



STUDY MATTERS

February 13, 2025

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

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, click the button below the meeting to 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 - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer: The M&M Study

Tuesday, February 25 2:30-3:00pm ET

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

Tuesday, March 11 3:00-4:00 pm ET

WF-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR

Wednesday, March 19 3:00-3:30 pm ET

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

Wednesday, March 19 3:00-3:30 pm ET

Quarterly Call

Wednesday, April 2 3:00-4:00 pm ET

Study Updates

(NEW!)WF-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR

Effective Immediately: Step 1 Participant Enrollment in OPEN is closed.

We have closed Step 1 enrollment for new participants to the WF-1805CD-HN-STAR study in OPEN. The full enrollment process is not complete until the Step 2 consent and Step 2 enrollment are completed in OPEN. **Only Step 1 of the 2-step process is now closed.** All Step 2 enrollments and DC visits must be completed by April 14, 2025. Any participant who cannot complete their Step 2 enrollment and DC visit by April 14 must be withdrawn from the study.

Thank you for helping us enroll to this important study!

If there are any questions regarding WF-1805CD, we are glad to help. Please contact us at NCORP@wakehealth.edu; Attn: WF-1805CD.

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

The total enrollment goal has been increased to 336. As of 2/12, we have 322 accruals!

Please make a final effort to approach and screen participants to help us finish this study soon! Everyone who enrolls a participant in February will get a candygram!

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

Thank you for continuing to screen and enroll M&M participants. We have 10 slots left in the 60 -74yo stratum and 53 slots in the >75yo stratum. In 2025, we will continue sending candygrams to the site that enrolls first each month. **Everyone that enrolls a participant in February will get a candygram!**

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

WF1901 IMPACTS Monthly Challenge Winner(s)!

Congratulations to: Margaret Blalock and Nitisha Patel were tied for January enrollments! They also have a chance to win a travel award to our ***Wake Forest Research Base NCORP Annual Meeting set for October 2025!***

Your help is essential for us to reach our goal of **250!** We are just **43** enrollments away and are needed by **July 31, 2025!**

If you need refresher trainings or have questions regarding eligibility, please contact NCOPR@wakehealth.edu. We are here to help!

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

We need your help with enrollment!

This study is open to patients with brain metastases currently receiving or planning to receive PD-1/PD-L1 targeted immune checkpoint inhibitor therapy within 30days of SSRS/FSRS for Melanoma, renal cell, non-small cell lung, small cell lung or breast cancer patients with brain metastases. We want to get the study started at your sites and look forward to working with you on this important research study.

Contact us at NCORP@wakehealth.edu if your site is interested in the study. Please note, your site must be IROC certified to participate or be willing to become certified

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

An updated Helpful Guide and FAQ (v02.02.2025) were posted to our website.

(NEW!)WF-2304-A172401 – COSMIC - Complementary Options for Symptom Management in Cancer

Participant Email Address: This study is survey driven, please remind participants to expect emails from NCORP@wakehealth.edu with the subject "COSMIC Study: See if it's Right for You" after they have consented, and advise them the links are safe. Contact us at NCORP@wakehealth.edu to assist with resending emails.

REDCap: Access to REDCap requires completion **WF2304-A172401 COSMIC Introductory Site Training** as well as current Good Clinical Practice certification (GCP). Please be sure those items are completed and current before requesting access to avoid delaying access to REDCap. Copies of the Introductory Site Training certificates are available on CLASS. **Note:** WF2304-A172401 COSMIC Introductory Site Trainings cannot be "skipped" or bypassed. Viewing in its entirety is required to receive certificate of completion. If you have issues with viewing, please contact CLASSHelpDesk@westat.com
Please complete the **Local NCORP Staff Contact** form in REDCap as soon as possible after enrollment. This is how we communicate to the sites about survey completions. If left undone sites will not receive baseline completion notifications.

Crediting group in OPEN: When enrolling participants into OPEN, and your site belongs to both crediting groups (ALLIANCE and WAKE), please choose WAKE to ensure proper credit. Please only select **ALLIANCE** if your site does not belong to a WAKE NCORP Group. Please see Helpful Guide. If this has been done in error, please contact ctsuoopenforms@westat.com and include NCORP@wakehealth.edu on this communication.

TRAVEL AWARD COMPETITION

Our Research Base will be offering a travel award to one site for each of the following studies: WF-1806 (M&M) , WF-1901 (IMPACTS) and WF-2301CD (CONNECT). The travel award will be given to the sites with the most enrollment between January 1st, 2025 – July 31, 2025, one award per study. This award will help cover expenses up to \$1000 for travel to the 2025 Wake Forest NCORP Research Base Annual Meeting in Asheville, North Carolina!

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 February 12, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	237	+0	300		
WF-1901	IMPACTS	207	+2	250	0	40
WF-1805CD	HN-STAR	336	+4	350	132	140
WF-2201	HYPOGRYPHE	19	+1	244		
WF-2202	SHINE	322	+4	336		
WF-2301CD	CONNECT	18 (pt/ caregiver dyad)	+8	120 (dyads)		
WF2304-A172401	COSMIC	15	--	2000		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	14	1	20	33	136