations to Maya Agosto (GA106) and her team for earning the IMPACTS Travel Award to the Wake Forest NCORP Research Base Annual Meeting in October!

WF-2201 - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy



HYPOGRYPHE (WF-2201) Amendment 2, Protocol Version Date 08/03/2023, Release Date 09/14/2023.

The WF NCORP Research Base study entitled *Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy (HYPOGRYPHE)* has been amended. The amended protocol and related documents were released on September 14, 2023.

Changes with this amendment include:

- Pushing Unacceptable Deviation from >10 days to >14 days after MRI for treatment planning.
- Adding Non-Member Collaborator Carolinas Medical Center/Levine Cancer Institute (NC042) to the protocol document.
- Updating Dr. Corbin A. Helis, MD organization's information.
- Removing Co-Investigator/ Neuropsychology Chair Tiffany L. Cummings.
- Adding inclusion criteria that states study is only available for English and Spanish speakers.

WF-2201 Document Access:

- The protocol and participant directed documents are available on the [CTSU](#) website.
- The *Helpful Guide* and *Training resources* are available on the [WAKENCORP](#) website.

Sites interested in participating should contact NCORP@wakehealth.edu; Attn: WF-2201 and request a start-up packet. **Your site must be IROC certified to participate or be willing to become certified.** Refer to Sections 5.2, 6.2 & 6.6 of the protocol for the Protocol Specific Requirements and Site Registration and Credentialing Requirements for site participation. Please refer to your study start-up packet details to begin this process if you are interested in participating in this new study.

Regulatory requirements to activate this study can be found in the protocol on the CTSU website.

If there are any questions regarding the WF-2201 activation, please contact NCORP@wakehealth.edu; Attn: WF-2201.

WF-97415 - UPBEAT - Understanding and Predicting Breast Cancer Events after Treatment

*****Remember to continue annual follow-up contact with participants through 11 years. This follow-up includes the KCCQ Questionnaire, documentation of any cardiovascular events and SAEs as described in the study protocol.*****

Accruals as of October 11, 2023

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	71	--	75		
WF-1806	M&M	163	+1	300		
WF-1901	IMPACTS	129	+3	250	0	40
WF-1805CD	HN-STAR	173	+7	350	109	140
WF-2201	HYPOGRYPHE	1	--	244		

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