NRG ONCOLOGY CONSENT FORM ADDENDUM #5

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.

There have been some changes made to the lists of side effects for MK-3475(pembrolizumab) from the time you signed the original consent form. These changes were made because of reports of patients who have had these side effects.

Side effects added to the Rare, and Serious category:

- A syndrome starting with flu-like symptoms and followed by swelling, tenderness which may cause flu-like symptoms, blurred vision, ringing in the ears, changes in hair or hair loss
- Swelling of the spinal cord

Provided further clarification note stating:

Pembrolizumab works by helping your immune system to fight your cancer. However, pembrolizumab can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects. These side effects may be serious (i.e. causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time.

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 been 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)