**PRINCIPAL INVESTIGATOR:** **Hoyoung Maeng, MD**

**STUDY TITLE:** **A Pilot Study of Long-Term TARP Vaccination Using a Multi-Epitope TARP Peptide Autologous Dendritic Cell Vaccination in Previously Vaccinated Men on NCI 09-C-0139**

**STUDY SITE:** **NIH Clinical Center**

Cohort: Addendum

Consent Version: 10/17/2019

## WHO DO YOU CONTACT ABOUT THIS STUDY?

**Principal Investigator:** Hoyoung Maeng, MD
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This addendum provides new information about the study "A Pilot Study of Long Term TARP Vaccination Using a Multi-Epitope TARP Peptide Autologous Dendritic Cell Vaccine in Previously Vaccinated Men on NCI 09-C-0139" 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 ME TARP 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 ME TARP 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 ME TARP 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.



IRB NUMBER: 15C0076
IRB APPROVAL DATE: 12/05/2019

**Adult Research Participant:** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

| Signature of Research Participant | Print Name of Research Participant | Date |
|---|---|---|

**Legally Authorized Representative (LAR) for an Adult Unable to Consent:** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

| Signature of LAR | Print Name of LAR | Date |
|---|---|---|

**Investigator:**

| Signature of Investigator | Print Name of Investigator | Date |
|---|---|---|

**Witness to the oral short-form consent process only:** This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

**Witness:**

| Signature of Witness* | Print Name of Witness | Date |
|---|---|---|

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.