**Wake Forest NCORP Research Base**

**Bi-Weekly Broadcast**

**March 19, 2021**

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



**ANNOUNCEMENTS**

**TRAVEL AWARDS FOR 2021 ANNUAL MEETING!**

**We need your help!** We are making **one final push** to successfully complete WF 30917CD, the Telehealth study and meet our goal of 90 participants by 9/17/21. To add a little bit of competitive motivation, we are offering two **travel awards** to cover two nights hotel accommodations at the Wake Forest NCORP 2021 Annual Meeting (The Renaissance Hotel, Asheville, NC) to the two highest accruing sites for all **Telehealth accruals** between 2/11/2021 – 9/1/2021.

 **Top Accruing Sites Thus Far: 1) MUSC 2) MetroMinn & Upstate**

**Additional Travel Awards:** We would like to announce that we will be awarding travel awards to the two highest accruing sites for all **IMPACTS accruals** between 3/19/2021 – 9/1/2021.

**Upcoming Meetings**

Wake Forest NCORP Research Base Health Equity Core April 15, 2021 @ 3pm EST

Wake Forest NCORP Research Base Quarterly Site Call May 12, 2021 @ 3pm EST

2021 Annual Meeting: 10/3/21 – 10/5/21 at the Renaissance, Asheville, NC

2022 Annual Meeting: 10/9/22 – 10/11/22 at the Marriott Grand Dunes, Myrtle Beach, SC

**NEW - CCDR Seminar Series: Wake Forest NCORP Research Base and IDAPT Implementation Science and CCDR Seminar Series**

*“Implementation Science for Cancer Care Delivery Researchers”*

Kristie Foley, PhD & Ray Osarogiagbon, MD

March 22nd, 1-1:30 pm, followed by a 15 min Q & A

Join us for a series of four webinars that will explore the intersection between implementation science and cancer care delivery research, with the ultimate goal of building capacity within the NCORP network to develop and carryout studies focused on integrating evidence-based practices within oncology practices. These webinars will be presented through a partnership between the Wake Forest NCORP Research Base and IDAPT (Implementation and Informatics- Developing Adaptable Processes and Technologies for Cancer Control), one of the seven NCI Implementation Science Centers in Cancer Control (ISC3).

In this first webinar, Dr. Kristie Foley (Wake Forest School of Medicine) and Dr. Ray Osarogiagbon (Baptist Memorial Health Care/Mid South Minority Underserved NCORP) will provide an introduction to implementation science and how it is critical to advance cancer care delivery in community oncology settings.

**Target Audience:** NCORP PIs, investigators, CCDR leaders, and staff engaged in CCDR studies and others interested in applying implementation science in oncology settings. Dates for Future webinars: 5/3, 7/7, & 9/9  1:00-1:30pm followed by a 15 min Q & A

For more information, please contact NCORP@wakehealth.edu

**WAKE NCORP WEBSITE UPDATE:**

When accessing the WAKE NCORP Website (<https://wakencorp.phs.wakehealth.edu/>) please use the Google Chrome browser (<https://www.google.com/chrome/>). Documents, guides, and training videos work best in this browser.

**Study Updates**

* **WF 97115 – ACUPUNCTURE - *A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer***
	+ **Please Help Get Us Across the Finish Line!**
	+ We only have **15 patients** left to register on **WF-97115 - Acupuncture for Radiation-Induced Xerostomia for head and neck cancer patients!**
	+ We really appreciate your participation in this trial and your efforts to help toward our goal of 240 participants. We hope to finish recruitment to the study in the next few months and we need your help to get us there. We have seen how much patients benefit from participating in this trial and for many they are getting salivary function back after years of suffering with xerostomia. Patients have shared with us how devastating lack of saliva has been in their lives and that even just a few sessions of acupuncture have helped them. We need to complete this clinical trial so we can share the findings with the larger community and let them know how acupuncture can help them too.
	+ If you have potentially eligible participants at your site, please consider recruiting them to this study. As a reminder, recruitment letters are available to send to eligible participants and flyers are available to post in your facility.
	+ Let us know if we can be of further assistance.
	+ Thank you for being part of this landmark study to reduce suffering in cancer survivors.
* **WF 97116 REMEMBER – *A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairment***
	+ **We’re almost there!**   Only 6 more patients to go.  Thanks to all who have a contributed to this important study.
* **WF-97415-UPBEAT - *Understanding and Predicting Breast Cancer Events after Treatment (UPBEAT) – Amendment 5, PVD 02/03/2021, Release Date 03/10/2021***
	+ Please remember to complete and submit a CRF01a Screening Log at the end of each month and to complete a CRF01b Decline Form for all eligible patients who decline participation. These forms provide valuable data for the study team regarding recruitment efforts and potential changes to study parameters. The forms can also be found on the CTSU website.
	+ If no patients were screened in a given month, please submit a form with your site info and indicate “No patients screened” on the form.
	+ A self-administered COVID-19 questionnaire was added with this amendment. A typo was discovered in the response headings. If possible, have patients complete the forms in REDCap. If completing in REDCap is not an option, please make the following correction to the paper form before giving it to the patient to complete.



* + The paper form will be corrected with the next amendment.
	+ If there are any questions regarding WF-97415, please contact NCORP@wakehealth.edu. Attn: WF-97415
	+ Thank you for all your hard work on this important study!
* **WF 1802 PCW – *Influence of Primary Treatment for Prostate Cancer on Work Experience, Amendment 3, Protocol Version Date 02/01/2021 to be released 3/23/2021.***
	+ In this amendment, we increased the white moderate to high-income stratum to 90 and the overall accrual number to 255 and received a waiver of documentation of consent to allow verbal consenting either in person or remotely using the Informed Consent Script. We also modified the inclusion/exclusion criteria to allow eligibility **if** participants worked during the first half of March 2020 **and** involuntarily lost their job due to COVID-19 and we modified the Baseline Questionnaire questions to clarify how participants should respond to employment questions if their employment status was affected by COVID-19.
	+ **WF-1802 Document Access:**
		- The protocol documents will be available on the [CTSU](https://www.ctsu.org/Public/Default.aspx?ReturnUrl=%2f) website on 03/23/21.
		- The FAQs and Training Attestation documents are still available on the WAKENCORP website.
	+ If there are any questions regarding the WF-1802, please contact NCORP@wakehealth.edu; Attn: WF-1802.
	+ A Site Call was held on 3/16/21, you can find the recorded WebEx and slides posted on the WAKENCORP website.
	+ The next site call will be held 5/18/21 @ 1:30pm
* **WF-1805 HN-STAR – *Implementation and Effectiveness Trial of HN-STAR***
	+ A Site Call was held 3/17/21, you can find the recorded WebEx and slides posted on the WAKENCORP website.
* **WF 1901 IMPACTS – *Internet-delivered Management of Pain Among Cancer Treatment Survivors*, *Amendment 3, Protocol Version Date 02/01/2021 to be released 3/23/2021***
	+ In this amendment, we have clarified eligibility criteria as it was not clear that patients who are taking no analgesics are eligible. We have added telephone based neurocognitive assessments as an alternative to the in-person assessment method in the event a face-to-face visit is not possible. We have removed the PAXGene Blood ccfDNA tube from the optional blood draw, leaving only the PAXGene Blood DNA tube as the necessary tube for collection. A poster has also been added to assist with recruitment.
	+ **WF-1901 Document Access:**
		- The protocol documents will be available on the [CTSU](https://www.ctsu.org/Public/Default.aspx?ReturnUrl=%2f) website on 03/23/21.
		- The *Helpful Guide* and other supplemental resources are available on the [WAKENCORP](https://wakencorp.phs.wakehealth.edu/) website.
		- If there are any questions regarding the WF-1901 activation or site registration procedures, please contact NCORP@wakehealth.edu; Attn: WF-1901.
* **WF-30917 Telehealth – *A Stepped-Care Telehealth Approach to Treat Distress in Cancer Survivors***
	+ **VIRGINIA SITES: Please immediately stop recruiting new participants due to reduced availability of the therapist. We anticipate accrual to resume April/May 2021.**
	+ For participants randomized to the Stepped Care Low Intensity Arm, please record your bi-weekly phone calls so that both sides of the conversation are audible.
	+ **The next Telehealth Site Call will be March 22, 2021 at 4 PM EST**.
	+ *If you would like to attend, but did not receive an invitation, please email* *NCORP@wakehealth.edu**.*
* **Accruals as of March 18, 2021**

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| --- | --- | --- | --- | --- | --- |
| **Open Studies** | **Name** |  **Enrolled (Patients)** | **Target (Patients)** | **Enrolled (Non-Patients)** | **Target (Non-Patients)** |
| WF-97115 | Acupuncture | 225 | 240 |  |  |
| WF-97116 | Remember | 270 | 276 |  |  |
| WF-97415 | Upbeat | 308 | 1000 |  |  |
| WF-1801 | Ramipril | 43 | 75 |  |  |
| WF-1802 | PCW | 95 | 220 |  |  |
| WF-1806 | M&M | 34 | 300 |  |  |
| WF-1901 | IMPACTS | 0 | 456 | 0 | 40 |
| WF-30917CD | Telehealth | 51 | 90 |  |  |
| WF-1804CD | AH-HA | 73 | 600 | 5 | 40 |
| WF-1805CD | HN STAR | 3 | 350 | 24 | 140 |