

Informed Consent Addendum Model for S1400I

S1400I, “A Phase III Randomized Study of Nivolumab Plus Ipilimumab Versus Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker (Lung-Map Sub-Study)”

The following information should be read as an update to the original Consent form that you read and signed at the beginning of the study. Unless specifically stated below, all information contained in that original Consent Form is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study doctor.

New or additional information

The following new risks related to nivolumab have been identified:

Added to Rare, and Serious: A syndrome starting with flu-like symptoms and followed by swelling, tenderness which may blurred vision, ringing in the ears, changes in hair or hair loss; Swelling of the bowels.

Patient Signature and Date

By signing this form, I acknowledge that I have read the information above or had it read to me. I have discussed it with a member of the study team and my questions have been answered. I understand that I will be given a copy of this form.

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

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