



STUDY MATTERS

July 31, 2025

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

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
Renaissance Hotel, Asheville, NC

Registration is Now Open!



- Once you register, you will be sent a confirmation email. Within this email is the link to the hotel for room reservations.
- **You must register for the meeting in order to receive the hotel reservation link.**

This meeting will be held *in person only* this year and the registration link will be posted on our website (and below) for members only.

Click here to register: <https://redcap.link/WFNCORPRB.2025AnnualMeeting>

Our Keynote Speaker will be Shellie Ellis, PhD. Dr. Ellis is a faculty member at the University of Wisconsin and is the Director of the Dissemination & Implementation Launchpad. She has implemented screening and treatment interventions in various primary and specialty settings, spanning federally qualified health centers, hospital-owned outpatient clinics, and private practices in rural, urban, and suburban settings. She is a health services researcher and implementation scientist. She has expertise in quantitative and qualitative methodologies and decades of experience assessing behavioral determinants to design effective and efficient implementation strategies.

Information about Wednesday Half-Day Sessions (you may register for only one):

WF-2401-STEPS BC

Study specific training for coordinators; includes overview of study workflow and hands-on guidance for required patient physical assessments.

"Mini" New Investigator Workshop

This half-day new investigator workshop is open to all interested in learning more about how studies are developed through the WF NCORP RB and how ideas evolve with feedback from multiple perspectives. This session will focus on enhancing understanding of NCORP operations/support, feasibility assessment, and approval processes, with breakout sessions offering opportunities for feedback on new potential NCORP study ideas.

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 [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

This site call series has been cancelled. Please check your calendar and remove any remaining invitations. These were previously scheduled every odd numbered month on the second Wednesday at 2:30 pm ET.

Quarterly Call

September 3, 2025 3:00 PM ET

Study Updates

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

New Spanish-language Documents Posted

Amendment 7, Protocol Version Date 05/12/2025 was posted on 06/25/2025.

The new Spanish Language document must be implemented within 30 days of this posting.

The Spanish version of the following document was posted on CTSU on **Thursday, July 17, 2025**.

- **Consent Form**, (PVD 05/12/25): Spanish

If there are any questions or your site is interested in participating in the WF-2201 study, please contact NCORP@wakehealth.edu; Attn: WF-2201.

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

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

****Temporarily Closing to Enrollment****
Effective July 31, 2025

We would like to extend our gratitude to all NCORP community sites that have enrolled to the WF-1901 IMPACTS Study. We have been informed that we can Temporarily Close this study to enrollment. A final decision will be made in the coming week on whether this study will be allowed to open back up to enrollment.

If you have any in-progress screenings or enrollments, please ensure these participants are fully enrolled in OPEN before 11:59 PM EDT on July 31, 2025. Let us know if you have concerns about meeting this deadline with an email to NCORP@wakehealth.edu.

Thank you for helping us enroll to this important study.

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

NEW AMENDMENT ACTIVATION

COSMIC (WF2304-A172401) Amendment 3, Protocol Version Date 04/01/2025 has been activated.

The WF NCORP Research Base study entitled 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 has been activated. The protocol and related documents were released on July 11, 2025.

The changes and documents within this amendment must be implemented within

30 days of this posting.

Changes with this amendment include:

1. Updated Inclusion Criteria 4.1.1 to provide specific examples of eligible non-small lung cancer subtypes and added additional criteria, 4.1.6 which states “Participant must reside in the United States, Puerto Rico, Guam or the US Virgin Islands, officially determined per patient report on the Self-reported Screening Survey.”
2. Added Inclusion Criteria 4.1.7 “In the treating provider’s opinion, the participant should have a life expectancy of ≥ 6 months. Participants in hospice are not eligible” and Exclusion Criteria 4.2.4 “Participants enrolled in hospice.”
3. Added Exclusion Criteria 4.2.3 stating “Participant received systemic therapy treatment for prior cancer(s) including chemotherapy, immunotherapy, targeted therapy, or hormonal therapy.”
4. Completion of the Baseline survey before Cycle 1 treatment was removed from the Eligibility Criteria in Section 4.3
5. In Protocol, removed references to “additional” measures collected in medical record review for the biospecimen sub-study participants.
6. Statement in Section 6.6 “If participants cannabis and/or cannabinoid use status has changed since initial screening, they will be taken off the Optional Biospecimen Sub-Study.” was removed.
7. Protocol and baseline survey reminders changed to say that the Baseline survey can be completed up to midnight of the day receiving Cycle 2 treatment. Currently, it states that the Baseline survey can be completed up to the start of Cycle 2 treatment.
8. On the Main Study + Biospecimen Sub-Study Combined Consent Form, the total amount of blood to be collected at each time point was increased from 1 to 1.5 TBSP / 15mL to 20mL
9. The consent form and protocol have been changed to include two email reminders 1 and 3 days after participants have been emailed the link for the Self-Reported Screening survey

10. Added the study email to the consent forms with a suggestion that the participant add it to their address book to ensure they receive communications.
11. Changed “Questionnaires” to “Surveys” on consent forms. Minor typos and grammatical errors were also corrected on the consent forms.
12. Changes have been made to confidential patient-facing REDCap surveys. These surveys are not available on CTSU for sites to download. Refer to Summary of Changes for a list of the survey updates.

WF2304-A172401 Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The Helpful Guide and FAQs are available on the [WAKENCORP](#) website.
- The introductory site training webinar and associated slides are available on CTSU-CLASS; Course Title: WAKE: WF2304-A172401 COSMIC Introductory Site Training.

If there are any questions, or your site is interested in participating, please contact NCORP@wakehealth.edu; Attn: WF2304-A172401.

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

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!

Travel Award recipients will be announced soon!

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 July 30, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	250	+4	300		
WF-1901	IMPACTS	228	+5	250	12	40
WF-1805CD	HN-STAR**	357	--	350	135	140
WF-2201	HYPOGRYPHE	34	+3	244		
WF-2202	SHINE**	341	--	336		
WF-2301CD	CONNECT	66 (pt/ caregiver dyad)	+2	120 (dyads)		
WF2304-A172401	COSMIC	633	+54	2000		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	19	+0	20	79	136

**Closed to enrollment

