

Wake Forest NCORP Research Base Special Broadcast August 14, 2019

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

Remember (WF-97116) Amendment 4, Protocol Version Date 06/07/2019, Release 08/14/2019:

The WF NCORP Research Base study titled *A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairment (REMEMBER)* (WF-97116) has been amended. The amendment has been released as of today, August 14, 2019. All protocol documents are now available on the [CTSU](#) website.

Currently enrolling participating sites must complete the following regulatory requirements prior to implementing Amendment 4:

- **Sites using NCI CIRB** as their IRB of record must activate the amended protocol and consent form within 30 days of the amendment release. Sites must submit their amendment activation date and updated consent form to NCORP@wakehealth.edu, Attn: WF-97116, in order to be granted access to the Amendment 4, Version 06/07/2019, Patient Registration Form in CCRBIS.
- **Sites not using the NCI CIRB** must submit the amended protocol documents to their IRB of record and receive IRB approval within 90 days of the amendment release. Submit IRB approval letters to NCORP@wakehealth.edu, Attn: WF-97116, in order to be granted access to the Amendment 4, Version 06/07/2019, Patient Registration Form in CCRBIS.

Protocol Document Access:

- The protocol, consent form, appendices, flyer and patient wallet card will be posted on the [CTSU](#) website.
- The Specimen Kit Request Forms and Sample Collection Forms are available on the [WAKENCORP](#) website under Helpful Guidelines.
- The Neurocognitive Testing Booklets (Appendix 3, 6, 10, 11 & 12) will be available on the [WAKENCORP](#) website (limited access).

Cardiac Monitoring Form:

- If you will be submitting the same Cardiac Monitoring Form for a patient throughout the study rather than submitting a new form with each data submission, please be sure to add the date of the assessment to the visit box.

For questions, please contact NCORP@wakehealth.edu; Attn: WF-97116.