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## STUDY MATTERS

February 15, 2024

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

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**\*\*NEW STUDY OPENING LATE FEBRUARY!\*\***

[WF-2202 - SHINE- Optimizing Psychosocial Intervention for Breast Cancer-related Sexual Morbidity: The Sexual Health and Intimacy Education Trial](#)



**Join us for the Introductory Webinar!**

### **Brief Summary**

The SHINE trial is designed to develop an internet-delivered sexual health program that can help breast cancer survivors with sexual concerns by studying four different cores (i.e., Sexual Health Essentials, Health Care Discussions, Partner Conversations, and Intimacy Insights) in different combinations. This study is a factorial study and seeks to identify which combination of these four intervention core components produces the greatest benefit with the least intervention burden over a 24-week period.

### **Study Population**

Adult women, status post treatment of Stage 0-III breast cancer, who are currently in an intimate relationship and are experiencing sexual concerns. 320 participants will be randomized (20 randomized into each of the 16 conditions).

**Upcoming Introductory Webinar  
February 20, 2024 at 3pm ET**

## Wake Forest NCORP Research Base Website

**\*\*\*If you have already registered, please update your roles on the website\*\*\***

We use this information for targeting email communications and surveys.

**If you have not registered, go to:**  
<https://wakencorp.phs.wakehealth.edu/>

Registering for an account will allow you to:

- Join site calls and other meetings from the Upcoming Events or Calendar sections
- Access study training materials
- View previous study meetings
- Download important study documents including training videos, study guides, and neurocognitive CRFs

**Once registered, you must update your user profile to sign up for study-specific mailing lists and meeting announcements, indicate your NCORP Community site, add your user roles, and update your GCP for database access.**

If you have any questions or need assistance with registration, please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)

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### Upcoming Site Calls

**\*\*Please note that your calendar may not update automatically if changes are made. Please check these emails and our website for meeting updates.\*\***

You can also join site calls from our <https://wakencorp.phs.wakehealth.edu/>. Click the call in the "Upcoming Events" section on the Home page or through the Calendar. You must be a registered user to join from the website.

If you are having trouble joining a call or have any other issues please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)

WF-1806-M&M- Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer  
**February 27, 2:30-3:00 PM ET**

WF-2201-HYPOGRYPHE- Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy  
**March 12, 3:00 PM ET**

WF-1901-IMPACTS- Internet-delivered Management of Pain Among Cancer Treatment Survivors  
**March 13, 2:30-3:30 PM ET**

Please email [7NCORP@wakehealth.edu](mailto:7NCORP@wakehealth.edu) when shipping biospecimen samples to the NCORP Research Base Biospecimens lab (Studies WF-1806, WF-1901, and WF-2201). Include the FEDEX tracking number in your email so that misplaced samples can be tracked before they spoil. Please ship by "FedEx Priority Overnight" (please change this on the pre-printed shipping label if this is not selected).

## Study Updates

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



#### **\*\*UPDATED\*\* - Oncology Medical Abstraction Form in the Usual Care Arm**

The Oncology Medical Abstraction Form has been updated in the Usual Care Arm with additional questions regarding patient diagnosis and treatment. If you're a Usual Care Arm site and have filled out any Oncology Medical Abstraction Forms prior to 2/14/24, please revisit them to answer these additional questions. Thank you for all your hard work on the study. We greatly appreciate your efforts!

#### **Travel Awards!**

We will be presenting two travel awards to our 2024 Wake Forest NCORP RB Annual Meeting in Myrtle Beach, SC! One will be awarded to the site with the **most accruals** and another award will be given to the site with the **most improved enrollment** to the HN-STAR study **between February 1 and September 15, 2024.**

Awards are worth up to \$1,000 each to cover travel and hotel expenses at The Grande Dunes Marriott Resort.

**Let the competition begin!!**

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



## New Spanish Documents Posted

WF-1806 (M&M) Amendment 8, Protocol Version Date 05/23/2023, Release Date 07/14/2023:

- Spanish WF-1806 PtMtl Brochure v.05.24.23\_fill-in
- Spanish WF-1806 PtMtl Study Summary v.05.24.23\_fill-in

**El punto de vista del paciente es importante**

Para saber si podrá participar en el estudio M&M, por favor contáctenos:

Para averiguar más ir a cancer.gov. Apunte: aquí la cámara del teléfono

El estudio M & M incluye preguntas acerca de su experiencia como paciente llamadas "resultados referidos por los pacientes." Tomar en cuenta la voz del paciente ayuda a mejorar la investigación y la atención de los pacientes en el futuro. ¡Usted puede marcar la diferencia!

**¿ Los músculos son importantes? Si se le ha diagnosticado un cáncer de colon o del recto que se ha diseminado a otras partes del cuerpo, usted podría ayudarnos a contestar esta pregunta**

Este es un estudio de Wake Forest NCORP Research Base (WF-1806) patrocinado por agencias públicas del Instituto Nacional del Cáncer (NCI) parte de los Institutos Nacionales de Salud (NIH).

**¿Qué es el estudio M&M?**

Este estudio observa si la baja masa muscular juega o no un papel en los efectos secundarios que usted sufre por el tratamiento de su cáncer.

**¿Su calidad de vida es valiosa?**

Por favor considere participar en el estudio. Lo que aprenderemos nos podría ayudar a reducir los efectos secundarios para pacientes de cáncer en el futuro.

**¿Puedo participar?**

Usted podría participar en el estudio si:

- Tiene 60 años o más y tiene un cáncer colorrectal (cáncer en el colon o en el recto)
- Va a tener o ha comenzado recientemente inmunoterapia y/o quimioterapia
- Puede entender inglés o español para completar las encuestas del estudio

**¿Qué implica participar en el estudio?**

Durante el tratamiento para su cáncer, su médico y el equipo del estudio le observarán para detectar efectos secundarios y registrarlos.

Cuando empiece el tratamiento y de nuevo a los 3 y 6 meses durante sus citas regulares con su médico:

- Encuestas
- Exámenes de las funciones físicas
- Las tomografías que son parte de su cuidado habitual

Una muestra de sangre cuando comience su tratamiento

**Resumen del estudio (WF-1806)**

Estudio M&M: Examinar la masa muscular y su papel en los efectos secundarios de la quimioterapia y/ o de la inmunoterapia en adultos mayores con cáncer colorrectal.

**¿Por qué debería participar en este estudio?**

- La información de su experiencia personal podría ayudar a mejorar la manera en la cual se tratará a pacientes futuros con cáncer colorrectal.
- Las actividades del estudio se llevarán a cabo junto a sus citas regulares del tratamiento. No se necesitarán citas adicionales.
- Usted puede marcar la diferencia para adultos mayores con cáncer en el futuro.

El WF-1806 M&M ayudará a los médicos a descubrir si la cantidad de masa muscular de un paciente afectará a la gravedad de los efectos secundarios durante el tratamiento para el cáncer.

**¿Qué deberá hacer yo?**

- Usted irá a sus citas regulares con su médico.
- Cuando empiece el tratamiento y de nuevo a los 3 y 6 meses, se le podrá que complete una encuesta y una serie de exámenes de fortaleza física.
- Se le tomará una muestra de sangre para el estudio cuando empiece su tratamiento.
- Su médico y el equipo del estudio le observarán para detectar efectos secundarios y registrarlos para el estudio.
- Las tomografías que hacen parte de su cuidado regular se usarán en el estudio para observar su masa muscular.

Participar en este estudio es su decisión. También puede cambiar de opinión en cualquier momento.

WF-1806 Resumen del Estudio para los pacientes v 05.24.2023 Page 1 de 2

**Resumen del estudio (WF-1806)**

**¿Quién participará en este estudio?**

- Adultos mayores de 60 años que tienen cáncer colorrectal que se ha diseminado (metástasis)
- Que van a tener o han comenzado recientemente un tratamiento de inmunoterapia y/ o quimioterapia para su cáncer.
- Que pueden entender inglés o español en el fin de completar las encuestas del estudio.

**¿Cuál es el costo de participar en este estudio?**

Todos los gastos relacionados directamente con el estudio serán costeados por el estudio. Los gastos de su atención médica regular no están relacionados y serán parte de su cobertura existente.

**¿Cómo puedo averiguar más?**

- Busque a WF-1806 en cancer.gov o apunte la cámara de su teléfono al código QR a la derecha. Para información acerca de las instalaciones clínicas donde está disponible el estudio, desplácese hacia abajo en la página hasta Ubicación y Contactos
- Llame al Servicio de Información del cáncer de NCI al 1-800-4-CANCER (1-800-422-6237)
- Para información general sobre el cáncer, visite la página web del NCI al [cancer.gov/espanol](http://cancer.gov/espanol)

Optional: Por favor contáctenos: Insert local site contact information

Estudio de Wake Forest NCORP Research Base, patrocinado por el Instituto Nacional del Cáncer (National Cancer Institute - NCI) parte de los Institutos Nacionales de Salud (NIH).

WF-1806 Resumen del Estudio para los pacientes v 05.24.2023 Page 2 de 2

## WF-1806 Document Access:

- The protocol and participant directed documents are available on the website: <https://www.ctsu.org/>
- The *Helpful Guidelines*, *FAQs*, *Provider Fact Sheet* and *Training Attestation* documents are available on the Wake NCORP website: <https://wakencorp.phs.wakehealth.edu/>

If there are any questions regarding WF-1806 we are glad to help. Please contact us at [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-1806.



### Announcement!

Every site who enrolls to M&M in the month of February will get a special valentine's candygram!

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



### **\*\*DATA ALERT\***

It is important to complete the medication diaries accurately and completely. In the event that the medication diaries are not fully filled out and we require more information regarding the site and patient (PID) information, there may be a slight delay in participants receiving their gift card for submitting their medication diaries.

#### **Before distributing the 7-Day Medication Diary to a patient (in person or by mail):**

1. Ensure that all pages have the **patient header, including PID and page numbers completed**. We recommend making a copy of the form, in case it gets lost in the mail.
2. Please complete the **Medication, Type** and **Dose/Strength** fields on the form for any medication that the participant currently is taking, using the medical record to provide a complete list of all medications. Please provide additional blank pages for medications, supplements or essential oils that the participant may need to add at home later.
3. At timepoints T3 and T4 the two typical usage questions are optional for patients. They are designated as "Staff Only". You may draw a line through them, initial and date these questions, if you prefer.

Participants will not receive payment for lost or unidentifiable diaries.

These items can be completed electronically on the PDF document or hand-written in the spaces provided prior to distribution.

**Please check the Helpful Guide on our website:**

<https://wakencorp.phs.wakehealth.edu/study/wf1901-impacts/> for more information.

**If you have questions about completing these diary forms please contact**  
[NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

**WF-2201 - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy**



**NEW SPANISH DOCUMENT POSTED**

**HYPOGRYPHE (WF-2201) Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy Amendment 3, Protocol Version Date 10/04/2023 was posted on 01/11/2024.**

The Spanish version of the following document was posted on CTSU on Thursday, **January 11, 2024.**

- **Consent Form**, (PVD 10/04/23): Spanish

If there are any questions or your site is interested in participating in the WF-2201 study, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-2201.

Please note, **your site must be IROC certified to participate or be willing to become certified.**

# WF-2300CD - CONNECT Survey - Practice Survey for Multi-Site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers



Caregiver Oncology Needs Evaluation Tool

**\*Practice Interest Form completion requested by TOMORROW, February 16, 2024\***

Thank you to all sites who have participated in the survey so far! We encourage any sites who have not yet completed the Practice Interest Form to do so **by February 16, 2024**. All NCORP Administrators and CCDR Leads should have received a link to the Practice Interest Form in mid-November. If you need the Practice Interest Form link re-sent, please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

If you have enrolled your sites and received the survey link but have not yet completed the survey, please enter your data within 30 days of receiving your survey. If you need the survey link re-sent, please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)

## Steps to Enroll

- 1. Complete Practice Interest Form**
  - Group together sites that share the same providers/community resources
  - If sites do not share providers/resources, then complete a separate Practice Interest Form for each site
  - If you're unsure, it's best to complete separate Practice Interest Forms
- 2. Once the Practice Interest Form is completed, the site contact will receive a Practice ID Email.**
- 3. The site will need to upload the Practice ID Email to CTSU Regulatory Submissions.** Be sure to include the PI name and their CTEP ID in the comments section.

CTSU Cancer Trials Support Unit  
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Home Protocols Dashboard Regulatory OPEN Data Management Auditing & Monitoring RUMS Delegation Log Resources Collaboration CLASS Reports

Site Registration Protocol Requirements Provider Association Regulatory Submissions

Add New Submission

STEPS

1. Select Sites and Protocols
2. Select Submission Priority
3. Upload Document(s)
4. Review and Submit Packet

Documents being submitted are for:

Specific Site(s) and Protocol(s):

Select applicable Site(s) and Protocol(s).  
Select either an individual site and protocol or groups of sites and protocols then click the Add to Cart button. Add all necessary site and protocol selections to your cart then

Pick from my sites:

- Select Site
- Site(s) not in list? Search and select site(s)

Protocols:  
Helpful Hint: Search by Protocol Number. Type minimum 3 characters  
Search Protocol

Add To Cart Reset

#	Site	Protocol
No records were found that matched the criteria		

Message regarding submission (optional)  
Helpful Hint: Provide the IRB number here if it is not indicated within the approval documentation



4. **Once approved, you will enroll each of the sites listed on the Practice ID Email into OPEN**, using the Practice ID. Be sure to enter the Practice ID exactly as stated.
5. **Once all sites from your Practice ID Email are enrolled into OPEN, the site contact will receive their survey(s).**

**\*\*The Introductory Webinars and slides from November 16 and December 12 have been posted to <https://wakencorp.phs.wakehealth.edu/study/wf2300cd-connect-survey/>**

**\*\*Be sure to update your Profile on our website to include this study so that you receive study related information.**

### Accruals as of February 14, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	190	+9	300		
WF-1901	IMPACTS	143	--	250	0	40
WF-1805CD	HN-STAR	228	+3	350	120	140
WF-2201	HYPOGRYPHE	2	--	244		

Open Studies	Name	Enrolled Practice Groups	Change in Past 2 Weeks	Target Practice Groups	Enrolled CTEP IDs	Change in Past 2 Weeks	Max CTEP IDs
WF-2300CD	CONNECT Survey	122	+7	200	224	+11	600

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