



STUDY MATTERS

April 10, 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.

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

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 22nd, 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**.

WF-2304-A172401: Complementary Options for Symptom Management In Cancer (COSMIC): Assessing Benefits and Harms of Cannabis and Cannabinoid Use Among a Cohort of Cancer Patients Treated in Community Oncology Clinics
May 12, 2025 3:00 PM ET

WF-2201 - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy (HYPOGRYPHE)
May 13, 2025 3:00 PM ET

WF-1901 Internet-delivered Management of Pain Among Cancer Treatment Survivors
May 14, 2025 2:30 PM ET

Study Updates

(NEW!) NCI Directive Amendments

The following studies have activated recent amendments per the NCI Directive sent on 2/7/25 regarding references to gender/ gender identity and sexual orientation. 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:** Understanding and Enhancing Health-related Social Needs (HRSN) Screening Among Community Oncology Practices - **Activated 03/26/2025**
- **WF-1806:** Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer (M&M) - **Activated 04/02/2025**
- **WF-2201:** Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy (HYPOGRYPHE) - **Activated 04/03/2025**
- **WF-2304-A172401:** Complementary Options for Symptom Management In Cancer (COSMIC): Assessing Benefits and Harms of Cannabis and Cannabinoid Use Among a Cohort of Cancer Patients Treated in Community Oncology Clinics - **Activated 04/04/2025**
- **WF-1805CD:** Implementation and Effectiveness Trial of HN-STAR (HN-STAR) - **Activated 04/08/2025**

Document Access:

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

(NEW!) WF-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR

Final Reminder: All Step 2 consents and DC visits must be completed by 11:59pm ET on April 14, or the patient must be withdrawn from the study. We greatly appreciate your hard work in helping reach our enrollment goal! Please continue to follow up with all participating patients as scheduled in the protocol.

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

Please email all completed consent forms (redacted except for initials) for Practice Staff and Key Informants to NCORP@wakehealth.edu, and include “WF-2303CD HRSN Consents” in the subject line.

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](#).

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.

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.

Accruals as of April 9, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	240	+0	300		
WF-1901	IMPACTS	215	+0	250	12	40
WF-1805CD	HN-STAR	357	+4	350	135	140
WF-2201	HYPOGRYPHE	26	+0	244		
WF-2202	SHINE**	341	--	336		
WF-2301CD	CONNECT	39 (pt/ caregiver dyad)	+2	120 (dyads)		
WF2304-A172401	COSMIC	239	+68	2000		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (<u>Non-Patients</u>)
WF-2303CD	HRSN	17	+0	20	60	136

**Closed to enrollment