



STUDY MATTERS

November 22, 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.



The NCI CIRB Operations Office will be closed **Thursday, November 23, 2023 through Friday, November 24, 2023** for the Thanksgiving Holiday. If you need to reach the CIRB Operations Office, please do so before Thursday, by sending an email to [CIRB Helpdesk](#), or by calling us toll-free at 1-888-657-3711.

Thank you and have a safe holiday.

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.

Strategies to Disseminate and Sustain Cancer Care Delivery Innovations Webinar

**Thursday, January 25th
4-5pm ET**

Dr. Kristie Foley and Dr. David Miller

You can join the webinar from our website: <https://wakencorp.phs.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).

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

Please add these meetings to your calendar

****Please note that your calendar will 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

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**. Please update 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**. Please update your calendar.

Study Matters

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

****CLOSED TO ACCRUAL****
Effective November 14, 2023

We would like to thank all sites who have participated in this study and helped us meet our goal of 75 participants. **We wanted to let you know that this study has met accrual and is now closed to accrual.**

REMINDER: You should still follow your current enrolled patients on study per protocol and continue with your IRB renewals at this time. Let us know if you have any questions by emailing NCORP@wakehealth.edu.

What's Next?

1. Please keep this study closed to accrual at your site. Please do not submit a Study Closure Request to the CIRB for this study until the Wake Forest NCORP Research Base gives your site permission.
2. Until this study has been officially FDAAA/IRB Completed by the Wake Forest NCORP Research Base, your site may still be audited on this study.
3. We should keep all study documents for at least five years once the study has been FDAAA/IRB completed, following the protocol requirements and your local site's record retention policies.

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



BLOOD SPECIMEN SHIPPING ALERT

Some sites are still sending samples to the University of Alabama - Birmingham location. Please be aware that the shipping location changed with our last amendment, which was announced via broadcast email on 7/14/2023.

WF-1806 (M&M) Amendment 8, Protocol Version Date 05/23/2023, Release Date 07/14/2023:

- Changing lab location for blood sample submission to WF NCORP Biospecimen Lab. – See updated Helpful Guidelines.

WF-1806 Helpful Guidelines document has been updated to version 07/05/2023 and reflects the new blood sample shipment destination below. This document is available on our Wake NCORP RB website;
<https://wakencorp.phs.wakehealth.edu/>.

ATTN: WF-1806 (M&M)
WF NCORP Biospecimen Lab
Bldg. A1A Lab 230 c/o Delivery on Time
Wake Forest School of Medicine
Richard Dean Bldg. Receiving Dock
391 Technology Way
Winston-Salem, NC 27101
Phone: (336) 716-2581

Please email 7NCORP@wakehealth.edu if you need replacement air bills for kits that you have in stock and be sure to include the **kit#** in your email.

If there are any questions, we are glad to help. Please contact us at NCORP@wakehealth.edu;
Attn: WF-1806.

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



****DATA ALERT****

Before distributing the 7-Day Medication diary to a participant (in person or by mail):

1. **Ensure that all pages have the patient header, including PID and page numbers completed.** We recommend making a copy of the form, in case it gets lost in the mail.
2. Please complete the **Medication, Type and Dose/Strength** fields on the form for any medication that the participant currently is taking, using the medical record to provide a complete list of all medications. Please provide additional blank pages for medications, supplements or essential oils that the participant may need to add at home later.
3. At timepoints T3 and T4 the two typical usage questions are optional for patients. They are designated as “Staff Only”. You may draw a line through them, initial and date these questions, if you prefer.

Participants will not receive payment for lost or unidentifiable diaries.

These items can be completed electronically on the PDF document or hand-written in the spaces provided prior to distribution.

Please check the Helpful Guide on our website: <https://wakencorp.phs.wakehealth.edu/study/wf1901-impacts/> for more information.

If you have question about completing these diary forms please contact NCORP@wakehealth.edu

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



Caregiver Oncology Needs Evaluation Tool

NEW STUDY ACTIVATION

CONNECT Practice Survey (WF-2300CD) Amendment 1, PVD 10/12/2023 was activated on November 13, 2023.

The WF NCORP Research Base study entitled, “*Practice Survey for Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers*” was activated on November 13, 2023

Participation:

All NCORP Administrators and CCDR Leads rostered with Wake Forest NCORP Research Base will receive the *Practice Recruitment Email*, containing a link to the *Practice Interest Form* which must be completed to initiate the start-up process and to receive your assigned *Practice ID Email*. The *Practice ID Email* is needed for 1) activation of the protocol at your site and 2) CTSU-OPEN practice site(s) registration.

- **How to Activate your Site:** Since there is no required IRB approval for this study, sites will be required to submit the *Practice ID Email* to CTSU Regulatory Office via the Regulatory Submission Portal to activate their site. Please refer to section 6.2 of the protocol for how to submit regulatory documents to CTSU. When you submit the *Practice ID Email* to the CTSU Regulatory Office, please add in the comment section the name and CTEP ID of your site PI for their reference.
- **Enrollment of Practice Site(s):** Sites are required to enroll all practice site(s) in CTSU-OPEN for this study. The Practice ID will be used in CTSU-OPEN during this process.

If your practice site is interested in participating in this study, contact your NCORP Administrator and/or CCDR Lead to have them complete the *Practice Interest Form*.

Document Access:

- The protocol and the NCI CIRB determination letter, stating this study is “Not Human Subjects Research” are posted on the [Wake NCORP \[wakehealth.us19.list-manage.com\]](http://wakehealth.us19.list-manage.com) website.

If you have any questions, please contact NCORP@wakehealth.edu; Attn: **WF-2300CD**.

REMINDERS

****Sites MUST upload *Practice ID Email Letter* sent from WF NCORP RB to CTSU Regulatory Submissions to be eligible to receive the Practice Survey. When uploading, be sure to add name and CTEP ID of your site PI in the Comments section.**

****The Introductory Webinar has also been posted to <https://wakencorp.phs.wakehealth.edu/study/wf2300cd-connect-survey/>.**

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 21, 2023

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	176	+5	300		
WF-1901	IMPACTS	135	+3	250	0	40
WF-1805CD	HN-STAR	189	+3	350	116	140
WF-2201	HYPOGRYPHE	1	--	244		

Open Studies	Name	Enrolled (Practice Groups)	Change in Past 2 Weeks	Target (Practice Groups)	Enrolled (CTEP IDs)	Change in Past 2 Weeks	Target (CTEP IDs)
WF-2300CD	CONNECT Survey	3	+3	120	11	+11	240

Copyright © 2023 Wake Forest NCORP Research Base, All rights reserved.
You were added to this email list when you were rostered to the WAKE NCORP Research Base

Our mailing address is:

Wake Forest NCORP Research Base
Medical Center Blvd
Winston Salem, NC 27157-0001

[Add us to your address book](#)

Want to change how you receive these emails?
You can [update your preferences](#) or [unsubscribe from this list](#).

