NRG ONCOLOGY CONSENT FORM ADDENDUM #2

Study Title for Participants: Testing the drug atezolizumab or placebo with usual therapy in first-line HER2-positive metastatic breast cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

NRG-BR004, "A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer," (NCT03199885)

When you joined the NRG-BR004 study, the group conducting the trial promised to tell you about new information that might affect your participation in the trial. The following are changes that have been made to the original NRG-BR004 consent form that you signed.

Change to side effect related to trastuzumab

Muscle spasms is no longer included as a side effect for trastuzumab and was deleted from the Occasional, Some May Be Serious category.

The costs of taking part in this study have changed

For patients in the United States, you or your insurance provider will not have to pay for the trastuzumab or the atezolizumab/placebo while you take part in the study. In the original consent form that you signed, you were told that you or your insurance provider would not have to pay for the atezolizumab/placebo while you take part in the study.

Re-consent to take part in optional studies

When you signed the original consent form, you were asked if you would allow your blood samples to be used for optional known future studies and your tissue samples to be used for optional unknown future studies. The researchers would like to ask you if you would allow both your blood and tissues samples to be used for optional known and unknown future studies.

If you have questions about the use of your samples for research, contact the study doctor. Contact information for your study doctor is listed on the consent cover page.

Please circle your answer below to show if you would or would not like to take part in each optional study:

Samples for known future studies:

I agree that my tissue and blood samples and related health information may be used for the laboratory study described above.*

YES NO

* *Please refer to the original consent form that you signed for the description of the use of your tissue and blood samples for known future studies.*

Samples for unknown future studies:

I agree that my tissue and blood samples and related health information may be kept in a biobank for use in future health research.*

YES NO

* *Please refer to the original consent form that you signed for the description of the use of your tissue and blood samples for unknown future studies.*

Who can answer my questions about this study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact information for your study doctor is listed on the consent cover page. You may withdraw from this study at any time, and it will not affect your future care.

Signatures

I have been given this new information that was not in the original consent form. I have read this consent form addendum or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this consent form addendum.

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)
(Required for initial consent only)