CONSENT FORM FOR RESEARCH
For Cedars-Sinai and Participating Affiliates[1]

Study title: Implementation of a Nurse-Led Clinical Program to Decrease Sexual Dysfunction among Gynecological Cancer Patients

Study support provided by: Cedars-Sinai

Cedars-Sinai Principal Investigator: Dr. Leah Spiro

Co-Investigator: Corina Hernandez, NP

Cedars-Sinai study contact phone number: 310-423-6074

To help guide your review of this form, the main sections include:

[1] The **Cedars-Sinai Affiliated Covered Entity ("ACE")** is comprised of covered entities under the common ownership or control of Cedars-Sinai Health System, including Cedars-Sinai Medical Center (CSMC); Cedars-Sinai Medical Care Foundation; Cedars-Sinai Marina Del Rey Hospital (MDRH); Torrance Memorial Medical Center (TMMC); Torrance Health Association, Inc., d/b/a Torrance Memorial Physician Network; Huntington Hospital (HH), and Huntington Medical Foundation.

1. Key Information

Thank you for considering research participation. Research helps make medical and scientific advancements possible. In this form, we are asking for your consent to take part in this research study. Taking part in this research study is voluntary.

This section provides key information about the study. Please take your time to read this entire form. Also, please ask questions before deciding whether to take part in this research study. You are welcome to talk with family, friends and other healthcare providers before you decide.

- **Purpose:** The purpose of this study is to try out a program run by nurses that aims to make treatment for sexual dysfunction better for patients with gynecological cancer. We hope this program will help by doing more screenings and making more referrals. Section 2 includes more details.

- **Duration:** Taking part in this study will last about 12 weeks.

- **Procedures:** The main things that will happen in this study are: Completing a visit with an advanced practice provider, filling out a survey (Female Sexual Function Index), and a review of medical records. Section 3 includes more details.

- **Benefits:** The possible benefits of taking part in this study are experiencing an improvement in sexual dysfunction treatment. Section 4 includes more details.

- **Risks:** All research studies involve some risks. Risks or discomforts from this study may be: Answering personal questions during the survey may cause you to feel uncomfortable. Our data security systems are designed to protect your personal health information. There is always a chance that a data breach could occur. Section 5 includes more details.
    - If you have problems during the study, contact the study team using the contact information on the first page of this consent form.

- **Alternatives:** You can choose not to be in the study. There may be other choices for you. These are described in Section 8 of this form.

- **New Information:** During the study, we may find out new information about this study. We will tell you about any important changes or new findings that may impact your decision to continue taking part in the study.

2. Purpose of the Study

We are doing this study to test a nurse-led clinical program that will hopefully improve the care a patient receives for their sexual health. Sexual dysfunction is a common issue for female cancer survivors after treatment, but it is rarely discussed between patients and their

providers. This study hopes to improve sexual health treatment by increasing provider knowledge of sexual dysfunction and providing a patient with more resources.

You are being asked to take part in this research study because you are a patient of the division of gynecologic oncology and have completed treatment for your cancer in the past twelve months.

The study will include up to 35 people total.

3. Study Procedures

This section talks about what will happen in this study.

When you read this section, also read the table of procedures. The table is given with this consent form. The flowchart of procedures shows a timeline of the study.

The table of procedures shows:

- When study procedures will occur,
- Whether they will be covered by the study or billed to you and/or your insurance, and
- Which study procedures are research-related and which are standard of care (routine).

Research-related procedures are procedures done only for the research study. They would not be performed for your routine care outside of the study. **Standard of care (routine) procedures** are routine care generally given to people with your condition. They would be performed even if you did not take part in this study. The researchers will schedule the visits and procedures at the listed timepoints.

The procedures in this study are often part of routine care for a person with your condition. They are not experimental procedures. The procedures and their risks are research-related. This means they are being done only for research purposes. These common procedures and their risks should be the same as when performed outside this study.

Description of research procedures:

- **Questionnaires:** You will be asked to complete a questionnaire. We will ask you questions to find out if the nurse led program helps improve sexual function. We think it should take about 5-10 minutes to complete the questionnaire. Questionnaires will ask you to respond to sensitive questions about overall sexual function.

- **Demographic Information:** We will ask you about demographics, which may include your age, gender identity, sexual orientation, race and ethnicity.

- **Medical History Review:** We will ask you about your medical and surgical history.

How long will you be in the study?
We think you will be in this study for about 12 weeks.

4. Possible Benefits From Taking Part in the Study

Being in this research study may or may not have direct medical benefit to you. The possible benefits of taking part in the research study are an improvement in screening and treatment for sexual dysfunction and possible referrals for sexual health support. However, no benefit is guaranteed. It is possible that your condition may stay the same or even get worse.

We hope the information learned from this research study will improve the sexual health care provided to gynecologic cancer survivors and improve the knowledge of gynecologic cancer nurses regarding sexual dysfunction.

5. Possible Risks and Discomforts of the Research Procedures

This section talks about the possible risks and discomforts of the study procedures.

- **Questionnaires:** Some questions may make you feel uncomfortable or embarrassed. The questionnaire will be labeled with a unique study number. This will link your identity so that only the research team can recognize you.

- **Demographic Information:** This does not have any physical risks.

- **Medical History Review:** This does not have any physical risks.

6. Reasons Participation May Be Stopped by the Researcher or Sponsor

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. If your participation is stopped early, the researcher will discuss next steps with you. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.

7. Voluntary Participation and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of

benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

8. Confidentiality Protections

General Confidentiality

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitor the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

Sharing Information or Samples

We might share your information and/or research samples collected in this study. The information shared may include genomic data and health data or samples that could be used in future genomic research. It might be shared with other researchers at Cedars-Sinai, other researchers outside of Cedars-Sinai, or third-party commercial entities for future research without additional informed consent from you. In some cases, your information and/or specimens may be submitted to a database or repository for future research. These databases and repositories have safeguards to prevent inappropriate access to and use of the information and specimens. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai. However, there is a remote possibility that someone could identify you.

9. Research-Related Illness or Injury

Contact in Case of Illness or Injury

We do not expect you will have any illness or injury from this research study. If you believe that you are ill or have been injured from this study, please contact the study team at the phone number listed on page 1 of this consent form.

10. Financial Considerations

Costs of Participation

The attached flowchart lists items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the Study Sponsor. Review the flowchart for details.

For items billed to your insurance, you remain responsible for all deductibles, copays and balances under your health benefit plan. If your insurance company does not pay, you will be billed for those charges. If you have questions or concerns about your insurance coverage, you should ask your health benefit plan.

Payment

You will not be paid for taking part in this research study.

Financial Interest in the Research

The principal investigator and institution have no potential financial conflict of interest with this study.

11. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH
FOR CEDARS-SINAI AFFILIATED COVERED ENTITIES[2]

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "**Implementation of a Nurse-Led Clinical Program to Decrease Sexual Dysfunction among Gynecological Cancer Patients**" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☐ Laboratory tests
☐ Pathology reports
☐ Imaging reports (e.g., x-rays or scans)
☐ Photographs or videos of your image
☒ Doctor/clinic records
☒ Hospital/medical records
☐ Billing records

☒ Demographics, which may include, but is not limited to, age, gender identity, race, ethnicity, and/or sexual orientation
☐ Mental health records
☐ Substance abuse records
☐ HIV test results

☒ Other tests or other types of medical information: Questionnaires

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

Your private information will be used by and/or shared with the Research Team.

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In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.
- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

Table of Visits, Tests and Procedures

Legend
R = Research item/procedure done only for research purposes and their costs are covered by the study. You are not responsible for the costs of these procedures.
S = Standard of care item/procedure that is part of regular care and billed to the patient/insurance. You and your insurance company will be responsible for these costs.

Procedures	Screening Period	Visit #1	Telephone Call	8-10 weeks after Visit #1
Informed Consent	R			
FSFI Survey	R			
Medical History		S		
Medication History		S	R	
Pelvic Exam		S		
Focused Sexual Health Questions		S		
Sexual Health Plan of Care, Education, and Referrals		S		
FSFI Survey				R

Footnotes:

Signature Page

Consent Form for Research and Authorization for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

Signature by the Investigator
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date

Signature by the Interpreter/Witness
(Signature of an interpreter is only required when enrolling a non-English-speaking subject with the assistance of an interpreter and IRB-approved "short form" consent processes. The

witness may be any person who is conversant in both English and the language of the non-English-speaking subject, such as a certified hospital interpreter, study staff, a family member or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.

Signature of a witness is required when an English-speaking subject who has been determined to have capacity to consent is unable to read or physically sign the consent form but chooses to indicate via a "mark" or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred and that the individual verbally consented to participate in the research.)

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Interpreter/Witness name (please print) Signature Date of signature