

**Wake Forest NCORP Research Base
Bi-Weekly Broadcast
September 11, 2020**
WAKE NCORP Website link <https://wakencorp.phs.wakehealth.edu/>



ANNOUNCEMENTS

The Wake Forest NCORP RB 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 in order to receive 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 STUDY ACTIVATION - WF 1901 – IMPACTS - *Internet-delivered Management of Pain Among Cancer Treatment Survivors* Amendment 1 , Protocol Version Date 06/01/2020 has been activated.

- The protocol and related documents were released on 09/01/2020.
- Document Access:
 - The protocol documents are available on the CTSU website.
 - The *Helpful Guide* and *Training resources* are available on the WAKENCORP website.
- **Please note: Due to technical difficulties, the painTRAINER™ training video is not yet available. WF NCORP will send a separate announcement once this is available.**
- 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.**
- An amendment is in progress with an anticipated activation date of late September.

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 08/21/20. 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 05/01/20, Release Date 08/20/20

- The amended protocol and related documents were released on Thursday, August 20th. This study has been amended to allow patients who cannot read but can comprehend English or Spanish to be eligible. There has also been the addition of an Off Study timepoint to mark the end of follow-up and allow for documentation of patients who withdraw consent.
- 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 quits taking the study medication for any reason or withdraws from the study.

General WF NCORP RB Biospecimen Lab Management:

NEW – Samples for DNA Isolation – 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 10, 2020

Open Studies	Name	Enrolled	Target
WF 97115	Acupuncture	214	240
WF 97116	Remember	257	276
WF 97415	Upbeat	258	1000
WF 10217	Ways	207	220
WF 30917CD	Telehealth	41	90
WF 1801	Ramipril	33	75
WF 1802	PCW	81	220
WF 1804CD	AH-HA	0	624
WF 1805CD	HN-STAR	0	350
WF 1806	M&M	22	300
WF-1901	IMPACTS	0	456