



STUDY MATTERS

January 16, 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.

NCI CIRB Office Closure

The NCI CIRB Operations Office will be closed Monday, January 20, 2025, for the Martin Luther King Holiday. If you need to reach the CIRB Operations Office, please do so before close of business Friday by sending an email to support@ncicirbcontact.zendesk.com, or by calling us toll-free at 1-888-657-3711.

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

Thursday, January 16 3:00-4:00pm ET

WF-2202 - SHINE- Optimizing Psychosocial Intervention for Breast Cancer-Related Sexual Morbidity: The Sexual Health and Intimacy

Education (SHINE) Trial
Wednesday, February 12 2:00-3:00pm ET

WF-1806 - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer: The M&M Study
Tuesday, February 25 2:30-3:00pm ET

Study Updates

WF-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR

We are nearing the enrollment goal! Earn a pack of Starburst for each new Step 2 enrollment beginning January 1! A special broadcast will be sent once we reach our enrollment goal.

(NEW!)WF-1901 – IMPACTS- Internet-delivered Management of Pain Among Cancer Treatment Survivors

Monthly Challenges started on **January 8, 2025**; we are just **44** enrollments away from 250! We have till June 30th, this year to meet this target!

The rules are easy! We will provide awards to the top accruing coordinators every month. The top prize is a travel award to our Wake Forest NCORP RB Annual Meeting-this year in Ashville, North Carolina! We have some fantastic prizes overall!

We have travel mugs, sling bags, rolling coolers and beach towels! The travel prize will be determined by cumulative enrollment from today until June 30.

The first winner will be highlighted in our bi-monthly newsletter and Study Matters on the week of February 10.



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

We need your help with enrollment!

This study is open to patients with brain metastases currently receiving or planning to receive PD-1/PD-L1 targeted immune checkpoint inhibitor therapy for Melanoma, renal cell, non-small cell lung, small cell lung or breast cancer patients with brain metastases. We want to get the study started at your sites and look

forward to working with you on this important research study.

Contact us at NCORP@wakehealth.edu if your site is interested in the study. Please note, your site must be IROC certified to participate or be willing to become certified

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

An updated Helpful Guide was posted to our website on 1/9/25. Please follow updated instructions for uploading patient and caregiver consents to REDCap.

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

- Instructions for enrolling Practices and Practice Staff have been updated on our website under the Helpful Guide section.
- Once your Practice and Practice Staff are enrolled in OPEN, we will reach out to schedule your Practice Staff Trainings.
- Please contact NCORP@wakehealth.edu with any questions.

WF-2304-A172401 – COSMIC - Complementary Options for Symptom Management in Cancer



New Study Activation - January 15, 2025

WF2304-A172401 Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The *Helpful Guide* is available on the [WAKENCORP](#) website.
- The recorded webinar and associated slides will be available within the next 2 weeks on CTSU-CLASS; **Course Title:** WAKE: WF2304-A172401 COSMIC Introductory Site Training.
A special broadcast will be distributed when these are available.

Sites interested in participating should contact NCORP@wakehealth.edu; Attn: WF2304-A172401 and request start-up information.

Regulatory requirements to activate this study can be found in section 5.0 of the protocol on the CTSU website.

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

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 (IMFACTS) 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 January 15, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	235	--	300		
WF-1901	IMPACTS	206	+1	250	5	40
WF-1805CD	HN-STAR	322	+4	350	133	140
WF-2201	HYPOGRYPHE	17	+1	244		
WF-2202	SHINE	317	--	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	13	--	20	11	136