**Wake Forest NCORP Research Base**

**Bi-Weekly Broadcast**

**June 4, 2020**

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



**ANNOUNCEMENTS**

**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 for the full RFA information.

**DNA Isolation Lab has reopened**

You may return to sending samples for DNA (APOE) genotyping for the following studies starting June 8th:

* WF 97116 Remember
* WF 97415 Upbeat
* WF 1801 Ramipril

Missed samples can be collected at any future clinical or study visit as it reflects a germline process that will not be affected by treatment.

**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 for guidelines 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=).
	+ 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. Please contact NCORP@wakehealth.edu with questions regarding this process.
* **WF 1802 – PCW (Prostate) – *Influence of Primary Treatment for Prostate Cancer on Work Experience***
	+ According to the protocol section 5.4.1.2 Training Interviewers – trained interviewers are required to re-train if their site has not enrolled a participant within a year of certifying.
	+ Individuals that will be due to re-certify will be contacted via email 2-4 weeks prior to their certificate expiration date, as a reminder..
	+ In order to re-certify, you will be required to re-watch the training webinar and send in an updated training attestation. You will then receive and update Training Certificate.
* **WF 30917CD – TELEHEALTH - *A Stepped-Care Telehealth Approach to Treat Distress in Rural Cancer Survivors***
	+ **Reminder:** The tracking log needs to be completed for every attempted and completed contact. This includes calls for screening, baseline assessments, bi-weekly check-in calls, 7- and 13-week assessments and when returning participant phone calls.
* **WF 1801 – RAMIPRIL – *A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy***
	+ A site call was held on May 27, 2020. The slide presentation is located on the WAKE NCORP website under Ramipril Webinar | 1801: Ramipril Site Call slides\_5/27/2020. The next site call is scheduled for July 22, 2020 at 3:00PM EST.
* **WF 1806 – M&M – *Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer***
	+ A site call was held on June 3, 2020. The slide presentation will posted on the WAKE NCORP website under M&M WebEx | 1806: M&M Site Call slides\_6/3/2020. The next site call will be schedule in the month of August.
* **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.
	+ Your 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.

**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.

**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**

*Please email* *NCORP@wakehealth.edu* *with any questions you may have regarding the Bi-Weekly information.*

* **Accruals as of May 31, 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 | 33 | 90 |
| WF 1801 | Ramipril | 31 |  75 |
| WF 1802 | PCW | 76 | 220 |
| WF 1803CD | Caregivers | 889 (Closed to rostering) | 828 |
| WF 1804CD | AH-HA | 0 | 624 |
| WF 1806 | M&M | 18 | 300 |