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.

There have been some changes made to the side effects for pertuzumab and trastuzumab from the time you signed the original consent form. These changes were made because of reports of patients who have had these side effects or because patients had the side effects either more or less often than reported in the original consent form that you signed.

New Information about Side Effects Related to Pertuzumab

The following side effects have been added to the **Occasional** category:

- Swelling and redness of the area of radiation
- Cough
- Nose bleed
- Change in or loss of some or all of the finger or toenails
- Hot flashes

The following side effects were not in the consent form that you originally signed because there had not been enough patients who had the side effects to know if they were related to pertuzumab. There have now been enough patients who have had the following side effects for them to be included in the **Occasional** category:

- Heartburn
- Feeling of "pins and needles" in arms and legs
- Redness, pain or peeling of palms and soles

The side effect of Rash was changed from the **Common** category to the **Occasional** category.

The side effect of Swelling of the arms, legs in the **Occasional** category was changed to Swelling of the body.

New Information about Side Effects Related to Trastuzumab

The following side effect was changed from the **Occasional** category to the **Rare** category:

- Damage to organs which may cause shortness of breath

The following side effect was deleted from the **Occasional** category:

- Swelling and redness of the eye. (This side effect is considered covered by "Infection" listed in the **Occasional** category.)

Changes to side effects in the **Occasional** category:

- Cough was added as a symptom to the side effect of heart failure.
- Swelling of the body which may cause shortness of breath was changed to Swelling of the body.
- Headaches were added as a symptom to the side effect of high blood pressure.

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.

Signature:

This study has been explained to me, and I have been told what my enrollment in the study involves. I have read all pages of this consent and have had my questions answered to my satisfaction at this time. I consent to participate in this study and any additional studies where I circled 'yes'. I understand that by signing this form I have not given up any of my legal rights. I will be given a copy of this consent form. I may also request a copy of the protocol (full study plan).

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

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