



STUDY MATTERS

June 5, 2025

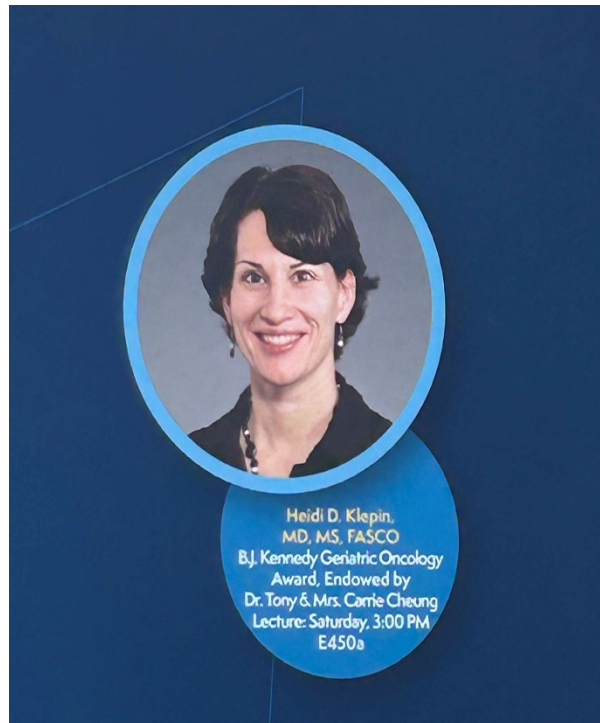
Wake NCORP Website: <https://wakencorp.phs.wakehealth.edu/>

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.

Honors and Awards!

Congratulations to **Dr. Heidi Klepin** on receiving the BJ Kennedy Geriatric Oncology Award at the 2025 ASCO meeting.



Congratulations to **Dr. Emily Dressler** who was inducted as a Fellow of the Society for Clinical Trials at the 2025 SCT meeting!



WF-2304-A172401-COSMIC Data Management Site Calls

The Wake NCORP Study Coordination and Data Management Teams are offering two open Q&A site calls to answer any questions you may have regarding data entry for the WF-2304-A172401-COSMIC study. Topics will include Cancer Treatment entries, Concomitant Medications, Quarterly Chart Review, and Data Submission Timing.

If you would like to submit topics or questions for discussion, please email them to ncorp@wakehealth.edu

Please click on the links below to add one or both of these calls to your calendar:

Wednesday, June 11, 2025 at 11 am ET

Thursday, June 12, 2025 at 3 pm ET

You can also join the calls from our website if you are a registered user.

You can register for an account

here: <https://wakencorp.phs.wakehealth.edu/membership-login/>

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

(HYPOGRYPHE)

July 2, 2025 3:00 PM ET

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

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

(NEW!)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 **5** slots left in the 60 -74yo stratum and **51** slots in the >75yo stratum.



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

NEW STUDY

INTRODUCTORY WEBINAR: Tuesday, June 17, 2025, 12 PM ET

The current protocol is available on CTSU, however, Amendment 1 will be activating next week. Please look for the special broadcast that will have more information then!

Study Goal: To investigate the impact of a focused education and structured mentorship intervention (COACH-APP) on APP research self-efficacy and integration into the research care team and NCORP activities.

Study Population: Advanced Practice Providers (APPs) employed at NCORP practice providing care to cancer patients potentially eligible for NCORP and/or NCTN trials who are registered as NPVR but have not served as a site PI for an NCORP trial.

Sample Size: 97 total: 70 APPs randomized 1:1 (35 COACH-APP Intervention/35 Education Control), Subset for Interviews: 10 of 35 COACH-APP APPs, 7 COACH-

APP Mentors, 20 Research Team members (e.g., 10 oncologists and 10 clinical research professionals)

Study Duration: APP study duration is 12 months. Pragmatic practice data collection is through 24 months.

Primary Objective: To compare change in research self-efficacy (RSE) scores (from baseline to 12 months post randomization) between APPs in the COACH-APP intervention compared to the education control.

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

WF2304-A172401 COSMIC – Frequently Asked Questions (FAQs) Document Update

29. **Recommended language for sites to communicate with patients who are not eligible. ADDED**

“We appreciate your interest in the COSMIC study. Unfortunately, you are not eligible for enrollment at this time. To protect your privacy based on the information you have provided, your local study team is unaware of the reasons for you not being able to enroll in the study. Thank you once again for the time you have spent to determine if the COSMIC study is right for you!”

Strata Closed for 1 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 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-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR

Final DC and SH Surveys

Now that enrollment has closed, DCs and SHs must complete final surveys so that our study team can set up their final interviews. For DCs, please complete the “DC Intro” form in REDCap for those who have not already completed their survey. For SHs, please complete the “SH-Email Trigger” form in REDCap for those who have not already completed their survey. These can be found under the “After 10th Completion” section. Thank you in advance for your assistance. Please reach out to NCORP@wakehealth.edu if you have any questions.

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

A couple reminders!

Please remember to trigger the 12-week surveys in REDCap at 12 weeks post baseline survey completion. Patients and caregivers have +14 days to complete these. All contact attempts should be documented in the Contact Attempt Log. A deviation form must be completed for any surveys completed outside this window.

Friendly reminder that caregivers can be recruited remotely and this is especially helpful when they are not attending a patient's appointment. Further, a caregiver does not need to provide hands-on medical care to be eligible. Care can come in many forms such as providing emotional support, transportation, helping the patient navigate the healthcare system, and more. If a patient is married or partnered, this role often defaults to the spouse/partner. However, caregivers often also include adult children, other family members, or a close "family-like" friend.

Please email NCORP@wakehealth.edu 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 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 June 4, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	244	+1	300		
WF-1901	IMPACTS	219	+1	250	12	40
WF-1805CD	HN-STAR**	357	--	350	135	140
WF-2201	HYPOGRYPHE	30	+1	244		
WF-2202	SHINE**	341	--	336		
WF-2301CD	CONNECT	57 (pt/ caregiver dyad)	+7	120 (dyads)		
WF2304-A172401	COSMIC	520	+35	2000		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	19	+0	20	65	136

**Closed to enrollment