



**Wake Forest NCORP Research Base**

**Bi-Weekly Broadcast**

**July 9, 2021**

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

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**WF97116- A Phase 3 Randomized Placebo Controlled Clinical  
Trial of Donepezil in Chemotherapy Exposed Breast Cancer  
Survivors with Cognitive Impairment (REMEMBER)**

**\*\*Closed to Enrollment\*\***

**Effective July 2, 2021 at 4PM.**

**We would like to thank all sites who have participated in this study. We wanted to let you know that we have reached our enrollment goal on July 2, 2021. After this date, you should still finish current patients on study per protocol. Let us know if you have any questions by emailing [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).**

**Shout out to Wake Forest Baptist Comprehensive Cancer Center -  
Clemmons for enrolling the final participant!**

**What's Next?**

1. Please keep this study active at your site until the WAKE NCORP Research Base gives your site permission to contact your IRB to closeout this study.
2. We ask that you still keep your data records for this study available until you have received notice from the WAKE NCORP Research Base that all data has been cleaned.
3. Until this study has been officially closed by the WAKE NCORP Research Base, your site may still be audited on this study.
4. When you are given permission to close at your site, please forward a copy of your IRB letter confirming your study's closure to [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

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**Annual Meeting Survey**

**The Wake Forest NCORP RB annual meeting will take place in Asheville, NC on October 4-6, 2021, with a planned virtual option. We would like all members of the NCORP network (CRAs, data & regulatory staff, PIs, administrators, and CCDR leads) to respond to this brief 3 question survey regarding your attendance to help us finalize arrangements.**

<https://redcap.link/WFNCORP2021AnnualMeeting>

**Thanks for your assistance!**

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## Study Updates

### WF-1805CD - HN-STAR - Implementing and Effectiveness Trial of HN-STAR

**Amendment 3 has been approved by the CIRB, we expect to activate mid to late July.**

**Changes to the protocol will include:**

- Expand eligibility criteria to include participants who are  $\leq 12$  months post-completed treatment for HNC
- Add Pre-Implementation Call survey
- Add End of Study Survey
- Waiver of documentation of consent for PCP
- Remove the limit on the number of designated clinicians (DC)

**Join us on upcoming Site Call on July 21, 2021 for all the details.**

**If your site has been approved for participant accrual, please be on the lookout for a survey from the WF Research Base.**

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### WF-30917CD - TELEHEALTH – A Stepped-Care Telehealth Approach to Treat Distress in Cancer Survivors

- This study will be closing to enrollment September 17, 2021. Please make every effort to screen for these participants.
  - Still accepting new sites! If your site would like to participate or would like to schedule a refresher, email NCORP@wakehealth.edu.
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**WF-97115 – ACUPUNCTURE - A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer**

**\*\*Closed to Enrollment\*\* Effective June 15, 2021**

We would like to thank all sites who have participated in this study. **We wanted to let you know that we closed this study to new patient enrollment effective June 15, 2021.** After this date, you will still be able to finish current patients on study per protocol. Let us know if you have any questions by emailing [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

**What's Next?**

1. Please keep this study active at your site until the WAKE NCORP Research Base gives your site permission to contact your IRB to closeout this study.
2. We ask that you still keep your data records for this study available until you have received notice from the WAKE NCORP Research Base that all data has been cleaned.
3. Your site may still be audited on this study for up to 3 years after your last patient completes the study.
4. When you are given permission to close at your site, please forward a copy of your IRB letter confirming your study's closure to [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)

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**WF-97415 - UPBEAT - Understanding and Predicting Breast Cancer Events after Treatment**

**Resume Enrollment of Control Participants**

- Please continue your efforts towards screening and approaching eligible women to join this study. We especially need African-American women and women with a BMI > 26 in our control group.
  - If there are any questions regarding WF-97415, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-97415
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## **WF-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer (M&M)**

The Spanish versions of the following documents were posted on CTSU **Tuesday, June 22<sup>nd</sup>, 2021**.

- **Consent Form**, Spanish, pvd 04.01.2021
- **FACT-G GP5 (Version 4)**, Spanish, pvd 04.01.2021 questionnaire

In addition, a **Protocol Note to File** dated 5/18/2021 is posted. This memo lists the Spanish documents from the previous protocol version 05.01.2021 that are still active, as there were no changes with this latest protocol amendment.

If there are any questions, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-1806.

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## **WF-1901 - IMPACTS - Internet Delivered Management of Pain Among Cancer Treatment Survivors**

### **Amendment 4, PVD 05/26/2021, Release Date 06/24/2021**

- **“IMPACTS - A New Beginning”** – Taped training webinar and video clips from 6/30/2021 are available on [WAKENCORP](#) website. Go to *DASHBOARD / Videos*.
- The WF-1901 IMPACTS **Helpful Guide** has been updated to version 06/24/2021. This can be downloaded from the [WAKENCORP](#) website. Go to *DASHBOARD / Protocol Documents / 1901-IMPACTS*.

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The Office of Cancer Health Equity Presents:

The Office of Cancer Health Equity is proud to virtually host Dr. Shellie Ellis from KU Medical Center at The University of Kansas on **Thursday, July 15<sup>th</sup> at 12pm EST**. Dr. Ellis will give the following presentation: *Putting Rural Cancer Care Delivery on the Map: Capacity for Cancer Care Delivery Research in the NCI Community Oncology Research Program*. Dr. Ellis is passionate about evidence-based practice in cancer care delivery and using qualitative and quantitative research methodologies to improve the quality of care.

Please register for this event  
here: <https://redcap.wakehealth.edu/redcapccc/surveys/?s=YFFA8CWALK>

Wake Forest NCORP Research Base and IDAPT Implementation Science and CCDR  
Seminar Series

“Design Considerations for Implementation Science CCDR Trials”

Emily Dressler, PhD and Sarah Birken, PhD

**July 21st, 1-1:30 pm**, followed by a 15 min Q & A

For more information, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

## Important Dates and Reminders:

### Upcoming Site Calls

**WF-1901 IMPACTS - Internet-delivered Management of Pain Among Cancer  
Treatment Survivors**

July 14, 2021 at 2:30 PM EDT

**WF-1805CD – HN-STAR - Implementation and Effectiveness Trial of HN-STAR**

July 21, 2021 at 3:00 PM EDT

**WF-1802 PCW – Influence of Primary Treatment for Prostate Cancer on Work Experience**

July 20, 2021 at 1:30 PM EDT

**WF-30917CD – TELEHEALTH – A Stepped-Care Telehealth Approach to Treat Distress in Cancer Survivors**

July 26, 2021 at 4 PM

**WF-1801 - RAMIPRIL – A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy**

July 28, 2021 at 3:00 PM EDT

**WF-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer**

August 11, 2021 at 2:30 pm EDT

If you would like to attend, but did not receive an invitation, please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)

## **Annual Meetings**

### **2021 Annual Meeting**

**October 4 – October 6, 2021**

Renaissance

Asheville, NC

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### **2022 Annual Meeting**

**October 10 – October 12, 2022**

Marriott Grand Dunes

Myrtle Beach, SC

## **TRAVEL AWARDS FOR 2021 ANNUAL MEETING!**

**WF-1901 IMPACTS:** We will be awarding travel awards to the two highest accruing sites for all IMPACTS accruals between 3/19/2021 – 9/1/2021. These awards will cover hotel accommodations for 1 person per site.

**WF 30917CD TELEHEALTH:** **We need your help!** We are making **one final push** to successfully complete the Telehealth study and meet our goal of 90 participants by 9/17/2021. To add a little bit of competitive motivation, we are offering two **travel awards** to cover two nights hotel accommodations at the Wake Forest NCORP 2021 Annual Meeting (The Renaissance Hotel, Asheville, NC) to the two highest accruing sites for all **Telehealth accruals** between 2/11/2021 – 9/1/2021.

**Top accruing sites so far:**

- 1) MUSC with 4**
- 2) Upstate with 3**

## **Audit Corner**

- **REDCap now notifies the user via email once a query is assigned. Please be sure to address all queries with 14 days.**
- **Ensure your site is activated before enrolling the first patient. Please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) if you have any issues.**
- **When amendments are activated you can find information on re-consenting requirements on the CIRB approval letter for the amendment. Detailed information will also be included in Special Bulletins issued by the Wake Forest NCORP Research Base.**



**Accruals as of July 8, 2021**

<b>Open Studies</b>	<b>Name</b>	<b>Enrolled (Patients)</b>	<b>Target (Patients)</b>	<b>Enrolled (Non-Patients)</b>	<b>Target (Non-Patients)</b>
WF-97116	REMEMBER	276	276		
WF-97415	UPBEAT	364	1000		
WF-1801	RAMIPRIL	46	75		
WF-1802	PCW	129	255		
WF-1806	M&M	46	300		
WF-1901	IMPACTS	5	456	0	40
WF-30917CD	TELEHEALTH	55	90		
WF-1804CD	AH-HA	121	600	5	40
WF-1805CD	HN STAR	7	350	37	140