

Wake Forest NCORP Research Base
Bi-Weekly Broadcast
August 21, 2020
WAKE NCORP Website link <https://wakencorp.phs.wakehealth.edu/>



ANNOUNCEMENTS

The Wake Forest NCORP RB ANNUAL MEETING FOR 2020 will be Virtual

Thursday, October 29 and Friday, October 30 for 2 half days. CME and CNE will be offered. Details and registration for the meeting to follow.

NEW

We are considering a new study of a brief yoga intervention implemented perioperatively among women undergoing surgery for suspected gynecologic malignancies. The yoga intervention is delivered remotely through video conferencing and would not require a yoga instructor onsite (the study team would facilitate use of a tablet computer for one intervention session). We would like feedback on your perception of “fit” because the study would be implemented in the inpatient setting, which is different from our generally outpatient studies. We would appreciate your time if you would click on the REDCap survey link below and give us your feedback.

<https://redcap.wakehealth.edu/redcapccc/surveys/?s=4M9PYNHYDJ>

Upcoming Holiday (Sept 7th) Hours

Wake Forest NCORP Research Base Office Hours – Our offices will be **closed Monday, September 7, 2020** and will resume regular business hours on Tuesday, September 8, 2020.

The Wake Forest NCORP Research Base Biospecimen Lab will be **closed Monday, September 7, 2020** and will resume regular business hours on Tuesday, September 8, 2020.

McKESSON

Clinical Research Services Closed September 7, 2020

In observance of Labor Day, McKesson’s Clinical Research Services will McKesson will be closed **Monday, September 7, 2020**. They will resume regular business hours on Tuesday, September 8, 2020.

Their regular business hours are Monday through Friday, 9 am to 6 pm ET.

Please take this information into consideration when placing your orders **prior to Labor Day.**

- Only non-refrigerated product will be shipped on **Friday, September 4.** Orders placed prior to 2 pm ET will be delivered on **Tuesday, September 8.**
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Thursday, September 3** prior to 2 pm ET.

Due to the influx of shipments around the holidays, carrier delays may occur. Please plan your orders accordingly.

If you have questions regarding the shipment schedule, please contact our Clinical Research Services team at 800.693.4906, or via email at clinicalresearchservices@mckesson.com.

NEW AMENDMENT

- **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 will be 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 will be available on the [CTSU](#) website on 08/20/20.
 - 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.

STUDY UPDATES:

- **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 February 2020 informational webinar is posted to the Wake Forest NCORP website and a subsequent webinar recording from this month is forthcoming. If you would like a copy of the August webinar slides or are interested in participating in this study, **please contact Eleanor Davidson (ecdavids@wakehealth.edu)**.
 - An amendment is in progress with an anticipated activation date of 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 (this is a **site specific protocol** which requires pre-approval to participate)

COMING SOON - WF 1901 – IMPACTS - *Internet-delivered Management of Pain Among Cancer Treatment Survivors*

- The Wake Forest NCORP Research Base is proud to announce a new study ***WF-1901 Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)*** that is on track to be activated this September. An **introductory webinar was held on July 24th**. The recorded WebEx will be available on the WAKE NCORP website along with a current version of the protocol which is not yet activated. Please email NCORP@wakehealth.edu if you are interested in receiving a start-up packet upon activation of this study.



- The primary objective of this study is to determine whether painTRAINER[®], an internet –based pain coping program, plus enhanced usual care compared to enhanced usual care alone, yields significant improvements in primary outcomes of pain severity (as measured by the *Brief Pain Inventory (BPI)*) and pain interference (also measured by the *BPI*). Assessments occur at baseline to the post-intervention time point (week 10) for cancer survivors with persistent pain. To achieve secondary objectives of the study, additional assessments will occur at 22 and 34 weeks to further assess the efficacy of painTRAINER[®] and to determine whether painTRAINER[®], compared to enhanced usual care alone, yields significant improvements in secondary outcomes of opioid/analgesic medication use, health-related quality of life (HRQoL), and pain management self-efficacy among cancer survivors with persistent pain. A total of 456 participants will be enrolled (228 per arm) and randomized into the painTRAINER[®] arm (plus enhanced usual care) or Enhanced Usual Care alone.
- **Follow-up from introductory webinar:** PAs and NPs will be allowed to enroll patients to the WF-1901 IMPACTS study; they must be registered as NPIVRs in RCR.
- **A Training Webinar will be held on Monday, August 24 from 4-5PM.** An invite will be send out shortly to everyone.

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

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 and WF-1806 – M&M) 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 August 20, 2020

Open Studies	Name	Enrolled	Target
WF 97115	Acupuncture	213	240
WF 97116	Remember	255	276
WF 97415	Upbeat	256	1000
WF 10217	Ways	207	220
WF 30917CD	Telehealth	40	90
WF 1801	Ramipril	33	75
WF 1802	PCW	79	220
WF 1804CD	AH-HA	0	624
WF 1806	M&M	21	300