



STUDY MATTERS

December 23, 2021

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

Dear Membership, the Wake Forest NCORP Research Base decided it was time to “name” the Bi-Weekly email and make slight revisions to the content. Going forward we will be calling this communication “Study Matters” whereby we will be giving you announcements on study specific updates, new amendment activations, accrual tables and other time sensitive announcements. We plan to introduce a quarterly Newsletter in January of 2022 which will be called “Community Connection”. This communication will be a more in-depth publication and will focus on achievements of local NCORP sites and investigators, updates from our committees, recent publications as well as tips and tricks for our studies. As always, we would appreciate any feedback on these communications.

WF NCORP RB OFFICE CLOSURES:

Our office will be closed Friday, December 24 and Friday, December 31.

Happy Holidays!

NCI CIRB OPERATIONS OFFICE CLOSURES:



The NCI CIRB Operations Office will be closed Friday, December 24, 2021 for the Christmas Holiday. We will also be closed Friday, December 31, 2021 and Monday, January 3, 2022 for the New Year's Holiday.

If you need to reach the CIRB Operations Office, please do so before the holiday by sending an email, NCICIRBContact@emmes.com, or by calling us toll-free at 1-888-657-3711.

NCORP BIOSPECIMEN LAB UPDATE:

The lab has moved!

NEW SHIPPING ADDRESS

DOT Receiving Richard H. Dean Research Building
391 Technology Way
NCORP Biospecimen Lab: K. Kourman & M. Morris
Winston-Salem, NC 27101

**Please be sure samples arrive by Thursday, December 30 or wait to ship until
Monday, January 3.**

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

McKesson Holiday Hours:

Clinical Research Services

Closed December 24, 2021 & December 31, 2021

In observance of the Christmas holiday, McKesson's Clinical Research Services will be closed **Friday, December 24, 2021**. We will resume regular business hours on Monday, December 27, 2021.

Please take this information into consideration when placing your orders **prior to the Christmas holiday**.

- Only non-refrigerated product will be shipped on **Thursday, December 23**. Orders placed prior to 2 pm ET will be delivered on **Friday, December 24**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Wednesday, December 22** prior to 2 pm ET. Orders placed prior to 2 pm ET will be delivered on **Thursday, December 23**.

In observance of the New Year holiday, McKesson's Clinical Research Services will be closed **Friday, December 31, 2021**. We will resume regular business hours on Monday, January 3, 2022.

Our regular business hours are Monday through Friday, 9 am to 6 pm ET.

Please take this information into consideration when placing your orders **prior to the New Year holiday.**

- Only non-refrigerated product will be shipped on **Thursday, December 30**. Orders placed prior to 2 pm ET will be delivered on **Friday, December 31**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Wednesday, December 29** prior to 2 pm ET. Orders placed prior to 2 pm ET will be delivered on **Thursday, December 30**.

Due to the influx of shipments around the holidays, carrier delays may occur. Please plan your orders accordingly.

If you have questions regarding the shipment schedule, please contact our Clinical Research Services team at 800.693.4906, or via email at clinicalresearchservices@mckesson.com.

We appreciate the opportunity to assist you and your patients.

Kind regards,

Clinical Research Services team

NCORP Webinar Series Announcement

**Registration is Now Open:
[click on link below]**

<https://events.cancer.gov/hdrp/ncorpcdrwebinars/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.

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

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

Upcoming Site Calls

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

January 19th, 2022 at 3:00pm EST

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

Site Call has been moved from December 16, 2021 to January 20, 2022

at 11:30am EST

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

Site Call has been moved from January 11th, 2022 to February 23, 2022

at 2:30pm EST

If you would like to attend, but did not receive an invitation, please
email NCORP@wakehealth.edu

**Please email 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.**

Study Updates

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

The Higher Income White stratum only has 3 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.

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

NEW AMENDMENT ACTIVATION

WF-1805CD Amendment 4, PVD 10/04/2021, Release Date 12/20/2021

The WF NCORP Research Base study titled *Implementation and Effectiveness Trial of HN-STAR* has been amended. The amended protocol and related documents were released on Monday, December 20, 2021.

Changes with this amendment include:

- Expanding eligibility criteria to include participants who are ≤ 24 months post-completed treatment for HNC.
- Updating and clarifying survivor inclusion criteria to include patients treated for locoregionally recurrent disease.
- Updating and clarifying survivor exclusion criteria to include evidence of prior cancer (excluding non-melanoma skin cancer) within 3 years of the designated clinic visit. Please see protocol for specific changes.
- Allowing completion of the FACT-HN portion of the **Survivor Baseline Health Assessment** up to 48 hours following the designated clinic visit

- Adding language stating the CDST should be used to guide clinical discussion and select management plans
- Removing the **Designated Clinician Acceptability & Feasibility CDST** instrument
- Adding three questions at the beginning of the **List Symptoms DC** instrument to assess Designated Clinician use of the CDST in the HN-STAR intervention arm

Regulatory 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).
- Site Open to Enrollment (SOTE) letter from the WF NCORP RB will be provided to the site after all onboarding activities are completed.

Document Access:

- The protocol documents are now available on the [CTSU \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) website.
- A Help Guide, data collection trainings and an FAQ document are available on the [WAKENCORP \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) website.

Participation

If there are any questions about the activation or if your site is interested in participating in this study, please contact NCORP@wakehealth.edu Attn: WF-1805 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

In accordance with Amendment #4, the following documents were updated and are available on the WAKE NCORP website:

- **Study Checklists (Usual Care and HN-STAR Arms)**
 - **Data Collection Trainings (Usual Care and HN-STAR Arms)**
 - **HN-STAR Tool Designated Clinician Training**
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WF-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer

The lab at UAB will be closed for the Christmas and New Year's Holidays on Dec. 23rd - 24th (Thursday-Friday) and Dec. 30th - 31st (Thursday-Friday). Plan your shipments accordingly and hold samples in the refrigerator as needed.

WF-30917CD - TELEHEALTH - A Stepped-Care Telehealth Approach to Treat Distress in Cancer Survivors

REMINDER: Complete a tracking log entry for all attempted and completed contacts. This includes screening, baseline assessments, bi-weekly check-in calls, 7- and 13-week assessments and when returning participant phone calls.

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 if you have any questions.

Accruals as of December 22, 2021

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	49	75		
WF-1802	PCW	169	255		
WF-1806	M&M	67	300		
WF-1901	IMPACTS	33	456	0	40
WF-1804CD	AH-HA	247	600	17	40
WF-1805CD	HN STAR	25	350	40	140

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Our mailing address is:

Wake Forest NCORP Research Base
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Winston Salem, NC 27157-0001

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