**Wake Forest NCORP Research Base Special Broadcast**

**March 23, 2020**

The distribution of this special broadcast is provided to notify members of recent updates to events, website updates, and protocol specific information.

**WF 97115 Acupuncture/WF 97116 Remember COVID-19 IMPACT**

* **WF 97115 Acupuncture**
  + **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.**
  + We understand that sites responses to the COVID-19 crisis will vary.
  + For those sites who can continue to provide treatments, they should of course 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 which means they have received 4 of 8 treatments, they can pause the study, and then after things return to normal after the virus issue resolves, re-do baseline, re-do the 4 acupuncture treatments, and proceed with the remainder of the 4 weeks of treatment and study assessments per protocol; However, if the patient is further along in treatment and has received at least 7 of the 8 treatments, this is an evaluable number of treatments and would be best for them to 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 and get the XQ and on the expected timelines. Keep the patient on-study and record the missed acupuncture treatments as a protocol deviation. The 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 obtain the XQ by phone.
  + Please document any deviations from the protocol in the usual manner.
* **WF 97116 Remember**
  + **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 it.
      * 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 someone within the patient’s household or the patient them self take the pulse and report the value to your site.
    - You may perform as many of the Neurocog, QOL’s, AE’s, concomitant medication form, med diaries and pill counts by phone.
    - Please document any deviations from the protocol in the usual manner.

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.