



STUDY MATTERS

November 9, 2023

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

Wake Forest NCORP RB Holiday Hours

The Wake Forest NCORP Research Base offices will be closed for Thanksgiving on **Thursday, November 23 and Friday, November 24**. Enjoy the time with your families.

McKesson Clinical Research Services Holiday Hours Clinical Research Services Closed November 23-24, 2023

In observance of the Thanksgiving holiday, McKesson's Clinical Research Services will be closed **Thursday, November 23 and Friday, November 24, 2023**. We will resume regular business hours on Monday, November 27, 2023.

Our regular business hours are Monday through Friday, 9 am to 6 pm ET.

Please take this information into consideration when placing your orders **prior to the Thanksgiving holiday**.

- Only non-refrigerated product will be shipped on **Wednesday, November 22**. Orders placed prior to 2 pm ET will be delivered on **Friday, November 24**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Tuesday, November 21** prior to 2 pm ET.

Due to the influx of shipments around the holidays, carrier delays may occur. Please plan your orders accordingly.

If you have questions regarding the shipment schedule, please contact our Clinical Research Services team at 800.693.4906, or via email at clinicalresearchservices@mckesson.com.

We appreciate the opportunity to assist you and your patients.

Kind regards,

Clinical Research Services team

Wake Forest NCI Community Oncology Research Program (NCORP) Research Base Boot Camp

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=NMANY9PEHTHONY9LK> by 11:59pm EST on Friday, December 1, 2023.

Wake Forest NCORP in the News!

Congratulations to **Dr. Chandysten Nightingale** for her publication discussing the WF-1803CD Caregivers study in the Journal of the National Cancer Institute.

https://www.cancer.gov/news-events/cancer-currents-blog/2023/cancer-caregivers-distress-screening?cid=eb_govdel [[cancer.gov](https://www.cancer.gov/)]

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

Please email 7NCORP@wakehealth.edu when shipping biospecimen samples to the NCORP Research Base Biospecimens lab (Studies 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).

Upcoming Site Calls

Please add these meetings to your calendar. You can join these meetings from the [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.

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

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

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. Please delete this from your calendar.

The new meeting time is **November 29th at 2:00pm ET**. Use the meeting link below to add this meeting to your calendar.

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 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.

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 only have 1 more to go!

We really appreciate your participation in this trial and your efforts to help reach our goal of 75 participants.

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

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.

HN-STAR Site to Site Mentorship Initiative

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

- **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 HN-STAR.

Site Mentor: Licking Memorial Hospital (OH122)

Luvdisa Glover, RN is the champion contact for **study team members** needing assistance with recruitment. Contact lglover@lmhealth.org. Thank you, Luvdisa!

If you or anyone at your site is interested in being a provider or study team mentor for HN-STAR, please contact NCORP@wakehealth.edu Attn: WF-1805CD to discuss.

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

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

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; Attn: WF-2201.

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.**

WF-2300CD - CONNECT Survey - Practice Survey for Multi-Site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers



Caregiver Oncology Needs Evaluation Tool

Join us for an introductory webinar on **Thursday, November 16, 2023 at 3pm ET** to learn more about this important study that is activating November 13th!

You can join the meetings from the [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.

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

Please submit any remaining MRI and CPET invoices before **December 15, 2023**.

*****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 November 8, 2023

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	74	+1	75		
WF-1806	M&M	171	+1	300		
WF-1901	IMPACTS	132	+2	250	0	40
WF-1805CD	HN-STAR	186	+10	350	114	140
WF-2201	HYPOGRYPHE	1	--	244		

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