



## STUDY MATTERS

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February 29, 2024

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

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**\*\*NEW STUDY OPENING TODAY- February 29th!\*\***

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



### **Brief Summary**

The SHINE trial is designed to develop an internet-delivered sexual health program that can help breast cancer survivors with sexual concerns by studying four different cores (i.e., Sexual Health Essentials, Health Care Discussions, Partner Conversations, and Intimacy Insights) in different combinations. This study is a factorial study and seeks to identify which combination of these four intervention core components produces the greatest benefit with the least intervention burden over a 24-week period.

### **Study Population**

Adult women, status post treatment of Stage 0-III breast cancer, who are currently in an intimate relationship and are experiencing sexual concerns. 320 participants will be randomized (20 randomized into each of the 16 conditions).

**Introductory webinar and slides are now posted on our website**

Click on the link below and open "Site Calls and Webinars"

<https://wakencorp.phs.wakehealth.edu/study/wf2202-shine/>

## Wake Forest NCORP Research Base Website

**\*\*\*If you have already registered, please update your roles on the website\*\*\***

We use this information for targeting email communications and surveys

**If you have not registered, go to:**

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

WF-2201-HYPOGRYPHE- Hypofractionated Radiotherapy vs Single Fraction  
Radiosurgery for Brain Metastasis Patients on Immunotherapy  
**March 12, 3:00 PM ET**

WF-1901-IMPACTS- Internet-delivered Management of Pain Among Cancer Treatment  
Survivors  
**March 13, 2:30-3:30 PM ET**

WF-1805CD - HN-STAR- Implementation and Effectiveness Trial of HN-STAR  
**March 20, 3:00 PM ET**

Please email [7NCORP@wakehealth.edu](mailto:7NCORP@wakehealth.edu) when shipping biospecimen samples to the NCORP Research Base Biospecimens lab (Studies WF-1806, WF-1901, and WF-2201). Include the FEDEX tracking number in your email so that misplaced samples can be tracked before they spoil. Please ship by "FedEx Priority Overnight" (please change this on the pre-printed shipping label if this is not selected).

## Study Matters

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



#### **\*\*UPDATED\*\* - Oncology Medical Abstraction Form in the Usual Care Arm**

The Oncology Medical Abstraction Form has been updated in the Usual Care Arm with additional questions regarding patient diagnosis and treatment. If you're a Usual Care Arm site and have filled out any Oncology Medical Abstraction Forms prior to 2/14/24, please revisit them to answer these additional questions. Thank you for all your hard work on the study. We greatly appreciate your efforts!

#### **Travel Awards!**

We will be presenting two travel awards to our 2024 Wake Forest NCORP RB Annual Meeting in Myrtle Beach, SC! One will be awarded to the site with the **most accruals** and another award will be given to the site with the **most improved enrollment** to the HN-STAR study **between February 1 and September 15, 2024.**

Awards are worth up to \$1,000 each to cover travel and hotel expenses at The Grande Dunes Marriott Resort.

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



#### **Travel Awards!**

We will be presenting two travel awards to our **2024 Wake Forest NCORP RB Annual Meeting** in Myrtle Beach, SC!

- Awards will go to the two sites with the most enrollments to the WF-1806 M&M Study between **February 1 and September 15, 2024.**
- Awards are worth up to **\$1,000 each** to cover travel and hotel expenses at **The Grande Dunes Marriott Resort**

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



### **Travel Awards!**

We will be presenting two travel awards to our **2024 Wake Forest NCORP RB Annual Meeting** in Myrtle Beach, SC!

- Awards will go to the two sites with the most enrollments to the WF-1901 IMPACTS Study between **February 1 and September 15, 2024**.
- Awards are worth up to **\$1,000 each** to cover travel and hotel expenses at **The Grande Dunes Marriott Resort**

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## WF-2300CD - CONNECT Survey - Practice Survey for Multi-Site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers



**\*Enrollment of sites into OPEN requested by March 15, 2024\***

Thank you to all sites who have participated in the survey so far! We encourage any sites who have not yet enrolled their site(s) to OPEN to do so **by March 15, 2024**.

If you have enrolled your sites and received the survey link but have not yet completed the survey, please enter your data within 30 days of receiving your survey. If you need the survey link re-sent, please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)

## Steps to Enroll

1. The site will need to upload the Practice ID Email to CTSU Regulatory Submissions. Be sure to include the PI name and their CTEP ID in the comments section.

The screenshot displays the CTSU Regulatory Submission web application. At the top, the header includes the CTSU logo, the text 'Cancer Trials Support Unit', and a navigation menu with items like 'Home', 'Protocols', 'Dashboard', 'Regulatory', 'OPEN', 'Data Management', 'Auditing & Monitoring', 'RUMS', 'Delegation Log', 'Resources', 'Collaboration', 'CLASS', and 'Reports'. Below the header, a breadcrumb trail shows 'Site Registration' > 'Protocol Requirements' > 'Provider Association' > 'Regulatory Submission'. The main content area is titled 'Add New Submission' and features a 'STEPS' sidebar with four steps: 1. Select Sites and Protocols (active), 2. Select Submission Priority, 3. Upload Document(s), and 4. Review and Submit Packet. The main form area includes a 'Previous', 'Next', and 'Discard' button bar. Below this, it states 'Documents being submitted are for:' followed by a text input field for 'Specific Site(s) and Protocol(s)'. A section titled 'Select applicable Site(s) and Protocol(s)' provides instructions and a 'Pick from my sites:' section with a 'Select Site' dropdown and a checkbox for 'Site(s) not in list? Search and select site(s)'. A 'Protocols:' section includes a 'Search Protocol' input field and a 'Helpful Hint: Search by Protocol Number. Type minimum 3 characters'. At the bottom of this section are 'Add To Cart' and 'Reset' buttons. A table titled 'Selected Sites and/or Protocols' is shown with columns for 'Site' and 'Protocols', and a message stating 'No records were found that matched the criteria'. Finally, there is a 'Message regarding submission (optional)' section with a 'Helpful Hint: Provide the IRB number here if it is not indicated within the approval documentation'.

4. Once approved, you will enroll each of the sites listed on the Practice ID Email into OPEN, using the Practice ID. Be sure to enter the Practice ID exactly as stated.

5. Once all sites from your Practice ID Email are enrolled into OPEN, the site contact will receive their survey(s).

\*\*The Introductory Webinars and slides have been posted to our website - <https://wakencorp.phs.wakehealth.edu/study/wf2300cd-connect-survey/>

**\*\*Be sure to update your Profile on our website to include this study so that you receive study related information.**

## Accruals as of February 28, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	194	+5	300		
WF-1901	IMPACTS	145	+2	250	0	40
WF-1805CD	HN-STAR	235	+7	350	121	140
WF-2201	HYPOGRYPHE	2	--	244		

Open Studies	Name	Enrolled Practice Groups	Change in Past 2 Weeks	Target Practice Groups	Enrolled CTEP IDs	Change in Past 2 Weeks	Max CTEP IDs
WF-2300CD	CONNECT Survey	122	--	200	246	+22	600

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