**Wake Forest NCORP Research Base**

**Bi-Weekly Broadcast**

**March 5, 2019**

**Reminders:**

* **The Wake Forest NCORP 6th Annual meeting will be held November 14 – 16** in Greenville, SC at the Hyatt Regency.
* **WF 97415** -**UPBEAT** MRI Encounter Guide

The WF-97415 MRI Encounter Form Guide has been revised, including: 1) MRI Encounter Forms should now be submitted to NCORP@wakehealth.edu and 2) Series References E, G, H and M are optional. Please go to the WAKENCORP member website to download and review the revised MRI Encounter Form Guide, Version 01/18/2019. There are no regulatory submission requirements for this document. Any questions should be directed to NCORP@wakehealth.edu, Attn: WF-97415.

* **WF 1804CD – AH-HA**

The Wake Forest NCORP Research Base has a new CCDR study (WF-1804CD: Assessing Effectiveness and Implementation of an Electronic Health Record (EHR) Tool to Assess Heart Health among Survivors (AH-HA)) that we expect to activate later this Spring. We would like to share some initial information about this study and invite you to a webinar with the study team on March 13th (2-3pm ET). The study has been approved by the CIRB, and the protocol is available on the Wake-NCORP website (<https://wakencorp.phs.wakehealth.edu/dspLogin.cfm>).

Briefly, we plan to include 12 NCORP affiliates/sub-affiliates in a cluster, randomized controlled trial to study the effectiveness of an EHR-based intervention to improve cardiovascular disease management among patients in survivorship care. Affiliates/sub-affiliates must use the EPIC EHR to be eligible to participate.

Below is a brief schema of the study design. To register for the webinar or ask study questions, please contact Eleanor Davidson ([ecdavids@wakehealth.edu](mailto:ecdavids@wakehealth.edu)). To obtain access to the Wake-NCORP website, please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

# SCHEMA

***Study Population:*** Breast, prostate, colorectal, endometrial, or Hodgkin and non-Hodgkin lymphoma cancer survivors presenting to 12 NCORP practices for post-treatment follow-up care

Title: Arrow down - Description: Arrow down

***Randomization:*** 1:1 practice level randomization (6 intervention, 6 usual care), matched on organizational characteristics (e.g., number of oncology providers and intention to implement the tool in a survivorship clinic)

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***Intervention:*** Implementation of the Automated Heart-Health Assessment (AH-HA) EHR cardiovascular health (CVH) assessment tool and provider education sessions

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***Data Collection from Survivors:*** Baseline (pre & post-visit), 6 months, and 1 year- Demographics, referrals to health services (including primary care and cardiology), CVH discussions, cardiovascular risk factor data

***Data Collection from Key Informants:* (**6 Months after AH-HA Implementation) Semi-structured interviews assessing perceptions and perceived impact of the AH-HA tool on practices, providers, and survivors; barriers and facilitators to implementing AH-HA into practice; and suggested changes to AH-HA to improve future adoption, implementation, and maintenance.

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***Primary Endpoint:*** Cardiovascular health discussions defined as patient-reported discussions with their provider for up to seven non-ideal CVH conditions identified for that patient. Conditions include CVH factors (cholesterol, blood pressure, glucose/hemoglobin A1c) and CVH behaviors (body mass index, smoking, diet, and physical activity).

***Study Sample*:** n=600 survivors of breast, prostate, colorectal, endometrial cancers; or Hodgkin and non-Hodgkin lymphomas; n=24-30 key informants

***Study Duration*:** 1 year

***Brief Eligibility Criteria*:**

***Practices****:* (1) use of the Epic© EHR, (2) willingness to incorporate the AH-HA tool in their EHR, (3) have two or more providers willing to be trained and use AH-HA, and (4) identified providers saw ≥100 potentially eligible patients for follow-up in prior 6 months.

***Survivors****:*

(1) ≥ 6 months post-potentially curative cancer treatment for breast, prostate, colorectal, endometrial cancers, or Hodgkin and non-Hodgkin lymphomas. Ongoing hormonal therapies such as tamoxifen, aromatase inhibitors, or androgen deprivation are allowed.

(2) Scheduled for a routine cancer-related follow-up care visit with an identified AH-HA provider.

(3) Able and willing to complete a follow-up assessment in one year;

(4) No evidence of disease at the time of last medical visit for all cancers, except non-melanoma skin disease.

* **WF-1803CD Caregivers Amendment 01, Protocol Version Date 12/03/2018, Released February 20, 2019**

The WF NCORP Research Base study titled Supportive Care Service Availability for Cancer Caregivers in Community Oncology Practices (WF-1803CD) has been amended (Amendment 1, Protocol Version Date 12/03/2018).  WF-1803CD Amendment 1 documents are now available on the [CTSU](http://www.ctsu.org/) website. Changes to the protocol and case report forms are included in this amendment.

**AMENDMENT NOTICE:** **The Caregivers Surveys will be updated in REDCap on February 21, 2019 to reflect protocol version 12/03/2018.** For the sites that have completed the first survey, the next steps will include:

* + - 1. ***CCDR Leads*** will receive the Practice Group Characteristics Survey REDCap link via email.
      2. ***Supportive Care Leaders*** will receive the REDCap link via email for the SCL survey.
      3. ***Oncology Providers*** identified by CCDR Leads and randomized by Wake Forest NCORP Research Base will receive the REDCap link via email for the Oncology Provider survey.

Study Participation Questions:

* The REDCap link for participation in this study was sent via email in January 2019. If your site did not receive the link to complete the rostering form, please have your CCDR Lead contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu), Attn: WF-1803CD Participation.
* For all other questions pertaining to this study please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu), Attn: WF-1803CD.

General Regulatory Requirements:

* The CIRB is not requiring NCORP sites to seek approval to participate in this study, as local NCORP staff will not be directly recruiting or consenting participants. For those choosing to receive IRB approval before participating, protocol documents can be accessed on [CTSU](http://www.ctsu.org/).
* **EAQ161CD – Biomarker Testing in Common Solid Cancers: An Assessment of Current Practices in Precision Oncology in the Community Setting**
* This study is being conducted by an ECOG-ACRIN investigator team. It involves a survey being sent to specific sites on biomarker testing practices in Lung, Colorectal, Breast and Melanoma cancers.
* The goal is to inform NCORP sites, and the cancer care community at large, how biomarker testing is conducted. Anonymous, un-attributable report of findings will be shared with all responding NCORP sites, components and subcomponents.
* Responses will be kept strictly confidential.
* This study has been reviewed by the Central IRB, which determined that this study does not constitute Human Subjects Research as defined by 45 CFR 46.
* The 43 adult NCORP PIs and CCDR Leads will be sent an invitational email explaining registration procedures. If you have questions about the study, please contact Irene Mahon (imahon@acr.org)
* There will be a Training Webinar offered two times. The access information is the same for both EAQ161CD Training Webinars:

1. **Wed 3/13/2019 at 1 pm ET**
2. **Tues 3/26/2019 at 10 am ET**

Please join my meeting from your computer, tablet or smartphone.   
[https://global.gotomeeting.com/join/471383285 [global.gotomeeting.com]](https://urldefense.proofpoint.com/v2/url?u=https-3A__global.gotomeeting.com_join_471383285&d=DwMFAg&c=yzGiX0CSJAqkDTmENO9LmP6KfPQitNABR9M66gsTb5w&r=tngVBjW8oDqwtNTRyd51D9bn8ffMNkCXyt0LOyIDHnM&m=LANE6GtxBYsfiSha-Dv9qzewxPWsklhdvhDtjtjEAIE&s=WJDZ8Cf9WL0LOj5SClMdSYyK577bIWeLEwbm23VxSD4&e=)

You can also dial in using your phone.   
(For supported devices, tap a one-touch number below to join instantly.)

United States: +1 (408) 650-3123   
- One-touch: [tel:+14086503123,,471383285#](tel:+14086503123,,471383285)

Access Code: 471-383-285

Joining from a video-conferencing room or system?   
Dial: 67.217.95.2##471383285   
Cisco devices: [471383285@67.217.95.2](mailto:471383285@67.217.95.2)

First GoToMeeting? Let's do a quick system check: [https://link.gotomeeting.com/system-check [link.gotomeeting.com]](https://urldefense.proofpoint.com/v2/url?u=https-3A__link.gotomeeting.com_system-2Dcheck&d=DwMFAg&c=yzGiX0CSJAqkDTmENO9LmP6KfPQitNABR9M66gsTb5w&r=tngVBjW8oDqwtNTRyd51D9bn8ffMNkCXyt0LOyIDHnM&m=LANE6GtxBYsfiSha-Dv9qzewxPWsklhdvhDtjtjEAIE&s=6g0PWgoVjgzffJzajYgBtICnXeFXNKJSSXFngqgM8Z4&e=)

* **WAYS WF-10217 – Amendment 3 – Effective 1/21/19, all Strata open once again for additional participants Each Strata will now accrue 55 to each. The number of participants enrolled has changed to account for those participants who are being replaced.**
* **Enrollment is now restricted to racial/ethnic minority participants**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **STRATUM** | **PARTICIPANTS ENROLLED** | **AGE** | **TIME SINCE ORIGINAL CANCER DIAGNOSIS** | **AA Patients Needed** |
| A | 49 | 25-29 | 2 years to < 6 years | 1 |
| B | 46 | 25-29 | 6 years to < 10 years | 1 |
| C | **55 (FULL)** | **30-34** | **2 years to < 6 years** | **Enrollment closed** |
| D | 47 | 30-34 | 6 years to < 10 years | 3 |

* **WF 1802 PCW**

The Wake Forest NCORP Research Base has a new study (WF-1802: *Influence of Primary Treatment for Prostate Cancer on Work Experience* (PCW)) that we expect to activate later this Spring. An introductory webinar will be conducted the week of March 18th.

Briefly, we plan to examine how prostate cancer treatment affects African American men’s ability to work. We will enroll 220 people in the study, stratified by race (African American, non-Hispanic; white, non-Hispanic) and income (low income, moderate to high income). Participants will be interviewed a total of three times – before treatment begins, 3 months after treatment, and 6 months after treatment. Each interview will last approximately 40-60 minutes and will include questions about participants’ job and workplace, medical leave from work, symptoms associated with prostate issues, and physical and mental well-being.

A draft protocol is available on the Wake NCORP website.

If your site is interested in participating in this study, please email your site name, CTEP ID and contact information to NCORP@wakehealth.edu



* **WF 1801 – Ramipril** – Only one blood draw kit for DNA isolation will be sent upon request to each site. Another kit can be requested when you have another patient identified as these kits are expensive to build and ship to sites.

**Current Accruals as of 03/04/19**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study Title** | **Study Number** | **Accrual** | **Target** |
| RELAX | 01213 | 36 | 75 |
| WAYS | 10217 | 198 | 200 |
| ACUPUNCTURE | 97115 | 181 | 240 |
| REMEMBER | 97116 | 149 | 276 |
| UPBEAT | 97415 | 151 | 1000 |
| OaSiS | 20817CD | 531 | 1114 |
| Telehealth | 30917CD | 9 | 9 |
| Ramipril | 1801 | 0 | 75 |
| Caregivers | 1803CD | 5 | 828 |