Wake Forest NCORP Research Base
Bi-Weekly Broadcast
August 6, 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 – 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 treatment.

STUDY UPDATES:

OPENING SOON- WF 1805CD – HN Star – *Implementation of and Effectiveness Trial of HN Star*

- The Wake Forest NCORP Research Base's new CCDR study (WF-1805CD: Implementation and Effectiveness Trial of HN-STAR) is activating August 10th, 2020. We would like to share some information about this study, including updates about an amendment we expect to be approved in September, and invite you to a **webinar with the study team on August 10th (3-4pm ET).** Please contact Eleanor Davidson (ecdavids@wakehealth.edu) if you have not received a webinar invitation from NCORP.

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 of 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.

NEW AMENDMENT ACTIVATIONS:

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

- Amendment 2, Protocol Version Date 05/08/20, will be released and **activated on 08/11/2020**.
- The study has been amended to include:
  - The 3-month and 6-month questionnaires were updated to account for the COVID-19 impact.

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

- Amendment 3 will be activated **soon**, hopefully within the next week or two. Look for a Special Broadcast Announcement in the future.
- The study has been amended to include:
  - Waiver of documentation of written consent
  - Will allow study visit to be conducted via videoconference
  - Updated site eligibility by removing list of participating sites from the cover page
- This is a **site specific protocol** which requires pre-approval to participate. **Please contact Eleanor Davidson at ecdavids@wakehealth.edu** if you would like to know if your site would qualify in order to participate.

WF 97415 – UPBEAT – *Understanding and Predicting Breast Cancer Events after Treatment*

- Please collect data when it is possible to do so without violating your institution's COVID-19 policies or otherwise endangering the patient's health status.

- Data Forms that can be completed remotely or through chart review include:
  - CRF03 – Chemotherapy Treatment Form
  - CRF04 – Radiation Oncology Intake Form
  - CRF05 – Radiation Treatment Summary Form
  - CRF06 – Medical Chart Review (chemo group only)
  - CRF07a – CV Medication Review
  - CRF07b – Other Medications Form
  - CRF08 – KCCQ-12
  - CRF16, 17, 18, 19 – Self Administered Questionnaires
  - CRF20, 21, 22, 23 – Neurocognitive Tests – COWA only

CPET Procedures

Given the uncertainty of airborne transmission of COVID-19 during heavy exercise, we have recently had questions specifically about the CPET exams required for selected patients enrolled on the WF 97415 UPBEAT trial. These concerns pertain to the potential risks to both study participants, and, importantly, staff performing the procedure in the setting of the current COVID 19 viral pandemic. We would like to provide the following guidance regarding this issue:

1) In keeping with NCI guidelines regarding study related deviations due to the COVID 19 crisis, these CPET exams may be deferred if sites are unable or unwilling to perform these research studies during the pandemic. Further guidance on whether these CPET studies should be "made up" in the future will be provided at such time as the pandemic is no longer disrupting patient/participant/study site activities.
2) Sites may, however, perform these studies per the trial schedule if study participants and staff feel comfortable and their local clinical and research guidelines allow such studies to be performed without limitations.

For all patients and participants, the remainder of study activities should continue as close to the study-specified time points as possible. All COVID 19 related deviations should be logged per NCI, institutional and WF NCORP RB guidelines previously issued."

Please contact NCORP@wakehealth.edu if you have questions.

WF 30917CD – TELEHEALTH - *A Stepped-Care Telehealth Approach to Treat Distress in Rural Cancer Survivors* Amendment 5 Upcoming Changes include:

- Amend the eligibility criteria to allow enrollment of patients who do not live in rural zip codes
- Per NCI, limit the states that can enroll participants to those who currently have therapists: California, Georgia, Illinois, Kansas, Minnesota, Missouri, Michigan, New Mexico, North Carolina, North Dakota, South Carolina, Tennessee, Virginia and Wisconsin
- Streamline the consenting process

We are grateful for the feedback from multiple sites that has contributed to this amendment that will streamline the recruitment process and open it up to more cancer survivors. We expect that these changes will ease the burden of recruitment and identification of participants. The next Site Call will be delayed until closer to the release of this amendment. We predict that Amendment 5 will be activated in 8 – 10 weeks. If you have any questions, feedback, or concerns, please email NCORP@wakehealth.edu.

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

EFFECTIVE IMMEDIATELY: The MD Anderson lab is open to receive saliva samples on Tuesday, Wednesday, Thursday and Friday. During the day, the working schedule is reduced due to COVID-19 precautions. Since the working schedule is reduced, it is more critical to do the following two steps when shipping saliva samples:

1) Select the delivery method that will ensure that the samples arrive to MD Anderson **before 10:30 AM the next day.**
2) Email Dr. Pelying Yang (pyang@mdanderson.org) and Jibin Ding (jding@mdanderson.org) on the day that you ship samples, including the shipment **Tracking Number**, so that they are aware and can coordinate receiving the samples from our shipment receiving dock on the next day.

These are the same steps that MD Anderson Lab had you do before and thank you for doing them. But, due to the reduced working schedule at the MD Anderson Lab, if these two steps are not completed, it becomes highly likely the samples will not be processed in time so it is more critical now to do these two steps.

General WF NCORP RB Biospecimen Lab Management:

- 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 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 July 31, 2020

Open Studies	Name	Enrolled	Target
WF 97115	Acupuncture	213	240
WF 97116	Remember	254	276
WF 97415	Upbeat	252	1000
WF 10217	Ways	206	220
WF 30917CD	Telehealth	40	90
WF 1801	Ramipril	32	75
WF 1802	PCW	78	220
WF 1804CD	AH-HA	0	624
WF 1806	M&M	20	300