OREGON HEALTH&SCIENCE UNIVERSITY

Information Sheet and Authorization
STUDY00023097

TITLE: Taking A Life Course Perspective To Examine Critical Points Of Intervention For Latinx Women Diagnosed With Cervical Cancer

PRINCIPAL INVESTIGATOR: Cirila Estela Vasquez Guzman Ph.D. 503-494-3660

WHO IS PAYING FOR THE STUDY?: National Center for Advancing Translational Sciences, OHSU Center for Women's Health Julie Stott Research Fund for Women's Cancer, and Office of Research on Women's Health.

WHY IS THIS STUDY BEING DONE?:

You have been invited to be in this study because you are a person that identifies as a Latina woman who is 35 years or older. You may have been diagnosed with cervical cancer, or you had a biopsy and were told that abnormal cervical cells were found. The study team wants to know more about your experience with diagnosis and treatment.

This is an interview study. This means that your current treatment and medical care will not change because you are participating in the study. We are also asking you to provide information for a data bank, also called a repository. This information will be stored indefinitely and may be used and disclosed in the future for research. Up to 40 people will take part in this study.

WHAT PROCEDURES ARE INVOLVED IN THIS

STUDY?:
You will be asked to complete an interview with the study team, which may last up to 3 hours. The study team will contact you via phone, or if you agree by email or text to arrange and remind you about your interview. Interviews will be conducted in person, via phone, or video conference. You may discuss with the study team which option works best for you. During the interview, the research team will ask questions about your experience with diagnosis and treatment. Each interview will be recorded. You may choose whether it is just audio recorded or audio and video recorded. Let the study team know your preference at the time of the interview. We will store the recordings and transcript of your interview in a data repository. This data may be used for future education and research purposes, without additional informed consent from you.

If you have any questions, concerns, or complaints regarding this study now or in the future, or you think you may have been injured or harmed by the study, contact Cirila Estela Vasquez Guzman Ph.D. 503-494-3660.

In the future, your information may be given to researchers, or the funders for other research studies. The information will be labeled as described in the **WHO WILL SEE MY PERSONAL INFORMATION?** section.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:
Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. Texts and

emails will be not be encrypted (data converted code, especially to prevent unauthorized access). If you choose to communicate via text or email there is a risk that information could be disclosed. You can opt out of text messaging at any time.

This can be emotionally triggering and/or some questions may feel uncomfortable brining up memories of difficult times. You are free to skip any question and/or do not need to respond to all.

If you agree to optional data sharing with HERN, portions of your interview may be fully identifiable on the internet. When content from the interview is posted it could contain information such as your name, or details of your experience with treatment. You will have an opportunity to review the content of your interview and cross out any material that you wish to exclude. The options for sharing your interview will be described in a separate "Future Use of My Interview" form.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?:

You may or may not benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS STUDY?:

You may choose not to be in this study.

WILL I RECEIVE RESULTS FROM THIS STUDY?

You will have an opportunity to review your transcript prior to

use. You may also request audio recordings and video recordings of your interview prior to use. We may ask for your email address in order to send you your transcripts.

WHO WILL SEE MY PERSONAL INFORMATION?:

In this study we will take steps to keep your personal information confidential, but we cannot guarantee total privacy. We will assign a code to you to label your study data. The code will not identify you in any way, and only the study staff will have access to the link that would identify you. We may request your social security number in order to process any payments for participation. In the future, your information may be given to researchers for other research studies. Other investigators who may receive your information for research will be given only the code number which will not identify you.

We may have to release this information to others for example, if the study is audited. However, we would try to do so without information that could identify you. This release could be to the Institutional Review Board (ethics review committee) at OHSU, The funders of this study, National Center for Advancing Translational Sciences (NCATS), OHSU Center for Women's Health Julie Stott Research Fund for Women's Cancer, and Office of Research on Women's Health , the National Cancer Institute (NCI), or Office of Human Research Protection (agencies that oversee research).

If your information goes outside of OHSU, it might not be protected under federal law from being used or further shared. We would like your permission to keep your data indefinitely. If

you decide you don't want us to use your name and information for this research you can request this by contacting us at:

Cirila Estela Vasquez Guzman Ph.D.
Family Medicine Department
3405 SW Perimeter Ct, Portland OR 97239
503-494-3660
vasquest@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. If you choose not to participate, or if you decide to stop at any time, that will not affect your ability to receive health care or insurance coverage. We may continue to use and disclose your information as described above indefinitely.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT? Information including any videotapes, or audiotapes about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or

ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?: There will be no cost to you or your insurance company to participate in this study. You will receive $100 for participating in the study. You may receive payment via gift card or a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet. We may request your social security number in order to process any payments for participation.

WHERE CAN I GET MORE INFORMATION?:

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and

available 24 hours a day, 7 days a week).

DO I HAVE TO TAKE PART IN THIS STUDY?

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

HOW DO I TELL YOU IF I WANT TO TAKE PART IN THIS STUDY?

Please tell us if you agree to participate in this research when we ask you before the interview starts.

OPTIONAL DATA SHARING WITH THE HEALTH EXPERIENCES RESEARCH NETWORK (HERN)

HERN is a group of researchers creating a collection of patients' narratives in order to make patients' voices available to researchers and clinicians. The purpose of this option is to share audio, video, or written transcripts of your interviews with the HERN for research, teaching, and-non-research purposes, including the creation of a website of health and illness experiences https://www.healthexperiencesusa.org. The website will be available to the public and use text, audio, and video clips from interviews to show what it is like for people facing illness or other health issues.

The options for sharing your interview with HERN will be described in a separate "future use of my Interview" form. After

you have reviewed your transcript, if you would like to participate in this optional data sharing, you may sign the "Future Use of My Interview" form. Your decision to participate in data sharing with HERN will not affect your participation in the interview. This website shows examples and may give you a better idea of how your information may be used: https://healthexperiencesusa.org/Depression-in-Young-Adults/overview