This consent form is not valid without a TTUHSC EP IRB stamp in the lower left corner of each page.

CONSENT TO TAKE PART IN A RESEARCH STUDY

This is a research study for people who voluntarily choose to take part. Please take your time to make a decision, and discuss the study with your personal doctor, family, and friends if you wish.

STUDY TITLE: Con cariño: Using Promotoras for a Hispanic Community Palliative Care Intervention – A pilot study

INVESTIGATOR(s): Vijaya Galic, MD, and Gabriela Villanueva, MD

CONTACT TELEPHONE NUMBERS: 915-215-5109
(You may contact the investigator(s) at the number listed above during normal business hours if you develop any of the conditions listed in Question #8 of this form or if you have any unexpected complications.)

INSTITUTION: Texas Tech University Health Science Center El Paso

1. **Why is this study being done?** This study is being done to investigate how a culturally sensitive palliative program (specialized medical care for people with serious illness) affects end of life care, quality of life, depression and pain among cancer patients.

2. **How many people will take part in this study?** We plan for 200 participants to take part in the study.

3. **Why am I being asked to participate in this research study?** You are being asked to participate in this research study because you are 18 years old or older, Hispanic, and have cancer.

4. **What will happen during this study?** If you qualify for the study, you will be randomized into either the control group or the study group. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed into either group.

   If you are placed into the study group, you will be asked to attend 3 educational meetings with a promotora, also known as a community health navigator and other participants to discuss a variety of educational topics such as the benefits of physical activity, the benefits of nutrition, pain management, family values, and planning for the future. If you are in the control group, you will not meet with the promotora in person. You will receive your standard of care as usual, and will only be asked to participate in two structured interviews either by phone or in person. In a structured interview, a member of the research team will as you a predetermined set of questions.

In both arms, you will receive educational materials and you will be asked to complete a series of questionnaires about your health, quality of life, pain, and depression symptoms. A chart review of your medical records will be conducted to review your cancer diagnosis and if any hospital visits have occurred up to a year after you have enrolled into the study.

It is important for the investigators to contact you. We will request you provide a current phone number, email address (if available), and address so that we may contact you to inform and remind you about the meetings with the promotora or to conduct the telephone interviews.

5. **What will be done that is different from my usual care?** If you are placed into the study group, you will be asked to attend 3 educational meetings with a promotora, this will be separate from your scheduled medical appointments. In these meetings you will meet with other participants to discuss educational topics already described. If you are in the control group, you will participate in two structured interviews either by phone or in person.

   As part of the research procedures, you will be asked to complete a series of questionnaires about your health, quality of life, pain, and depression symptoms. You may fill out the survey yourself or a member of the research team can conduct the survey as a structured interview. A chart review of your medical records will be conducted with your permission.

6. **How much time will this study take? How long will I be in your study?** Your participation in the study will be for one year after enrollment. Your active participation, if you are a part of the study group, will take approximately 4 hours total over a three month period which will include the meetings with the promotora. There will be three educational meetings which will take approximately 45 minutes each. Additionally you will be asked to complete a baseline survey that will take about 25 minutes.

   If you are in the control group, the study will take approximately 2 hours total over a three month period which will include two phone surveys. You will be asked to complete a baseline survey that will take 25 minutes. You will also receive 2 phone calls that will take about 15 minutes each.

7. **Are there any benefits to <u>me</u> if I take part in this study?** It is possible by participating in this study; you may experience a decrease in depression and pain symptoms, an improvement in quality of life, and important information about end of life care and advanced directives.

8. **What are the risks or discomforts to me if I join this study?** The study does pose a risk of increased anxiety as a result of awareness. Patients actively involved with end of life discussions in a group education setting may experience anxiety surrounding end of life issues through involvement in activities directly addressing end of life issues. The treating

oncologists involved in the study recognize this and are prepared to provide medical support and referral for psychological support if needed.

9. **Will there be added risks to me from this study if I am female?** No.

10. **What other choices do I have if I don't take part in the research study?** Taking part in this study is your choice. You do not have to take part in this study. If at any time you decide not to be in the study, it will not affect any benefits or rights to which you are entitled.

    If you are a student or employee, your participation in this study will have no effect on your grades or employment status.

11. **What about confidentiality and the privacy of my records?**
    We will keep your involvement in this research study confidential to the extent permitted by law. In addition to the staff carrying out this study, others may learn that you are in the study. This might include federal regulatory agencies such as the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), Texas Tech University Health Sciences Center El Paso (TTUHSC EP) representatives, representatives from any hospital or site where the research takes place, and the TTUHSC EP Institutional Review Board (a committee that reviews and approves research). These people may review and copy records involving your participation in this research.

    Study results that are used in publications or presentations will not use your name.

12. **Who is funding this study?**
    The TTUHSC EP Department of Obstetrics and Gynecology is providing the space and supplies for this study. No one on the research staff will receive anything of value from other agencies, organizations, or companies to carry out this research.

13. **Will it cost me anything to take part in this research study?** No.

14. **Will I receive anything for taking part in this research study?** As a way to thank you and compensate you for your time, you will receive a gift card based on which arm of the study you are participating. This will be provided to you in the form of a Visa gift card.

    If you are in the study group, you will receive $25 at randomization, $10 at the first meeting with the promotora, $10 for the second meeting with the promotora, $25 at the third meeting with the promotora where exit surveys will be administered. You will be compensated for you time in this study up to $70.

    If you are in the control group, you will receive $25 at randomization, $15 will be mailed to you after your first phone interview, and $30 will be mailed to you after your second phone interview.

    Payment for participation in this research is considered taxable income. In order for you to receive payment for this research, we will need to collect your name, address, and social

security number. If you are not able to provide this information, 30% of the amount being paid for this research study will be automatically deducted and sent to the Internal Revenue Service (IRS).

If you receive payments that total more than $600 in one calendar year, Texas Tech University Health Sciences Center El Paso is required to report this information to the IRS. A Miscellaneous Income form (1099-MISC) will be sent to you and to the IRS.

15. **Does anyone on the research staff have a personal financial interest in this study?** No.

16. **What if I am hurt by participating in this study?** Texas Tech University Health Sciences Center El Paso and University Medical Center does not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness.

    It is very unlikely that you will be hurt by participating in this study.

    If you have a research related illness or injury, care will be available to you as usual, but you and/or your medical or hospital insurance company will be responsible for the cost of treatment. Before entering this study, you should check whether your insurance company might limit your insurance coverage if you take part in a research study.

17. **What are my rights as a voluntary participant?** Taking part in this study is your choice. If you sign this form, it means that you choose to be in the study.

    You may also choose not to be in this study. If you decide not to be in the study, it will not affect any medical care, benefits or rights to which you are entitled.

    If new information becomes available during the study that may affect your willingness to take part in the study, you will be told.

18. **Can I stop being in the study?** You may leave the study at any time. If you leave the study, we cannot remove any information we have collected to that point.

19. **Can someone else end my participation in the study?** Under certain circumstances, the investigators, TTUHSC EP, or the study sponsor may decide to end your participation in this research study earlier than planned. This might happen because you become incapacitated due to your illness such that you are unable to respond to the survey questions or attend the meetings.

20. **What if I have questions?** For questions about this study, contact the Investigator, Vijaya Galic, M.D. at 915-215-5109.

    If you would like to speak to someone who is not involved in the study about your rights as a participant, research-related injuries, or any other matter related to the study, you can call

the TTUHSC EthicsPoint Hotline: 1-866-294-9352.

Or, you can file an EthicsPoint report online: https://secure.ethicspoint.com/domain/media/en/gui/44534/index.html. Please choose the "Regulatory Compliance" option when making an online report.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

Your signature indicates that:

- **this research study has been explained to you,**
- **you have been given the opportunity to ask questions and have received answers;**
- **you agree to take part in this study.**

You will be given a signed copy of this form.

_____
Printed Name of Subject

_____ _____ AM/PM
Signature of Subject Date Time

_____ _____ AM/PM
If applicable, Signature of Authorized Representative Date Time

I have discussed this research study with the subject using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation. I have given a copy of this form to the subject.

_____
Printed name of authorized research personnel who conducted the informed consent discussion

_____ _____ AM/PM
Signature of authorized research personnel who conducted the informed consent discussion Date Time

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO
AUTHORIZATION TO USE AND/OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION for a RESEARCH STUDY

STUDY TITLE: Con cariño: Using Promotoras for a Hispanic Community Palliative Care Intervention – A pilot study

This form is intended to tell you about the use and/or disclosure (sharing) of your personal **Protected Health Information** (PHI) if you decide to participate in the research study described on the previous pages. The health information about you that may be used or disclosed is described below. This information is usually found in your medical records. Only the health information about you that is needed for this research study will be used or disclosed. When you consider taking part in this research study, you are also being asked to give your permission for your Protected Health Information to be released from your doctors, clinics, and hospitals to the research personnel approved for this research study. This Authorization specifically relates to the research study described in the attached Informed Consent document.

1. This Authorization is valid indefinitely or until such time as legal requirements will allow this Authorization to be destroyed.

2. If you choose to cancel this Authorization, please give notice in writing to:

TTUHSC-EP Privacy Officer
Office of Institutional Compliance
5001 El Paso Drive
El Paso, TX 79905

If you sign this Authorization, the following persons, groups or organizations may rely on this Authorization to disclose your Protected Health Information to the Principal Investigator and other research personnel who are conducting this Study:

- your treating physicians and healthcare providers and their staff,
- associated healthcare institutions and hospitals where you have or may receive care.

While this research study is in progress, the Principal Investigator or research personnel working on this study will inform you whether or not you will be allowed to see the research related health information that is created about you or collected by the research personnel prior to the end of the study. After the study is finished you may request this information as allowed by the TTUHSC EP Notice of Privacy Practices.
The Protected Health Information that you authorize to be used or disclosed for research purposes may include your current or future health information from some or all of your health records, including:

• hospital records and reports • admission history, and physical examination	• immunizations • allergy reports

• X-ray films and reports; operative reports • laboratory reports, treatment and test results (including sexually transmitted diseases, HIV or AIDS) • any other Protected Health Information needed by the research personnel listed above. (* use separate form for disclosure of psychotherapy notes)	• prescriptions • consultations • clinic notes • mental health records • alcohol / substance abuse records

For the purposes of this study, your Protected Health Information may need to be reviewed or disclosed to individuals or organizations within and/or outside of TTUHSC EP who sponsor, approve, assist with, monitor or oversee the conduct of research studies. This includes, but is not limited to, the TTUHSC EP Institutional Review Board, TTUHSC EP compliance reviews, the US Food and Drug Administration (FDA) or governmental agencies in other countries. Some of these individuals or organizations may share your health information further, and your health information may not be protected by the same privacy standards that TTUHSC EP is required to meet.

If you choose to sign this Authorization form, you can change your mind about this later. If you change your mind, send a letter to the person identified above telling us to stop collecting and sharing your Protected Health Information. When we receive your request, you may be asked to leave the research study if all the necessary information has not been collected. We may still use the information about you that we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

You have the right to refuse to sign this form. If you choose not to sign this form, your regular health care will not be affected. However, not signing this form will prevent you from participating in this research study and prevent you from receiving research related health care services provided under this study.

I have had the opportunity to review and ask questions regarding this Authorization to use or disclose my personal health information, and I will receive a copy of this form. By signing this Authorization, I am confirming that it reflects my wishes.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____ _____
If applicable, Signature of Authorized Representative Date