



## STUDY MATTERS

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March 28, 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](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)

### **Quarterly Call**

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

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

**Wednesday, April 9 2:00-3:00 pm ET**

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

**IMPORTANT: We will be discontinuing site calls for the M&M study.**

Our next scheduled call would fall on April 22<sup>nd</sup>, 2024, 2:30 – 3:00 EDT. Please use the meeting link button below to locate the meeting on your calendar and remove the **entire series**.

## **Study Updates**

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

**AMENDMENT 3 ACTIVATION**

**HRSN (WF-2303CD) Amendment 3, Protocol Version Date 03/05/2025 has been**

activated.

The WF NCORP Research Base study entitled **Understanding and Enhancing Health-related Social Needs (HRSN) Screening Among Community Oncology Practices** has been activated. The protocol and related documents were released on March 26, 2025.

**Changes with this amendment include:**

1. Removed references to gender, gender identity, and sexual orientation.
  - Changes are being requested per the NCI directive sent on 2/7/25 stating that all references to ‘gender’ must be removed in our documents and replaced with ‘sex’. Removed information about sexual orientation or gender identity. All changes to the protocol and other participant facing documents are required to be reviewed by the CIRB and submitted to the DCP PIO per routine procedures.

**WF-2303CD Document Access:**

- The protocol documents are available on the [CTSU](#) website.

**This is an invitation only study. Sites interested in being added to our waitlist** should contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-2303CD.

Regulatory requirements to activate this study can be found in the protocol on the CTSU website.

If there are any questions regarding the WF-2303CD, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-2303CD.

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## **(NEW!)WF-2301CD - CONNECT - Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers**

The Helpful Guide has been updated (v.03.26.2025) describing next steps if a patient or caregiver does not complete their baseline survey within window. An updated FAQ (v.03.26.2025) is also now available on our [Wake Forest NCORP RB website](#).

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

### **NEW SPANISH DOCUMENT POSTED**

**WF-1806 (M&M) Amendment 10, Protocol Version Date 12/30/2024, Release Date 02/24/2025**

**The Spanish version of the following document was posted on CTSU on Friday, February 28, 2025. Please implement this version within 30 days of this post.**

- **Consent Form, (PVD 12/30/24): Spanish**

**Previously approved Spanish versions of the patient assessments have not been updated with this amendment and will remain in force.**

1. CARE Questionnaire\_v05.01.20\_Spanish
2. Demographic and Health Behaviors\_v05.01.20\_Spanish
3. Hand-Grip Physical Test\_v05.01.20\_Spanish
4. Life-Space Survey\_v05.01.20\_Spanish
5. Short Physical Performance Battery Protocol\_v05.01.20\_Spanish
6. NCI PRO-CTCAE Items\_v05.01.20\_Spanish
7. GP5\_v04.01.21\_Spanish
8. Was It Worth It Questionnaire\_v11.08.21\_Spanish

If there are any questions regarding WF-1806 we are glad to help. Please contact us at [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-1806.

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

### **WF2304-A172401 COSMIC – Frequently Asked Questions (FAQs) Document Updated**

Thank you all for joining the WF2304- A172401 COSMIC site call on March 10, 2025. In response to the feedback received, we held discussions with the study team that focused solely on the comments and questions you all provided regarding eligibility. Clarifications in the FAQs, are highlighted as **ADDED** or **UPDATED**. The new version of the FAQs can be found on our Wake Forest NCORP Research Base website <https://wakencorp.phs.wakehealth.edu>

#### **5. What if a participant is diagnosed with cancer, but they do not receive treatment until 9 months later, if we register them before cycle two, are they still eligible? (UPDATED)**

The protocol currently does not define a required timeframe between diagnosis and treatment start. If this is a new cancer that has not been treated before then the patient may be eligible.

#### **26. Recurrent vs. New Primary Cancers. (ADDED)**

We will allow enrollment of patients with a new primary cancer if the site's medical team confirms it as a new tumor and not a recurrence. Patients with recurrent cancers of breast, colorectal, melanoma, non-Hodgkin lymphoma, or non-small cell lung cancer are not eligible for this study.

#### **27. Prior Therapies. (ADDED)**

Participants who have undergone treatment for a different cancer, may qualify for participation in the COSMIC study.

#### **28. Hormonal Therapy Prior to Chemotherapy or Immune Checkpoint Inhibitor Therapy. (ADDED)**

Participants receiving neoadjuvant hormone therapy and/or aromatase inhibitors prior to planned chemo- and/or targeted- therapy are eligible.

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**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!

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## 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).

## Accruals as of March 26, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	240	+1	300		
WF-1901	IMPACTS	215	+4	250	12	40
WF-1805CD	HN-STAR**	353	+4	350	135	140
WF-2201	HYPOGRYPHE	26	+3	244		
WF-2202	SHINE**	341	+7	336		
WF-2301CD	CONNECT	37 (pt/ caregiver dyad)	+3	120 (dyads)		
WF2304-A172401	COSMIC	171	+58	2000		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	17	+2	20	49	136

\*\*Protocol closed to enrollment