

Wake Forest NCORP Research Base
Bi-Weekly Broadcast
September 25, 2020
WAKE NCORP Website link <https://wakencorp.phs.wakehealth.edu/>



ANNOUNCEMENTS

The Wake Forest NCORP Research Base 7th Annual Meeting for 2020 will be virtual.

Please register online at www.nwahec.org/64134

The meeting will be held Thursday, October 29 and Friday, October 30 for 2 half days beginning at noon. CME and CNE will be offered. Log in links to the meeting will be sent out 2 weeks before the meeting date. You must log into the meeting each day individually in order to receive the credits. The Northwest Area Health Education Center (AHEC) will be providing the IT support and continuing education credits for this meeting. They will monitor those that log into the meeting and record when participants log out of the meeting.

You may also find the registration link on our WAKENCORP webpage

STUDY UPDATES:

NEW AMENDMENT RELEASE - WF 1901 – IMPACTS - *Internet-delivered Management of Pain Among Cancer Treatment Survivors* Amendment 2 , Protocol Version Date 08/01/2020 has been activated.

- The protocol and related documents were released on 09/22/2020.
- Updates Include:
 - Participants randomized to the painTRAINER® arm will have the option to add their cell phone number directly into painTRAINER®. This will allow for SMS messaging of reminders to complete their 8 sessions.
 - We are requesting that sites report unexpected grade 3, 4 or 5 adverse events that are felt to be possibly, probably or definitely related to the specific use of the painTRAINER® intervention, if the event occurs after the informed consent is signed through the T2 time point (Intervention use period).
- Document Access:
 - The protocol documents are available on the CTSU website.
 - The *Helpful Guide, Neurocognitive Test Booklets (Limited to trained personnel only), painTRAINER® and Neurocognitive Training resources* are available on the WakeNCORP website.



- Note: Helpful guide has been updated to version 9/22/20 with revised path to painTRAINER® training on page 3 and additional painTRAINER® troubleshooting for malware on page 20.
- Sites interested in participating should contact NCORP@wakehealth.edu; Attn: WF-1901 and request a start-up packet. Please note that the Per Patient Reimbursement for this study will come directly from Wake NCORP, therefore subawards must be in place before your site can become activated. Please refer to your study start-up packet details to begin this process now, if you are interested in participating in this new study.
- Regulatory requirements to activate this study can be found in the protocol on the [CTSU](#) website.
- If there are any questions regarding the WF-1901 activation or site registration procedures, please contact NCORP@wakehealth.edu; Attn: WF-1901

WF 1805CD – HN Star – Implementation of and Effectiveness Trial of HN Star

- The Wake Forest NCORP Research Base's new CCDR study was activated on August 10, 2020. The recording of the August informational webinar is posted to the [WAKENCORP](#) website. If you would like a copy of the webinar slides or are interested in participating in this study, **please contact NCORP@wakehealth.edu.**
- An amendment is in progress with an anticipated activation date in October.

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

- Amendment 3 has been activated, and all revised documents have been posted to CTSU.
- The study has been amended to include:
 - Waiver of documentation of written consent
 - Study visit conducted via videoconference
- Updated site eligibility by removing list of participating sites from the cover page.
- Spanish documents (surveys and recruitment materials) were posted to CTSU 08/21/2020. The protocol version date is 06/05/2020.

Please contact Eleanor Davidson at ecdavids@wakehealth.edu if your site is interested in participating in this study. **NOTE:** *this is a site specific protocol which requires pre-approval to participate.*

WF-1806 M&M Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer (M&M) Amendment 3, Protocol Version Date 05/01/2020

- The amended protocol and related *English* documents were released on Thursday, August 20th.
- The associated translated Spanish documents for the same version are now posted to the CTSU website (Post date: 09/16/2020)
- The protocol documents are available on the [CTSU](#) website at this time.
- The *Helpful Guidelines, FAQs, and Training Attestation* documents are still available on the [WAKENCORP](#) website.

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

WF 97116 REMEMBER – A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairment

- **WE NEED YOUR HELP!** We are closing in on our target accrual for the REMEMBER study. Currently we have accrued 257 patients and our target is 276! We would like to encourage you to focus on minority accruals as we would like to increase our percentage for this study. This is NOT a restriction, just a reminder and update for this study.
- **Patient Status Forms** – Please remember to fill out a Patient Status form once your patient has completed the study intervention and follow-up. You should also fill out a Patient Status form whenever your patient stops taking the study medication for any reason or withdraws from the study.

General WF NCORP RB Biospecimen Lab Management:

Shipping Address Change

The address for samples to be shipped for DNA isolation on the two studies listed below has changed. ***Please request new pre-paid shipping labels by sending your Site's contact name and address to NCORP@wakehealth.edu.*** If you have a sample to send before you receive your replacement labels, you may still use your current labels as we will be monitoring the other address for packages.

- WF-97116 Remember
- WF-1801 Ramipril

The new address is: WF NCORP Biospecimen Lab
Wake Forest Biotech Place
575 Patterson Avenue, Suite 240-250
Winston-Salem, NC 27101
Phone: (336) 716-2581

NOTE: Missed samples can be collected at any future clinical or study visit as it reflects a germline process that will not be affected by treatments.

- Please request your lab kits before you run completely out of kits. This will ensure that there will be no delay in getting samples shipped to the Biospecimen Laboratory.
- Please check and record your stored Biospecimen kit expiration dates.
- Please do not ship samples on Thursday or Friday so that samples will not arrive on the weekend.

General Data Management – How do I find my REDCap data queries?

For studies using REDCap data entry (WF-20817CD OASIS, WF-97415 UPBEAT, WF-1801 RAMIPRIL, WF-1802 PCW, WF-1804CD AH-HA, WF-1805CD HN-STAR, WF-1806 M&M and WF-1901 IMPACTS) please click the “Resolve Issues” link on the left side menu to check for any open data queries.

Please email NCORP@wakehealth.edu with any questions you may have regarding the Bi-Weekly information.

Accruals as of September 24, 2020

Open Studies	Name	Enrolled	Target
WF 97115	Acupuncture	216	240
WF 97116	Remember	257	276
WF 97415	Upbeat	261	1000
WF 10217	Ways	207	220
WF 30917CD	Telehealth	41	90
WF 1801	Ramipril	33	75
WF 1802	PCW	83	220
WF 1804CD	AH-HA	0	624
WF 1805CD	HN-STAR	0	350
WF 1806	M&M	24	300
WF-1901	IMPACTS	0	456