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Wake Forest NCORP Research Base

Bi-Weekly Broadcast

September 16, 2021

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

ANNOUNCEMENT – WAKE FOREST NCORP RESEARCH BASE VIRTUAL ANNUAL MEETING REGISTRATION LINK IS NOW ACTIVE

Please click below to register for the 2021 Wake Forest NCORP Research Base Annual Meeting.

[Click here to register](#)

This link will also be posted on the WAKENCORP website

<https://wakencorp.phs.wakehealth.edu/>.

If you encounter any issues, please contact Lisa Thomas at

lisathom@wakehealth.edu.

Reminder that if you do not have a NW AHEC account, you will need to create one before you can register.

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to the Annual Meeting date.

Credits will be offered for CME and CNE for those that register and attend.

Wake Forest NCORP Research Base Annual Meeting Agenda

The agenda for the meeting can also be found on our website: <https://wakencorp.phs.wakehealth.edu/secure/dspHome.cfm> and downloaded.

Follow these steps:

- Click Open Protocol Documents
- Click Wake Forest NCORP Research Base Annual Meetings
- Click Wake Forest NCORP Research Base 2021 Annual Meeting
- Click on Document Name "WF NCORP RB Annual Meeting Agenda 2021"

New Workshop Opportunity!

*****Deadline for applications has been extended to October 8, 2021*****



This meeting will be held virtually, Time and Date TBD

Overview: The goal of this workshop include: (1) to offer consultation to NCORP community sites to support implementation of evidence-based practices into oncology settings, (2) to advance local quality improvement projects into generalizable CCDR research, and (3) to strengthen concept or grant proposals for implementation science research within NCORP.

Each participant (or team) will submit a brief concept and work with implementation scientists and biostatisticians to achieve their concept goal(s). A workshop will be held

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group (aka “The Pitch”), and feedback from an expert panel and peers.

Eligibility: Investigators and senior research staff associated with NCORP Community and M/U Community sites and/or investigators with an interest in CCDR and implementation science within the NCORP network are encouraged to apply.

Additional Information: You may view the recorded video of the August 13th Webinar explaining the process and plans for the workshop by going to the WAKENCORP website: <https://wakencorp.phs.wakehealth.edu/>, click on Dashboard dropdown, then Videos. Please contact the Wake Forest NCORP Research Base at NCORP@wakehealth.edu for more information.

To Apply: Please click below to apply for the workshop.

[IDAPT/WF NCORP Workshop Application \(REDCap\)](#)

Upcoming Site Calls

WF-1801 - RAMIPRIL - A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy
September 22, 2021 at 3:00 pm EDT

WF-30917CD - TELEHEALTH - A Stepped-Care Telehealth Approach to Treat Distress in Cancer Survivors
September 27 - **Meeting Cancelled**

WF-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer
October 13 - **Meeting Cancelled** - Please join us for the WF NCORP Research Base Annual Meeting instead

WF-1804CD - AH-HA - Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors
October 21, 2021 at 11:00 am EDT

Please email 7NCORP@wakehealth.edu when shipping biospecimen samples. Include the FEDEX tracking number in your email so that misplaced samples can be tracked before they spoil

Study Updates

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

NEW AMENDMENT ACTIVATION

AH-HA (WF-1804CD) Amendment 4, PVD 08/13/2021, Release Date 09/02/2021

The WF NCORP Research Base study titled Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors (WF-1804CD) has been amended (Amendment 4, Protocol Version Date 08/13/2021). Protocol documents are available on the CTSU website: <https://www.ctsu.org/>. Site registration requirements are listed in Protocol Section 11 and additional onboarding requirements will be provided by the Wake Forest NCORP Research Base coordinating center during onboarding. Please note this is a CIRB approved protocol. Participating sites are required to submit to the CIRB as their IRB of record.

Changes associated with this amendment include:

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- Reduced Black or African American to 10% of total accruals and Hispanic or Latino to 4% of total accruals
- Changed the number of participating practices from 12 to a range of 8 to 12
- Removed the limit of two practices per NCORP eligible to participate
- Changed the IT/Administrator Key informant interview guide
- Changed the wording of survivor eligibility criterion to specify that the study visit should be to provide follow-up cancer care for one of our targeted cancers

Note: This is a limited participation protocol. Sites must receive a Site Open to Enrollment (SOTE) letter from WF NCORP RB which is provided to the site once all site set up activities have been completed. Upon receipt of the SOTE letter, sites can complete the registration process. If you have any questions or if your site is interested in participating in this study, please send an email with your site's name and CTEP ID to NCORP@wakehealth.edu; Attn: WF-1804CD or to Eleanor Davidson at ecdavids@wakehealth.edu.

WF-1901 - IMPACTS - Internet Delivered Management of Pain Among Cancer Treatment Survivors

We have posted a ***Study Staff Fact Sheet*** to be used by local NCORP Staff as a quick reference for WF-1901 schema and inclusion criteria. This document is available on the Wake NCORP website:

<https://wakencorp.phs.wakehealth.edu/>.

Go to: DASHBOARD/Protocol Documents/1901-IMPACTS. We will also offer laminated copies of this 2-sided document to our active sites for use as a desktop reference.

If your site has not been activated for this exciting study, we would love to bring you onboard! Please email us at NCORP@wakehealth.edu for more information.

WF-30917CD - TELEHEALTH – A Stepped-Care Telehealth Approach to Treat Distress in Cancer

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- **Last call for Telehealth participants! Enrollment will end September 17, 2021.**
- We appreciate your continued support as we try to reach our accrual goals. Every participant makes a difference!

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

As part of the study closure procedures, please mail in the following study supplies:

- Scale set (scale, calibration weight, and balance bubble (if included))
- 50 ml tubes used for sialometry collection
- Any blank labels, unused biohazard bags, and pipettes provided by study

Please mail the supplies to:

Wake Forest Baptist Health
525 Vine Street, Suite 430
Winston Salem NC 27101
ATTN: Tammy Vogler

WF-97415 - UPBEAT - Understanding and Predicting Breast Cancer Events after Treatment

NEW AMENDMENT ACTIVATION

WF-97415 - UPBEAT Amendment 6, PVD 08/05/2021, Release Date 08/31/2021

The WF NCORP Research Base study titled Understanding and Predicting Breast Cancer Events after Treatment (UPBEAT) has been amended. The

The study closed to enrollment on July 31, 2021. Changes with this amendment include:

- Added new Social Determinants of Health questionnaire to capture Socioeconomic Status, Race and Gender Based Discrimination, and Medical Mistrust questions.
- Added Addendum Consent Script. All enrolled participants will need to be re-consented before the new Social Determinants of Health questionnaire can be administered.
- Please complete the Addendum Consent script with each participant prior to their next scheduled visit.
- For patients in the 3-11 year follow-up period, please complete the Addendum Consent and administer the Social Determinants of Health Questionnaire at the next follow-up call.
- Updated the UPBEAT Specimen Log Form to better capture time point for DNA, Serum, and Plasma collection and shipping (see the last page of the protocol).

Regulatory Requirements:

- All sites are required to use the NCI CIRB as their IRB of record per the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NPT-OD-17-076).
- Implementation of this amendment is required within 30 days of this broadcast.

Document Access:

- The protocol documents are available on the CTSU website: <https://www.ctsu.org/>.
- The limited access Neurocognitive test booklets are available on the WAKENCORP website: <https://wakencorp.phs.wakehealth.edu/>.

If there are any questions about the activation please contact NCORP@wakehealth.edu, Attn: WF-97415.

[AWARDS FOR 2021 ANNUAL MEETING!](#)

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tuned for more information!

WF-1901 IMPACTS:

- 1) Northwestern University with 7
 - 2) Illinois Cancer Care Peoria with 4
-

WF-30917CD TELEHEALTH:

- 1) UPSTATE with 6
 - 2) MUSC with 5
-

Audit Corner

Informed Consent Process Documentation for ALL Study Participants

During audits involving CCCR studies we have noted several instances where informed consent process notes are not being documented for Non-Patient study participants. This documentation can be as simple as a “Note to File” that documents the process and is kept with the signed informed consent and provided at the audit.

Per Section 5.4.1 of the September 2021 CTMB Guidelines, failure to document the informed consent process with a study participant is a “Major Deficiency” on your audit report.

Please remember this guidance applies to any study participant, including both Patient and Non-Patient.

Accruals as of September 15, 2021

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				Patients)	
WF-1801	RAMIPRIL	47	75		
WF-1802	PCW	139	255		
WF-1806	M&M	54	300		
WF-1901	IMPACTS	15	456	0	40
WF-30917C	TELEHEALTH	68	90		
WF-1804CD	AH-HA	167	600	5	40
WF-1805CD	HN STAR	10	350	52	140



A program of the National Cancer Institute
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