INSTITUTE: National Cancer Institute

STUDY NUMBER: 15-C-0075 PRINCIPAL INVESTIGATOR: Hoyoung Maeng, M.D.

STUDY TITLE: A Randomized, Placebo-Controlled Phase II Study of Multi-Epitope TARP Peptide Autologous Dendritic Cell Vaccination in Men with Stage D0 Prostate Cancer

Continuing Review Approved by the IRB on 09/24/18
Amendment Approved by the IRB on 08/10/18 (F) Date posted to web: 10/03/18

Addendum 2 to 15-C-0075

This addendum provides new information about the study "A Randomized, Placebo-Controlled Phase II Study of Multi-Epitope TARP Peptide Autologous Dendritic Cell Vaccination in Men with Stage D0 Prostate Cancer" on which you are enrolled. The information in the consent you signed previously is unchanged.

The NIH Clinical Center (CC) Cell Processing Section produces the cells used for your upcoming therapy. Recently the facility flooded from a broken sprinkler in the ceiling and there is a risk that the facility no longer meets the Food and Drug Administration's (FDA's) strict requirements for facilities producing cellular therapies. Our current testing shows that the facility is clean and cells are safe to give to patients. The NIH CC continues to work on cleaning the facility but during the cleaning there is a very low risk that the cellular products being made could become contaminated with bacteria, viruses or fungus. The Cell Processing Facility and all cellular products are routinely tested for infective agents and will continue to be tested throughout the cleaning. Although we believe this risk is very low, we want you to be aware of this potential risk. The NIH convened a Risk Assessment Review Committee which has determined the benefit of receiving this product outweighs the minimal risk of potential infection. However, it is up to you to decide if you would like to receive these cells. If you have questions or concerns about the product or the way that it is made, you should talk with Dr. Hoyoung Maeng and be sure to have all of your questions answered before you sign this form.

REVISION COPY

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/ Legal Representative _____ Date _____

Print Name _____

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.
(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/ Guardian _____ Date _____

Print Name _____

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian _____ Date _____ Print Name _____

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM SEPTEMBER 24, 2018 THROUGH OCTOBER 15, 2019.

Signature of Investigator _____ Date _____

Print Name _____

Signature of Witness _____ Date _____

Print Name _____