COVER SHEET:

Title of Study:

Nueva Vida Intervention for Latina Breast Cancer Survivors and Caregivers

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Informed Consent (Trial Phase)

#: _____ Date: _____
Team Member: _____
Consent achieved (**circle one**):
By Phone In Person

Hello, my name is: _____ and I am from (**circle one**:) Nueva Vida; Gilda's Club NYC; SHARE; Latinas Contra Cancer. I would like to talk with you about a research project. (**Circle one**:) Nueva Vida; Gilda's Club NYC; SHARE; Latinas Contra Cancer SHARE and I are part of a team that is doing a research study called "Nueva Vida Intervention for Latina Breast Cancer Survivors and Caregivers". This study is being led by Dr. Kristi Graves at Georgetown University and (**circle Site PI**:) Margaret Darling, Migdalia Torres, Ivis Febus-Sampayo, Ysabel Duron at (**Circle one**:) Nueva Vida; Gilda's Club NYC; SHARE; Latinas Contra Cancer. We want to learn more about how to improve quality of life for Latina breast cancer survivors and their caregivers.

Is this a good time to talk with you a little bit more about the study? _____Yes _____No
If not: Is there another time that would be better to speak with you? _____

You are being invited to participate in this study because you are Latina breast cancer survivor or a primary caregiver for a Latina breast cancer survivor and you are between 18 and 85 years of age. You also speak English or Spanish. In this study, we would like to look at the impact of different types of programs for Latina survivors and caregivers. If you are interested in being a part of this study, you would first talk with one of our team members from Georgetown on the phone who will ask you questions about your experiences [and your loved one's experiences] with breast cancer, its treatment and how you are feeling now. We will ask a range of questions at different times throughout the study. Then you [and your caregiver / and your loved one] would be assigned by chance – like the flip of a coin – to either a new program we are testing or to any of the usual services here at (**circle one**:) Nueva Vida; Gilda's Club NYC; SHARE; Latinas Contra Cancer. You can of course go to any groups or programs that we usually offer whether you want to be in the research study or not. Saying "no" to the study will not take away any of the services you can use here. The new program we are testing is one that has been used at an organization called Nueva Vida in Washington D.C. If you [and your caregiver/loved one] get assigned by chance to the new program, you would come to eight workshops here at (**Circle one**:) Nueva Vida; Gilda's Club NYC; SHARE; Latinas Contra Cancer. After about 4 months, we would ask you [and your caregiver/loved one] to complete another telephone survey and then a third and final survey in about 10 months. Your total time in the study will be about 10-12 months. We hope that the information we learn in this study will help us provide better programs and services to Latina breast cancer survivors and their families. Our goal is to improve quality of life in the best ways possible. If you decide to be a part of this research study, you would be contributing to research that may benefit other Latina survivors and their families in the future.

The risks related with the study are minimal. Sometimes, some people may feel slightly uncomfortable thinking or speaking about cancer. This might happen during the programs we offer, the workshops we are testing or with some of the telephone interview questions. Of course, you can stop participating in the study at any time and skip any questions you don't want to answer. You can also end the telephone interviews at any time. Stopping the interview will not harm your relationship with (**circle one**:) Nueva Vida; Gilda's Club NYC; SHARE; Latinas Contra Cancer and will not take away any services you could use.

All the information that you will give us would be completely confidential. Your name will not be linked in any way with your responses on the surveys or anything you share during the programs or workshops. The information you tell us will never be shared with anybody from your health care team. To better protect your confidentiality, all the interviews and computer files will be labeled with only a number. All the files in the computer will be protected by a password. Only people who are approved to be part of the study team will be able to access protected files. All the written data from the study will be kept in locked drawers inside of locked offices. We also have a Certificate of Confidentiality from the National Institutes of Health for this project. The Certificate of Confidentiality protects your information and helps make sure that your information is only seen by study staff. The Certificate prevents study staff from being forced to share any information about you with anyone not working on the study, including Federal, State, or local officials. Your information is protected against being given to any criminal, administrative, or legislative

representatives. If you ever want access to the information we have about you, you can ask for it in writing. Please know that the Certificate does not prevent your research records from being accessed under some circumstances (for example, during an internal program evaluation).

Although we do not anticipate any injuries from participating in the sessions and telephone interviews, we will make every effort to prevent study-related injuries and illnesses. If you become distressed during the study, we will refer you to a licensed mental health professional.

There are no costs to you and your [survivor/caregiver] for participating in this study. You and your [survivor/caregiver] will both receive a gift card of $10 for completing the first telephone interview, $15 for the second telephone interview, and $20 for the third telephone interview. To thank you for your time, if you are assigned by chance to the workshops, you will also receive a $10 gift card for each workshop session you attend. No matter whether you are assigned by chance to continue with your usual programs and services or the workshops for this study, you can continue to take advantage of programs offered at (**circle one**:) Nueva Vida; Gilda's Club NYC; SHARE; Latinas Contra Cancer during and after the study.

Your participation in this study is voluntary and you will not lose access to services offered by (**Circle one**:) Nueva Vida; Gilda's Club NYC; SHARE; Latinas Contra Cancer. You will not be penalized in any other way if you decide not to participate or if you later decide to stop participating in the study. Again, you can choose not to participate or you can leave the study at any moment. In the same way, the investigator can take you out of the study if it will be better for you to stop participating. Throughout the study, we will tell you about any new information that may affect your interest in remaining in the study.

At the end of the study, you have the right to request the study results. We will share study results with anyone who takes part in the study who is interested. About 200 people from around the country will take part in the study (100 Latina breast cancer survivors and 100 caregivers). There are no medical benefits to participating in this study.

For questions about the study or any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Kristi D. Graves, Ph.D. at 202-687-1591. If you need to speak with a bilingual study representative at Georgetown, you can call Christina L. Rush, M.A., at 202-687-0192.You may also contact Georgetown University at 202-687-1506 if you have any questions about your rights as a research subject.

Does this sound like a study you would like to participate in? Yes ____ No ____

IF NO: May I ask why you are not interested in participating?

____ too busy ____ not interested in the topic ____questions too personal
____other_____

[*Then thank them for their time and say goodbye*].

WRITTEN CONSENT:

_____
Signature of Participant Date

_____
Printed Name of Participant Date

OR VERBAL CONSENT ACHIEVED:

_____
Interviewer Signature Date