



## STUDY MATTERS

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September 15, 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)

The group rate for **Hotel** reservations is no longer valid; however, rooms are still available- [https://www.marriott.com/en-us/hotels/myrgd-marriott-myrtle-beach-resort-and-spa-at-grande-dunes/overview/?scid=cd5470db-cd64-4033-afea-9c893567388c&gclid=Cj0KCQjwmouZBhDSARIsALYcourNBOS3YGxqXPowZyT8q89VvOAKRSaRb48ld6FYIfgwZl6ykcKPobkaAh-EEALw\\_wcB&gclidsrc=aw.ds](https://www.marriott.com/en-us/hotels/myrgd-marriott-myrtle-beach-resort-and-spa-at-grande-dunes/overview/?scid=cd5470db-cd64-4033-afea-9c893567388c&gclid=Cj0KCQjwmouZBhDSARIsALYcourNBOS3YGxqXPowZyT8q89VvOAKRSaRb48ld6FYIfgwZl6ykcKPobkaAh-EEALw_wcB&gclidsrc=aw.ds)

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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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## **2022 Landscape Assessment**

### **Data Requests**

Investigators who wish to use the data for scholarly products should first seek approval from affiliated Research Base and then submit a request to the Landscape Committee using the following

link: <https://redcap.wakehealth.edu/redcapccc/surveys/?s=P9FEAHJLFAWW44FW>

CCDR/Administrator leads at NCORP M/U and Community Sites will have access to affiliates/sub-affiliates dataset, if consent was provided. To request dataset or summary of results contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)

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## **OPEN CALL FOR COMMITTEE MEMBERS**

**The Wake Forest NCORP Research Base is soliciting applications for NCORP Community/ M/U Community Site representatives for the Cancer Control and Cancer Care Delivery Research (CCDR) Scientific Committees and the Health Equity Core Committee.**

Community site representation on all committees is being expanded. Responsibilities for members will include:

- Attend committee meetings (monthly for the scientific committees and quarterly for the Health Equity Core)

- Provide feedback about studies early and throughout the study lifecycle to improve feasibility and alignment of studies with community site priorities and provide feedback on implementation challenges
- Provide scientific/feasibility/equity review of new concepts/protocols
- Oversee active studies, including minority/underserved accrual progress
- Periodically review and make recommendations about committee priorities and activities
- Act as a liaison between NCORP community sites/investigators and the Wake Forest NCORP Research Base

We are looking for committee members who bring diversity with regards to their expertise, service within NCORP (PIs or scientific leaders, CRAs, research nursing, and Administrators), and background and populations engaged. Interested individuals should apply using the REDCap link below. The application will include a brief statement (5-10 sentences) on your prior involvement with the Wake Forest NCORP Research Base, experience with cancer control, cancer care delivery research, and/or health equity research, interest in committee service, and contributions to the diversity of the committee. You will also be asked to upload a CV or biosketch. The initial committee term will be 2 years. **The due date to apply is October 31, 2022.** Selection of committee members will take place in November and committees will begin meetings in January 2023.

Click here to

apply: <https://redcap.wakehealth.edu/redcapccc/surveys/?s=PYEDAF7EFY78J773>

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**For Funding Opportunities Announcements Relevant to  
NCORP CCCR, 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.

**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](#)

**WF1801-RAMIPRIL - A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy**

October 5, 2022 at 2:00pm EDT. Please update your calendars.

[Click to add this WF1801-RAMIPRIL meeting to your calendar](#)

**WF1806-M&M - Myopenia and Mechanisms of Chemotherapy  
Toxicity in Older Adults with Colorectal Cancer**

October 12, 2022 Site Call is **cancelled**. Join us for the WF NCORP Research Base Annual Meeting on October 10-11th.

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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 Higher 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 lower income AA strata and higher income white strata are 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 **8/3/2022**. 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-1901 - IMPACTS - Internet-delivered Management of Pain Among Cancer Treatment Survivors**

### **Recruitment Flyer with Opt-In Survey (version 07.29.22) Now Available**

#### **Aligned with IMPACTS (WF-1901) Amendment 5, PVD 02/28/2022, Release**

## Date March 22, 2022

Two versions of a new recruitment flyer were posted to the CTSU website on 9/7/2022. You now have the option to use a site specific QR Code which links to a participant **opt-in survey** in REDCap. When using the QR code, site coordinators will be alerted when a potential participant fills out the survey. Site specific QR codes and printed flyers will be supplied by the Wake Forest Research Base IMPACTS Study Team.

**Do you experience physical or emotional pain related to your cancer or cancer treatment?**

✓ Pain\* is one of the most common symptoms in cancer patients and one of the symptoms least likely to be adequately treated.  
\*Unpleasant sensory and emotional experience that may include either physical pain and/or non-painful discomfort such as aching, throbbing, numbness, tingling, burning, etc.



✓ **The IMPACTS Study; Internet-delivered Management of Pain Among Cancer Treatment Survivors**, is designed to help you manage your pain so you can enjoy your quality of life.

✓ Cancer patients 18 and older who experience pain from cancer or cancer treatment are invited to discuss possible participation in the IMPACTS study.

✓ Compensation for your time will be provided. In-person and remote visits are available!

**Based on your response below, you may be eligible to take part in the IMPACTS Study.**


1. In the past seven days, how would you rate your pain on average on a scale from 0 to 10 with 0 being No Pain and 10 being the Worst Imaginable Pain?

 ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10   
No Pain Worst Imaginable Pain

2. In the past 3 months, how often did you have pain:  
☐ Never ☐ Some Days ☐ Most Days ☐ Every Day

If you would like for someone to contact you to find out if you are eligible to participate, please print your contact information below and return form to the clinic staff.

Name: \_\_\_\_\_  
Phone: \_\_\_\_\_ Email: \_\_\_\_\_



Version 07/25/2022 WF-1301

## Do you experience physical or emotional pain related to your cancer or cancer treatment?

- ✓ Pain\* is one of the most common symptoms in cancer patients and one of the symptoms least likely to be adequately treated.

\*Unpleasant sensory and emotional experience that may include either physical pain and/or non-painful discomfort such as aching, throbbing, numbness, tingling, burning, etc.

- ✓ The IMPACTS Study - *Internet-delivered Management of Pain Among Cancer Treatment Survivors*, is designed to help you manage your pain so you can enjoy your quality of life.

- ✓ Cancer patients 18 or older who experience pain from cancer or cancer treatment are invited to discuss possible participation in the IMPACTS study.

- ✓ Compensation for your time will be provided. In-person and remote visits are available!

**Based on your response below, you may be eligible to take part in the IMPACTS Study.**

Scan QR code with your phone's camera to access a short survey.	Insert Site Specific QR Code here
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Version 07/29/2022

WF-1901

Additional instructions may be found in the **2022.09.07 - WF-1901 Site Recruitment Material Guide**, posted on the Wake Forest NCORP Research Base website IMPACTS Study Page on 9/7/2022; <https://wakencorp.phs.wakehealth.edu/>.

### **Resource for Usual Care Arm – Thank you note (version 07.29.22) Now Available**

A “Thank you” note with instructions for accessing painTRAINER® has been approved by the CIRB and posted to CTSU on 9/7/2022. This should only be given to patients on the enhanced usual care arm who have **completed the study** and are interested in trying the internet program on their own.



Thank you for being a part of the **IMPACTS** study. Since you have completed all of the requirements on the usual care arm of our study, we would like to invite you to try the **painTRAINER**® tool on your own. Instructions are included below.

1. **painTRAINER® Start Up:** You can use **painTRAINER**® on a smartphone, tablet computer, or personal computer. Supported web browsers include **Chrome** for Windows, Mac or Android phone/tablet. **Edge** for Windows or Mac. **Safari** for Mac.
2. Open your web browser and use it to go to the [mypaintrainer.org](http://mypaintrainer.org) website.
3. Once you are on the [mypaintrainer.org](http://mypaintrainer.org) website, you will see the screen shown below. Now you need to register to use the program. Start by selecting **REGISTER** in the upper right corner of your screen.



4. After you select **REGISTER**, you will see the screen shown below. Click in the white **Study Code** box to see a list of studies and select **I'm not in a study**. Create your own username, add your personal email and create a password using the guidelines listed. Click the box to accept the Terms of Use and click **REGISTER**.

5. Complete the registration information and follow the on screen prompts to start using **painTRAINER**® at your own pace. We hope you will benefit from some of the tools that are taught by this program.

Version 07/29/2022

WF-1901

If there are any questions regarding the materials listed above, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-1901.

## **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!

## **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, Cheng, RK, Nguyen, J, Ladd, A, Jordan, J, Lucas, A, Shepherd, V, Ge, Y, Salloum, F, Kim, Y, Lesnefsky, E, Franco, RL, Melendez, G, Sutton, A, D'Agostino Jr, R, Weaver, KE, Lesser, GJ, Hundley, WG	American Heart Association	Poster Session for in-person presentation	November 5–7 2022	Chicago, IL
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, Sutton, A, Bottinor, W, Ladd, A, D'Agostino Jr., R, Hundley, WG, the UPBEAT Study Team	American Heart Association	Poster Session for in-person presentation	November 5–7 2022	Chicago, IL

## **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>, ...

[Show More](#) 

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.

 Tweet

Published August 18, 2022  
NEJM Evid 2022; 1 (9)  
DOI: <https://doi.org/10.1056/EVIDoa2200097>

[Issue](#) >

ADVERTISEMENT

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, Franco, RL, Reding, KW, Kim, Y, Cheng, R, Sheppard, VB, Weaver, KE, Lesser, GJ, Hundley, WG	American Heart Association	Moderated Digital Poster Session for in-person presentation	November 5–7 2022	Chicago, IL
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Accruals as of September 14, 2022

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	57	75		
WF-1802	PCW	227	255		
WF-1806	M&M	100	300		
WF-1901	IMPACTS	60	456	0	40
WF-1804CD	AH-HA	488	600	24	40
WF-1805CD	HN STAR	101	350	73	140

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