



August 3, 2023

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

Wake Forest NCORP Research Base Website

*****If you have already registered, please update your roles on the website*****

We use this information for targeting email communications and surveys

If you have not registered, go to:

<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

Wake Forest NCORP RB Annual Meeting

The 2023 Wake Forest NCORP RB Annual Meeting will be held **October 16-17, 2023** at the Renaissance Hotel in Asheville, NC. We hope to see you there!

A block of rooms has been reserved with a group rate of \$269 per night beginning October 15 – October 18.

You will need to book your rooms by 09/24/2023.

[Book your group rate hotel for the Wake Forest NCORP Research Base Annual Meeting \[url.emailprotection.link\]](#)



Cancer Care Delivery Workshop at the Wake Forest NCORP Research Base Annual Meeting

Implementing Change with Context-Driven Co-Design (CD2) October 18, 2023 8:30-11:30am ET

Description: Change is the only constant in health care. NCORP settings, in particular, are often tasked with implementing new interventions, protocols, workflows, or other change efforts. In this workshop, we will summarize a process to support implementation: Context-Driven Co-Design (CD2). CD2, developed by Drs. Haines, Birken, and Morris at Wake Forest University School of Medicine, is a state-of-the-science approach to developing and tailoring strategies to support the implementation of evidence-based interventions and other innovations. CD2, which combines elements of user-centered design and implementation science, includes two components: (1) a detailed assessment of the setting in which an intervention will be implemented (i.e., context assessment) and (2) co-design sessions with intervention end users (e.g., patients and providers) to identify intervention adaptations and implementation strategies to improve intervention-context fit. This workshop will provide an in-depth understanding of the CD2 process through both didactic lecture and group discussion activities and equip participants with CD2 templates (e.g., interview guides, co-design materials) and the opportunity for participants to apply the steps of CD2 to a past, present, or future change effort relevant to their own setting.

Space is limited for this workshop. Interested participants should complete this [REDCap form](#) by 8/15 for greatest consideration (others may be allowed as space permits). We strongly encourage (but do not require) participants to engage in a workshop evaluation (e.g., focus group; survey) to be conducted directly following the workshop. Selected attendees will be notified by 8/23.

Upcoming Site Calls

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

August 22, 2023 at 2:30pm ET. Please update your calendars.

Please email 7NCORP@wakehealth.edu when shipping biospecimen samples to the NCORP Research Base Biospecimens lab (Studies WF-97415, WF-1801, WF-1901, and WF-2201). Include the FEDEX tracking number in your email so that misplaced samples can be tracked before they spoil. Please ship by "FedEx Priority Overnight" (please change this on the pre-printed shipping label if this is not selected).

Study Updates

[WF-1802 - PCW - Influence of Primary Treatment for Prostate Cancer on Work Experience](#)



*****Now Closed to Accrual***
(Effective August 1, 2023 at 11:59 PM EDT)**

We would like to thank all sites who have participated in this study. **This study is now closed to accrual.**

REMINDER: You should still follow your current enrolled patients on study per protocol and continue with your IRB renewals at this time. Let us know if you have any questions by emailing NCORP@wakehealth.edu.

What's Next?

1. Please keep this study closed to accrual at your site. Please do not submit a Study Closure Request to the CIRB for this study until the Wake Forest NCORP Research Base gives your site permission.
2. Until this study has been officially FDAAA/IRB Completed by the Wake Forest NCORP Research Base, your site may still be audited on this study.
3. We should keep all study documents for at least five years once the study has been FDAAA/IRB Completed, following the protocol requirements and your local site's record retention policies.

WF-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR

HN-STAR TRAVEL AWARDS

Available for the **2023** Wake Forest NCORP RB Annual Meeting

We are pleased to announce that we will be offering travel awards to the **first 4 sites who enroll 4 patients to the HN-STAR study between July 20, 2023 and September 15, 2023**. Awards are worth up to \$1,000 to cover travel and hotel expenses at the Renaissance Hotel in Asheville, NC.

Please contact NCORP@wakehealth.edu Attn: WF-1805CD if you have any questions.

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



NEW AMENDMENT ACTIVATION

WF-1806 (M&M) Amendment 8, Protocol Version Date 05/23/2023, Release Date 07/14/2023:

The WF-1806, *Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer (M&M)* study has been amended. The amended protocol and related documents were released on Friday, July 14, 2023.

Changes with this amendment include:

- Update to contact information for Protocol Principal Investigator Grant R. Williams, MD.
- Addition of new Co-Principal Investigator, Smith Giri, MD, MHS.
- Correction to the footnote references in the participant schedule of events section; replacing symbol b with β and replacing symbol \square with Φ .
- **Changing lab location for blood sample submission to WF NCORP Biospecimen Lab. – See updated Helpful Guidelines info below**
- Update to CTSU language based on 05/05/2023 support logistical template language document.

WF-1806 Helpful Guidelines document has been updated to version 07/05/2023 and reflects the new blood sample shipment destination below.

ATTN: WF-1806 (M&M)
WF NCORP Biospecimen Lab
Bldg. A1A Lab 230 c/o Delivery on Time
Wake Forest School of Medicine
Richard Dean Bldg. Receiving Dock
391 Technology Way
Winston-Salem, NC 27101
Phone: (336) 716-2581

Please email 7NCORP@wakehealth.edu if you need replacement air bills for kits that you have in stock and be sure to include the kit# in your email.

Note: The shipping destination for the CT scans is still UAB-Birmingham but the contact names and FedEx account have changed:

For Fed Ex billing, please use the following account:

Account #: 027403727

Internal Reference: WF NCORP Research Base

Ship discs to:

Ref: M&M Study

Smith Giri

C/O Abigail Tucker

ICOS, Lowder 500

1600 7th Ave South

Birmingham, AL 35233

Phone 205-638-2146

NEW RECRUITMENT MATERIALS

WF-1806 (M&M) Amendment 8, Protocol Version Date 05/23/2023, Release Date 07/14/2023:

The following recruitment documents were posted to the CTSU website on 08/02/2023.

Recruitment Brochure - Trifold brochure explaining the WF-1806 (M&M) study.

Does Muscle Matter?
If you have been diagnosed with colon or rectal cancer, there are parts of the body you may be able to help us answer this question.

The patient view is important
The M&M study includes questions that ask about your patient experience. Capturing the patient voice helps to improve research and care for patients in the future.

What is the M&M Study?
This study looks at whether or not low muscle mass plays a role in the side effects you have from cancer treatment.

What is it like to be in the study?
During the treatment for your cancer, your doctor and study team will watch you for side effects and record them.

Can I participate?
You may be able to join the study if you are:

- Age 60 or older and have colorectal cancer (cancer in the colon or rectum)
- Planning to or recently started immunotherapy and/or chemotherapy
- Able to understand English or Spanish to complete study surveys

Your quality of life is precious!
Please consider joining the study. What we learn may help us reduce side effects for future cancer patients.

Around treatment start and again at 3 and 6 months during regular doctor appointments:

- Surveys
- Physical Function tests
- CT Scans that are part of your regular care
- One time blood sample around the start of your treatment

Study Summary - One page two-sided summary of the WF-1806 (M&M) study.

Study Summary (WF-1806)

M&M: Study examining Muscle Mass and its Role in Side Effects from Chemotherapy and/or Immunotherapy in Older Adults with Colorectal Cancer.

Why should I be in this study?

- Information about your **personal experience** may help improve the way future patients are treated for colorectal cancer.
- Study activities will be done along with your regular treatment visits. **No additional appointments are needed.**
- You can make a **difference** for older adults with cancer in the future.

WF-1806 M&M will help doctors find out if a patient's amount of muscle mass has an impact on the severity of side effects during treatment for colorectal cancer.

What will I have to do?

- You will keep your regular doctor appointments.
- Around treatment start and again at 3 and 6 months, you will be asked to **complete a survey** and a set of **physical strength tests**.
- There will be **one blood sample** taken for the study around the start of your treatment.
- Your doctor and study team will **watch you for side effects** and record them for the study.
- The CT scans that are part of your regular care will be used by the study to look at **your muscle mass**.

Taking part in this study is your choice. You also can change your mind at any time.

Who will take part in this study?

- Adults **age 60 and older** who have colorectal cancer that has spread (metastasis)
- Planning to or recently started immunotherapy and/or chemotherapy as **treatment for their cancer**.
- Able to understand **English or Spanish** in order to complete study surveys.

What is the cost of taking part in this study?

All costs related directly to the study will be paid for by the study. The costs of your regular medical care are unrelated and fall under your existing coverage.

How can I learn more?

- Visit **WF-1806 at cancer.gov** or scan QR Code to the right with your smartphone camera. For information about medical facilities where the study is available, scroll down the page to Locations and Contacts
- Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237)
- For general cancer information, visit the NCI website at www.cancer.gov

Optional: Please contact us: Insert local site contact information

WF-1806 Document Access:

- The protocol and participant directed documents are available on the [CTSU](#) website.
- The Helpful Guidelines, FAQs, Provider Fact Sheet and Training Attestation documents are available on the [WAKENCORP](#) website.

If there are any questions regarding WF-1806 we are glad to help. Please contact us at NCORP@wakehealth.edu; Attn: WF-1806.

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



TRAVEL AWARDS

Available for the **2023** Wake Forest NCORP RB Annual Meeting

We are pleased to announce that we will be offering travel awards to sites who **enroll 5 patients to the IMPACTS study between June 19, 2023 and September 19, 2023**. Awards are worth up to \$1,000 to cover travel and hotel expenses at the Renaissance Hotel in Asheville, NC.

Please contact NCORP@wakehealth.edu Attn: WF-1901 if you have any questions.

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



NEW SPANISH DOCUMENTS POSTED

HYPOGRYPHE (WF-2201) Amendment 1, Protocol Version Date 01/15/2023 was posted on 03/17/2023.

The Spanish versions of the following documents that align with this amendment were posted on CTSU **Friday, July 7, 2023**.

- **Recruitment Brochure** (version 02/13/23): Spanish
- **Recruitment Flyer** (version 02/13/23): Spanish
- **Recruitment Letter** (version 02/13/23): Spanish
- **Study Summary** (version 02/13/23): Spanish

If there are any questions, please contact NCORP@wakehealth.edu; Attn: WF-2201

WF-97415 - UPBEAT - Understanding and Predicting Breast Cancer Events after Treatment

Thank you for collecting the remaining 24-Month data!

Please enter all 24-Month participant data in REDCap as soon as you can.

If any of your participants are missing 24-Month data, please let us know and we will help you with documentation.

*****Remember to continue annual follow-up contact with participants through 11 years. This follow-up includes the KCCQ Questionnaire, documentation of any cardiovascular events and SAEs as described in the study protocol.*****

Accruals as of August 2, 2023

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	67	--	75		
WF-1802	PCW	255	+3	255		
WF-1806	M&M	153	+4	300		
WF-1901	IMPACTS	115	+2	456	0	40
WF-1805CD	HN STAR	153	+3	350	106	140
WF-2201	HYPOGRYPHE	1	--	244		

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