



STUDY MATTERS

August 28, 2025

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

Labor Day Office Closures

The **Wake Forest NCORP Research Base** will be closed for Labor Day on Monday, September 1, 2025. We will resume regular business hours on Tuesday, September 2, 2025.

The **NCI CIRB Operations Office** will be closed Monday, September 1, 2025, for the Labor Day holiday. If you need to reach the CIRB Operations Office, please do so before the holiday, by sending an email to support@ncicirbcontact.zendesk.com, or by calling us toll-free at 1-888-657-

3711.



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.

Half-Day 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.

TRAVEL AWARD COMPETITION - WINNERS!

Travel Award Recipients:

- WF-1901 IMPACTS - Atlantic NCORP
- WF-1806 M&M - Stroger MU NCORP
- WF-2301CD - Upstate NCORP & WINCORP

Sincerest thank you to these sites for your efforts in enrolling the most participants to these studies from 1/1/2025 - 7/31/2025. We look forward to seeing you at our Annual Meeting in Asheville, NC in October!

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 [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

Quarterly Call

September 3, 2025 3:00 PM ET

[Click to add the Quarterly Call to your Calendar](#)

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

September 8, 2025 3:00 PM ET

[Click to add the COSMIC Site Call to your Calendar](#)

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

September 9, 2025 3:00 PM ET

[Click to add the HYPOGRYPHE Site Call to your Calendar](#)

**WF-1901- IMPACTS - Internet Delivered Management of Pain Among
Cancer Treatment Survivors (New Series)**

September 10, 2025 2:30 PM ET

[Click to add the IMPACTS site call to your Calendar](#)

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

September 18, 2025 3:00 PM ET

[Click to add the CONNECT Site Call to your Calendar](#)

Study Updates

**(NEW!)WF-1805CD- HN-STAR - Implementation and
Effectiveness Trial of HN-STAR**

****Closed to Enrollment**
Effective June 26, 2025**

We have closed all enrollment for the WF-1805CD-HN-STAR study.

Thank you for helping us enroll to this important study!

If there are any questions regarding WF-1805CD, we are glad to help. Please contact us at NCORP@wakehealth.edu; Attn: WF-1805CD.

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

Thank you for continuing to screen and enroll M&M participants. We are still moving toward our goal. There are **no available slots in the in the 60-74yo stratum** and 49 slots in the >75yo stratum.

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

Reopening for Accrual - Selected Sites Effective August 7, 2025**

We are pleased to announce that **WF1901 IMPACTS** will reopen for accrual effective **08/07/2025** at selected sites. These selected sites have demonstrated continued commitment to enrollment goals and have played a key role in shaping amendments that improve study workflows and recruitment efforts. We sincerely appreciate their dedication and collaboration.

Selected site administrators will be contacted regarding their continued participation and support. For sites that have not enrolled participants within the past year, leadership has made the difficult decision to conclude their involvement with WF1901 by ending their SOTE letters effective **08/7/2025** in CTSU. This decision reflects our desire to be respectful of site capacity.

Monthly Site Calls-

As part of the relaunch, we will initiate monthly site calls facilitated by NCORP staff and study PIs. These calls will replace the bi-monthly newsletters and serve as a dedicated space to discuss recruitment challenges, share updates, and collaborate on strategies to enhance enrollment. If you have any questions or concerns, please contact NCORP@wakehealth.edu, Attn: **Relaunching WF1901 IMPACTS**.

Thank you again for your continued support and partnership.

****List of approved Sites:**

CA156	HI049	LA014	NC275	WI009
CA175	HI051	MI221	NC295	WI031
CA191	IA066	MI347	NJ028	WI069
CO034	IA072	MN001	NJ048	WI103
CO112	IL101	MN008	NJ141	WI109
CO125	IL168	MN014	NJ304	WI129
GA045	IL188	MN019	OH245	WI132
GA106	IL232	MN028	OH428	WI144
HI004	IL352	MN041	PA052	WI208
HI005	IL353	MN054	SC015	WI210
HI006	IL354	MN098	SC036	WI218
HI007	IL405	MN119	SC053	
HI010	IL439	MO056	SC060	
HI012	KY106	NC002	SC117	
HI022	LA007	NC274	VA010	

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

NEW AMENDMENT ACTIVATION

CONNECT (WF-2301CD) Amendment 5, Protocol Version Date 04/28/2025 has been activated.

The WF NCORP Research Base study entitled **Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers** has been activated. The protocol and related documents were released on August 19, 2025.

****Note:** The Caregivers randomized to the CONNECT intervention who haven't completed their 4-week Navigator call **will be reconsented**.

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

Changes with this amendment include:

1. Updated Section 4.2.1, Caregiver Inclusion Criteria. Added “informal (i.e., not professional)” to first bullet point. ***Must self-report providing informal (i.e., not professional) care during cancer treatment for a patient who meets the criteria below in sections 4.2.3 and 4.2.4 and who is willing to participate.***
2. Updated 4.2.3, Patient Inclusion Criteria. Added “(i.e., initial diagnosis)” to first bullet point. ***Must have a current diagnosis of new (i.e., initial diagnosis) or recurrent stage II-IV lung cancer.*** Added “informal (i.e., not professional)” to last bullet point. ***Must self-report receiving informal (i.e., not professional) care from a caregiver who meets the criteria in sections 4.2.1 and 4.2.2 above and who is willing to participate.***
3. Updated 4.2.4 Patient Exclusion Criteria. Added “Patients who have completed treatment for their lung cancer” to first bullet point.
4. Added clarifying footnote language to the Caregiver and Patient assessment sections of the Schedule of Events.
5. Added clarifying language regarding randomization in the Schedule of Events Table.
6. Added text message language to protocol and Caregiver consent.
7. Created new document: Condolence letter.
8. Added items to the Acceptability survey (*CG Acceptability CONNECT 2*).
9. Added items to the Acceptability survey for caregivers randomized to the Generic Resource Group (*CG Acceptability Resource List*).
10. Added items to the Acceptability survey for caregivers randomized to the Usual Care Group (*CG Acceptability Usual Care*).
11. Updated titles and format of the protocol cover page.

12. Updated Section 6.1 based on 7/19/24 CTSU language recommendations memo.

WF-2301CD Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The Helpful Guide, FAQ, OPEN enrollment forms and introductory webinars are available on the [WAKENCORP](#) website.

Operational & Enrollment Updates

Our study team is now working with Calendly to help schedule our Navigator calls. Instructions for sites can be found under the CONNECT Study/Helpful Guide on our Wake Forest NCORP RB website, along with our other study related materials- <https://wakencorp.phs.wakehealth.edu/study/wf2301cd-connect>.

We greatly appreciate everyone's efforts on this study! Please continue to focus on screenings and enrollments, as we currently have 67 *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.**

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

[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

Gift Card Redemption: Please let us know if any of your participants need assistance with their gift cards. We have posted general redemption instructions on our website in the FAQ/Helpful Guides section of the WF2304-A172401-COSMIC page here: <https://wakencorp.phs.wakehealth.edu/study/wf2304-cosmic/>. For help with specific card redemption questions please contact NCORP@wakehealth.edu

Reminder for Study Coordinators! We've implemented a gentle reminder email in REDCap that will prompt you to follow up with participants who have missed a monthly survey. While participants are still eligible to remain in the study if a survey is missed, this message serves as a friendly nudge to help them stay engaged and on track.

WF-2403 - COACH-APP - Building Capacity within the NCORP Network through an Education and Mentorship Intervention for Advanced Practice Providers (COACH-APP)

We are still accepting *Study Interest Surveys* for this study and are beginning to enroll our first cohort of participants! As a reminder, you may have more than one APP Practice participate in this study within your NCORP Community or Minority Underserved Community Site, but we encourage you to start with no more than 2 to allow for an opportunity for all Community Sites to participate initially.

Please email NCORP@wakehealth.edu with any questions about this study!

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 August 27, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)
WF-1806	M&M	251	+1	300	
WF-1901	IMPACTS	229	+1	250	12
WF-1805CD	HN-STAR**	357	--	350	135
WF-2201	HYPOGRYPHE	36	+2	244	
WF-2202	SHINE**	341	--	336	
WF-2301CD	CONNECT	72 (pt/ caregiver dyad)	+5	120 (dyads)	
WF2304-A172401	COSMIC	742	+59	2000	
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)
WF-2303CD	HRSN	19	--	20	81

**Closed to enrollment

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