



## STUDY MATTERS

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**May 8, 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)

**WF2304-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

### 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**
- **WF2304-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.
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**(NEW!)WF2304-A172401- COSMIC - 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**

**Pause of some recruitment strata for 1 month  
Effective May 12, 2025  
9:00 AM EDT**

**We would like to extend our gratitude to all NCORP community sites that have enrolled and continue to enroll to the WF2304-A172401 COSMIC Study.**

Due to recruitment occurring at such a rapid pace, we are going to pause recruitment in some strata to ensure we maintain a balanced representation of all groups throughout the recruitment phase.

**Please continue to screen patients as you normally would.** Be aware that with this temporary pause in place, you may see an increased number of screening results come back as “Not Eligible”, depending on the potential participant’s responses to the self-screening questionnaire. We will send an updated special broadcast email once the restriction is lifted.

Please let us know if you have questions with an email to [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

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## **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](mailto:NCORP@wakehealth.edu); Attn: WF-1805CD.

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## **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](mailto:NCORP@wakehealth.edu); Attn: WF-2201.

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

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## 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](mailto: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!

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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).

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## Accruals as of May 7, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	243	+0	300		
WF-1901	IMPACTS	217	+0	250	12	40
WF-1805CD	HN-STAR**	357	--	350	135	140
WF-2201	HYPOGRYPHE	27	+0	244		
WF-2202	SHINE**	341	--	336		
WF-2301CD	CONNECT	46 (pt/ caregiver dyad)	+4	120 (dyads)		
WF2304-A172401	COSMIC	427	+96	2000		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	18	+1	20	65	136

\*\*Closed to enrollment

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