**Wake Forest NCORP Research Base**

**Bi-Weekly Broadcast**

**May 21, 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=). |

**ANNUAL MEETING FOR 2020 will be Virtual**

In light of the ongoing COVID-19 pandemic and current expectations of its long lasting effects on travel and in-person gatherings, Wake Forest NCORP RB leadership has examined the feasibility and advisability of hosting our scheduled in-person group meeting in October, 2020. After consultation with NCI/DCP NCORP leadership and considering the potential extension of current Wake Forest institutional guidelines on travel and in-person meetings during the fall and winter, we have decided to switch to a condensed virtual meeting format for 2020. We are actively developing the modified agenda for this meeting in an effort to maintain as many of the positive features of our typical meeting as possible including updates on active and planned studies, new concepts under consideration, data management and site coordination discussions, and, most importantly, opportunities for informal interactions with study PI’s, WF team members and colleagues from other NCORP sites.  We are currently leaning towards meeting in the afternoons on Thursday Oct. 29 and Friday Oct. 30 in order to allow NCORP sites in all time zones to participate. The meeting will also likely be a combination of some prerecorded brief presentations (to minimize connectivity disruptions as multiple study teams potentially in many different locations will need to present), each of which will be followed immediately by “live” question and answer periods. We also hope to have one or more live panel discussions. We welcome your suggestions on other approaches to virtual meetings that you have been a part of that have been particularly engaging and successful.  We will provide more information regarding this meeting including registration instructions and CME options in the coming weeks to months.  Thanks for working with us during what we hope is a temporary change in how we interact with our colleagues.

**Funding Opportunity for Pilot Projects**

The Wake Forest NCI Community Oncology Research Program (NCORP) Research Base seeks applications for meritorious pilot projects that will generate preliminary data in support of future NCORP cancer control and cancer care delivery research (CCDR) protocols. Areas of interest include symptom intervention and surveillance, health outcomes research, new approaches to cancer care delivery, and implementation of evidence-based practice in cancer care. Wake Forest NCORP priorities include cancer- and treatment-related cardiotoxicity, neurocognitive toxicity, cancer survivorship, implementation science, and cancer caregiving. Investigators may request up to $75,000 for a one year pilot project.

Additional information can be found on the WAKE NCORP website, Open Protocols, Pilot Awards Information Tab or by contacting [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) for the full RFA information.

**STUDY UPDATES:**

* **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 97415 – UPBEAT – *Understanding and Predicting Breast Cancer Events after Treatment***
  + **Data Update:**
  + As the COVID pandemic continues to affect the timeliness of study visits for several months, the Upbeat study team now recommends that you obtain as much data as you can on patients for their study visits. We realize this may mean that some data will be out of window but, some data is preferred rather than extremely delayed or no data. Please continue to keep in touch with your study patients. Reschedule them as needed and if possible you may obtain questionnaires and some of the Neurocog assessments via telephone. Please refer to the WAKE NCORP website and click on the Training Materials (Neurocog video) tab for Guidelines on Telephone Neurocog Testing.
  + Data Forms that can be used to obtain information remotely:
    - CRF03 – Chemotherapy Treatment Form
    - CRF04 – Radiation Oncology Intake Form
    - CRF05 – Radiation Treatment Summary Form
    - CRF06 – Medical Chart Review (chemo group only)
    - CRF07a – CV Medication Review
    - CRF07b – Other Medications Form
    - CRF08 – KCCQ-12
    - CRF16, 17, 18, 19 – Self Administered Questionnaires
    - CRF20, 21, 22, 23 – Neurocognitive Tests (Partial)
  + Please continue to obtain out of window MRIs, blood draws etc. If you have questions on any out of window tests/procedures, please contact the study team at NCORP@wakehealth.edu
* **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.

**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 20, 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 | 30 | 75 |
| WF 1802 | PCW | 76 | 220 |
| WF 1803CD | Caregivers | 886 (Closed to rostering) | 828 |
| WF 1804CD | AH-HA | 0 | 624 |
| WF 1806 | M&M | 18 | 300 |
| EAQ161CD | Biomarker Survey | 60 (closed to rostering) | 201 |