



STUDY MATTERS

April 24, 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-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 (IMPACTS)

May 14, 2025 2:30 PM ET

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

May 15, 2025 3:00 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**
- **WF-2301CD:** Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers - **Activated 04/16/2025**
- **WF-1901:** Internet-delivered Management of Pain Among Cancer Treatment Survivors - **Activated 04/16/2025**
- **WF-2202:** Optimizing Psychosocial Intervention for Breast Cancer-related Sexual Morbidity: The Sexual Health and Intimacy Education (SHINE) Trial - **Activated 04/17/2025**

Document Access:

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

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

All Participant Enrollment in OPEN is now closed.

We have closed all enrollment for new participants to the WF-1805CD-HN-STAR study in OPEN.

Thank you for helping us enroll to this important study!

If there are any questions regarding WF-1805CD, we are glad to help. Please contact us at NCORP@wakehealth.edu; Attn: WF-1805CD.

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

WF-1806 (M&M) Amendment 11, Protocol Version Date 03/05/2025, Release Date 04/02/2025:

The Spanish version of the following document was posted on CTSU on Friday, April 11, 2025.

Consent Form, (PVD 03/05/25): 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

WF-1806 Document Access:

- The protocol and participant directed documents are available on the [CTSU](#) website.
- The *Helpful Guidelines*, *FAQs*, *Provider Fact Sheet* and *Training Attestation* documents are available on the [WAKENCORP](#) website.

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

(NEW!)WF-2201 - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy

HYPOGRYPHE (WF-2201) Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy Amendment 6, Protocol Version Date 03/07/2025 was posted on 04/03/2025.

The Spanish version of the following document was posted on CTSU on **Thursday, April 10, 2025.**

- **Consent Form**, (PVD 03/07/25): Spanish

If there are any questions or your site is interested in participating in the WF-2201 study, please contact NCORP@wakehealth.edu; Attn: WF-2201.

Please note, your site must be IROC certified to participate or be willing to become certified.

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.

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 23, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	243	+3	300		
WF-1901	IMPACTS	217	+2	250	12	40
WF-1805CD	HN-STAR**	357	--	350	135	140
WF-2201	HYPOGRYPHE	27	+1	244		
WF-2202	SHINE**	341	--	336		
WF-2301CD	CONNECT	42 (pt/ caregiver dyad)	+3	120 (dyads)		
WF2304-A172401	COSMIC	331	+92	2000		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	17	+0	20	63	136

**Closed to enrollment