NRG ONCOLOGY CONSENT FORM ADDENDUM #1

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL/SMILOW CANCER HOSPITAL CARE CENTERS/SAINT FRANCIS HOSPITAL

Study Title: A Randomised, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy
Principal Investigator: Erin Hofstatter, MD
Principal Investigator's Phone Number: (203) 785-2876
24-Hour Phone Number: (203) 785-4191
Principal Investigator's Mailing Address: 300 George St, Suite 120, New Haven CT 06511

When you joined the NSABP B-55/BIG 6-13 study, the group conducting the trial promised to tell you about new information that might affect your participation in the trial.

Increase in sample size

The number of people who participate in the study has been changed from 1320 to 1500 because patients who have breast cancer that is HER2 negative and sensitive to hormone therapy are now eligible to join the study.

Information about side effects related to olaparib/placebo

There have been some changes made to the side effects for olaparib/placebo 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 did not have the side effects as often as originally reported.

Risks moved from the Common, Some May Be Serious category to the Occasional, Some May Be Serious category:

Low white blood cell count which may lead to an infection

New risks added to the consent form in the Occasional, Some May Be Serious category:

Abnormal heartbeat
Constipation
Weight loss
Cough, shortness of breath

Risks moved from the Occasional, Some May Be Serious category to the Common, Some May Be Serious category:

Belly pain was moved from the Occasional, Some May Be Serious category to the Common, Some May Be Serious category as the general term Pain.

Use of birth control during and after the last dose of study drug or placebo

You were told that you should not get pregnant or breastfeed (for women) or father a baby (for men) for at least 3 months after stopping study drug or placebo. The requirement has been changed for women. If you are a women, you should not get pregnant or breastfeed while receiving study drug or placebo and for at least 1 month after your last dose of study drug or placebo. If you are a man, you still should not father a baby or donate sperm while receiving study drug or placebo and for at least 3 months after your last dose of study drug or placebo.

Vaccines

You must not receive live virus and/or bacterial vaccines while receiving study treatment.

Additional organization that may see your medical information

Four organizations have been added to the list of organizations that may see your medical information. The organizations are:

- Alliance for Clinical Trials in Oncology
- ECOG-ACRIN Cancer Research Group
- SWOG
- Frontier Science

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 your study doctor, Dr. Erin Hofstatter, at (203) 785-2876. 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 been given a copy of this consent form addendum.

_____	_____
Date	Patient's signature
	_____
	Print patient's name
_____	_____
Date	Signature of person conducting the informed consent discussion
	_____
	Print name of person conducting the informed consent discussion

Interpreter/ Witness (print name) – only if applicable, otherwise blank	Signature	Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Erin Hofstatter, at (203) 785-5876. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.