



## STUDY MATTERS

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September 1, 2022

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

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**Register Now!**

**Wake Forest NCORP Research Base Annual Meeting**

**October 10 – 11, 2022 @ The Marriott Grand Dunes Resort & Spa, Myrtle Beach, SC**



Our keynote speaker this year will be Dr. Ray Osarogiagbon from the Baptist Memorial Health Care/Mid South Minority Underserved NCORP.

Please use the **Registration** link below to register for the upcoming 9th Annual Wake Forest NCORP Research Base Meeting, October 10 – 11, 2022 with the Northwest AHEC. You will be asked if you will attend In-Person or Virtual. The link below should take you to the facepage and a gray “Register” button. Once you click on this button, you will be asked to Sign In. If you do not have an account, you will need to create one at this time using the links on this page.

[www.nwahec.org/69183](http://www.nwahec.org/69183)

Please use the **Hotel Reservation** link below to make your hotel reservations for the Wake Forest Annual Meeting October 10 – 11, 2022 at the Marriott Grand Dunes, Myrtle Beach, SC. **A block of rooms are reserved at the special rate of \$149 until September 9, 2022.**

[Book your group rate for Wake Forest Baptist Medical Center 2022 \[marriott.com\]](#)

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**To Be Rescheduled: October 12, 2022 iDAPT Training**

Due to trainer conflicts, the iDAPT workshop that had previously been scheduled for October 12th immediately following the Wake Forest NCORP Research Base Annual Meeting will be rescheduled. We apologize for this inconvenience.

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### **Wake Forest NCORP RB Holiday Hours**

Our office will be closed on Monday, September 5, 2022 for the Labor Day holiday.

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### **NCI CIRB Operations Office Holiday Hours**

The NCI CIRB Operations Office will be closed Monday, September 5, 2022, 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 [NCICIRBContact@emmes.com](mailto:NCICIRBContact@emmes.com), or by calling us toll-free at 1-888-657-3711.

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## Clinical Research Services Closed September 5, 2022

In observance of Labor Day, McKesson's Clinical Research Services will be closed **Monday September 5, 2022**. We will resume regular business hours on Tuesday, September 6, 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 Labor Day**.

- Only non-refrigerated product will be shipped on **Friday, September 2**. Orders placed prior to 2 pm ET will be delivered on **Tuesday, September 6**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Thursday, September 1** prior to 2 pm ET.

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](mailto:clinicalresearchservices@mckesson.com).

We appreciate the opportunity to assist you and your patients.

Kind regards,

Clinical Research Services team



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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](#)**

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

Click the button below the meeting to add it to your Outlook Calendar

**\*\*Please note that your calendar may not update automatically if changes are made. 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.

**WF1901- IMPACTS- Internet-delivered Management of Pain Among Cancer Treatment Survivors**

September 14, 2022 at 2:30pm EDT. Please update your calendars. Our NCI Leadership, Dr. Wortz McCaskill-Stevens, will be present on this call to hear your feedback on challenges and successes on the IMPACTS study at your site thus far.

[Click to add this WF1901-IMPACTS meeting to your calendar](#)

**WF1804CD- AH-HA- Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors**

September 15, 2022 at 11:30am EDT. Please update your calendars.

[Click to add this WF1804CD-AH-HA meeting to your calendar](#)

**WF1802- PCW- Influence of Primary Treatment for Prostate Cancer on Work Experience**

September 20, 2022 at 1:30pm EDT. Please update your calendars.

[Click here to add this WF1802-PCW meeting to your calendar](#)

### **WF97415-UPBEAT - Understanding and Predicting Breast Cancer Events after Treatment**

Meeting has been changed to "Bi-Monthly". The next site call will be September 21, 2022 at 1:00pm EDT. Please update your calendars.

[Click to add this WF97415-UPBEAT meeting to your calendar](#)

### **WF1805CD-HN-STAR - Implementation and Effectiveness Trial of HN-STAR**

September 21, 2022 at 3:00pm EDT. Please update your calendars.

[Click to add this WF1805CD-HN-STAR meeting to your calendar](#)

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## **New Wake Forest NCORP Research Base Website**

**Please visit and register on our new Wake Forest NCORP Research Base website**

<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.

# Wake Forest NCORP Research Base

## Email Preferences

NCORP

Other

## Subscribe to General Email Updates

☒ General

### Studies

- ☒ WF01213-RELAX
- ☒ WF01414-NAVIGATOR
- ☒ WF10217-WAYS
- ☒ WF1801-RAMIPRIL
- ☒ WF1802-PCW
- ☒ WF1803CD-CAREGIVERS
- ☒ WF1804CD-AH-HA
- ☒ WF1805CD-HN-STAR
- ☒ WF1806-M&M
- ☒ WF1901-IMPACTS
- ☒ WF20817CD-OASIS
- ☒ WF30917CD-TELEHEALTH
- ☒ WF97115-ACUPUNCTURE
- ☒ WF97116-REMEMBER
- ☒ WF97415-UPBEAT
- ☒ WF98213-PREVENT

### Roles

- ☒ CCDR Lead
- ☒ Investigator
- ☒ NCORP Administrator
- ☒ CRA
- ☒ Data Management
- ☒ Regulatory
- ☒ Operations Manager
- ☒ Quality Control

## GCP certificate

Upload new certificate

No file chosen

Accepted file types: jpg, png, pdf, jpeg, Max. file size: 2 MB.

If you have any questions or need assistance with registration 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 to the NCORP Research Base Biospecimens lab (Studies WF-97415, WF-1801, and WF-1901). 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).

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## Study Updates

**[WF-1801 - Ramipril - A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma \(GBM\) Patients Receiving Brain Radiotherapy](#)**

### **LabCorp Billing Errors**

We are receiving monthly billing errors with the LabCorp lab orders. Please be very careful when picking your accounts when placing LabCorp orders. The WF-1801 account is only to be used for CMP's using your patient's PID. There are some sites who have incorrectly ordered tests using their patient's PHI for testing



that is not covered by WF-1801. Please relay this information to your colleagues who may be coordinating care for this study. Thank you.

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

**The Lower Income AA stratum only has 1 remaining slot 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. Try to approach individuals from the Lower income white strata that is slowly accruing. The higher income AA strata has **5** slots available. A reminder- the higher income white strata is already closed.

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

### **Data Entry Updates**

- When entering Demographic Data in OPEN Step 1 for Survivors please pay close attention to Initials, Date of Birth, and Zip Code. Survivor Participants will be using these data points to log into the HN-STAR tool website and these must match the data in OPEN in order for the login to succeed.
- Several Survivors have reported not receiving emails sent through REDCap using our [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) email address. Please check with participants to make sure they are receiving these emails for Pre-Visit SSA, Post-Visit, Quarterly, and 1-Year surveys. If not, please verify email addresses and contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) so we can troubleshoot and make other arrangements. We only receive "bounce" messages for incorrect email addresses.

- For the best user experience, survey links should be opened in Google Chrome, Safari, or Firefox on a computer or tablet. Surveys are not optimized for smartphones and may not work.

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

### **Spanish Consent Form Available**

#### **WF-1806 (M&M) Amendment 6, Protocol Version Date 06/24/2022, Release Date 08/03/2022**

The Spanish version of the consent form which aligns with protocol version 06/24/2022 was posted to CTSU on **8/30/2022**. Re-consent is not required for your Spanish speaking participants. Spanish versions of the protocol supporting documents are unchanged and remain in force until an amendment is necessary.

1. CARE Questionnaire\_v05.01.20\_Spanish
2. Demographic and Health Behaviors\_v05.01.20\_Spanish
3. Hand-Grip Physical Test\_v05.01.20\_Spanish
4. Life-Space Survey\_v05.01.20\_Spanish
5. Short Physical Performance Battery Protocol\_v05.01.20\_Spanish
6. NCI PRO-CTCAE Items\_v05.01.20\_Spanish
7. GP5\_v04.01.2021\_Spanish

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-97116 - REMEMBER - A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairments**

As we are updating our policies/procedures on CTSU study status, such as *close to enrollment*, *complete* and *FDAAA/IRB complete*, we want to clarify the status for WF-97116 the Remember study.

We recently stated that your sites could close this study with your local IRB and/or CIRB, as it was assigned the status of *complete* (*Note Special Broadcast dated 08/01/22 and Study Matters dated 08/04/22*). However, we ask that you do not submit a request for closure at this time, as the data is still being analyzed and audited during this *complete* status.

Going forward in our updated policies/procedures, we will not allow sites to close studies with their local IRB and/or CIRB until we have notified you that the study has been assigned the CTSU status of *FDAAA/IRB completed*.

**If you have already closed this at your site with your local IRB and/or CIRB prior to today, we ask that you send us an email to [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) with your approved IRB closure memo to let us know.**

We appreciate your cooperation and continued support to our studies!

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

Due to hardware issues there will be a delay in MRI image review report distribution. Please continue to submit MRI scans as usual. If there are any questions, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu). Attn: WF-97415.

## UPCOMING PRESENTATIONS

UPBEAT WF97415	Longitudinal assessment of racial differences in exercise capacity after breast cancer treatment: WF-97415	Reding, KW, O'Connell, NS, Szewczyk, W, Cl Nguyen, J, Ladd, A, Jordan, J, Lucas, A, Shep Ge, Y, Salloum, F, Kim, Y, Lesnefsky, E, Franc Melendez, G, Sutton, A, D'Agostino Jr, R, W Lesser, GJ, Hundley, WG
UPBEAT WF97415	Hypertension Severity Impacts Declines in Left Ventricular Ejection Fraction Among Women Receiving Adjuvant Chemotherapy for Breast Cancer (UPBEAT WF-97415)	Garg, R, O'Connell, N, Lesser, GJ, Jordan, JH Bottinor, W, Ladd, A, D'Agostino Jr., R, Hundley, WG, the UPBEAT Study Team

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## WF-98213 - PREVENT - Preventing Anthracycline Cardiovascular Toxicity with Statins

### RECENT PUBLICATION

Hundley WG, D'Agostino R, Crotts T, et al. Statins and left ventricular ejection fraction following doxorubicin treatment. NEJM Evidence. 2022:EVIDoa2200097.



ORIGINAL ARTICLE

# Statins and Left Ventricular Ejection Fraction Following Doxorubicin Treatment

W. Gregory Hundley, M.D.<sup>1</sup>, Ralph D'Agostino, Jr., Ph.D.<sup>2</sup>, Teresa Crotts, B.S.<sup>3</sup>, Karen Craver, M.T.<sup>4</sup>, Mary Helen Hackney, M.D.<sup>5</sup>, Jennifer H. Jordan, Ph.D.<sup>1,6</sup>, Bonnie Ky, M.D.<sup>7</sup>, Lynne I. Wagner, Ph.D.<sup>4</sup>, David M. Herrington, M.D., M.H.S.<sup>3</sup>, Joseph Yeboah, M.D.<sup>3</sup>, ...  
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NEJM Evid 2022; 1 (9)  
DOI: <https://doi.org/10.1056/EVIDoa2200097>  
[Issue](#)

[Article](#) [Figures/Media](#)

[23 References](#) [1 Citing Article](#)

## Abstract

### BACKGROUND

Statins taken for cardiovascular indications by patients with breast cancer and lymphoma during doxorubicin treatment may attenuate left ventricular ejection fraction (LVEF) decline, but the effect of statins on LVEF among patients with no cardiovascular indications is unknown.

ADVERTISEMENT

## UPCOMING PRESENTATION

PREVENT WF98213	Examining the association between socioeconomic factors and left ventricular ejection fraction declines in breast cancer and lymphoma survivors receiving doxorubicin: WF-98213	Sutton, AL, O'Connell, NS, Lucas3, AR, Franc Reding, KW, Kim, Y, Cheng, R, Sheppard, VB KE, Lesser, GJ, Hundley, WG
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Accruals as of August 31, 2022

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	57	75		
WF-1802	PCW	222	255		
WF-1806	M&M	98	300		
WF-1901	IMPACTS	59	456	0	40
WF-1804CD	AH-HA	475	600	24	40
WF-1805CD	HN STAR	98	350	73	140

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