



STUDY MATTERS

December 19, 2024



Wake Forest NCORP Research Base Upcoming Holiday Hours

The Wake Forest Research Base NCORP offices will be **closed** **December 24 & 25** for Christmas. We will also be closed on **January 1**.

Happy Holidays! We look forward to working with you in the new year!

Clinical Research Services Closed December 25, 2024 & January 1, 2025

In observance of the Christmas holiday, McKesson's Clinical Research Services will be closed **Wednesday, December 25, 2024**. We will resume regular business hours on Thursday, December 26, 2024.

Our regular business hours are Monday through Friday, 9 am to 6 pm ET.

Please take this information into consideration when placing your orders **prior to the Christmas holiday**.

- Only non-refrigerated product will be shipped on **Tuesday, December 24**. Orders placed prior to 2 pm ET will be delivered on **Thursday, December 26**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Monday, December 23** prior to 2 pm ET. Orders placed prior to 2 pm ET will be delivered on **Tuesday, December 24**.

In observance of the New Year holiday, McKesson's Clinical Research Services will be closed **Wednesday, January 1, 2025**. We will resume regular business hours on Thursday, January 2, 2025.

Our regular business hours are Monday through Friday, 9 am to 6 pm ET.

Please take this information into consideration when placing your orders **prior to the New Year holiday**.

- Only non-refrigerated product will be shipped on **Tuesday, December 31**. Orders placed prior to 2 pm ET will be delivered on **Thursday, January 2**.

- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Monday, December 30** prior to 2 pm ET. Orders placed prior to 2 pm ET will be delivered on **Tuesday, December 31**.

Due to the influx of shipments around the holidays, carrier delays may occur. Please plan your orders accordingly.

If you have questions regarding the shipment schedule, please contact our Clinical Research Services team at 800.693.4906, or via email at clinicalresearchservices@mckesson.com.

We appreciate the opportunity to assist you and your patients.

Kind regards,

Clinical Research Services team

*****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

Study Updates

(NEW!)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.

(NEW!)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.
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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 December 18, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	234	+3	300		
WF-1901	IMFACTS	205	+2	250	5	40
WF-1805CD	HN-STAR	321	+3	350	133	140
WF-2201	HYPOGRYPHE	13	+0	244		
WF-2202	SHINE	316	+5	336*		
WF-2301CD	CONNECT	9 (pt/ caregiver dyad)	+7	120 (dyads)		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	17	+6	20	17	136