

Wake Forest NCORP Research Base Special Broadcast
July 31, 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 will be released on August 14, 2019. All protocol documents will be available on the [CTSU](#) website on the release date (08/14/2019). Changes to the protocol, consent, and appendices are included in this amendment. Changes clarify the patient re-consenting process. Please note that this is a CIRB approved protocol.

Currently enrolling participating sites must complete the following regulatory requirements prior to implementing *Remember* 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 being provided as guide documents and are available on the [WAKENCORP](#) website.
- The Neurocognitive Testing Booklets (Appendix 3, 6, 10, 11 & 12) will be available on the [WAKENCORP](#) website (limited access).