



## STUDY MATTERS

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January 20, 2022

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

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### **NCORP BIOSPECIMEN LAB UPDATE:**

*The lab has moved!*

#### **NEW \*REVISED\* SHIPPING ADDRESS**

K. KOURMAN & M. MORRIS

NCORP Biospecimen Lab

Phone: 336-716-2581

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

New air bills will be printed and sent to sites for old kits. New kits going out soon will have the new return address.

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## **NCORP Webinar Series Announcement**

**Registration is Now Open:**

**[click on link below]**

<https://events.cancer.gov/hdrp/ncorpccdrwebinars/registration>

Our team of Research Base, Community Site, Minority/Underserved Community Site, and NCI representatives is pleased to invite you to the final session of a three-part webinar series titled “Collaborating to Develop New Practice Randomization Trials for NCORP Cancer Care Delivery Research (CCDR).” The series has provided an opportunity to share experiences with these types of trials and strategize about how best to conduct similar trials in the future. It is designed to be broadly applicable to NCORP members involved in CCDR, regardless of their level of engagement with practice randomized trials.

The final webinar is scheduled for January 26, 2022 from 4 – 5:30pm EST.

### **FINAL WEBINAR**

**“Making the Numbers Work: Design Considerations in NCORP CCDR Trials”**

Goal: discuss approaches to balance the design features and analysis plans of future NCORP CCDR practice-randomized trials and the reality of their conduct in NCORP CCDR. The emphasis will be on pre-protocol approval activities.

This webinar will include opportunities for attendees to interact with panelists. Attendance is limited to those affiliated with an NCORP Site or Research Base to allow for open discussion.

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# For Funding Opportunities Announcements Relevant to NCORP CCDR, click on this link:

<https://healthcaredelivery.cancer.gov/funding/opportunities.html>

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## Upcoming Site Calls

**WF-1801 - Ramipril - A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma Patients Receiving Brain Radiotherapy**

January 26, 2022 at 3:00pm EST

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

February 9, 2022 at 2:30pm EST

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

February 23, 2022 at 2:30pm EST

If you would like to attend, but did not receive an invitation, please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)

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Please email [7NCORP@wakehealth.edu](mailto:7NCORP@wakehealth.edu) when shipping biospecimen samples. Include the FEDEX tracking number in your email so that misplaced samples can be tracked before they spoil.

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## Study Updates

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### **WF-1802 - PCW - Influence of Primary Treatment for Prostate Cancer on Work Experience**

**The Higher Income White stratum only has 2 remaining slots available.** Please keep this in mind when screening for participants and check the slot reservation report in CTSU-OPEN to see how many slots are available before registering.

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### **WF-1804CD - AH-HA - Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors**

**\*\*Last call for NCORP sites/affiliates interested in WF-1804 CD\*\***

The NCI has requested that we identify all potentially interested sites for the Automated Heart Health Assessment (AH-HA) for Survivors study by Feb 1, 2022. If your NCORP site/affiliate is interested in opening this study or adding an additional affiliate, please contact the Wake Forest NCORP Research Base at [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

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

**HN-STAR (WF-1805CD) is actively looking for new sites to enroll!** We have recently made significant changes that dramatically expand patient eligibility, such as allowing telehealth study visits, enabling remote consent, including patients with a history of other cancers, and including patients up to 2 years out from treatment completion. We are happy to have individual meetings with site staff to discuss any questions and concerns about HN-STAR involvement. Please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) if interested.

**Please join us at one of our upcoming HN-STAR refresher trainings!** This training is relevant to the entire study team. During the training we will review the study process and answer any site questions. If you would like to attend and did not receive a WebEx invitation, please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) for the calendar invite.

### Usual Care Arm

January 26 @ 12:00 PM EST

February 3 @ 3:30 PM EST

### Intervention Arm

January 27 @ 3:30 PM EST

February 2 @ 12:00 PM EST

**We are pleased to announce that we will be offering travel awards to the top two accruing sites between January 19 and July 31, 2022.** Each award will cover two nights' accommodations at the Wake Forest NCORP 2022 Annual Meeting in Myrtle Beach, SC at the Marriott Grand Dunes in October.

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

### **NEW AMENDMENT ACTIVATION**

**WF-1806 (M&M) Amendment 5, Protocol Version Date 11/08/2021, Release Date 12/30/2021:**

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 **Thursday, December 30<sup>th</sup> 2021.**

Changes with this amendment include:

- In addition to patients who are being treated for metastatic colorectal cancer with 5-FU, patients who are being treated with immunotherapy only are now eligible for the study.

**WF-1806 Document Access:**

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

**\*Note: [A new version of the Helpful Guidelines \(v12.30.2021\) for this study has been posted.](#)**

**Registration Requirements:**

- All sites are required to use the NCI CIRB as their IRB of record per the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NPT-OD-17-076).
- Toxicity Grading Certificates will be required for any staff member who will grade toxicities for this study.
- Physical Testing Certificate will be required for any staff member who will be administering the SPPB or HGS tests.
- Site Open to Enrollment (SOTE) letter from the WF NCORP RB will be provided to the site after all onboarding activities are completed.

### **WF-1806 Participation:**

Sites interested in participating who have not started the onboarding process should contact the WF NCORP RB at [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-1806 and provide the following information:

- Parent CTEP ID
- Parent Institution Name
  - Participating Site(s) (affiliates and sub-affiliates):
    - Site CTEP IDs
    - Site Names
- Principal Investigator:
  - First and Last Name
  - Phone Number
  - Email Address
- Primary Point of Contact:
  - First and Last Name
  - Phone Number
  - Email Address

If there are any questions regarding the WF-1806 activation or site registration procedures, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-1806.

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

When shipping Serum, Plasma, and DNA samples to the Biospecimen Lab, please change the Express Package Service selection from "FedEx Standard Overnight" to "**FedEx Priority Overnight**"

Several samples have been arriving late to our Biospecimen lab due to delays encountered through FedEx shipping.

As always, please do not ship samples for the WF97415-UPBEAT study on Friday as they will not be processed at the lab until the following Monday.

Samples that thaw to room temperature are no longer evaluable.

New kits received from the Biospecimen Lab will have the correct shipping service indicated.

Please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) if you have any questions.

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### Accruals as of January 19, 2022

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	50	75		
WF-1802	PCW	174	255		
WF-1806	M&M	69	300		
WF-1901	IMPACTS	34	456	0	40
WF-1804CD	AH-HA	276	600	17	40
WF-1805CD	HN STAR	32	350	66	140

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Winston Salem, NC 27157-0001

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