NCI Community Oncology Research Program – Kansas City (NCORP-KC)

Informed Consent Addendum Model for S1512

S1512, "A Phase II and Pilot Trial of PD-1 Blockade with MK-3475 (Pembrolizumab) in Patients with Resectable or Unresectable Desmoplastic Melanoma (DM)" Study Chairs: Kari Kendra, M.D., Ph.D. Siwen Hu-Lieskovan, M.D., Ph.D. (Translational Med), William E. Carson III, M.D., FACS (Surgery)

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 have been identified:

- **Added New Risk**:
  - **Occasional**: **Blood clot which may cause bleeding, confusion, paralysis, seizures and blindness**
  - **Rare:** **Feeling of "pins and needles" in arms and legs; Redness, pain or peeling of palms and soles; Damage to organs in the body when donor cells attack host organs which may cause yellowing of eyes and skin, itchy dry skin; Damage to organs in the body when the body produces too many white cells; A condition with high blood sugar which leads to tiredness, frequent urination, excessive thirst, headache, nausea and vomiting, and can result in a coma; Inflammation of the brain (encephalitis/meningitis) which may cause headache, confusion, sleepiness, seizures, and stiff neck**

The following risks have been found to occur more often than originally thought:

- **Increase in Risk Attribution:**
  - **Changed to Occasional from Also Reported on MK-3475 Trials But With Insufficient Evidence for Attribution (i.e., added to the Risk Profile):** **Pain in back; Cough**

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 _____

Participant's signature_____

Date of signature_____

Person obtaining consent_____

Signature of person obtaining consent_____

Date of signature_____