

Wake Forest NCORP Research Base
Bi-Weekly Broadcast
October 7, 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:

WF 10217 WAYS Work Ability in Young Adult Survivors (WAYS)

- We would like to thank all sites who have participated in this study and for those who continue to screen and recruit for the remaining minority slots that we have available. We wanted to let you know that we will be closing this study to enrollment as of December 4, 2020 unless we meet the enrollment goal before this deadline. We still have several slots open so we encourage you to continue to recruit.

FUTURE NEW AMENDMENT - WF 97415 – UPBEAT – Understanding and Predicting Breast Cancer Events after Treatment – Amendment 4, PVD 08/31/2020, FUTURE Release Date 10/12/2020

- The amendment protocol and related documents will be released on Monday, October 12. Changes with this amendment include:
 - Added echocardiogram (ECHO) as an option for patients who are unable to have an MRI performed due to medical reasons.
 - Allowing women with hormone receptor positive breast cancer who receive estrogen antagonist aromatase inhibitors with or without additional chemotherapy to be eligible for this trial if they meet all other eligibility and ineligibility criteria.
 - Changed the **Chemotherapy Group** to the **Cancer Treatment Group** throughout the protocol and on case report forms (CRFs) to provide clarity.
- If there are any questions regarding WF-97415, please contact NCORP@wakehealth.edu. Attn: WF-97415

WF 1901 – IMPACTS - *Internet-delivered Management of Pain Among Cancer Treatment Survivors* Amendment 2 , Protocol Version Date 08/01/2020 was activated on Sept. 22, 2020.

- 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 9/30/20 with slight change to DNA specimen shipping instructions.*
- **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**.
- Amendment 2 has been approved and updated study materials have been posted to CTSU.

WF 1804CD AH-HA – *Assessing Effectiveness and Implementation of an EHR 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:
 - A 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

- **Reminder: Do not enter Leucovorin Calcium on the Treatment Summaries; See FAQ #5 on the WAKENCORP website for this study.**
- The protocol documents are available on the [CTSU](#) website.
- 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.

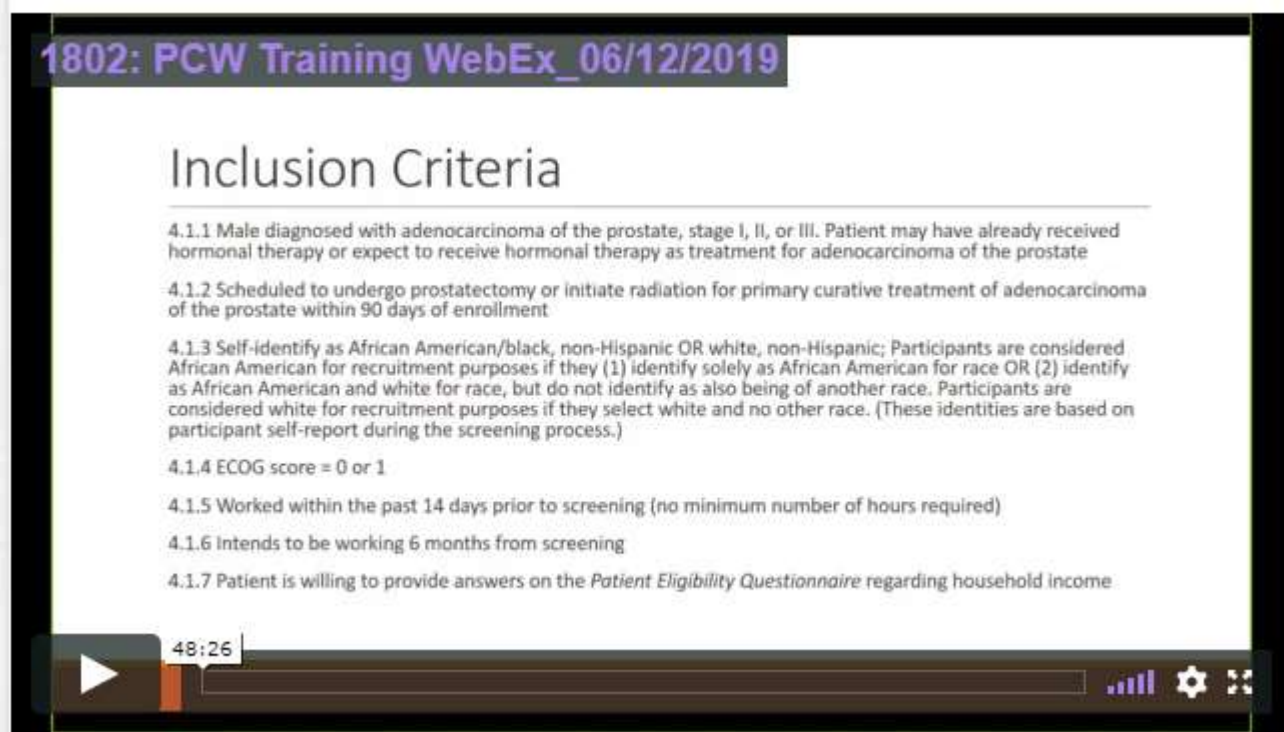
WF 97116 REMEMBER – A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairment

- **WE NEED YOUR HELP!** We are closing in on our target accrual for the REMEMBER study. Currently we have accrued 260 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.

WF 1802 – PCW (Prostate) – Influence of Primary Treatment for Prostate Cancer on Work Experience RE-CERTIFICATION FOR INTERVIEWERS

– If your site’s certified interviewer for this study has not conducted an interview within the last year of your site being activated, they will have to Re-certify before performing another interview. See section 5.4.1.2 within the PCW protocol “Interviewers will be required to

- *repeat a certification process, if their site does not enroll a patient in a year.”*
 - To Re-certify, a site interviewer needs to do is go to the WAKENCORP website, click on the Dashboard button, then click on videos. Scroll down to the video entitled “1802: PCW Training WebEx_06/12/2019.
 - Once you view this video, please print out, sign and date a new attestation form also found on the WAKENCORP website under the PCW tab.



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 October 6, 2020

Open Studies	Name	Enrolled	Target
WF 97115	Acupuncture	218	240
WF 97116	Remember	260	276
WF 97415	Upbeat	264	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	2	624
WF 1805CD	HN-STAR	0	350
WF 1806	M&M	25	300
WF-1901	IMPACTS	0	456