



STUDY MATTERS

March 14, 2024

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

****NEW STUDY NOW OPEN****

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).

Protocol documents are now available on CTSU. Please note that patient surveys are not posted to CTSU, as these are to be directly entered into the REDCap Database.

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/>

If your site is interested in participating in this study, please email

NCORP@wakehealth.edu with Subject: WF-2202

****CLOSING TO ENROLLMENT****

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



Caregiver Oncology Needs Evaluation Tool

Enrollment of sites into OPEN will close March 15, 2024

Thank you to all sites who have participated in the survey so far! **Any sites who have not yet enrolled their site(s) to OPEN must do so by March 15, 2024 at 11:59pm ET.**

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

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 shows the CTSU Regulatory Submission interface. At the top, there is a navigation bar with the CTSU logo and the text "Cancer Trials Support Unit A DIVISION OF THE NATIONAL CANCER INSTITUTION". Below this is a user profile section for "Jessica Shendy" with a "Logout" button and a password expiration notice. The main navigation menu includes "Home", "Protocols", "Dashboard", "Regulatory", "OPEN", "Data Management", "Auditing & Monitoring", "RUMS", "Delegation Log", "Resources", "Collaboration", "CLASS", and "Reports". The "Regulatory" menu is expanded, showing "Site Registration", "Protocol Requirements", "Provider Association", and "Regulatory Submission".

The "Add New Submission" page is displayed, with a progress bar showing four steps: "1. Select Sites and Protocols", "2. Select Submission Priority", "3. Upload Document(s)", and "4. Review and Submit Packet". The current step is "1. Select Sites and Protocols". Below the progress bar, there are "Previous", "Next", and "Discard" buttons. A section titled "Documents being submitted are for:" contains a text input field for "Specific Site(s) and Protocol(s)".

Below this, there is a section for "Select applicable Site(s) and Protocol(s)". It includes instructions: "Select either an individual site and protocol or groups of sites and protocols then click the Add to Cart button. Add all necessary site and protocol selections to your cart then". Under "Pick from my sites:", there are checkboxes for "Select Site" and "Site(s) not in list? Search and select site(s)". Under "Protocols:", there is a "Helpful Hint: Search by Protocol Number. Type minimum 3 characters" and a "Search Protocol" input field. "Add To Cart" and "Reset" buttons are located below the search field.

At the bottom, there is a table titled "Selected Sites and/or Protocols" with columns for "Site" and "Protocols". The table is currently empty, with a message: "No records were found that matched the criteria". Below the table, there is a section for "Message regarding submission (optional)" with a "Helpful Hint: Provide the IRB number here if it is not indicated within the approval documentation" and a text input field.

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.**

Upcoming Site Calls

If you haven't already, 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

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

WF-2202 - SHINE- Optimizing Psychosocial Intervention for Breast Cancer-related Sexual Morbidity: The Sexual Health and Intimacy Education Trial
April 10, 2:00 PM ET

WF-1806 - M&M- Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer
April 23, 2:30-3:00 PM ET

Please email 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 Updates

WF-1804CD - AH-HA- Assessing Efficacy and Implementation of an EHR Tool to Assess Heart Health Among Survivors



****DATA UPDATE****

We are nearing the end of data collection! Please make a final push to get the 1-Year surveys in as soon as possible. We greatly appreciate all your help!

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



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**

Upcoming Abstract Presentations

American College of Cardiology Conference: April 6-8, 2024 in Atlanta, GA



UPBEAT WF-97415

- a. Daniel L, Bellissimo-Myers M, D'Agostino R, et al. Association of intermuscular fat and physical activity levels on exercise capacity in breast cancer survivors (WF-97415).
 1. *Moderated Poster Presentation*
- b. Trakhtman E, Mabudian L, D'Agostino R, et al. Lower HDL is associated with reduced LVEF three months following initiation of breast cancer treatment (UPBEAT WF-97415).
 1. *Poster Presentation*

PREVENT WF-98213

- a. Rodriguez JL, O'Connell NS, Ruddy KJ, et al. Changes in skeletal muscle quality during receipt of anthracycline-based chemotherapy.
 1. *Poster Presentation*

American Association for Cancer Research Annual Meeting: April 5-10, 2024 in San Diego, CA

AACR ANNUAL MEETING 2024

April 5 - 10, 2024
San Diego Convention Center
San Diego, California

PCW WF-1802

- a. Sandberg JC, Dressler EV, Krane LS, et al. Employment Characteristics and Work Ability Differences by Race and Income Before Undergoing Curative Treatment for Prostate Cancer (PCW WF-1802)
 1. *Presentation and publication in Cancer Research*

UPBEAT WF-97415

- a. Reding KW, Vasbinder A, O'Connell NS, et al. Biomarkers associated with Atherosclerosis-related cardiovascular dysfunction in Cancer Survivors treated with Anthracyclines
 1. *Presentation and publication in Cancer Research*

Scientific Network on Female Sexual Health and Cancer: April 18-19, 2024 in Columbus, OH



SHINE WF-2202

- a. Shaffer KM, Reese J, Dressler EV, et al. Optimizing internet-based psychosocial intervention for breast cancer-related sexual morbidity: Protocol for a factorial trial.
 1. *Oral Presentation*

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.

<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 March 13, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	195	+1	300		
WF-1901	IMPACTS	149	+4	250	0	40
WF-1805CD	HN-STAR	237	+2	350	121	140
WF-2201	HYPOGRYPHE	3	+1	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	123	+1	200	251	+5	600

Copyright © 2024 Wake Forest NCORP Research Base, All rights reserved.
You were added to this email list when you were rostered to the WAKE NCORP Research Base

Our mailing address is:

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

[Add us to your address book](#)

Want to change how you receive these emails?
You can [update your preferences](#) or [unsubscribe from this list](#).

