INSTITUTE: National Cancer Institute

STUDY NUMBER: 13-C-0016 PRINCIPAL INVESTIGATOR: Hoyoung Maeng, M.D.

STUDY TITLE: A Phase I Study of an Adenoviral Transduced Autologous Dendritic Cell Vaccine Expressing Human HER2/neu ECTM in Adults with Tumors with 1-3+ HER2/neu Expression

Continuing Review Approved by the IRB on 11/05/18
Amendment Approved by the IRB on 08/19/19 (O) Date posted to web: 08/24/19

Addendum to 13-C-0016

This addendum provides new information about the study "A Phase I Study of an Adenoviral Transduced Autologous Dendritic Cell Vaccine Expressing Human HER2/neu ECTM in Adults with Tumors with 1-3+ HER2/neu Expression" on which you are enrolled. The information in the consent you signed previously is unchanged.

The NIH Clinical Center Pharmaceutical Development Service (PDS) helps to make the AdHER2 DC vaccine used in this study. The PDS was recently closed down by NIH leadership after a vial of contaminated material was discovered on another study just before it was supposed to be given to a research participant. The PDS is undergoing a full review and changes are being made to make sure that processes are in place to prevent anything like this from happening again. The FDA and NIH decided that it might be better and safer to make an exception to the PDS shutdown for some research studies as long as those decisions are made on a case by case or protocol by protocol basis. The AdHER2 DC vaccine received one of those exceptions because the parts of the vaccine made by the PDS are just used in the preparation of the vaccine and are never actually given to you, the research participant. Additionally, all of the materials used in making the AdHER2 DC vaccine have to pass many tests or they can't be used. Before giving the exception, the FDA and NIH determined that the risk to you from receiving a vaccine that includes the portions made by the PDS, before all of the reviews and changes to the PDS are finished, is extremely low.

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 NOVEMBER 05, 2018 THROUGH NOVEMBER 12, 2019.

Signature of Investigator _____ Date _____

Print Name _____

Signature of Witness _____ Date _____

Print Name _____