



STUDY MATTERS

January 2, 2025

Wake NCORP Website: <https://wakencorp.phs.wakehealth.edu/>



Wake Forest NCORP Research Base Upcoming Office Closure

The Wake Forest Research Base NCORP offices will be closed Monday, January 20.

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-1901 - IMPACTS - Internet-delivered Management of Pain Among

Cancer Treatment Survivors
Wednesday, January 8, 2:30-3:00 pm ET

WF-2201 - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy
Tuesday, January 14, 3:00-4:00 pm ET

WF-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR
Wednesday, January 15 3:00-3:30pm ET

WF-2301CD - CONNECT - Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers
Thursday, January 16 3:00-3:30pm ET

(NEW!) WF-2301CD - CONNECT

An updated Helpful Guide was posted to our website on 12/30/24. Please follow updated instructions for uploading patient and caregiver consents to REDCap.

(NEW!) WF-1805CD - HN-STAR

We are nearing the enrollment goal! Earn a pack of Starburst for each new Step 2 enrollment beginning January 1!

WF-2304 – COSMIC - Complementary Options for Symptom Management in Cancer



Coming Soon: New Study - Please join us!
Upcoming Introductory Webinar January 9, 2025, at 3:30pm ET

Brief Study Summary

The COSMIC study will examine the association between cannabis and/or cannabinoid use and cancer-related symptoms. This study will enroll both cannabis users and non-users. Symptoms will be assessed monthly for one year in adults newly diagnosed with breast, colorectal, melanoma, non-Hodgkin lymphoma, or non-small cell lung cancer. Potential participants should be planning to or recently started on one or more systemic cancer directed therapies with chemotherapy and/or immune check point inhibitors (ICIs) PD-1, PD-L1 or CTLA-4.

Study Population

Individuals who are 18 years of age or older, have been newly diagnosed with a cancer type (e.g., breast, colorectal, melanoma, non-Hodgkin lymphoma, non-small cell lung cancer), are able to read and write in English or Spanish, and have a working email address.

Target N =2000 participants

Contact us at NCORP@wakehealth.edu for any questions! Click the button below to add the COSMIC Introductory Webinar to your calendar.

[Click here to add the COSMIC Introductory Webinar to your Calendar](#)

[WF-1901 – IMPACTS- Internet-delivered Management of Pain Among Cancer Treatment Survivors](#)

New Year Approaching- SNEAK PEAK of What's Coming!

Beginning in January, we're excited to launch monthly challenges to help us reach our target goal of 250 by July 31st! Every month, we'll have fun site competitions where you can win **awesome prizes** and even a **travel award** to our Wake Forest NCORP Research Base Annual Meeting 2025 in Asheville, North Carolina! Make sure you tune in to our first bi-monthly site call for 2025 on **January 8th at 2:30** for more information!

[WF-2303CD HRSN- Understanding and Enhancing Health-related Social Needs \(HRSN\) Screening Among Community Oncology Practices](#)

Onboarding Updates

- SOTE letters have been sent to all invited sites. Please upload your SOTE letter to CTSU to obtain final IRB approval.
 - Once you have IRB approval, please enroll your practice (each individual CTEP ID that is listed on your SOTE letter separately) into OPEN.
 - Consent and enroll your Practice Staff into OPEN.

Training Updates

- **Please be sure all Practices and Practice Staff are enrolled in OPEN by January 3, 2025** so that we can begin training up to 4-5 practices in each session starting in January. OPEN Enrollment forms can be found on our [Wake Forest NCORP website](#) under HRSN Study “Study Documents & Forms”
- Once your Practice (all approved CTEP IDs on your SOTE letter must be enrolled separately) and both Practice Staff are registered in OPEN, Wake Forest NCORP RB will contact you to set up your trainings.
- Please contact NCORP@wakehealth.edu with any questions.

AMENDMENT 2 ACTIVATION

HRSN (WF-2303CD) Amendment 2, Protocol Version Date 11/11/2024 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 December 16, 2024.

Changes with this amendment include:

- Updating the **Practice Level Demographics** survey.
- Removing the Practice ID number and language from the **Practice Interest Form, Practice Selection Email and Section 5.1.1 of the protocol.**

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; 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; Attn: WF-2303CD.

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 January 1, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	235	+4	300		
WF-1901	IMPACTS	205	+2	250	0	40
WF-1805CD	HN-STAR	322	+4	350	132	140
WF-2201	HYPOGRYPHE	16	+3	244		
WF-2202	SHINE	317	+6	336*		
WF-2301CD	CONNECT	10 (pt/ caregiver dyad)	+8	120 (dyads)		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	11	--	20	9	136