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STUDY MATTERS

August 4, 2022

Wake NCORP Website: <https://wakencorp.phs.wakehealth.edu/wakehealth.us19.list-manage.com>

Save the Date: WF 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 may create one at this time using the links on this page.

www.nwahec.org/69183 [wakehealth.us19.list-manage.com]

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 \[marriott.com\]](http://marriott.com)

[\[wakehealth.us19.list-manage.com\]](mailto:wakehealth.us19.list-manage.com)

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.

REDCap Maintenance and Upgrade **Saturday, August 6th**

To our REDCap userbase,

This is a notification regarding planned maintenance for the REDCap system on:

Saturday, August 6th

REDCap will be Offline between 8:00AM - 12:00PM, Saturday August 6th.

This will be a standard system upgrade, bringing our current REDCap version up to 12.4.x. This is being done across the Enterprise (Atrium Health and Wake Forest Baptist Health) in order to streamline the user experience for all of our REDCap users.

As with any upgrade, we want to include our standard reminder of a few key points which you should be aware of during this process:

- 1) **Data and projects will not be able to continue to be collected or accessed until REDCap is brought back online.**
- 2) **Any automated events in REDCap will be temporarily disrupted.** This includes surveys functions, ASIs, API calls, Alerts/Notifications, Twilio triggers, Messenger notifications, and system notifications. Once REDCap is brought back Online it will be recommended to all users who use these functions in their projects, to review them and retrigger them if necessary.
- 3) In the very unlikely event that a system restore is required for our server, data will be reverted to the previous day's system backup. Users should simply take note that all data captured through the end of day (5 PM) the day before will be preserved, but any data collected thereafter would not be restored.

Please plan any REDCap work that you may have on this day (and weekend) accordingly, as well as communicate this message to any appropriate members of your team. Stay tuned for further announcements regarding new features once the upgrade/maintenance is completed.

As always, if you have any questions or concerns, please contact I'sis Perry, Kisuar Sultana, or I directly.

Cheers,

Kyle Raub, MA

Enterprise REDCap Manager

Research Administration

Atrium Health & Wake Forest School of Medicine

WF NCORP RB Quarterly Calls

In case you missed the June 15th quarterly call, the recording has been added to the Wake NCORP website.

Use this link to access the recording: <https://vimeo.com/721099276>
[\[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com)

Our next quarterly call is scheduled for August 31st at 3pm EDT.

[Click to add the WF NCORP RB Quarterly Call to your calendar](https://wakehealth.us19.list-manage.com)
[\[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com)

Please note that your calendar may not update automatically if changes are made. Please check these emails and our website for meeting updates.

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

<https://healthcaredelivery.cancer.gov/funding/opportunities.html>
[\[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com)

Upcoming Site Calls

If you would like to attend one of these calls, but did not receive an invitation, please email 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 \[wakehealth.us19.list-manage.com\]](http://wakehealth.us19.list-manage.com). Click the call in the "Upcoming Events" section on the Home page or through the Calendar.

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

August 10, 2022 at 2:30pm EDT

[Click to add this WF1806-M&M meeting to your calendar \[wakehealth.us19.list-manage.com\]](http://wakehealth.us19.list-manage.com)

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

September 14, 2022 at 2:30pm EDT. Please update your calendars.

[Click to add this WF1901-IMPACTS meeting to your calendar \[wakehealth.us19.list-manage.com\]](http://wakehealth.us19.list-manage.com)

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 \[wakehealth.us19.list-manage.com\]](http://wakehealth.us19.list-manage.com)

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 \[wakehealth.us19.list-manage.com\]](#)

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/> [\[wakehealth.us19.list-manage.com\]](#)

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

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Subscribe to General Email Updates

General

Studies

- WF01213-RELAX
- WF01414-NAVIGATOR
- WF10217-WAYS
- WF1801-RAMIPRIL
- WF1802-PCV
- WF1803CD-CAREGIVERS
- WF1804CD-AH-HA
- WF1805CD-HN-STAR
- WF1806-M&M
- WF1901-IMPACT5
- WF20817CD-OASIS
- WF30917CD-TELEHEALTH
- WF97115-ACUPUNCTURE
- WF97116-REMEMBER
- WF97415-UPBEAT
- WF98213-PREVENT

Roles

- OCCR 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

Please email 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).

Study Updates

[WF-1806 - M&M- Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer](#)

NEW AMENDMENT ACTIVATION

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

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 Wednesday, August 3, 2022.

Changes with this amendment include:

- Updated inclusion criteria to allow enrollment through the first month of chemotherapy.
- Updated inclusion and exclusion criteria to decrease allowable time since previous chemotherapy treatment from ≥ 12 months to ≥ 3 months (12 weeks).

WF-1806 Document Access:

- The protocol documents are available on the [CTSU \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) website.
- The Helpful Guidelines, FAQs, and Training Attestation documents are available on the [Wake NCORP \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) website.

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; 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; Attn: WF-1806.

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.

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

The Lower Income AA 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. 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.

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

- 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 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 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.

CONGRATULATIONS!! We are pleased to announce the travel awards to

the top two accruing sites between January 19 and July 31, 2022-

Medical University of South Carolina (MUSC) - 12 new patients

Spartanburg Medical Center (UPSTATE) - 10 new patients

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. Thank you for all your hard work in accruing patients to HN-STAR. Your efforts are greatly appreciated!

WF-97115 - ACUPUNCTURE - A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer

****Study Complete** Effective July 29, 2022**

We appreciate all sites who participated in this study. The study has now completed follow-up and data analysis is being reviewed. As soon as the primary manuscript has been published we will inform you and create a brief synopsis in layman's terms based on the published results that you may share with your patients that participated, if you desire. What's Next?

1. The "complete" status means the protocol has been closed to accrual, all participants have completed therapy, and the study has met its primary objectives.
2. Proceed with closing the study at your site.
3. Hold on to all study documents for 5 years from the date above.

If you have any questions, email NCORP@wakehealth.edu

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

****Study Complete** Effective July 29, 2022**

We appreciate all sites who participated in this study. The study has now completed follow-up and data analysis is being reviewed. As soon as the primary manuscript has been published we will inform you and create a brief synopsis in layman's terms based on the published results that you may share with your patients that participated, if you desire. What's Next?

1. The "complete" status means the protocol has been closed to accrual, all participants have completed therapy, and the study has met its primary objectives.
2. Proceed with closing the study at your site.
3. Hold on to all study documents for 5 years from the date above.

If you have any questions, email NCORP@wakehealth.edu

**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. Attn: WF-97415.

Accruals as of August 3, 2022

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	57	75		
WF-1802	PCW	220	255		
WF-1806	M&M	92	300		
WF-1901	IMPACTS	53	456	0	40
WF-1804CD	AH-HA	446	600	24	40
WF-1805CD	HN STAR	89	350	69	140

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Our mailing address is:

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

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