



August 15, 2024

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

Wake Forest NCORP Research Base Holiday Hours

Our office will be closed **September 2, 2024** in observance of Labor Day.

MCKESSON

McKesson's Clinical Research Services Closed September 2, 2024

In observance of Labor Day, McKesson's Clinical Research Services will be closed **Monday, September 2, 2024**. We will resume regular business hours on Tuesday, September 3, 2024.

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 Labor Day**.

- Only non-refrigerated product will be shipped on **Friday, August 30**. Orders placed prior to 2 pm ET will be delivered on **Tuesday, September 3**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Thursday, August 29** 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 NCORP Research Base Quarterly Call

Our quarterly call was held on **July 31, 2024**

[Click here to access the recording](#)

2024 Wake Forest NCORP Research Base Annual Meeting

Registration is Now Open!



October 21 – 23, 2024

At the Marriott Myrtle Beach Resort & Spa at Grande Dunes in Myrtle Beach, SC

- If you plan to attend the Health Equity Luncheon, you must register as space is limited to 60.
- If you plan to attend the half day, Just Ask™ Training on Wednesday, October 23, you must register as space is limited to 60.
- Once you register, you will be sent a confirmation email. Within this email is the link to the hotel for room reservations.
- **You must register for the meeting in order to receive the hotel reservation link.**

This meeting will be held in person only this year and the registration link will be posted on our website (and below) for members only.

[Click here to register](#)

Our Keynote Speaker will be **Karriem Watson, DHSc, MS, MPH** who presides over the *All of Us* Research Program at the NIH.

Nadine Barrett, PhD, MA, MPH will be leading our Just Ask™ Training on Wednesday. This is a special ASCO-ACCC resource for research sites to help improve equity, diversity, and inclusion in cancer clinical trials.

2024 WF NCORP RB Annual Meeting Travel Awards

- **Awards given to top 2 accruing community sites for each study based on enrollments from February 1 - July 31, 2024. There were a max of two awards per NCORP community across all studies.**
- Travel awards assist with travel to our 2024 Wake Forest NCORP RB Annual Meeting in Myrtle Beach, SC, October 21-23.
- **Awards are worth up to \$1,000 each** to cover travel and hotel expenses at The Marriott Myrtle Beach Resort & Spa at Grande Dunes.
- **The Wake Forest NCORP RB will reach out to each of the winners with more details soon.**

Congratulations to our Travel Award Winners!

WF-1805CD HN-STAR

- **CROWN- 13**
- **STROGER MU- 10**

WF-1806 M&M

- **STROGER MU- 7**
- **MCRC- 6**

WF-1901 IMPACTS

- **ATLANTIC- 14**
- **HAWAII MU- 6**

WF-2201 HYPOGRYPHE

- **MONTEFIORE MU- 1**

WF-2202 SHINE

- **OZARKS- 81**
- **CARLE- 31**



*****REMINDER*****

Current Good Clinical Practice (GCP) certification is required for access to our REDCap database. GCP certification dates in RSS always default to the 1st of the expiration month. If you receive a notice from REDCap about your account expiring this is most likely due to an expiring GCP certification. You can upload new certificates to our website (<https://wakencorp.phs.wakehealth.edu/>) or you can email them to NCORP@wakehealth.edu.

Upcoming Site Calls

If you haven't already added the meeting to your calendar, please add it now.

****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

WF-1806- M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer
August 27, 2:30-3:00 PM ET

WF-2303CD - HRSN - Understanding and Enhancing Health-related Social Needs (HRSN) Screening Among Community Oncology Practices
Introductory Webinar
August 27, 1:30-2:30 PM ET

WF-1901 - IMPACTS - Internet-delivered Management of Pain Among Cancer Treatment Survivors
September 11, 2:30-3:00 PM ET

Study Updates

WF-30917CD - Telehealth- A Stepped-Care Telehealth Approach to Treat Distress in Cancer Survivors

****Study Complete** Effective 12/31/2023**

We appreciate all sites who participated in this study. The study has now completed follow-up and data analysis is being reviewed. As soon as the primary manuscript has been published we will inform you and create a brief synopsis in layman's terms based on the published results that you may share with your patients that participated, if you desire.

What's Next?

1. The "complete" status means the protocol has been closed to accrual, all participants have completed therapy, and the study has met its primary objectives.
2. Proceed with closing the study at your site.
3. Hold on to all study documents for 5 years from the date above.

If you have any questions, email NCORP@wakehealth.edu.

WF-1801 - Testing Ramipril to Prevent Memory Loss in People with Glioblastoma

If your site participated in the Ramipril study, please ensure that your staff ceases using the LabCorp account set up for this study. All patients should have completed any necessary blood draws or testing.

We have been receiving several incorrectly charged labs to this account monthly. We cannot close out the account until everything is cleared.

Thank you for your attention to this matter.

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

NEW SPANISH DOCUMENTS POSTED

WF-1806 (M&M) Amendment 9, Protocol Version Date 06/17/2024, Release Date 07/25/2024:

The Spanish version of the following document was posted on CTSU on Tuesday, July 30, 2024.

- Consent Form, (PVD 06/17/24): Spanish

WF-1806 Document Access:

- The protocol and participant directed documents are available on the [CTSU](#) website.
- The *Helpful Guidelines, FAQs, Provider Fact Sheet* and *Training Attestation* documents are available on the [WAKENCORP](#) website.

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

NEW AMENDMENT ACTIVATION

WF-1806 (M&M) Amendment 9, Protocol Version Date 06/17/2024, Release Date 07/25/2024:

The WF-1806, *Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer (M&M)* study has been amended. The amended protocol and related documents were released on **Thursday, July 25, 2024**.

Changes with this amendment include:

- Updated age strata enrollment minimums throughout protocol and consent which will allow for additional enrollments to the younger stratum.
- Updated Protocol Cover Page to reflect current language and representation of the Multi Principal Investigators.
- Removed the following Non-member Collaborators from the protocol cover page: Carolinas Medical Center-Levine Cancer Institute (NC042), Atrium Health Cabarrus/LCI-Concord (NC083), Atrium Health Pineville/LCI-Pineville (NC193), Atrium Health University City/LCI-University (NC154)
- Updated CTSU language based on 01/25/24 and 03/26/2024 support logistical template language documents.
- Administrative changes to language.

WF-1806 Document Access:

- The protocol and participant directed documents are available on the [CTSU](#) website.
- The *Helpful Guidelines*, *FAQs*, *Provider Fact Sheet* and *Training Attestation* documents are available on the [WAKENCORP](#) website.

If there are any questions regarding WF-1806 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



SITE CHECK-INS



Site check-ins will resume this month. During this time, we can address any challenges or barriers you may have encountered as well as provide guidance on recruitment and/or eligibility questions you may have. An email will be sent to your site requesting the dates and times that are most convenient for your team. Additionally, if your site is in need of a refresher training for WF-1901 IMPACTS, feel free to reach out to us at NCORP@wakehealth.edu to schedule.

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 5, Protocol Version Date 06/20/2024 was posted on 7/12/2024.

The Spanish version of the following document was posted on CTSU on Thursday, July 25, 2024.

- **Consent Form**, (PVD 06/20/24): Spanish

If there are any questions or your site is interested in participating in the WF-2201 study, please contact NCORP@wakehealth.edu; Attn: WF-2201.

Please note, your site must be IROC certified to participate or be willing to become certified.

HELPFUL GUIDE

A revised Helpful Guide is now posted to the [WAKENCORP](https://www.wakehealth.edu/ncorp) website, updating the lab and tissue section.

NEW AMENDMENT ACTIVATION

HYPOGRYPHE (WF-2201) Amendment 5, Protocol Version Date 06/20/2024, Release Date: 07/12/2024.

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 consent were released on July 12, 2024.

Changes with this amendment only affected the protocol and consent. Therefore, only the protocol and consent have the version date 6/20/2024.

The changes include:

- Added Emily V. Dressler, PhD to protocol cover page
- Updated position title for the Protocol Principal Investigator on protocol cover page
- Removed Non-Member Collaborator from protocol cover page
- Protocol version date
- Consent version date

WF-2201 Document Access:

- The protocol documents 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.

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-2202 - SHINE - Optimizing Psychosocial Intervention for Breast Cancer-related Sexual Morbidity: The Sexual Health and Intimacy Education (SHINE) Trial



WF-2202 SHINE Study: Minority Enrollment Concern

We would like to extend our gratitude to all NCORP community sites that have enrolled to the WF-2202 SHINE Study. This study is accruing at an extremely high rate, and we need to make a few short-term adjustments to ensure our sample reflects the racial and ethnic diversity of breast cancer survivors as a whole. For example, although we have enrolled 239 towards our total accrual goal of 320 survivors (75% of goal for the total sample), we have only enrolled 10 Black/African American survivors (20% of our goal from this population) and 2 Asian American survivors (15% of our goal from this population). To achieve a diverse sample of participants, we are **temporarily suspending enrollment of non-Hispanic White participants effective August 22, 2024**. Note, unknown race or ethnicity will be allowed. This suspension will continue for a few months, and we will send updated communications once this is lifted.

If you have any in-progress screenings or enrollments, please ensure these participants are fully enrolled in OPEN before August 22, 2024. Please let us know if you have concerns about meeting this deadline with an email to NCORP@wakehealth.edu.

WF-2301CD - CONNECT - Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers



Caregiver Oncology Needs Evaluation Tool

NEW AMENDMENT ACTIVATION

CONNECT (WF-2301CD) Amendment 2, Protocol Version Date 07/08/2024 has been activated.

The WF NCORP Research Base study entitled **Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers** has been activated. The protocol and related documents were released on August 8, 2024.

Changes with this amendment include:

- Updating brief eligibility in the schema to match Sections 4.1 and 4.2.3 of the protocol.
- Adding plain language names/titles to the Table 3 Assessment Plan in Section 7.8.
- Adding “Refuse to answer” response option to patient and caregiver surveys.
- Simplifying screening process.
- Clarifying referral tracking process for Local Referral Coordinators.
- Clarifying EHR abstraction.
- Adding Contact Attempt Logs for use of local NCORP site staff.
- Updating 12- and 24-week survey completion windows on the schedule of events.
- Updating Caregiver eligibility.

To be used by the Central CONNECT Navigator only:

- Adding an Interim Navigation Call Guide.
- Adding a Tailored Resource List Letter.
- Adding a Generic Resource List Letter.
- Adding a CONNECT Additional Resources Letter.

WF-2301CD Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The FAQ, OPEN enrollment forms and introductory webinars are available on the [WAKENCORP](#) website.

Sites are selected for participation in this study and selected sites have already been contacted. Once your site has entered your community resources into the CONNECT intervention, please email us at CONNECT@wakehealth.edu so that we can schedule a pre-implementation call. Once this call and all forms are completed, we will send your SOTE letter to upload to CTSU.

If there are any questions regarding the WF-2301CD activation, please contact NCORP@wakehealth.edu; Attn: WF-2301CD.

WF-2303CD - HRSN - Understanding and Enhancing Health-related Social Needs (HRSN) Screening Among Community Oncology Practices



NEW STUDY ACTIVATION

HRSN (WF-2303CD) Amendment 1, Protocol Version Date 05/20/2024 has been activated.

The WF NCORP Research Base study entitled **Understanding and Enhancing Health-related Social Needs (HRSN) Screening Among Community Oncology Practices** has been activated. The protocol and related documents were released on July 23, 2024.

WF-2303CD Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The *OPEN Eligibility Checklist* for practices is available on the [WAKENCORP](#) website.
- The **Introductory Webinar** will be held on **August 27 @ 1:30pm ET**. Click below to add this to your calendar.

Following the Introductory Webinar, all NCORP Administrators and CCDR Leads will receive a *Practice Recruitment Email* that includes a link to the *Practice Interest Form*. The *Practice Interest Form* must be completed to be considered for participation in this 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-2303CD activation, please contact NCORP@wakehealth.edu; Attn: WF-2303CD.

Wake Forest NCORP Research Base Website

Reminder: Additional resources, **which are not CIRB approved**, are maintained on our Wake Forest NCORP RB website and **are not available on CTSU**. Note, these resources include a **Helpful Guide** for each study, which provides guidelines for the study team, as well as other study instructions.

Remember to update your profile to include any new studies you may be involved in

We use this information for targeting email communications and surveys.

<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

Accruals as of August 14, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	218	+3	300		
WF-1901	IMPACTS	186	+3	250	0	40
WF-1805CD	HN-STAR	291	+1	350	132	140
WF-2201	HYPOGRYPHE	8	--	244		
WF-2202	SHINE	242	+31	320		

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Research Base

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