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## STUDY MATTERS

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July 3, 2024

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

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### Wake Forest NCORP Research Base Holiday Hours

The Wake Forest Research Base NCORP offices will be **closed both July 4 and 5** in observation of Independence Day.

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**MCKESSON**

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### McKesson's Clinical Research Services Closed July 4, 2024

In observance of Independence Day, McKesson's Clinical Research Services will be closed **Thursday, July 4, 2024**. We will resume regular business hours on Friday, July 5, 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 Independence Day**.

- Only non-refrigerated product will be shipped on **Wednesday, July 3**. Orders placed prior to 2 pm ET will be delivered on **Friday, July 5**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Tuesday, July 2** 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](mailto:clinicalresearchservices@mckesson.com).

We appreciate the opportunity to assist you and your patients.

Kind regards,  
Clinical Research Services team

## CIRB Holiday Hours

The NCI CIRB Operations Office will be closed **Thursday, July 4th**, for Independence Day. If you need to reach us, please do so before the holiday by sending an email to [support@ncicirbcontact.zendesk.com](mailto:support@ncicirbcontact.zendesk.com) or by calling us toll-free at 1-888-657-3711.

Thank You,  
NCI CIRB Helpdesk  
NCI CIRB Operations Office  
The EMMES Company  
401 N. Washington Street, Suite 700  
Rockville, MD 20850  
1-888-657-3711  
[support@ncicirbcontact.zendesk.com](mailto:support@ncicirbcontact.zendesk.com)  
CIRB Website: <https://www.ncicirb.org>



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## 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 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.

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## 2024 WF NCORP RB Annual Meeting Travel Awards

***To ensure that sites receive timely notification of travel award winners, allowing for adequate travel planning before the WF NCORP RB Annual Meeting, we are changing the cutoff date for tracking patient accruals to July 31, 2024. The new tracking timeframe will be February 1, 2024 - July 31, 2024.***

- **Awards will be given to top 2 accruing community sites for each study. There will be 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

## **Leaderboard as of July 2, 2024**

### **WF-1805CD HN-STAR**

- CROWN- 11
- HAWAII MU- 9
- STROGER MU- 9
- METROMIN- 7

### **WF-1806 M&M**

- STROGER MU- 7
- PRISMA- 5
- MCRC- 5
- GEISINGER- 3
- IWORC- 3

### **WF-1901 IMPACTS**

- ATLANTIC- 14
- HAWAII MU- 5
- CARLE- 2
- METROMIN- 2
- MUSC MU- 2

### **WF-2201 HYPOGRYPHE**

- MONTEFIORE MU- 1

### **WF-2202 SHINE**

- OZARKS- 63
- CARLE- 22
- IWORC- 18
- UPSTATE- 6



## Wake Forest NCORP Research Base Quarterly Call

Our next quarterly call is scheduled for **July 31, 2024 from 3:00-4:00pm ET**

[Wake Forest NCORP Research Base Quarterly Call page](#)

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### Upcoming Site Calls

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

**\*\*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-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR**

**July 17, 3:00-3:30 PM ET**

#### **WF-1805CD - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy**

**July 23, 3:00 PM ET**

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



### NEW AMENDMENT ACTIVATION

#### WF-1805CD Amendment 6, PVD 04/01/2024, Release Date 06/13/2024

The WF NCORP Research Base study titled *Implementation and Effectiveness Trial of HN-STAR* has been amended. The amended protocol and related documents were released on **Thursday, June 13, 2024**.

Changes with this amendment include:

- Updated protocol sections 4.2.5 and 4.2.6 Schedule of Events and Footnotes.
- Added “I am able to work (include work at home)” to the FACTHN(v4) instrument.
- Added “Have you visited your primary care provider in the last year” to the Visits with Other Providers instrument.
- Added new document “Survivor Interview Email Script.”
- Updated CTSU language based on 03/26/2024 support logistical template language document.

#### **Regulatory Requirements**

- All sites are required to use the NCI CIRB as their IRB of record per the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NPT-OD-17-076).
- Site Open to Enrollment (SOTE) letter from the WF NCORP RB will be provided to the site after all onboarding activities are completed.

#### **Document Access:**

- The protocol documents were made available on the [CTSU](#) website on 06/13/2024.
- Data collection trainings and an FAQ document are available on the [WAKENCORP](#) website.

#### **Participation**

If there are any questions regarding WF-1805CD activation or participating in this study, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu). Attn: WF-1805CD

### Quarterly Surveys for Intervention Group

Please remind your participants that **quarterly surveys using the HN-STAR tool must be completed on a computer or tablet, not on their phone.** The surveys will not be complete if they attempt them on their phone. Thank you in advance for your help with this!

### Sites with 10 Enrollments

We have had several sites reach the minimum goal of 10 enrollments, and more that are very close. If you haven't already, once your site has reached 10, please be sure to send **all** Designated Clinicians and Stakeholders at your site (even if they have not enrolled any HN-STAR patients) their final survey in REDCap so that we can complete interviews. Please check consistently for completion.

- Please complete the "DC Intro" section and click the "Send Survey" button. You will do the same thing for your Stakeholder(s) under the "SH-Email Trigger" section.

Remember that each site can continue to enroll up to 50 patients. Thanks so much to everyone for all your efforts!

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



**The younger stratum for WF-1806, Age 60 – 74, is currently closed. Our older stratum, Age 75 and older, still has plenty of slots.**



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



### **UPDATE ON ENROLLMENT**

As you may recall, we have been encouraging sites to help WF-1901 reach a goal of achieving 75 enrollments by 06/30/2024. Thanks to the efforts of some dedicated sites, we were only 6 enrollments away from reaching that goal. Please note as of today, we have not received any notice of change in study status. Therefore, we kindly ask that all sites continue to enroll until further notice.

Glad to answer any questions or concerns at [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

Thank you all for your ongoing support!

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## 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 27<sup>th</sup>, 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.

### **NEW AMENDMENT ACTIVATION**

**SHINE (WF-2202) Amendment 2, Protocol Version Date 04/30/2024 has been released.**

The WF NCORP Research Base study entitled **Optimizing Psychosocial Intervention for Breast Cancer-related Sexual Morbidity: The Sexual Health and Intimacy Education (SHINE) Trial** has been amended. The amended protocol and related documents were released on **June 12, 2024**.



### Changes with this amendment include:

- Removed requirement for enrollment to occur within 7 days of consent.
- Removed options to not respond in two of the PRO documents. (Requirement for an option to not respond was covered in a separate CIRB approved document and remains in the REDCap survey that is viewed by the participant.)
- Removed dollar amounts in email notifications for gift cards.
- Added relationship questions to PROMIS SexFS Screener form at 12- and 24-week surveys.
- Added relationship question to Communication with Partners PRO form for 12- and 24-week surveys.
- Administrative changes to language in protocol.
- Updated CTSU language based on 1/24/2024 and 3/25/2024 support logistical template language documents.

***An updated Helpful Guide v.06.12.24 is now available along with a new FAQ document. Note: These documents can only be downloaded from the Wake NCORP RB website.***

### WF-2202 Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The *Helpful Guide* and *FAQ* documents are available on the [WAKENCORP](#) website.
- The Introductory Webinar recording and slides are available on the [WAKENCORP](#) website. The webinar recording is also available on CTSU-CLASS; **Course Title:** WAKE: WF-2202 (SHINE) Introductory Webinar

If there are any questions regarding the WF-2202 study or your site is interested in participating, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-2202.

Regulatory requirements to activate this study can be found in the protocol, Section 6.0.

# 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 July 2, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	213	--	300		
WF-1901	IMPACTS	177	+2	250	0	40
WF-1805CD	HN-STAR	285	+6	350	131	140
WF-2201	HYPOGRYPHE	6	--	244		
WF-2202	SHINE	129	+19	320		

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

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