NRG ONCOLOGY CONSENT FORM ADDENDUM #3

Study Title for Participants: Testing an investigational drug with standard treatment before surgery for rectal cancer

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

NRG-GI002: A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer (NCT 02921256)

When you joined the NRG-GI002 study, the group conducting the trial promised to tell you about new information that might affect your participation in the trial.

For patients receiving mFOLFOX6:

The statement "Do not drive or use machines." was removed from the mFOLFOX6 risks.

Change in side effect description for pembrolizumab:

There has been a change made to the lists of side effects for pembrolizumab from the time you signed the original consent form. This change is a clarification of the description of lung problems.

- Lung problems (pneumonitis and pleural effusion). Symptoms may include: new or worsening cough, chest pain, shortness of breath (under Occasional) is now reported as “Lung problems (pneumonitis and other conditions). Symptoms may include: new or worsening cough, chest pain, shortness of breath.

Information about side effects related to radiation therapy:

The following side effect was removed from the consent form in the Occasional, Some May Be Serious category as it was not related to the treatment area being studied:

- Sores in mouth which may cause difficulty swallowing

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)