



STUDY MATTERS

August 1, 2024

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

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

****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-2202 - SHINE - Optimizing Psychosocial Intervention for Breast Cancer-related Sexual Morbidity: The Sexual Health and Intimacy Education (SHINE) Trial
August 14, 2:00 PM ET

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

Study Updates

WF-1801 - Ramipril- 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



UPDATE ON ENROLLMENT

A big **THANK YOU** to our site partners for continuing to work with us on this study. We plan to continue enrolling through next year.

Glad to answer any questions or concerns at NCORP@wakehealth.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 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, **Helpful Guide 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](#) 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



OPEN Enrollment Form Addition

As of June 27th, sites are required to enter the Screening Record ID in OPEN when enrolling patients to the SHINE study. This Record ID is unique and can be obtained from the REDCap project “WF-2202 SHINE Screening Log”. The format is XXXX-XX and is numeric.

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**.

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 July 31, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	215	+2	300		
WF-1901	IMPACTS	183	+4	250	0	40
WF-1805CD	HN-STAR	290	+3	350	132	140
WF-2201	HYPOGRYPHE	8	+1	244		
WF-2202	SHINE	211	+38	320		

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Research Base

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

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