

Wake Forest NCORP Research Base
Bi-Weekly Broadcast
October 22, 2020

WAKE NCORP Website link <https://wakencorp.phs.wakehealth.edu/>



ANNOUNCEMENTS

7th Annual Wake Forest NCORP Research Base

October 29 – 30, 2020

Presented via Livestream Webinar with
Opportunities for Small Group Discussion

Program Overview and Objectives

This virtual meeting is designed to familiarize attendees with current understanding of the etiology and treatment options for selected unmet cancer and treatment related symptoms/toxicities and CCDR challenges. It will also review the current and planned studies developed by the Wake forest NCORP Research Base addressing these issues.

Upon completion of the activity, participants should be better able to:

Describe symptom management for cancer patients and survivors (e.g. neurocognitive toxicity, cardiovascular toxicity of cancer and its treatment).

Discuss Cancer Care Delivery (CCDR) (e.g. integration of evidence based tobacco cessation, telehealth support for assessing patient's and caregiver's psychosocial status, survivorship care plan) needs in community-based oncology practices around the country.

Describe procedures relevant to the unique needs of new clinical trials.

Credit

9.25 Contact Hours from Northwest AHEC

0.925 CEU from Wake Forest School of Medicine

9.25 Nursing Contact Hours

Cost and Registration

There is no per person fee for this event; however, all participants must register by noon on the day preceding the session in order to receive the WebEx link to attend. Instructions for accessing the livestream webinar will be sent with your confirmation letter.

Register at www.nwahec.org/64134

If you have not received confirmation of your registration 24 hours before the program date, please call Gail Pawlik at 336-713-7761 or email gpawlik@wakehealth.edu to verify the status of your registration.

Agenda

Thursday, October 29, 2020

12 pm Welcome and Meeting Overview/Business/Awards

12:30 pm Cancer Control - Accruing Protocols

Upbeat / Greg Hundley, MD

Acupuncture / Lorenzo Cohen, PhD

Remember / Steve Rapp, PhD

Ramipril / Michael Chan, MD

Prostate / Joanne Sandberg, PhD

M&M / Grant Williams, MD

IMPACTS / Don Penzien, PhD

2 pm Break

2:10 pm Cancer Control - Emerging Symptom Science Opportunities

Unpacking Breast Cancer Outcome Disparities in African American Women / Nestor Enasola, MD

Mobile-Health Delivery of Lifestyle Interventions for Women with Breast Cancer (Pilot)
Lorenzo Cohen, PhD

Sleep Study in AA (Concept) / Lee Ritterband, PhD

Skin Toxicities / Karen Winkfield, MD and Ryan Hughes, MD

Radiation Necrosis for Brain Metastases Treated with SRS while on Immunotherapy / Michael Chan, MD

PainTRAINER for Chemotherapy Induced Peripheral Neuropathy / Don Penzien, PhD

3:30 pm Break

3:40 pm NCI Update / Sandra Russo, MD and Wortia McCaskill-Stevens, MD

Health Equity and Health Disparities Research - Unconscious Bias / Nadine Barrett, PhD

Selected Findings from NCORP Studies

OaSiS / Kristie Foley, PhD

Landscape / Kathryn Weaver, PhD

Prevent / Greg Hundley, MD

5:40 pm Adjourn

Agenda

Friday, October 30, 2020

12 pm Welcome

CCDR Protocols and Concepts

Telehealth / Suzanne Danhauer, PhD

AH-HA / Kathryn Weaver, PhD

HN Star / Talya Salz, PhD

New Caregiver study (Concept) / Chandysten Nightingale, PhD

Cancer Pain (Concept) / Meredith Adams, PhD

Food Insecurity & Cancer (Pilot) / Deepak Palakshappa, MD and Jean McDougal, PhD

START (Pilot) / Sarah Birken, PhD

ENGAE (Concept) / Tuya Pal, MD

1:50 pm Break

2 pm Health Equity - Panel Discussion / Led by Karen Winkfield, MD, Dr. Bruce Rapkin, Dr. Alex Wilson

3 pm Community Advisory Committee (chat room) / Led by Glenn Lesser, MD & Kathryn Weaver, PhD

Site Coordination/Data Management Training & Updates (chat room) / Led by NCORP Staff

4 pm Talk to Study PI (Round Tables) / Hosted by Glenn Lesser, MD & Kathryn Weaver, PhD

5 pm Adjourn

For More Information and Assistance

If you have questions about registering for this activity or need auxiliary aids or special services to attend, please contact Gail Pawlik at least five working days before the activity by calling 336-713-7761 or emailing gpawlik@wakehealth.edu.

Regulatory Request: If you have obtained permission from the CIRB on your study specific worksheet to obtain your consents in a process that is different than that described in the study specific protocol, please send your CIRB approval letter to NCORP@wakehealth.edu. This will better assist our auditing team with your future audits.

Survey for Potential Study: An investigator at Wake Forest School of Medicine is proposing to test an intervention, Prepare to Care, in a multi-site randomized clinical trial.

We would like to understand the level of interest in potential participation at your site if this project is funded in the future.

Please take 2 minutes to complete this 4 - item survey by 10/23/20 by visiting the following link: <https://redcap.link/erf0anbe>

We appreciate your feedback. Thank you!

STUDY UPDATES:

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

- The amendment protocol and related documents 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.
 - Created a video and study recruitment flyers [found on the WAKE NCORP website].
 - **Document Access:**
 - The protocol documents are available on the [CTSU](#) website.
 - The updated **Recruitment and Retention Incentive** document and limited access neurocognitive test booklets are available on the [WAKENCORP](#) website.
- If there are any questions regarding WF-97415, please contact NCORP@wakehealth.edu. Attn: WF-97415

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*

- Updated FAQ document dated 10.13.20. Changes made to #12 regarding full cycle Dose Delay and posted on WAKE NCORP website. Please review.
- 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 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 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.

Inclusion Criteria

- 4.1.1 Male diagnosed with adenocarcinoma of the prostate, stage I, II, or III. Patient may have already received hormonal therapy or expect to receive hormonal therapy as treatment for adenocarcinoma of the prostate
- 4.1.2 Scheduled to undergo prostatectomy or initiate radiation for primary curative treatment of adenocarcinoma of the prostate within 90 days of enrollment
- 4.1.3 Self-identify as African American/black, non-Hispanic OR white, non-Hispanic; Participants are considered African American for recruitment purposes if they (1) identify solely as African American for race OR (2) identify as African American and white for race, but do not identify as also being of another race. Participants are considered white for recruitment purposes if they select white and no other race. (These identities are based on participant self-report during the screening process.)
- 4.1.4 ECOG score = 0 or 1
- 4.1.5 Worked within the past 14 days prior to screening (no minimum number of hours required)
- 4.1.6 Intends to be working 6 months from screening
- 4.1.7 Patient is willing to provide answers on the *Patient Eligibility Questionnaire* regarding household income

48:26

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.

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 approval is pending.

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 21, 2020

| Open Studies | Name | Enrolled | Target |
|---------------------|-------------|-----------------|---------------|
| WF 97115 | Acupuncture | 218 | 240 |
| WF 97116 | Remember | 261 | 276 |
| WF 97415 | Upbeat | 266 | 1000 |
| WF 10217 | Ways | 207 | 220 |
| WF 30917CD | Telehealth | 41 | 90 |
| WF 1801 | Ramipril | 34 | 75 |
| WF 1802 | PCW | 84 | 220 |
| WF 1804CD | AH-HA | 5 | 624 |
| WF 1805CD | HN-STAR | 0 | 350 |
| WF 1806 | M&M | 25 | 300 |
| WF-1901 | IMPACTS | 0 | 456 |