**Wake Forest NCORP Research Base**

**Bi-Weekly Broadcast**

**May 27, 2021**

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





**What’s New?**

**WF-97115 – ACUPUNCTURE - *A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer-*** **Closing to New Patient Enrollment on June 15, 2021**

We would like to thank all sites who have participated in this study and for those who continue to screen and recruit for the remaining slots that we have available. **We wanted to let you know that we will be closing this study to new patient enrollment on June 15, 2021 unless we meet the enrollment goal before this deadline.** After this date, you will still be able to finish current patients on study per protocol. We are making a final PUSH to try and recruit the final 11 participants that we need. If you have potentially eligible participants at your site, please consider recruiting them to this study by June 15th.  Let us know if we can be of further assistance by emailing NCORP@wakehealth.edu.

**Reminder regarding Saliva Sample Shipments to the MD Anderson Lab, including a change in staff:**

Please email Bo Wei (BWei1@mdanderson.org) and Dr. Yang (pyang@mdanderson.org) the email notification regarding the saliva sample shipment on the day you ship.

No longer include the following staff on the email notification as they are no longer with our group:

* Ding,Jibin (jding@mdanderson.org)
* Jiang,Yan (YJiang5@mdanderson.org)
* Peguero Pereira,Eveliz M (EMPeguero@mdanderson.org)

Below are the reminders regarding the saliva sample shipments, please:

* Select the delivery method that will ensure that the samples arrive to MD Anderson before 10:30 AM the next day.
* Email **Dr. Peiying Yang** (pyang@mdanderson.org) and **Bo Wei** (BWei1@mdanderson.org) on the day that you ship samples, including the shipment **Tracking Number**, so that they are aware and can coordinate receiving the samples from our shipment receiving dock on the next day.
* In the email shipment notification, please indicate if the samples are the **Fresh Samples** or the **Frozen Samples.**
* Please include a copy of the **Sialometry Form** in the shipping package for the Fresh Samples shipped immediately.
* Please include a copy of the **Stored Saliva Sample Transmittal form** in the shipping package for the Frozen Samples when shipped.
* Sialometry appointments should be scheduled **Monday-Thursday**.

**WF-30917CD Telehealth – A Stepped-Care Telehealth Approach to Treat Distress in Rural Cancer Survivors**

* Virginia sites can resume participant recruitment.
* If you missed the last Site Call on May 24, 2021, you can find the recording and slide deck on the WAKE NCORP website.

**WF-1805CD HN-STAR – Implementation and Effectiveness Trial of HN-STAR**

* If you missed the last Site Call on May 19, 2021, you can find the recording and slide deck on the WAKE NCORP website.

**McKesson - Memorial Day Closure**

In observance of Memorial Day, McKesson’s Clinical Research Services will be closed Monday, May 31, 2021. We will resume regular business hours on Tuesday, June 1, 2021.

Our regular business hours are Monday through Friday, 9 am to 6 pm ET.

Please take this information into consideration when placing your orders prior to Memorial Day.

* Only non-refrigerated product will be shipped on Friday, May 28. Orders placed prior to 2 pm ET will be delivered on Tuesday, June 1.
* If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by Thursday, May 27 prior to 2 pm ET.

Due to the influx of shipments around the holidays, carrier delays may occur. Please plan your orders accordingly.

If you have questions regarding the shipment schedule, please contact our Clinical Research Services team at 800.693.4906, or via email at clinicalresearchservices@mckesson.com.

**Study Updates**

**WF-1806 (M&M) *Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer (M&M)*, Amendment 4,Protocol Version Date 04/01/21,** *Release Date 5/10/2021:*

The WF-1806, *Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer (M&M)* study has been amended. The amended protocol and related documents were released on **Monday, May 10th**, **2021.**

Changes with this amendment include:

* Patients who are 60 years and older can now participate, as the lower age strata has been extended.
* The timeframe for the baseline CT has been extended to 60 days.
* A single item questionnaire; FACT-G GP5, has been added to time-points 2 and 3.

*Note: Re-consenting of patients is not required with this amendment.*

**WF-1806 Document Access:**

* The protocol documents are available on the [CTSU](https://www.ctsu.org/Public/Default.aspx?ReturnUrl=%2f) website.
* The *Helpful Guidelines*, *FAQs*, and *Training Attestation* documents are available on the [WAKENCORP](https://wakencorp.phs.wakehealth.edu/) website.

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

**Resume Enrollment of Control Participants**

Please continue your efforts towards screening and approaching eligible women to join this study. We have revised our enrollment goal, which is to recruit 65 participants (**18 cancer patients** and **47 healthy controls**) between now and August 31, 2021.  We especially need African-American women and women with a BMI > 26 in our control group.

If there are any questions regarding WF-97415, please contact NCORP@wakehealth.edu; Attn: WF-97415

**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 **1** more patient to go. Thanks to all who have a contributed to this important study.

**Accruals as of May 26, 2021**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Open Studies** | **Name** | **Enrolled (Patients)** | **Target (Patients)** | **Enrolled (Non-Patients)** | **Target (Non-Patients)** |
| WF-97115 | ACUPUNCTURE | 229 | 240 |  |  |
| WF-97116 | REMEMBER | 275 | 276 |  |  |
| WF-97415 | UPBEAT | 334 | 1000 |  |  |
| WF-1801 | RAMIPRIL | 45 | 75 |  |  |
| WF-1802 | PCW | 114 | 255 |  |  |
| WF-1806 | M&M | 41 | 300 |  |  |
| WF-1901 | IMPACTS | 2 | 456 | 0 | 40 |
| WF-30917CD | TELEHEALTH | 53 | 90 |  |  |
| WF-1804CD | AH-HA | 102 | 600 | 5 | 40 |
| WF-1805CD | HN STAR | 4 | 350 | 37 | 140 |

**Save the Date**

**\*\*Note - dates have been adjusted\*\***

* **2021 Annual Meeting:**

**October 4 – October 6, 2021** Renaissance, Asheville, NC

* **2022 Annual Meeting:**

**October 10 – October 12, 2022** Marriott Grand Dunes

Myrtle Beach, SC

**Holiday Closures**

**Memorial Day – May 31, 2021**

* **WF NCORP RB**
* **McKesson**
* **WF Biospecimen**
* **MD Anderson (for WF-97115-ACUPUNCTURE Specimens)**
* **UAB Lab (for WF-1806-M&M Specimens)**

Normal Operations will resume on Tuesday, June 1, 2021. Please contact NCORP@wakehealth.edu if you have questions

**Upcoming Site Calls**

**WF-1806 M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer: The M&M Study**

June 9, 2021 at 2:30 PM EDT

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

June 17, 2021 at 11:00 AM EDT

If you would like to attend, but did not receive an invitation, please email NCORP@wakehealth.edu

**TRAVEL AWARDS FOR 2021 ANNUAL MEETING!**

**WF-1901 IMPACTS:** We will be awarding travel awards to the two highest accruing sites for all IMPACTS accruals between 3/19/2021 – 9/1/2021. These awards will cover hotel accommodations for 1 person per site.

**WF 30917CD TELEHEALTH:** **We need your help!** We are making **one final push** to successfully complete the Telehealth study and meet our goal of 90 participants by 9/17/2021.  To add a little bit of competitive motiv