



## STUDY MATTERS

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December 5, 2024

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

### **Wake Forest NCORP Research Base Upcoming Holiday Hours**

The Wake Forest Research Base NCORP offices will be **closed December 24 & 25** for Christmas.

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#### **\*\*\*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](mailto:NCORP@wakehealth.edu).

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## 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](mailto:NCORP@wakehealth.edu)

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

**Wednesday, December 11 2:00-3:00pm ET**

**(NEW!)WF-2201 - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy**

**Tuesday, January 14, 3:00-4:00 pm ET**

**Study Updates**

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

### **Increased enrollment target**

In an effort to meet our protocol designated goal of 320 randomized participants, we are going to be replacing subjects that came off study before randomization by increasing the current accrual target to **336**. As of 12/4 enrollment is at 311 so please continue to screen and enroll participants. Enrollment will still be limited to racial and ethnic minority participants.

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

### **IMPORTANT REMINDER**

Fed Ex account # for CT scan shipment was changed 7/5/2023. Some sites are still using the old account number resulting in inappropriate charges to UAB. Please refer to your **Helpful Guidelines version 07/05/2023 p.9** for the correct account number. The Helpful Guidelines are available for download from the WF1806-M&M Study page on the Wake NCORP website <https://wakencorp.phs.wakehealth.edu/>. If you have questions please contact us at [ncorp@wakehealth.edu](mailto:ncorp@wakehealth.edu).

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

## Onboarding Updates

- SOTE letters have been sent to all invited sites. Please upload your SOTE letter to CTSU to obtain final IRB approval.
  - Once you have IRB approval, please enroll your practice (each individual CTEP ID that is listed on your SOTE letter separately) into OPEN.
  - Consent and enroll your Practice Staff into OPEN.
  - Wake Forest NCORP RB will enter your Practice ID into REDCap; you will not need to enter the Practice ID for enrollment into OPEN.

## Training Updates

- Wake Forest NCORP RB will contact you once your Practices and Practice Staff are enrolled into OPEN to set up your training. The goal is to have all Practices and Practice Staff enrolled by January 3, 2025 so that we can begin training up to 4-5 practices in each session.
- Practice Staff Training dates will begin in January. Please be sure your Practice (all approved CTEP IDs on your SOTE letter) are registered in OPEN, as well as your Practice Staff. We will begin reaching out to each NCORP to schedule your trainings soon.
- Please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) with any questions.

## 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](mailto:NCORP@wakehealth.edu).

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## Accruals as of December 5, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	231	+1	300		
WF-1901	IMPACTS	203	+2	250	0	40
WF-1805CD	HN-STAR	318	+6	350	132	140
WF-2201	HYPOGRYPHE	13	+1	244		
WF-2202	SHINE	311	+2	336*		
WF-2301CD	CONNECT	2 (pt/ caregiver dyad)	+1	120 (dyads)		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	11	--	20	9	136