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Wake  
Forest  
NCORP RESEARCH BASE



STUDY MATTERS

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October 26, 2023

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

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**Wake Forest NCORP Research Base Annual Meeting**

Many thanks to everyone who participated with us in Asheville, NC last week! It was a beautiful and productive time spent learning, networking, and sharing ideas.

We hope to see you next year October 21-22, 2024 at Grand Dunes Resort in Myrtle Beach, SC!







# NATIONAL HISPANIC HERITAGE MONTH

**Mariana Rodriguez-Pardy, MPH**

Hispanics and Latine Americans routinely experience disparities in cancer-related care 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





## **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:**

<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](mailto: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.

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## 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](mailto:NCORP@wakehealth.edu)

## Upcoming Site Calls

Please add these meetings to your calendar,

**\*\*Please note that your calendar may not update automatically if changes are made. Please check these emails and our website for meeting updates.\*\***

You can also 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](mailto:NCORP@wakehealth.edu)

**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.

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

**November Site Call Time Change Alert**

The WF-2201 HYPOGRYPHE Site Call scheduled for **November 14th (2:00pm ET)** has been moved. The new meeting time is **November 29<sup>th</sup> at 2:00pm ET**.

Please update your calendars

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

**December Site Call Time Change Alert**

The WF-1806 M&M Site Call scheduled for **December 26<sup>th</sup> (2:30 pm ET)** has been moved. The new meeting time is **December 12<sup>th</sup> at 3:00pm ET**.

Please update your calendars

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Please email [7NCORP@wakehealth.edu](mailto: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).



## Study Updates

### [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 **2** 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](mailto:NCORP@wakehealth.edu)

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### [WF-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR](#)

# HN-STAR

#### [FAQs](#)

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

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### [WF-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer](#)



**Every site who enrolls a patient in October will get Halloween treats in the mail. You have a few days left!**

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



### **IMPACTS 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](mailto: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](mailto:cchun@cc.hawaii.edu)

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



### **NEW SPANISH DOCUMENT POSTED**

**HYPOGRYPHE (WF-2201) Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy Amendment 2, Protocol Version Date 08/03/2023 was posted on 10/13/2023.**

The Spanish version of the following document was posted on CTSU on Friday, **October 13, 2023**.

- **Consent Form**, (PVD 08/03/23): Spanish

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

Sites interested in participating should contact [NCORP@wakehealth.edu](mailto: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.**

## 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.\*\*\***

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### Accruals as of October 25, 2023

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	73	+2	75		
WF-1806	M&M	170	+7	300		
WF-1901	IMPACTS	130	+1	250	0	40
WF-1805CD	HN-STAR	176	+3	350	109	140
WF-2201	HYPOGRYPHE	1	--	244		

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