NRG ONCOLOGY CONSENT FORM ADDENDUM #3

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 Taxane/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer," (NCT03199885)

When you joined the NRG-BR004 study, you were told that your study doctor would tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. The following are changes that have been made to the original NRG-BR004 consent form that you signed.

Change to the length of time you will be followed in the study

The original consent form that you signed stated that you after you have completed atezolizumab or placebo and you are getting trastuzumab and pertuzumab, your doctor and study team will continue to watch you for side effects. They will check you every 3 months for 3 years and then every six months for the next 4 years. This will be done at a visit to your study doctor. You will be in this study for about 9 years. The length of time that you will be followed has been changed from every 3 months for 3 years and then every six months for the next 5 years. You will now be in this study for about 10 years. This change was made so that the researchers are able to collect the information they need for the study.

End User Licensing Agreement information

The IRB for NRG-BR004, which is a group of people who review the research with the goal of protecting the people who take part in the study, now requires that patients be informed about the importance of reading the End User License Agreements for any applications or devices used in this study. It is important for you to understand what can and will happen to your data collected by the application or device.

As part of this study, we will collect information from an application downloaded from the Internet and/or from a personal electronic device such as your smart phone or tablet or from an electronic device such as a tablet that you may use at your health care institution.

The electronic device at your health care institution is only for use while you are at the health care institution. It will not be given to you to take home for use in this study.

The maker of the application and/or device may collect and store personal information, such as health information, location data, and internet usage. A complete description of what data will be collected and what the company will do with it can be found in the Terms of Service. You will need to agree to the Terms of Service to participate in this study.

The researchers in this study may not have any control over what the company does with your information. The application and/or device may collect and transmit more information to the company than is needed for this study.

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.

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)