**Wake Forest NCORP Research Base**

**Bi-Weekly Broadcast**

**April 3, 2020**

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



**COVID-19 IMPACT and UPDATE**

The Wake Forest NCORP Research Base leadership team has carefully reviewed the recent NCI guidance on research activities during the COVID-19 pandemic and consulted with the Wake Forest IRB leadership. As always, patient, provider and staff safety is paramount as we navigate these challenging times. Our coordinating center staff are teleworking, and we will maintain our daily Research Base activities to the best of our abilities. We will continue to closely monitor the NCORP@wakehealth.edu mailbox and answer questions as they come in as quickly as possible. You may always call 336-716-0891 as we will be monitoring this main number as well.

We recognize that, unfortunately, it is not “business as usual” at any of our sites. We will continue to follow NCI guidance and emphasize that local leadership decision-making and guidance, as well as ongoing NCI updates, should guide each site’s research activities for the foreseeable future. Our studies currently remain open and data collection and reporting can continue if allowed and achievable at each site. Likewise, standard study deviation reporting (in REDCap for instance) can be used to document any of the expected deviations that will occur as a result of the current pandemic, whenever it is safe and appropriate to do so.

We will not be activating any new studies, including 1805CD-HN-STAR, until instructed by the NCI to proceed. We are providing further details for each study below but all of our current active studies do remain open to accrual at this time.

Finally, our central Wake Forest NCORP biospecimen lab currently remains open and is able to receive samples, as per standard guidelines. We will let you know if this lab needs to shut down due to staffing issues. Please note these study-specific lab changes below.

* For WF 97116 and WF 1801, do **NOT** draw any samples for APOE genotyping as Dr. Tim Howard’s lab is **CLOSED** at this time due to COVID-19. This sample can be “made up” at any future clinical or study visit as it reflects a germline process that will not be affected by treatment.
* The MD Anderson biospecimen lab is currently CLOSED. Please do not collect or send any samples for the WF 97115 Acupuncture study.

Please be safe, socially distanced and, as always, prioritize patient, provider and staff safety as we collectively deal with weeks and months of disruption that will challenge all of our “normal” activities. As always, we appreciate your partnership.

**STUDY UPDATES:**

* **WF 97115 – ACUPUNCTURE - *A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer***
	+ Open for accrual.
	+ **EFFECTIVE IMMEDIATELY, do NOT collect or send any saliva samples to the MD Anderson lab. MD Anderson has halted all unnecessary research and their lab for these samples is closed.**
	+ For those sites who can continue to provide treatments, please continue.
	+ For patients who have completed baseline, and randomized into acupuncture and have not reached the 4 weeks assessment time point, their acupuncture treatments can also be re-done.
		- For example, if the patient did baseline, was randomized into acupuncture and was half-way into the 4 weeks of treatment, meaning they have received 4 of 8 treatments, they can pause the study. After things return to normal, the patient can re-do baseline, the 4 acupuncture treatments, and then proceed with the remainder of the 4 weeks of treatment and study assessments per protocol. However, if the patient is further along in treatment, meaning they have received at least 7 of the 8 treatments, this is an evaluable number of treatments and they can proceed with the expected time points in the manner deemed appropriate by their local authorities.
	+ If you have a patient who is greater than 4 weeks, do NOT collect any more saliva samples but please continue to collect study assessments at the specific time points via phone if needed.
	+ For those who need to stop treatments, it would be ideal to continue to try to get data at the expected timepoints. Keep the patient on-study and record the missed acupuncture treatments as a protocol deviation. The XQ, MDASI-HN, FACT-G, concomitant meds and AE’s can be completed via phone.
	+ If you cannot get the actual forms to patients, please try to obtain XQ questionnaire data by phone.
	+ Please document any deviations from the protocol in the usual manner using your deviation log. If you do not have one, we will be posting a Deviation Log Template on the WAKENCORP website under the General Forms & Template tab.
* **WF 97116 – REMEMBER – *A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairment***
	+ Open for Accrual.
	+ **EFFECTIVE IMMEDIATELY**, in order to avoid unnecessary research visits for your patients, use the following as guidance:
		- If your patient is on a QTc prolonging medication and per protocol requires an ECG to proceed, check with the patient to make sure there have been no adverse side effects.
			* If the patient is able to come in for the ECG as part of a needed clinical care visit then get the ECG at that time and follow protocol instructions.
			* If the patient is due to dose escalate the donepezil and they are not able to get the ECG, continue their current dose of donepezil and try to obtain the ECG and dose escalate whenever the pandemic situation allows.
			* If the patient is due to get an ECG to follow-up on a recent dose escalation, we will allow the treating provider’s discretion as to whether they wish to continue the recently escalated dose of donepezil or go back to the prior dose until the pandemic situation stabilizes and research study visits can again be scheduled.
		- If your patient is on a bradycardia medication, attempt to have the patient or someone within the patient’s household take their pulse and report the value to your site.
		- APOE testing should NOT be collected at this time as the Dr. Tim Howard’s lab is currently CLOSED due to the COVID-19. This sample can be “made up” at any future clinical or study visit as it reflects a germline process that will not be affected by treatment.
		- Please document any deviations from the protocol in the usual manner using your deviation log. If you do not have one, we will be posting a Deviation Log Template on the WAKENCORP website under the General Forms & Template tab.
		- Regarding Neurocog testing: You may choose to perform certain Neurocog tests via phone. At the end of this document are some brief tips/comments on performing tests in this manner. Please document on your form that you have performed the test via a telephone. A more detail description regarding Neurocog testing by telephone can be found on the WAKENCORP website, under the Training Materials tab.
* **WF 97415 – UPBEAT – *Understanding and Predicting Breast Cancer Events after Treatment***
	+ Open for accrual.
	+ Please schedule UPBEAT follow up appointments when you are able to resume in-clinic contact with participants and can deliver all study activities in their entirety. At this time we will discourage sites from capturing partial study activities. Should anything change, we will keep you posted.
	+ Please remember to check REDCap for any queries that may have been sent to you.
	+ Please document any missed visits/procedures as Protocol Deviations in REDCap – these need to be reported to NCI as minor deviations due to COVID-19.
* **WF 98213 – PREVENT – *Preventing Anthracycline Cardiovascular Toxicity with Statins***
	+ For those who have a patient who is coming up on their 24 month final assessment but you had to push their visit out due to COVID-19, record the missed visit as a deviation with reason “COVID-19”. Please follow-up in 30 days via telephone per protocol.
	+ We are submitting an amendment to allow ongoing drug treatment to continue and the “24 month” assessment to be delayed for up to an additional 3 months (i.e. 27 month timepoint) but that has not been approved at this time.
	+ Please document any deviations from the protocol in the usual manner using your deviation log. If you do not have one, we will be posting a Deviation Log Template on the WAKENCORP website under the General Forms & Template tab.
* **WF 10217 – WAYS – *Work Ability in Young Adult Survivors (WAYS)***
	+ Open for accrual.
	+ Due to the COVID-19 pandemic, consent may be discussed via the telephone, mail the paper consent to the participant who would the sign and mail back to your site. The participant can then complete the surveys online. This would still be considered a minor deviation and would need to be noted.
	+ Please document any deviations from the protocol in the usual manner using your deviation log. If you do not have one, we will be posting a Deviation Log Template on the WAKENCORP website under the General Forms & Template tab.
* **WF 1801 – RAMIPRIL – *A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy***
	+ Open for accrual.
	+ APOE testing should NOT be collected at this time as Dr. Tim Howard’s lab is currently CLOSED due to the COVID-19. This sample can be “made up” at any future clinical or study visit as it reflects a germline process that will not be affected by treatment.
	+ Regarding Neurocog testing: You may choose to perform certain Neurocog tests via phone. At the end of this document Please document are some brief tips/comments on performing tests in this manner. Please document on your form that you have performed the test via a telephone. A more detail description regarding Neurocog testing by telephone can be found on the WAKENCORP website, under the Training Materials tab.
	+ Please contact NCORP@wakehealth.edu if you have any questions regarding your patient who may be in the midst of treatment for this study.
* **WF 1802 – PCW (Prostate) – *Influence of Primary Treatment for Prostate Cancer on Work Experience***
	+ Open for accrual.
	+ 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**.
* **WF 1806 – M&M – *Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer***
	+ Open for accrual.
* **WF 20817CD – OaSiS – IMPLEMENTATION OF SMOKING CESSATION SERVICES WITHIN NCI NCORP COMMUNITY SITES WITH ORGANIZED LUNG CANCER SCREENING PROGRAMS**
	+ **CLOSED to Enrollment as of 3/26/2020**
	+ Please make every attempt to collect follow-up data from enrolled patients. All follow-up data collection activities can be completed by local site NCORP staff by telephone.
	+ Please remember to check REDCap for any data queries that may have been sent to you.
	+ Our study statistician has determined that we have sufficient power to detect the proposed study effect size, provided current follow-up completion rates remain steady. We appreciate your partnership on this important study.
* **WF 30917CD – TELEHEALTH - *A Stepped-Care Telehealth Approach to Treat Distress in Rural Cancer Survivors***
	+ Open for Accrual.
	+ Telehealth is still accruing participants and the entire process, both consenting and study intervention, can be completed remotely. In fact, this study was designed to be able to be implemented in this way and can offer supportive care to cancer survivors who may be experiencing additional distress at this time.
* **WF-1803CD-CAREGIVERS - *Supportive Care Service Availability for Cancer Caregivers in Community Oncology Practices***
	+ Data collection for this study will end on April 30, 2020.
	+ Please complete the rostering process as soon as possible, so that all study data can be collected before this date. If you have any questions regarding this process, please contact NCORP@wakehealth.edu
* **EAQ161CD – BIOMARKERS – Rostering of new sites for this survey is now CLOSED. Please complete all planned data collection in conjunction with pathology practices.**
* **WF 1805CD HN Star – *Implementation and Effectiveness Trial of HN Star***
	+ Study activation is on hold per NCI guidance.
* **Tips & Comments on delivering Neurocog tests via Telephone**

*Telephone connections*

* If examiners use a telephone head-set with built-in earphones and a microphone they can remain hands-free for typing or writing. Voice clarity is better, too.
* Make it clear to the examinee at the very beginning of the call what you will do if the call is interrupted. Typically, that is an immediate call-back by the examiner.
* Work with the examinee to determine the best way to use their phone during testing. Options might include holding it, using the speaker phone or using earphones/ear buds with a built-in microphone. If the examinee is hands-free, the risk of inadvertent disconnection by accidentally pressing cell phone buttons is less.
	+ - Instruct the examinee to position themselves close to the microphone at all times. If you cannot hear them clearly, instruct the examinee to speak directly into the microphone, You may need to remind them throughout the call.
* At the end of testing, have examiner record their impression whether hearing significantly influenced test results. It can be difficult to judge sometimes but knowing it might have been a factor is helpful in adjudication and data analysis. It is ideal to rate each test in this way as some tests rely more heavily on adequate hearing (e.g., a paragraph recall) than others (e.g., verbal fluency).

*Examiner’s physical environment*

* Examiner’s environment should be quiet, free of distracting voices or sounds. This can be challenging. Posting signs on office doors that testing is underway and discussing noise reduction strategies with officemates may be necessary.
* The examiner’s space should be acoustically favorable. Large open rooms do not convey sound as well as closed-in areas.
* Having materials ready before testing both reduces extraneous noise and saves time.

*Examinee’s physical environment*

* Testing should be done with the examinee alone in a room. If someone else is there you should ask that they or the examinee leave the space. If other people enter the examinee’s space, you may have to temporarily interrupt testing to ensure s/he gives the tasks their full attention.
* Ask if the examinee to ensure they are comfortable and if the testing environment is as free of distractions as possible.

*Examiner voice clarity*

* Speak a bit slower than you would face-to-face. The pace newscasters use is good. You need to give yourself time to say each work clearly and completely.
* Enunciate each word. Some sounds are not heard as clearly over the phone or are difficult distinguish from different sounds. The ‘p’ in ‘whip’ is often heard as a ‘t’ (‘wit’). This can be a problem on word list recall tasks. You may need to exaggerate certain letters or syllables a bit. Over time you may develop a list of very commonly misheard words on such tasks and decide to give credit for them. Of course, the first action should be to speak more clearly and crisply.
* If you speak with an accent, you may need to adjust your speech for some words. You can practice with a person who does not speak your native tongue until you are ready. Whenever possible, use native speakers for the language of administration.

**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.

**Reminder to Record Deviations** and remark if they are due to the COVID-19 pandemic.

**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 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.
* **Accruals as of March 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 20817CD | OaSiS | 1,100 closed to enrollment | 1114 |
| WF 30917CD | Telehealth | 31 | 90 |
| WF 1801 | Ramipril | 29 |  75 |
| WF 1802 | PCW | 75 | 220 |
| WF 1803CD | Caregivers | 769 | 828 |
| WF 1804CD | AH-HA | 0 | 624 |
| WF 1806 | M&M | 17 | 300 |
| EAQ161CD | Biomarker Survey | 56 (closed to rostering) | 201 |