



STUDY MATTERS

July 17, 2025

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

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ATTENTION PLEASE!



Current Good Clinical Practice (GCP) certification is required for access to our REDCap database. GCP certification dates in RSS always default to the 1st of the expiration month. **If you receive a notice from REDCap about your account expiring this is most likely due to an expiring GCP certification.** You can upload new certificates to our website (<https://wakencorp.phs.wakehealth.edu/>) or you can email them to NCORP@wakehealth.edu.

2025 Wake Forest NCORP Research Base Annual Meeting

**October 6-8, 2025
Asheville, NC**



Registration link coming very soon!

Upcoming Site Calls



ALERT!

The Site Calls listed below have been transitioned to a **Microsoft Teams** format.

- Click the associated link to add the new **Microsoft Teams** meeting to your calendar.
- **DELETE** the old **WebEx** meeting invitation (entire series not just occurrence).

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

You can also join site calls from our [Wake NCORP website](#). 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

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

This site call series has been cancelled. Please check your calendar and remove any remaining invitations. These were previously scheduled every even numbered month on the second Wednesday at 2 pm ET.

**WF-2301CD - Multi-site Community Oncology Planning for the
CONNECT Intervention Targeting Lung Cancer Caregivers**

July 17, 2025 3:00 PM ET

[Link to WF-2301CD CONNECT Site Call](#)

Study Updates

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

New Spanish-language Documents Posted

**HYPOGRYPHE (WF-2201) Hypofractionated Radiotherapy vs Single Fraction
Radiosurgery for Brain Metastasis Patients on Immunotherapy Amendment
7, Protocol Version Date 05/12/2025 was posted on 06/25/2025.**

**The new Spanish Language document must be implemented within 30 days
of this posting.**

The Spanish version of the following document was posted on CTSU
on **Thursday, July 17, 2025.**

- **Consent Form, (PVD 05/12/25): Spanish**

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

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

NEW AMENDMENT ACTIVATION

HYPOGRYPHE (WF-2201) Amendment 7, Protocol Version Date 05/12/2025, Release Date: 06/25/2025.

The WF NCORP Research Base study entitled *Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy (HYPOGRYPHE)* has been amended. The amended protocol and consent were released on June 25, 2025.

The changes and documents within this amendment must be implemented within 30 days of this posting

The changes include:

- Now allowing Neurocognitive testing after signing consent, but prior to OPEN Enrollment.
- Updated visit windows stated within protocol
- Format changes to protocol cover page.
- Administrative Updates
- Updated CTSU language based on 3/26/2024 support logistical template language document.

WF-2201 Document Access:

- The protocol documents and participant directed documents are available on the [CTSU](#) website.
- The *Helpful Guide* and *Training Resources* are available on the [WAKENCORP](#) website.

Sites interested in participating should contact NCORP@wakehealth.edu; Attn: WF-2201 and request a start-up packet. **Your site must be IROC certified to participate or be willing to become certified.** Refer to Sections 5.2, 6.2 & 6.6 of the protocol for the Protocol Specific Requirements and Site Registration and Credentialing Requirements for site participation.

Regulatory requirements to activate this study can be found in the protocol on the

CTSU website.

If there are any questions regarding the WF-2201 activation, please contact NCORP@wakehealth.edu; Attn: WF-2201.

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

We're still pushing hard to get IMPACTS across the finish line — and we truly can't do it without your help!

We're just **27 enrollments away from reaching our goal of 250 participants**, and the finish line is in sight. The study will officially close for enrollment on **July 31, 2025**.

As a thank-you for your incredible efforts, the top enrolling site will receive a travel award covering hotel and travel expenses to attend the **2025 Wake Forest NCORP Research Base Annual Meeting in beautiful Asheville, North Carolina**.

Let's make this final push together — your dedication makes all the difference! Please reach out to us if you have any questions NCORP@wakehealth.edu

(NEW!) WF2304-A172401- COSMIC - Complementary Options for Symptom Management In Cancer (COSMIC): Assessing Benefits and Harms of Cannabis and Cannabinoid Use Among a Cohort of Cancer Patients Treated in Community Oncology Clinics

NEW AMENDMENT ACTIVATION

COSMIC (WF2304-A172401) Amendment 3, Protocol Version Date 04/01/2025 has been activated.

The WF NCORP Research Base study entitled Complementary Options for Symptom Management In Cancer (COSMIC): Assessing Benefits and Harms of Cannabis and Cannabinoid Use Among a Cohort of Cancer Patients Treated in Community Oncology Clinics has been activated. The protocol and related documents were released on July 11, 2025.

The changes and documents within this amendment must be implemented within 30 days of this posting.

Changes with this amendment include:

1. Updated Inclusion Criteria 4.1.1 to provide specific examples of eligible non-small lung cancer subtypes and added additional criteria, 4.1.6 which states "Participant must reside in the United States, Puerto Rico, Guam or the US Virgin Islands, officially determined per patient report on the Self-reported Screening Survey."
2. Added Inclusion Criteria 4.1.7 "In the treating provider's opinion, the participant should have a life expectancy of ≥ 6 months. Participants in hospice are not eligible" and Exclusion Criteria 4.2.4 "Participants enrolled in hospice."
3. Added Exclusion Criteria 4.2.3 stating "Participant received systemic therapy treatment for prior cancer(s) including chemotherapy, immunotherapy, targeted therapy, or hormonal therapy."
4. Completion of the Baseline survey before Cycle 1 treatment was removed from the Eligibility Criteria in Section 4.3
5. In Protocol, removed references to "additional" measures collected in medical record review for the biospecimen sub-study participants.
6. Statement in Section 6.6 "If participants cannabis and/or cannabinoid use status has changed since initial screening, they will be taken off the Optional Biospecimen Sub-Study." was removed.

7. Protocol and baseline survey reminders changed to say that the Baseline survey can be completed up to midnight of the day receiving Cycle 2 treatment. Currently, it states that the Baseline survey can be completed up to the start of Cycle 2 treatment.
8. On the Main Study + Biospecimen Sub-Study Combined Consent Form, the total amount of blood to be collected at each time point was increased from 1 to 1.5 TBSP / 15mL to 20mL
9. The consent form and protocol have been changed to include two email reminders 1 and 3 days after participants have been emailed the link for the Self-Reported Screening survey
10. Added the study email to the consent forms with a suggestion that the participant add it to their address book to ensure they receive communications.
11. Changed “Questionnaires” to “Surveys” on consent forms. Minor typos and grammatical errors were also corrected on the consent forms.
12. Changes have been made to confidential patient-facing REDCap surveys. These surveys are not available on CTSU for sites to download. Refer to Summary of Changes for a list of the survey updates.

WF2304-A172401 Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The Helpful Guide and FAQs are available on the [WAKENCORP](#) website.
- The introductory site training webinar and associated slides are available on CTSU-CLASS; Course Title: WAKE: WF2304-A172401 COSMIC Introductory Site Training.

If there are any questions, or your site is interested in participating, please contact NCORP@wakehealth.edu; Attn: WF2304-A172401.

Regulatory requirements to activate this study can be found in section 5.0 of the protocol on the CTSU website.

WF2304-A172401 COSMIC – New Spanish-language Documents Now Available

Aligned with (English) COSMIC (WF2304-A172401) Amendment 2, Protocol Version Date 03/11/2025, Release Date 04/04/2025.

The following Spanish-language documents have been approved by the CIRB and are available for use:

- Spanish Surveys – PVD 03/11/2025, available via REDCap on 7/11/2025
- Spanish Recruitment Documents – PVD 3/11/2025, posted to CTSU 7/11/2025 (see below)

The following **Spanish recruitment documents** were posted to the CTSU website on 07/11/2025.

Recruitment Brochure – trifold brochure explaining the COSMIC study with a space for your site's contact information. QR code can be scanned to obtain more information about the study on the cancer.gov website.



Recruitment Flyer – explains the COSMIC study. May be posted in exam rooms, given to the participant while in clinic or mailed to the participant. QR code can be

scanned to obtain more information about the study on the cancer.gov website.



¿CÓMO MANEJA SUS SINTOMAS?

El estudio COSMIC quiere saber cómo los pacientes manejan sus síntomas relacionados con el cáncer.

¿Meditación?
¿Yoga?
¿Hipnosis?

¿Vitaminas?
¿Suplementos?
¿Dietas especiales?

¿Cannabis?
¿Masajes?
¿Acupuntura?

Es posible que pueda participar en el estudio si le diagnosticaron uno de los siguientes tipos de cáncer:

- Mama
- Colorrectal
- Melanoma
- Linfoma no Hodgkin
- Pulmonar de células no pequeñas

También debe tener al menos 18 años y tener planeado recibir tratamiento o haberlo comenzado hace poco tiempo.


Para conocer más sobre el estudio, escanee aquí con la cámara de su teléfono inteligente.

CONTÁCTENOS:

22 Estudio de la Base de Investigación de Síntomas de Cáncer (COSMIC) de la NCI, parte de la Iniciativa Nacional de Cáncer (NCI), parte de la Iniciativa Nacional de Cáncer (NCI).

WF2304 - A172401 - 1/12/2024

Study Summary – a one-page, two-sided summary of the COSMIC study with a space for your site's contact information.



Resumen del estudio (WF2304 - A172401)

El estudio COSMIC quiere comprender cómo los pacientes con cáncer manejan sus síntomas relacionados con el cáncer durante el tratamiento.

¿Por qué debería participar en este estudio?

- Muchos pacientes con cáncer tienen síntomas molestos relacionados con su cáncer e, incluso, con los medicamentos que toman. Los pacientes suelen tratar de aliviar sus síntomas de diferentes maneras.
- El estudio COSMIC quiere comprender los posibles riesgos y beneficios de las maneras elegidas por los pacientes. Algunos ejemplos incluyen terapias como la acupuntura o la meditación, el uso de cannabis, suplementos dietéticos y muchos otros.

Por su participación en el estudio COSMIC, podrá recibir de \$10 a \$20 por cada encuesta mensual que complete.

¿Qué tendré que hacer?

- Se le pedirá que complete una encuesta corta para ver si es elegible.
- Si es elegible para el estudio, se le pedirá que participe en el estudio durante alrededor de 13 meses y complete las siguientes encuestas:
 - Encuesta inicial (de referencia)
 - 12 encuestas mensuales (1 por mes durante 12 meses)
- Cada encuesta se realiza de forma electrónica y es confidencial. No se compartirán sus respuestas con su equipo médico.

La participación en este estudio es elección suya y podrá cambiar de parecer en cualquier momento.

¿Quién participará en este estudio?

Adultos de 18 años o más que:

- Estén siendo tratados actualmente por uno de los siguientes tipos de cáncer recién diagnosticado: cáncer de mama, cáncer colorrectal, melanoma, linfoma no Hodgkin o cáncer pulmonar de células no pequeñas.
- No hayan iniciado tratamiento o estén en las primeras etapas del tratamiento.
- Estén dispuestos a participar en el estudio durante 13 meses y completar una encuesta electrónica cada mes.
- Estén recibiendo atención médica de una clínica oncológica.

¿Cuál es el costo de participar en este estudio?

Todos los costos relacionados directamente con el estudio serán pagados por el estudio. Los costos de su atención médica regular no están relacionados y estarán a cargo de su cobertura existente. El estudio no cubre cargos de internet o consumo de datos celulares personales.

¿Cómo puedo saber más?


- Visite [El estudio COSMIC](#) o escanee el código QR a la derecha con la cámara de su teléfono inteligente.
- Llame al Servicio de Información sobre el Cáncer del NCI al 1-800-4-CANCER (1-800-422-6237)
- Para información general sobre el cáncer, visite el sitio web del NCI en [cancer.gov/espanol](#)

Insert local site contact information

WF2304-A172401 Resumen del estudio para pacientes - 02/06/2024

Página 1 de 2

Recruitment Letter or Email – one page letter explaining the COSMIC study with a space for your site’s contact information.



(IF DESIRED: INCDP SITE LETTERHEAD)

[Title]

Estimado(a): (patient's name)

Esta carta es para informarle sobre un estudio de investigación que puede interesarle. Nos comunicamos con usted porque hemos identificado que es una persona que actualmente está siendo tratada por uno de los siguientes cánceres recién diagnosticado: cáncer de mama, colonrectal, melanoma, linfoma no Hodgkin o cáncer pulmonar de células no pequeñas.

El estudio COSMIC (vea elige en inglés para [Opciones Complementarias para el Manejo de Síntomas en el Cáncer](#)) se está realizando porque queremos comprender cómo los pacientes manejan sus síntomas relacionados con el cáncer durante el tratamiento. Queremos entender la positiva y la negativa de las distintas opciones. Esto incluye terapias complementarias como acupuntura y meditación, así como el uso de suplementos como cannabis y suplementos dietéticos. Para saber si puede participar en el estudio COSMIC, se le pedirá que complete una breve encuesta.

- Si califica para el estudio, se le pedirá que complete una encuesta inicial (de referencia), ya sea al iniciar su tratamiento de cáncer habitual o poco después.
- Después de terminar la encuesta inicial, se le pedirá que complete una encuesta en línea todos los meses durante 12 meses más.
- En el estudio entero habrá 14 encuestas (1 encuesta de selección, 1 encuesta inicial y 12 encuestas de seguimiento) y su participación en el estudio durará alrededor de 13 meses.

Como muestra de nuestro agradecimiento, se le compensará por su tiempo con tarjetas de regalo electrónicas en varios momentos durante el estudio, por un valor de \$20 a \$25 por cada encuesta mensual.

Si desea saber más sobre el estudio o saber si podría ser elegible para participar, comuníquese con:

[Local Site CONTACT information]

WFO0000 – AUTOMATED COSMIC Contact/Screening electronic para pacientes v 1.0 06.2020 Página 1 de 1

Patient Portal Message – one page message explaining the COSMIC study with space for your site’s contact information; distributed via the patient portal/MyChart.



Mensaje de reclutamiento para un estudio de investigación para MyChart o otro portal de pacientes con Registros Médicos Electrónicos (RME)

Subject Line of Message: Oportunidad para participar en un estudio de investigación: ¿Cómo maneja usted los síntomas relacionados con el cáncer?

From (Line of Message (Who will the message be sent by?)) **[INSERT NAME OF LOCAL INSTITUTION]**

Message Body:

El cáncer afecta la calidad de vida de muchas maneras. El manejo de los síntomas es diferente según la persona. Investigadores de todo el país, incluido su equipo de atención del cáncer, están reclutando para un importante estudio llamado COSMIC. En este estudio, los investigadores recopilarán información confidencial sobre la forma en que las personas manejan sus síntomas relacionados con el cáncer.

Si le interesa participar en el estudio COSMIC, siga leyendo para obtener más información.

Usted puede ser elegible si le diagnosticaron hace poco tiempo uno de los siguientes tipos de cáncer:

- Mama
- Colonrectal
- Melanoma
- Linfoma no Hodgkin
- Pulmonar de células no pequeñas

Debe tener pensado recibir tratamiento o haber iniciado tratamiento hace poco tiempo.

Lo que se le pedirá que haga:

- Participar en el estudio durante alrededor de 13 meses.
- Completar encuestas confidenciales cada mes en su teléfono, tablet o computadora.

Usted puede recibir \$20-\$25 por cada encuesta mensual que complete.

Si le interesa participar, **[\[INSERT CONTACT INFORMATION HERE\]](#)**

Gracias por su tiempo.

[INSERT LOCAL STUDY CONTACT/STUDY NAME]

WFO0000 – AUTOMATED COSMIC Message para pacientes de portal v 1.0 06.2020 Página 1 de 1

Regulatory requirements to activate this study can be found in the protocol on the CTSU website.

If there are any questions regarding the WF2304-A172401 activation contact NCORP@wakehealth.edu Attn: WF2304-A172401. To request printed copies of recruitment materials, please use the WF2304-A172401 Recruitment Request survey: <https://redcap.link/WF2304-A172401.RecruitmentMaterials>

TRAVEL AWARD COMPETITION

Our Research Base will be offering a travel award to one site for each of the following studies: WF-1806 (M&M) , WF-1901 (IMPACTS) and WF-2301CD (CONNECT). The travel award will be given to the sites with the most enrollment between January 1st, 2025 – July 31, 2025, one award per study. This award will help cover expenses up to \$1000 for travel to the 2025 Wake Forest NCORP Research Base Annual Meeting in Asheville, North Carolina!

Wake Forest NCORP Research Base Website

Reminder: Additional resources, **which are not CIRB approved**, are maintained on our Wake Forest NCORP RB website and **are not available on CTSU**. Note, these resources include a **Helpful Guide** for each study, which provides guidelines for the study team, as well as other study instructions.

Remember to update your profile to include any new studies you may be involved in

We use this information for targeting email communications and surveys.

<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.

Accruals as of July 16, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)
WF-1806	M&M	247	+1	300	
WF-1901	IMPACTS	223	--	250	12
WF-1805CD	HN-STAR**	357	--	350	135
WF-2201	HYPOGRYPHE	33	+2	244	
WF-2202	SHINE**	341	--	336	
WF-2301CD	CONNECT	64 (pt/ caregiver dyad)	+1	120 (dyads)	
WF2304-A172401	COSMIC	600	+21	2000	
		Practices Enrolled	Change in past 2 weeks	Target (Practices)	Enrolled (Non-Patients)
WF-2303CD	HRSN	19	--	20	75

****Closed to enrollment**

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