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## Wake Forest NCORP Research Base

### Bi-Weekly Broadcast

June 24, 2021

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

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## **NEW AMENDMENT ACTIVATION**

### **WF-1901 - IMPACTS - Internet-Delivered Management of Pain**

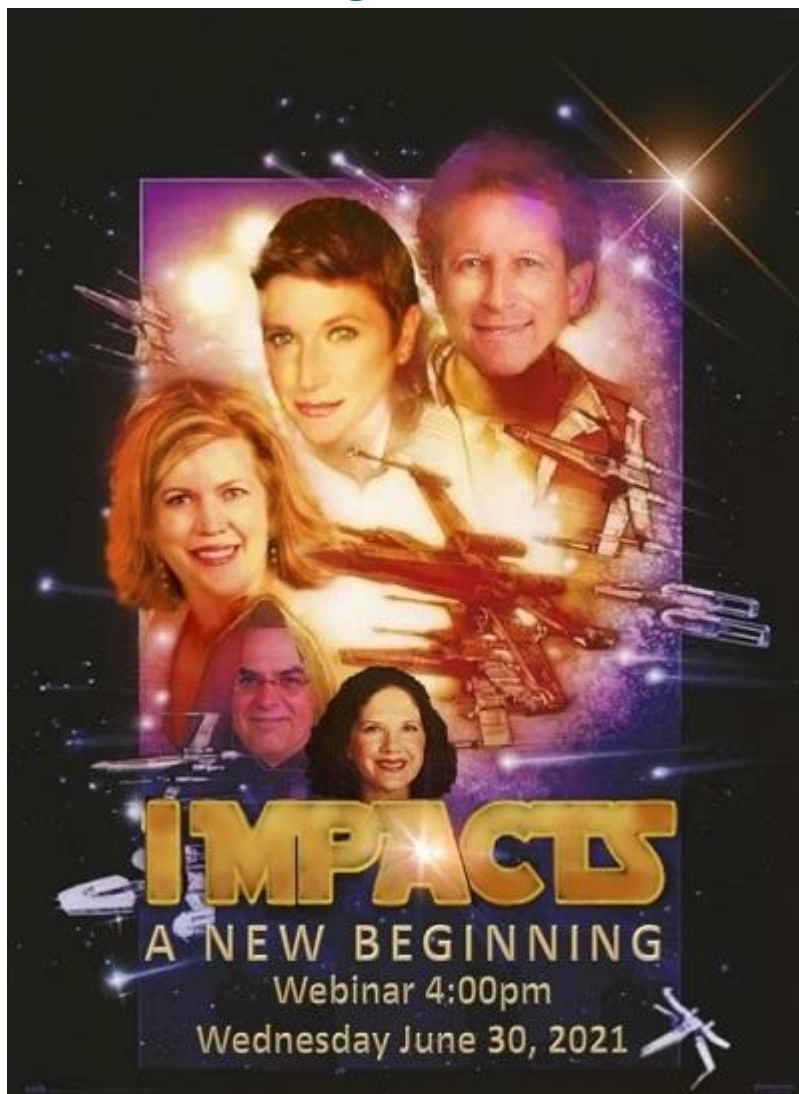
#### **Among Cancer Treatment Survivors**

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

The WF NCORP Research Base study titled *Internet-delivered Management of Pain Among Cancer Treatment Survivors* has been amended.

Big eligibility changes with this amendment include:

- Patients may be either off all treatment OR actively receiving anticancer therapy for active cancer that is considered stable.
- Patients who are no longer receiving anticancer therapy must be  $\leq 5$  years since the completion of their anticancer therapy.

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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.

Thanks for your assistance!

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## Holiday Closures Independence Day (Observed) Monday, July 5, 2021

- WF NCORP RB
- McKesson
- WF Biospecimen
- UAB Lab (for WF-1806-M&M Specimens)
- MD Anderson (for WF-97115-ACUPUNCTURE Specimens)

Normal Operations will resume on Tuesday, July 6, 2021. Please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) if you have questions.

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## Study Updates

### **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](mailto:NCORP@wakehealth.edu).
  - The FAQs have been updated on the WAKE NCORP website: <http://wakencorp.phs.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**

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-97116 REMEMBER – A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairment**

We're almost there! Only **1** more patient to go. Thanks to all who have contributed to this important study. **The site with the final participant will be recognized in the Biweekly newsletter.**

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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)**

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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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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

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July 17, 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

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

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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.
- Please submit consents as soon as possible after patient registration. Please redact or send securely through secure email or RightFax - (336) 713-6476.

### Accruals as of June 23, 2021

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-97116	REMEMBER	275	276		
WF-97415	UPBEAT	356	1000		
WF-1801	RAMIPRIL	46	75		
WF-1802	PCW	121	255		
WF-1806	M&M	43	300		
WF-1901	IMPACTS	5	456	0	40
WF-30917CD	TELEHEALTH	54	90		
WF-1804CD	AH-HA	116	600	5	40
WF-1805CD	HN STAR	5	350	37	140

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