**Wake Forest NCORP Research Base**

**Bi-Weekly Broadcast**

**May 6, 2020**

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



**ANNOUNCEMENTS**

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| **Clinical Research Services Closed May 25, 2020**  In observance of Memorial Day, McKesson’s Clinical Research Services will be closed **Monday, May 25, 2020.**  We will resume regular business hours on Tuesday, May 26, 2020.  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 22**. Orders placed prior to 2 pm ET will be delivered on **Tuesday, May 26.** * If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Thursday, May 21** 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](mailto:clinicalresearchservices@mckesson.com). |
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| **The Wake Forest NCORP Research Base office will be closed Monday, May 25, 2020.** We will resume regular business hours on Tuesday, May 26, 2020.  **The Wake Forest NCORP Research Base Biospecimen Lab** **will be closed Monday, May 25, 2020** and will resume regular business hours on Tuesday, May 26, 2020.  **Remote Consent Guidelines Regarding COVID-19**  The remote consent guidelines from the CIRB can be found in Section 8 using this link:  [CIRB Frequently Asked Questions Regarding COVID-19 and the CIRB [nam05.safelinks.protection.outlook.com]](https://urldefense.proofpoint.com/v2/url?u=https-3A__nam05.safelinks.protection.outlook.com_-3Furl-3Dhttps-253A-252F-252Fncicirb.org-252Fannouncements-252Ffrequently-2Dasked-2Dquestions-2Dregarding-2Dcovid-2D19-2Dand-2Dcirb-26data-3D02-257C01-257Cwreid-2540emmes.com-257C83941a17d8fc431c8b7e08d7e8597048-257C4aedf6ad32c04bb6b6bcaf5597447e81-257C0-257C0-257C637233343135568067-26sdata-3DwHwXfdYZBuhl2nx9Qe2uOKyQaEe2DxOVP0olxh7og6s-253D-26reserved-3D0&d=DwMFAg&c=yzGiX0CSJAqkDTmENO9LmP6KfPQitNABR9M66gsTb5w&r=TnCUknn7SuuKiZZ9xYiqqVGRRW44n91mFcfkV4OTZdE&m=Ieu-VYbPh9fvn8I8pfxh5DIc7nwgJi8d4-jwy25Y93g&s=0b2fAwNInS0ZjRqSkuxzrzMdcs5VVKalWc5CJeyQzWM&e=)  Additional information or FAQs regarding Remote Consenting can be found using this link: [Remote Consent Procedures: Revised FAQs Due To COVID-19 [nam05.safelinks.protection.outlook.com]](https://urldefense.proofpoint.com/v2/url?u=https-3A__nam05.safelinks.protection.outlook.com_-3Furl-3Dhttps-253A-252F-252Fncicirb.org-252Fannouncements-252Fremote-2Dconsent-2Dprocedures-2Drevised-2Dfaqs-2Ddue-2Dcovid-2D19-26data-3D02-257C01-257Cwreid-2540emmes.com-257C83941a17d8fc431c8b7e08d7e8597048-257C4aedf6ad32c04bb6b6bcaf5597447e81-257C0-257C0-257C637233343135568067-26sdata-3D8KtkezYvHDmYWxYzcLS1bDc-252B0QfdUmpkQTtiuianSBM-253D-26reserved-3D0&d=DwMFAg&c=yzGiX0CSJAqkDTmENO9LmP6KfPQitNABR9M66gsTb5w&r=TnCUknn7SuuKiZZ9xYiqqVGRRW44n91mFcfkV4OTZdE&m=Ieu-VYbPh9fvn8I8pfxh5DIc7nwgJi8d4-jwy25Y93g&s=rZQbplgUh5VAm-GWVj7wSMbBulGHVy-UCiUDkJPK7_U&e=). |

**Clarifications and Corrections**

* **Recording Deviations** – Please remember to record your deviations and also notify the WF NCORP RB via [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) or via REDCap per the table below. Please document on your log if the deviation was due to the COVID pandemic (e.g. Rescheduling patient visit out of window due to safety concerns or clinic closure). If you need a deviation log, you can find a template on the WAKE NCORP website under the General Forms & Template tab.
  + The following table indicates whether the WF NCORP study requires you to keep a paper/electronic log for our review or enter directly into REDCap:



* **WF 98213 – PREVENT – *Preventing Anthracycline Cardiovascular Toxicity with Statins***
  + **Clarification** - Any Deviations for the Prevent study need to be documented on your own site’s deviation log, as it is not currently available to sites in REDCap. If you need a deviation log, you can find a template on the WAKE NCORP website under the General Forms & Template tab.
* **WF 30917CD – TELEHEALTH - *A Stepped-Care Telehealth Approach to Treat Distress in Rural Cancer Survivors***
  + **Correction:** The Protocol Version date for the New Amendment was incorrect on the Special Broadcast sent out last week, which has been corrected and reposted on our website. The correct version date is 11/20/19.

**STUDY UPDATES:**

* **WF 98213 – PREVENT – *Preventing Anthracycline Cardiovascular Toxicity with Statins***

**NEW Amendment** **Protocol Version Date 03/27/2020, Release 5/4/2020**

Changes with this amendment were made to address only those patients who have a 24 month visit pending and were rescheduled due to the COVID-19 pandemic. Changes include:

* + Extending the time period to collect the 24 month assessment to within 24-27 months.
  + Additional study drug will be provided but will expire June 30, 2020. Patients must be scheduled on or before June 30, 2020.
  + You patient will need to sign the Addendum to the consent before receiving additional study drug.
  + All documents are posted on the WAKE NCORP website.
  + Sites will need to submit this amendment to your local IRB for approval. After obtaining local IRB approval, send the approval document to [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

Please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) with any questions.

* **WF 10217 – WAYS – *Work Ability in Young Adult Survivors (WAYS)***
  + Due to the COVID-19 pandemic, remote consenting may be used. Please refer to the CIRB link noted at the beginning of this Broadcast for specific steps you will need to take and document in order to obtain consent in this manner.
  + Cogstate – Arrangements have been made so that your patient will not need to come into your clinic in order to access Cogstate for study questionnaires. A special link will need to be sent from your clinic to the patient. Please refer to the WAKE NCORP website, Open Protocols, WAYS, Helpful Guidelines and look for pdf files Quick Start Guide Web Based Testing and Cogstate Research CBB URL Links. An email was sent out previously this week to active sites but please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) with questions regarding this process.
* **WF 1802 – PCW (Prostate) – *Influence of Primary Treatment for Prostate Cancer on Work Experience***
  + The **Moderate to High Income, White** stratum is **CLOSED**.
  + You can determine the remaining slots left for any stratum by going to **CTSU-OPEN** -> **Slot Reservation** -> **Report**.
  + Due to the COVID-19 pandemic, remote consenting may be used. Please refer to the CIRB link noted at the beginning of this Broadcast for specific steps that you will need to take and document in order to obtain consent in this manner.
  + If you have any questions or would like more information on this study, email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).
* **WF 30917CD – TELEHEALTH - *A Stepped-Care Telehealth Approach to Treat Distress in Rural Cancer Survivors***
  + New Study Therapists have been trained. Sites who see rural patients residing in the following states can now participate: California, Michigan and Tennessee.
  + A complete list of states with study trained licensed therapists include: California, Georgia, Illinois, Michigan, Minnesota, New Mexico, North Carolina, North Dakota, South Carolina, Tennessee, Virginia, Wisconsin.
  + If your site is interested in participating, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)
* **WF-1803CD-CAREGIVERS - *Supportive Care Service Availability for Cancer Caregivers in Community Oncology Practices***
  + Rostering of new sites is now closed.
  + Please continue to complete surveys as we will be accepting data until 5/30/20.
* **EAQ161CD – BIOMARKERS – Rostering of new sites for this survey is now CLOSED. Please complete all planned data collection in conjunction with pathology practices by May 31, 2020.**

**Mark Your Calendars** Wake Forest NCORP Research Base Annual Meeting, October 29 – October 31, 2020 at the Grand Dunes Resort in Myrtle Beach, SC.

**NEW TRAVEL AWARDS FOR PRIORITY ACCRUALS in 2020:**

The Wake Forest NCORP Research Base will offer travel awards to cover two nights hotel accommodations at the Wake Forest NCORP 2020 Annual Meeting for NCORP Community and M/U Community sites that accrue the highest number of racial/ethnic minority (WF 10217 & WF 1802) and rural patients (WF 30917CD), see below. Two travel awards per study will be offered for each of the following protocols:

* TELEHEALTH: WF 30917CD (all accruals between 1/1/2020 and 8/31/2020)
* PCW: WF 1802 (all accruals to AA and/or low-income strata between 1/1/2020 and 8/31/2020)
* WAYS: WF 10217 (all accruals between 1/1/2020 and 04/30/2020); This study was going to close to enrollment on 5/1/2020 but the closure date will likely be extended once the duration of the pandemic effects on research activities becomes clear.

**General Site email address**: If your site has a general email address that you would like for WF NCORP RB to use in order to assure that your site gets all of the Bi-Weekly and Special Broadcasts, please send that email along with your site name and CTEP ID to [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

**General WF NCORP RB Biospecimen Lab Management:**

* Please request your lab kits before you run completely out of kits. This will ensure that there will be no delay in getting samples shipped to the Biospecimen Laboratory.
* Please do not ship samples on Thursday or Friday so that samples will not arrive on the weekend.

**General Data Management** – **How do I find my REDCap data queries?**

* **For studies using REDCap data entry (WF-20817CD-OASIS, WF-97415-UPBEAT, WF-1801-RAMIPRIL, WF-1802-PCW and WF-1806 – M&M) please click the “Resolve Issues” link on the left side menu to check for any open data queries**
* **Accruals as of May 5, 2020**

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| **Open Studies** | **Name** | **Enrolled** | **Target** |
| WF 97115 | Acupuncture | 212 | 240 |
| WF 97116 | Remember | 251 | 276 |
| WF 97415 | Upbeat | 251 | 1000 |
| WF 10217 | Ways | 206 | 220 |
| WF 30917CD | Telehealth | 32 | 90 |
| WF 1801 | Ramipril | 29 | 75 |
| WF 1802 | PCW | 76 | 220 |
| WF 1803CD | Caregivers | 884 | 828 |
| WF 1804CD | AH-HA | 0 | 624 |
| WF 1806 | M&M | 18 | 300 |
| EAQ161CD | Biomarker Survey | 60 (closed to rostering) | 201 |