**Wake Forest NCORP Research Base**

**Bi-Weekly Broadcast**

**April 1, 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 with 4 2) MetroMinn & Upstate both tied with 2**

**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”*

Randi Foraker, PhD: Improving Oncology Care with Informatics and IT Tools

May 3, 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).

**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](mailto: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**

**NEW AMENDMENT ACTIVATION**

**WF-1802 PCW – *Influence of Primary Treatment for Prostate Cancer on Work Experience* Amendment 3, Protocol Version Date 02/01/2021 Released 03/23/2021**

Amendment 3 contains the following changes:

* Increased the white moderate to high-income stratum to 90 and the overall accrual number to 255.
* Obtained a waiver of documentation of consent to allow verbal consenting either in person or remotely using the Informed Consent Script.
* 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.
* 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 are available on the [CTSU](https://www.ctsu.org/Public/Default.aspx?ReturnUrl=%2f) website.

* + The FAQ document and Training Attestation documents are still available on the [WAKENCORP](https://wakencorp.phs.wakehealth.edu/) website. The FAQ document was revised on March 23, 2021.
  + A ***Study Info Sheet*** was developed to assist with recruitment. Sites will share the sheet with local urology providers and seek their assistance in referring eligible participants to the site to obtain information about the study. The study purpose, eligibility information, study activities and a placeholder for site contact information are listed on the ***Study Info Sheet***.
  + The ***Study Info Sheet*** is posted on the [WAKENCORP](https://wakencorp.phs.wakehealth.edu/) site under the Study Info Sheet tab, within the “1802 – Prostate Cancer Work (PCW)” section
  + If there are any questions regarding the WF-1802, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-1802.
  + The next site call will be held 5/18/21 @ 1:30pm

**NEW AMENDMENT ACTIVATION**

* **WF-1901 IMPACTS – *Internet-delivered Management of Pain Among Cancer Treatment Survivors* Amendment 3, PVD 02/01/2021, Released 03/23/2021**

**Still looking for our first accrual to come in!**

Amendment 3 contains the following changes:

* Clarified eligibility criteria.
* Added telephone based neurocognitive assessments for use in the event that a face-to face visit is not possible.
* Removed the PAXGene Blood ccfDNA tube from the optional blood draw, leaving only the PAXGene Blood DNA tube as the necessary tube for collection.
* Added a pain scale recruitment poster.

**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).
* Site Open to Enrollment (SOTE) letter from the WF NCORP RB will be provided to the site after all onboarding activities are completed.

**Document Access:**

* The protocol documents are available on the [CTSU](https://www.ctsu.org/Public/Default.aspx?ReturnUrl=%2f) website.
  + The updated **Helpful Guide** document and limited access Neurocognitive test booklets 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](mailto:NCORP@wakehealth.edu); Attn: WF-1901.
* **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 available on the [WAKENCORP](https://wakencorp.phs.wakehealth.edu/) website.
  + Let us know if we can be of further assistance by email NCORP@wakehealth.edu.
  + 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 **4** more patients to go.  Thanks to all who have a contributed to this important study.
* **Accruals as of March 31, 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 | 272 | 276 |  |  |
| WF-97415 | Upbeat | 314 | 1000 |  |  |
| WF-1801 | Ramipril | 44 | 75 |  |  |
| WF-1802 | PCW | 98 | 220 |  |  |
| WF-1806 | M&M | 38 | 300 |  |  |
| WF-1901 | IMPACTS | 0 | 456 | 0 | 40 |
| WF-30917CD | Telehealth | 51 | 90 |  |  |
| WF-1804CD | AH-HA | 77 | 600 | 5 | 40 |
| WF-1805CD | HN STAR | 3 | 350 | 32 | 140 |