



## STUDY MATTERS

---

January 30, 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).

---

### **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, February 12 2:00-3:00pm ET

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

Tuesday, February 25 2:30-3:00pm ET

**Study Updates**

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

The total enrollment goal has been increased to 336. As of 1/29, we have 318 accruals!

**Please make a final effort to approach and screen participants to help us finish this study soon!**

---

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

Thank you for continuing to screen and enroll M&M participants. We have 10 slots left in the 60 -74yo stratum and 53 slots in the >75yo stratum. In 2025, we will continue sending candygrams to the site that enrolls first each month. **Everyone that enrolls in February will get a candygram!**

---

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

Monthly Challenges started on **January 8, 2025**; we are just **43** enrollments away from 250! We have until July 31, this year to meet this target!

The rules are easy! We will provide awards to the top accruing coordinators every month. The top prize is a travel award to our Wake Forest NCORP RB Annual Meeting-this year in Asheville, North Carolina! We have some fantastic prizes overall!

We have travel mugs, sling bags, rolling coolers and beach towels! The travel prize will be determined by cumulative enrollment from today until July 31.

The first winner will be highlighted in our bi-monthly newsletter and Study Matters on the week of February 10.



---

## **WF-2201 - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy**

**We need your help with enrollment!**

This study is open to patients with brain metastases currently receiving or planning to receive PD-1/PD-L1 targeted immune checkpoint inhibitor therapy within 30 days of SSRS/FSRS for Melanoma, renal cell, non-small cell lung, small cell lung or breast cancer patients with brain metastases. We want to get the study started at your sites and look forward to working with you on this important research study.

Contact us at [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) if your site is interested in the study. Please note, your site must be IROC certified to participate or be willing to become certified

---

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

An updated Helpful Guide was posted to our website on 1/9/25. Please follow updated instructions for uploading patient and caregiver consents to REDCap.

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

Site staff who completed training in **CLASS** and need **REDCap** access after your site obtained their SOTE letter must provide a copy of their training certificate to [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) ATTN:WF2304-A172401- REDCAP ACCESS

### **Recruitment Material Now Available: Aligned with COSMIC (WF2304-A172401) Amendment 1, Protocol Version Date 11/19/2024, Release Date 01/15/2025.**

The following recruitment documents were posted to the CTSU website on 01/29/2025.

**Recruitment Brochure** – trifold brochure explaining the COSMIC study with a space for your site's contact information. QR code can be scanned to obtain more information about the study on the cancer.gov website.

**Cancer affects quality of life in many ways. Managing symptoms looks different from person to person.**

The COSMIC Study aims to understand how patients manage their cancer symptoms over time.

**Approaches may include:**

- Meditation, yoga, and hypnosis
- Vitamins, dietary supplements, and special diets
- Cannabis and/or cannabinoids
- Massage therapy and reflexology
- Reiki, acupuncture, and naturopathic medicine
- And many others

**CONTACT US**

To find out if you are eligible to participate:

- Talk to your healthcare provider.
- They will send you an email with a link to a confidential survey to see if you are eligible.

To learn more about the study scan here with your smartphone camera

**COSMIC**  
Complementary Options for Symptom Management in Cancer

**Enroll in the COSMIC Study**

**Can I join the study?**

You may be eligible if you were recently diagnosed with one of the following cancers:

- Breast
- Colorectal
- Melanoma
- Non-Hodgkin lymphoma
- Non-small cell lung

You must also plan to receive or recently started to receive chemotherapy or immunotherapy. You must be at least 18 years old.

**You can receive \$10-\$20 for each monthly survey you complete.**

**WHAT WILL I BE ASKED TO DO?**

- Be in the study for about 18 months.
- Complete confidential surveys each month on your phone, tablet or computer.

Your survey responses will be stored in a secure database and will not be available to your medical team.

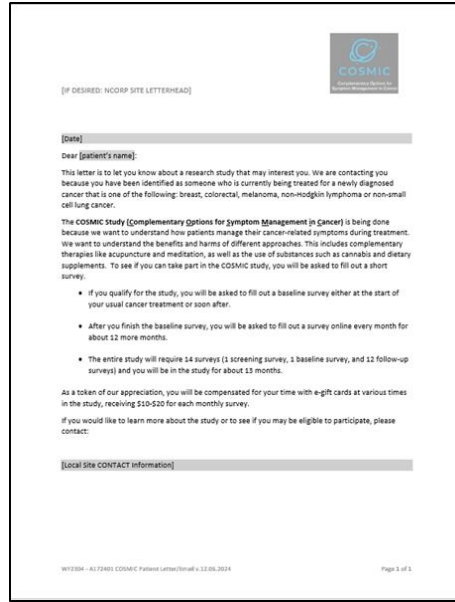
This study is a Wake Forest NCORP Research Base Study (WF2304-A172401) supported by public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH).

WF2304 - A172401 v.12.06.2024

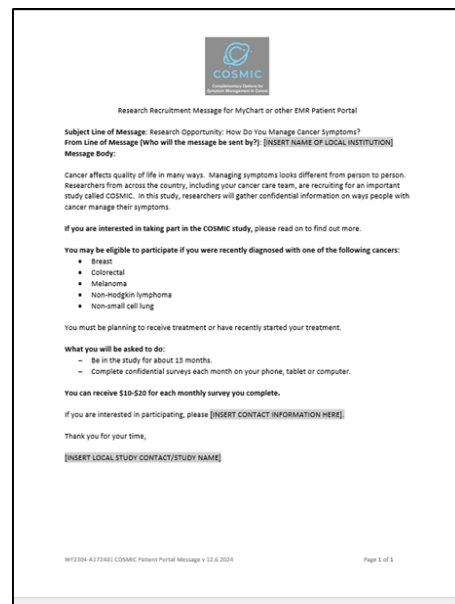
**Recruitment Flyer** – explains the COSMIC study. Can be posted in exam rooms, given to the participant while in clinic or mailed to the participant. QR code can be scanned to obtain more information about the study on the cancer.gov website.

**Study Summary** – a one page, two-sided summary of the COSMIC study with a space for your site’s contact information.

**Recruitment Letter or Email** – one page letter explaining the COSMIC study with a space for your site’s contact information.



**Patient Portal Message** – one page message explaining the COSMIC study with space for your site’s contact information; distributed via the patient portal/MyChart.



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

If there are any questions regarding the WF2304-A172401 activation contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) Attn: WF2304-A172401. To request printed copies of recruitment materials, please use the WF2304-A172401 Recruitment Request survey below. <https://redcap.link/WF2304-A172401.RecruitmentMaterials>

---

## **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!

---

## **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 January 29, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	237	+2	300		
WF-1901	IMPACTS	207	+2	250	0	40
WF-1805CD	HN-STAR	332	+10	350	132	140
WF-2201	HYPOGRYPHE	18	+2	244		
WF-2202	SHINE	318	+0	336		
WF-2301CD	CONNECT	18 (pt/ caregiver dyad)	+8	120 (dyads)		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	13	2	20	26	136