

# **STUDY MATTERS**

July 3, 2025

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

# **Holiday Hours**

The Wake Forest NCORP Research Base will be closed on Friday, July 4, 2025. We will resume normal hours on Monday, July 7.

In Memory: Dell Campbell



We are deeply saddened to share the passing of our dear team member, Dell Campbell, on June 18. Dell joined the WF NCORP Research Base in 2012 and worked as a data manager on numerous studies. She took pride in the work she accomplished and was a dedicated and beloved member of our team. While fighting her own battle with cancer, she understood the importance of NCORP clinical trials and was our biggest champion. Dell's presence brightened our work and our lives, and she will be truly missed by all.

### **ATTENTION PLEASE!**



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.

### 2025 Wake Forest NCORP Research Base Annual Meeting

October 6-8, 2025 Asheville, NC



Registration link coming very soon!

# **Upcoming Site Calls**



ALERT! The Site Calls listed below have been transitioned to a **Microsoft Teams** format.

- Click the associated link to add the new **Microsoft Teams** meeting to your calendar.
- **DELETE** the old **WebEx** meeting invitation (entire series not just occurrence).

\*\*Please note that your calendar may not update automatically if changes are made at a later date. Please check these emails and our website for meeting updates.\*\*

You can also join site calls from our <u>Wake NCORP website</u>. 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 <u>NCORP@wakehealth.edu</u>

### <u>WF-2202 - SHINE - Optimizing Psychosocial Intervention for Breast</u> <u>Cancer-related Sexual Morbidity: The Sexual Health and Intimacy</u> <u>Education (SHINE) Trial</u>

This site call series has been cancelled. Please check your calendar and remove any remaining invitations. These were previously scheduled <u>every even</u> <u>numbered month on the second Wednesday at 2 pm ET.</u>

WF-1901 - Internet-delivered Management of Pain Among Cancer <u>Treatment Survivors (IMPACTS)</u> July 9, 2025 2:30 PM ET

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 July 14, 2025 3:00 PM ET

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

July 17, 2025 3:00 PM ET

### Study Updates

WF2403- COACH-APP- Building Capacity within the NCORP Network through an Education and Mentorship Intervention for Advanced Practice Providers (COACH-APP)

#### **NEW AMENDMENT ACTIVATION**

COACH-APP (WF-2403) Amendment 1, Protocol Version Date 04/14/2025 has been activated.

The WF NCORP Research Base study entitled **Building Capacity within the NCORP Network through an Education and Mentorship Intervention for Advanced Practice Providers (COACH-APP)** has been activated for Amendment 1.

The protocol and consents were released on June 9, 2025.

#### WF-2403 Document Access:

- The protocol and consents are available on the <u>CTSU</u> website.
- The *Helpful Guide* and *Quick Facts* documents are available on the <u>WAKENCORP</u> website.

A recording of the introductory webinar is available on the WAKE NCORP Website.

NCORP Administrators were sent a *Study Recruitment Email* with a link to the *Study Interest Survey on June 18, 2025*. This will collect information needed to open your site and give further instruction about participant and site enrollment.

Regulatory requirements to activate this study can be found in the protocol on the

CTSU website.

If there are any questions regarding the WF-2403 activation, please contact <u>NCORP@wakehealth.edu</u>; Attn: WF-2403.

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

### **NEW AMENDMENT ACTIVATION**

HYPOGRYPHE (WF-2201) Amendment 7, Protocol Version Date 05/12/2025, Release Date: 06/25/2025.

The WF NCORP Research Base study entitled *Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy (HYPOGRYPHE)* has been amended. The amended protocol and consent were released on June 25, 2025.

The changes and documents within this amendment must be implemented within 30 days of this posting

#### The changes include:

- Now allowing Neurocognitive testing after signing consent, but prior to OPEN Enrollment.
- Updated visit windows stated within protocol
- Format changes to protocol cover page.
- Administrative Updates
- Updated CTSU language based on 3/26/2024 support logistical template language document.

#### WF-2201 Document Access:

- The protocol documents and participant directed documents are available on the <u>CTSU</u> website.
- The *Helpful Guide* and *Training Resources* are available on the <u>WAKENCORP</u> website.

**Sites interested in participating** should contact <u>NCORP@wakehealth.edu</u>; Attn: WF-2201 and request a start-up packet. **Your site must be IROC certified to participate or be willing to become certified.** Refer to Sections 5.2, 6.2 & 6.6 of the protocol for the Protocol Specific Requirements and Site Registration and Credentialing Requirements for site participation.

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

If there are any questions regarding the WF-2201 activation, please contact <u>NCORP@wakehealth.edu</u>; Attn: WF-2201.

### WF-1806- M&M - Myopenia and Mechanisms of Toxicity in Older Adults with Colorectal Cancer

Thank you for continuing to screen and enroll M&M participants. We are still climbing toward our goal. We have **4** slots left in the 60 -74yo stratum and **50** slots in the >75yo stratum.



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

#### Strata Closure Extended Another Month

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 note: This notification <u>does not</u> indicate a pause in recruitment. 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.

# WF-1901- IMPACTS - Internet Delivered Management of Pain Among Cancer Treatment Survivors

We're still pushing hard to get IMPACTS across the finish line — and we truly can't do it without your help!

We're just **29 enrollments away from reaching our goal of 250 participants,** and the finish line is in sight. The study will officially close for enrollment on **July 31, 2025**.

As a thank-you for your incredible efforts, the top enrolling site will receive a travel award covering hotel and travel expenses to attend the **2025 Wake Forest NCORP Research Base Annual Meeting in beautiful Asheville, North Carolina.** 

Let's make this final push together — your dedication makes all the difference! Please reach out to us if you have any questions <u>NCORP@wakehealth.edu</u>

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

Our goal is to enroll **120 dyads** by **this December**, and we are halfway there! Please continue to screen and enroll and let us know if you have any eligibility questions. Together, we can make this happen! We greatly appreciate all your work on this study

**Please remember** to trigger the 12 and 24 week surveys the day their 14 day window begins to maximize the time participants have to complete them.

\*An updated FAQ (v. 06.11.2025) has been added to our <u>website</u>.

Please email <u>NCORP@wakehealth.edu</u> with any questions.

# **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 studyspecific 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 <u>NCORP@wakehealth.edu</u>.

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled ( <u>Non-</u> Patients)	Target ( <u>Non-</u> <u>Patients</u> )
WF-1806	M&M	246	+0	300		
WF-1901	IMPACTS	223	+2	250	12	40
WF-1805CD	HN-STAR**	357		350	135	140
WF-2201	HYPOGRYPHE	31	+1	244		
WF-2202	SHINE**	341		336		
WF-2301CD	CONNECT	63 (pt/ caregiver dyad)	+4	120 (dyads)		
WF2304-A172401	COSMIC	579	+22	2000		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non- patients)	Target ( <u>Non-</u> <u>Patients</u> )
WF-2303CD	HRSN	19	+0	20	74	136

# Accruals as of July 2, 2025

\*\*Closed to enrollment