

STUDY MATTERS

September 25, 2025

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



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

The final day to register is October 1st!



- 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

OPEN CALL for Committee Members



The Wake Forest NCORP Research Base is soliciting applications for NCORP Community Site representatives for the Cancer Control, Cancer Care Delivery Research (CCDR) Scientific Committees and the Community Engagement Core Committee.

Community site representation on all committees has been expanded. Responsibilities for members will include:

- Attend committee meetings (monthly for the scientific committees and quarterly for the Community Engagement Core)
- Provide feedback about studies early and throughout the study lifecycle to improve feasibility and alignment of studies with community site priorities and provide feedback on implementation challenges
- Provide scientific and feasibility review of new concepts/protocols
- Oversee active studies, including accrual progress
- Periodically review and make recommendations about committee priorities and activities
- Act as a liaison between NCORP community sites/investigators and the Wake Forest NCORP Research Base

We are looking for committee members who bring their expertise within NCORP (PIs or scientific leaders, CRAs, research nursing, and Administrators), their scientific background and populations with whom they engage. Interested individuals should apply using the REDCap link below. The application will include a brief statement (5-10 sentences) on your prior involvement with the Wake Forest NCORP Research Base, experience with cancer control, cancer care delivery research, and/or community engagement research. You will also be asked to upload a CV or biosketch. The initial committee term will be 2 years. **The due date to apply is October 20, 2025.** Selection of committee members will take

place in November and committees will begin meetings in January 2026. https://redcap.school.wakehealth.edu/surveys/?s=TCCPENFPRFW87W8N

Upcoming Site Calls

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 NCORP@wakehealth.edu

WF2304-A172401-COSMIC - Data Management Q&A

October 2, 2025, 3 PM ET

Study Updates

BLOOD SPECIMEN SHIPPING ALERT – FedEx Account Invalid







Be advised that the account number on the pre-printed FedEx Airbills is no longer valid for the **WF-1806**, **WF-1901** and **WF-2201** studies. These airbills are currently included in the specimen kits that you may have in stock. Our Biospecimen

Laboratory is now supplying airbills (via email) upon request.

Please email <u>7NCORP@wakehealth.edu</u> or call 336-716-2581 and include the **kit#** in your communication.

(NEW!)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 4, Protocol Version Date 08/01/2025 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 September 23, 2025.

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

Changes with this amendment include:

1. Received a waiver of consent to administer the eight-question Self-Report Screening Survey to participants. **Please note:** Sites may still obtain consent from participants before administering the Self-Report Screening Survey, even if a waiver of consent is in place.

- 2. Modified protocol language to allow screening to be completed prior to consenting participant.
- 3. Updated cannabis use strata limits.
- 4. Updated the completion of the baseline survey window in both informed consents to read as follows: "Complete the baseline survey no later than midnight on the day you complete Cycle 2."
- Changed 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.

The Spanish-language consent documents that align with the protocol are being translated by the CIRB. A separate broadcast will be distributed when the Spanish-language consents are posted to the CTSU.

WF2304-A172401 Document Access:

- The protocol documents are available on the <u>CTSU</u> website.
- The Helpful Guide and FAQs are available on the <u>WAKENCORP</u> 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.

WF-2301CD- CONNECT - Multi-site Community
Oncology Planning for the CONNECT Intervention

Targeting Lung Cancer Caregivers

We greatly appreciate everyone's efforts on this study! Please continue to focus on screenings and enrollments, as we currently have **81 dyads** enrolled out of our goal of 120. We are striving to reach our enrollment goal by the end of December, which is just a few short months away. Remember that each site has a minimum goal of 10 enrollments, but sites are able and encouraged to enroll beyond 10.

Please remember to complete the Caregiver and Patient Status Forms in REDCap once they have completed their 24 week surveys or if they have withdrawn from the study.

Feel free to reach out to MCORP@wakehealth.edu with any questions or challenges you may be facing.

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 September 24, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non- Patients)	Target (Non- Patients)
WF-1806	M&M	251	+0	300		
WF-1901	IMPACTS	229	+0	250	12	40
WF-1805CD	HN-STAR**	357		350	135	140
WF-2201	HYPOGRYPHE	39	+2	244		
WF-2202	SHINE**	341		336		
WF-2301CD	CONNECT	81 (pt/ caregiver dyad)	+5	120 (dyads)		
WF2304-A172401	COSMIC	830	+34	2000		
WF-2403	COACH-APP				17	97
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non- patients)	Target (Non- Patients)
WF-2303CD	HRSN	19		20	84	136

^{**}Closed to enrollment