**Wake Forest NCORP Research Base**

**Bi-Weekly Broadcast**

**March 19, 2019**

**Reminders:**

* **The Wake Forest NCORP 6th Annual meeting will be held November 14 – 16** in Greenville, SC at the Hyatt Regency.
* **WF 01213 – RELAX and WF 97115 – ACUPUNCTURE**

Site calls for these studies will be QUARTERLY moving forward. To be added to these calls or if you have other study related questions or concerns please send them to [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu). Please reference the study number so that your email can be routed properly.

* **WF-10217 - WAYS**

**Enrollment is now restricted to racial/ethnic minority participants**

Accrual Update: 197 participants enrolled

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **STRATUM** | **PARTICIPANTS ENROLLED** | **AGE** | **TIME SINCE ORIGINAL CANCER DIAGNOSIS** | **African American 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 | 0 |
| D | 47 | 30-34 | 6 years to < 10 years | ≥ 3 |

* **WF 30917CD - TELEHEALTH**

We will be hosting a Telehealth Site Call via GoToWebinar® on 03/21/2019 from 4:15pm to 5:00pm EST. Please plan to join us. Please click the link below to register for the webinar.

Meeting Agenda:

* Overview of upcoming amendment for Telehealth
* Status of upcoming amendment
* Sample recruitment letter approved and posted to CTSU

Please register for Telehealth Site Call Webinar on Mar 21, 2019 4:15 PM EDT at:   
  
<https://attendee.gotowebinar.com/register/4619027855006194178>  
  
After registering, you will receive a confirmation email containing information about joining the webinar.  
  
Brought to you by GoToWebinar®  
Webinars Made Easy®

* **WF-1801 – RAMIPRIL**

**Amendment 2, Protocol Version Date 01/31/2019, Release Date 03/20/2019:**

The WF NCORP Research Base study titled *A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy* (WF-1801) has been amended (Amendment 2, Protocol Version Date 01/31/2019). The amended protocol and related documents will be released on **March 20, 2019** and will be made available on the [CTSU](https://www.ctsu.org/Public/Default.aspx?ReturnUrl=%2f) website. The enrollment form in OPEN will also update to the amended version on March 20, 2019. With this amendment, enrollment will be open to participants using the Tumor Treating Fields (TTFields or Optune®) device. Other changes made to the protocol, informed consent, CRFs and funding sheet are listed in the Summary of Changes document that will be posted to CTSU.

**Note - Limited Access Case Report Forms:** Online access to CRF 17-20 (Baseline Assessment, 6 Week Assessment, 10 Week Assessment, 22 Week Assessment) is restricted to neurocognitive test certified site personnel only and can be downloaded from the Protocol Documents page of the Wake Forest NCORP Research Base (WF NCORP RB) member website, [WAKENCORP](https://wakencorp.phs.wakehealth.edu/dspLogin.cfm). For site staff who have questions or need to complete the neurocognitive test certification, please contact the WF NCORP RB at [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

**Sites interested in participating** who have not started the onboarding process should contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu), Attn: WF-1801, and provide the following information:

* + Parent CTEP ID
  + Parent Institution Name
    - Participating Site(s) (affiliates and sub-affiliates):
      * Site CTEP IDs
      * Site Names
  + Principal Investigator:
    - First and Last Name
    - Phone Number
    - Email Address
  + Primary Point of Contact:
    - First and Last Name
    - Phone Number
    - Email Address
* **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 March 26th at 2:00PM.** Please hold this date/time; WebEx invitations will be sent this week.

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](mailto:NCORP@wakehealth.edu)

* **WF-1803CD – CAREGIVERS**

**Amendment 01, Protocol Version Date 12/03/2018, was 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 have been updated in REDCap 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/).

* **WF 1804CD – AH-HA**

We are polling the NCORP community to determine which sites are potentially interested in this study. Please activate the link below to provide your contact information and the Sub-Affiliate/Affiliate CTEP IDs. This screener and rostering form must be completed in order to be considered for participation. Please complete them by March 29th so that you can be added to study protocol as a potential site.

[Preliminary Site Eligibility Screener](https://redcap.wakehealth.edu/redcapccc/surveys/?s=EJYL3F9CT7)

Dear NCORP Colleagues,

The Wake Forest NCORP Research Base invites you to participate in a new CCDR Study, *Assessing Effectiveness and Implementation of an Electronic Health Record (EHR) Tool to Assess Heart Health among Survivors* (AH-HA). We anticipate including 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.

The objectives of the study are to:

(1) Assess the impact of the AH-HA tool on providers’ efforts to: 1a) discuss CVH during visits, 1b) refer survivors to primary care and cardiology, and 1c) manage CV risk (ordering of CVH-relevant labs and treatments);

(2) Measure the impact of the AH-HA tool on survivors’: 2a) completed visits with primary care providers and cardiologists and 2b) control of CVH factors [cholesterol, blood pressure, glucose/hemoglobin A1c] and CVH behaviors [body mass index, smoking, diet, and physical activity]

(3) Examine factors influencing current and future implementation of the AH-HA tool.

Selection of NCORP Sites:

NCORP affiliate/sub-affiliate interest and preliminary eligibility will be determined by an online screener.  We are asking you to submit information on all affiliates that have or will be considered for participation. The study PIs will be providing additional information about the study in multiple formats (e-mails & webinars) and confirming eligibility criteria, prior to asking for a commitment to participate in the study. If multiple affiliates from an NCORP community or minority/underserved community site are interested, we will enlist your help to rank order their study participation. We anticipate that no more than two affiliates per NCORP community site will be selected for participation.

We will cluster interested practices according to organizational characteristics (e.g., oncology provider number, and anticipated implementation in a designated survivorship clinic) and then randomly select practices from within each cluster to receive the intervention (n=6) or usual care (n=6). All patients within a practice (n=50) will be randomized to either the intervention or the usual care group.  Following acceptance into the trial, intervention practices will be invited to participate in webinar and conference call training. Usual care clinics will receive instruction in patient recruitment and assessment procedures.

The study will not detract from and/or compromise the usual care currently being provided to patients at either the "intervention” or "usual care" sites.

All practices must meet all of the following eligibility criteria:

* Use of the Epic EHR
* Agrees to incorporate the AH-HA tool in their EHR
* Have 2 or more providers willing to be trained and use AH-HA
* Identified providers saw 100 or more potentially-eligible patients for follow-up in the prior 6 months

**Summary of Expectations for Participating in this Study**:

* Participate in study data collection trainings and ongoing bi-monthly conference calls.
* Recruit and complete all assessments for enrolled patients (n=50).

Eligibility criteria for patients include:

* ≥ 18 years of age AND
* Currently receiving follow-up care for breast, prostate, colorectal, endometrial or lymphoma cancer AND
* 6 months or more post potentially-curative cancer treatment, excluding hormonal therapies AND
* With no current evidence of disease, except non-melanoma skin disease

**Expectations for Practices Randomized to the Intervention**:

* Webinars: healthcare providers and staff who are central to implementing the AH-HA tool are expected to watch the training webinars.  We will record all webinars and make them available to maximize the opportunities for staff to watch the training videos. Providers will be asked to watch (2) 30-minute videos in the month prior to tool implementation.
* AH-HA Tool Implementation: Intervention practices will work closely with Wake Forest NCORP study team members to implement the AH-HA tool at their practice. Extensive training and technical assistance will be made available, including provision of an Epic© trained consultant for integration of the tool into the clinic and troubleshooting as necessary
* Coordination of Site Visit:  Our team may visit each intervention practice. We will need local support for scheduling and managing the site visit.
* Intervention practices will also be asked to identify 4-5 paid personnel to volunteer to participate in “Key Informant” interviews.  These personnel can/will include clinic administrators, health care providers (e.g. physicians, nurses) and other staff (e.g. information technology specialists).  Participants will take part in a 30 minute, taped qualitative interview.

**Resources Available to Support Study Participation**:

* Gift cards will be provided by the study for survivors ($20 total) and key informants ($20).
* $5,000 will be provided to all participating practices to support study implementation. An additional $6,500 can be provided to intervention practices, if requested, for reimbursement of IT services needed for AH-HA implementation.
* Tablet technology will be provided to all practices, if requested, to support online data collection.
* **EAQ161CD – Biomarker Testing in Common Solid Cancers**

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 for EAQ161CD Training Webinar: **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=)

* **Accruals as of 03/19/19**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study Title** | **Study Number** | **Accrual** | **Target** |
| RELAX | 01213 | 36 | 75 |
| WAYS | 10217 | 198 | 220 |
| ACUPUNCTURE | 97115 | 183 | 240 |
| REMEMBER | 97116 | 156 | 276 |
| UPBEAT | 97415 | 153 | 1000 |
| OaSiS | 20817CD | 576 | 1114 |
| Telehealth | 30917CD | 9 | 90 |
| Ramipril | 1801 | 0 | 75 |
| Caregivers | 1803CD | 47 | 828 |
| Biomarkers | EAQ161CD | 1 | N/A |