Informed Consent Form

Title: ZOSTAVAX in Persons Imminently Receiving Chemotherapy for Solid Organ Tumors

NCT02444936

October 15, 2014

**DEPARTMENT OF VETERANS AFFAIRS**

# Memorandum

September 11, 2015

David Canaday, MD
111W

**RE: IRB** #14044-H30 **At:** Louis Stokes Cleveland DVA Medical Center

Dear Dr. Canaday:

**Meeting Date:** 9/10/2015
**Protocol Title:** Shingles Vaccine in Oncology Patients

The Continuing Review report and Study Staff Change were reviewed and APPROVED by the Institutional Review Board of the Cleveland VA Medical Center on September 10, 2015.

**Internal #:** 6561
**Expiration Date:** **10/8/2016**
**Description:** Continuing Review - Active with no findings to date. Study staff change submitted to add Charles Nock. HSP training and R&DC requirements checked 8/26/15 and all study staff are up to date.
**IRB ACTION:** **APPROVED**
**Risk Determination:** **Greater than Minimal Risk**
**Approval Period:** **12 months**
**Flagging of Medical Record:** **Yes**

The approval for this study will expire on **10/8/2016**. Although the Board will normally give notice of the expiration of approval, it is the investigator's responsibility to note the study's expiration date and submit the continuing review documents on a timely basis to maintain approval.

If this study uses a consent form or oral script, only use the newly stamped version (see attached) which contains the latest approval and expiration dates.

If you have any questions, please contact the IRB office at (216) 791-3800 ext. 4658.

Subject Name: _____ Date: _____

Title of Study: Shingles vaccine in oncology patients

Principal Investigator: Dr. David H. Canaday VAMC: Cleveland (541)

Consent Version Date: 10-9-14

## DESCRIPTION OF RESEARCH BY INVESTIGATOR

NOTE: The consent form must include the following section headings:

I. Purpose of the Study
II. Description of the Study
III. Inconveniences
IV. Discomforts/Risks/Side Effects
V. Benefits
VI. Alternative Procedure(s)/Treatment(s)
VII. Privacy, Confidentiality, and Use of Research Results
VIII. Special Circumstances
IX. Contact Information

TO POTENTIAL PARTICIPANTS: Federal regulations require written informed consent before participation in a research study. This is to be certain that research volunteers know the nature and risks of the study, so they can make an informed decision about participation. You are asked to read the following information and discuss it with the investigator, so that you understand this research study and how it may affect you. Your signature on this form means that you have been fully informed and that you freely give your consent to participate. It is also important that you read and understand these principles that apply to all individuals who agree to participate in the research project below:

1. Taking part in the research is entirely voluntary.

2. ~~You may not personally benefit from taking part in the research but the knowledge obtained~~ may help the health care professionals caring for you to better understand the disease/condition and how to treat it.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If, during your participation in the research project, new information becomes available concerning your condition (disease) or concerning better therapies, which may affect your willingness to continue in the research project, your doctor will discuss the new information with you and will help you make a decision about continuing in the research.



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5. The purpose of the research, how it will be done, and what your part in the research will be, is described below. Also described are the risks, inconveniences, discomforts, and other important information, which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions, concerns, or complaints you have about this research with the research staff members.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

I. PURPOSE OF THE STUDY:

You are being asked to participate in a research study of the shingles vaccine (ZOSTAVAX™) in those that will receive chemotherapy because you have a malignancy and your oncologist thinks that you may receive chemotherapy as one of your treatments in the next weeks to months.

The purpose of this study is to understand if the shingles vaccine works in those persons that receive it before they receive chemotherapy for malignancy. The shingles vaccine is currently FDA approved for persons over age 50. Oncology patients are usually not offered the shingles vaccine prior to chemotherapy even though its use is approved by the FDA. People that get chemotherapy are at an increased risk of getting shingles during and immediately after the course of chemotherapy. There is very little information as to whether the vaccine will actually work in this group of people. This study is designed to provide information that may help Oncology physicians decide whether or not to recommend the vaccine to their patients before chemotherapy.

This study is sponsored by the vaccine manufacture, Merck, and will enroll 60 subjects here at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) and 30 subjects from Duke University.

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## II. DESCRIPTION OF STUDY:

As a participant in this study, most of your interaction with the study team will be in the course of your Oncology clinic visits and treatment visits at LSCDVAMC. Your participation in this study will last from when you enroll and until 3-6 month after your last dose of chemotherapy. During the course of your routine care most of the study blood draws will be on the same days that you have for routine care and blood draws monitoring for the cancer treatment as much as possible to make it more convenient for you.

### Randomization/Study Intervention

You will be randomly assigned (like the flip of a coin) to one of two groups: the experimental group that receives the standard FDA approved shingles vaccine or control group that does not receive any vaccine. You will have a 50% chance of being assigned to either group.

### What will I be asked to do?

If you consent to participate in this research study, you will need to do the following:

- Visit the study staff about 4 times: initial visit at Day 1 (Visit 1), at the day of first chemotherapy as determined by you and your treating oncologist that is at least two weeks or longer from the time you received your vaccine (Visit 2), at the start of your second round of chemotherapy as determined by your oncologist (Visit 3), and 3-6 months after your last dose of chemotherapy is given (Visit 4). The study related aspects of your visits will be up to 1 hour on the first visit to go over the study and consent and receive the vaccine, the other visits are much faster 15-30 minutes to obtain blood and discuss any issues that have arisen.

- Answer questions during two telephone contacts with a study staff member between Visits 2 and 3 and then between Visits 3 and 4. You will be asked if you had a side effects or event that may have been serious since your last study visit or telephone contact. You will also be asked if you were exposed to anyone who has chickenpox or shingles, and if you had any symptoms of shingles.



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- **For 4 weeks after you receive your shot,** you will be asked to record the following on a Vaccination Report Card:
  - Any reaction at the injection site (for example: redness, swelling, or pain)
  - Your temperature, by mouth, only if you feel like you have a fever
  - Any medications you are taking and the doses
  - Any rashes or other bad effects
  - If you were exposed to anyone who has chickenpox or shingles
  - If you experience a serious illness or event that required an unplanned visit for medical care

- **Avoid all medications that you don't really need** during the study period. The study doctor or staff will discuss these with you.

- **Notify the study staff** as soon as possible if you get **a rash that looks like chickenpox or s**hingles at any time up to Visit 3. The study doctor will want to see you as soon as possible, preferably on the day you get the rash or within 3 days.

- **Call the site immediately** if you experience a **serious illness** or event, a **worsening of a pre-existing condition**, or if you have to go to the **hospital**.

**What will happen during the study visits?**

When you come in for your study visits, the study doctor or staff may do any or all of the following:

- Review your medical history.

- Ask you about how you have been feeling, your daily activities, and what medications you have taken or are currently taking.

- Give you a shot of shingles vaccine under the skin of your (preferably non-dominant) arm at Visit 1 if you are in the vaccine group.

- **Collect blood samples** 4 times (approximately 1 ½ tablespoons, each time) during the study: at Visits 1, 2, 3, and 4. The blood samples will be tested to see how well your immune system responds to shingles virus and to the vaccine.

  It will be used only for tests to measure immune cell responses related to the shingles virus and the study vaccine. No genetic or DNA testing will be done on these blood samples.

- Give you a Vaccination Report Card at Visit 1 and instruct you on how to fill it out.

- Review and collect your Vaccination Report Card at Visit 3.

- Ask you about any bad effects you may have had or if you have had any symptoms of shingles.

- Ask you about any serious illnesses or events you may have had during the study.

**Discontinuation Visit**

- If you withdraw from the study prior to its completion or if the study staff determines that you are no longer eligible, you will be asked to return if possible the Adult Vaccine Report Card by mail if necessary or at a subsequent clinic visit.

**End of Study**

- Those who did not have the shingles vaccine in the study will have the opportunity to obtain the vaccine from their primary provider at the LSCDVAMC after the study is completed.

III. INCONVENIENCES:

The inconveniences will be having slightly more blood drawn (approximately 1 ½ tablespoons, each time) at the clinical visits than would be the routine clinical care and the 4th visit may not be on a routine visit in the course of normal clinical care. You will have to complete the Vaccine Report Card that may take time out of your day.



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IV. DISCOMFORTS / RISKS / SIDE EFFECTS:

You may feel discomfort during some of these tests blood draws and the vaccination and may also have risks, such as:

**Blood samples**: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples do not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.

**Shingles vaccine:** Some reported risks of shingles vaccine include:

- Injection site reactions such as: local redness, swelling, pain and tenderness, itching, bruising, and warmth.
- Headache
- Fever
- Allergic reaction, which may be life-threatening
- Rash, which may resemble chickenpox
- Swollen glands near the injection site (may last a few days to a few weeks)
- Joint pain
- Muscle pain

**NOTE: If you develop a rash at any point during the study after your vaccination, you must tell the doctor immediately and come to the clinic to be evaluated.**

In other clinical trials with ZOSTAVAX, the vaccine virus has not been reported to spread to other people. However, a person who receives ZOSTAVAX may rarely spread the vaccine virus to a person who is susceptible. For this reason, you should tell your health care provider if you expect to be in close contact (including household contact) with newborn infants, someone who may be pregnant and has not had chickenpox or not been vaccinated against chickenpox, or someone who has problems with their immune system. The study doctor can tell you what situations you may need to avoid.

There may be other side effects or risks that are not presently known about ZOSTAVAX. Other less common side effects have been reported. The study doctor or staff can discuss these with you.

You will be told in a timely manner about significant new information that might affect your decision to stay in the study

V. BENEFITS:

If you are in the group that receives the shingles vaccine you may benefit from the vaccine by having a reduced risk of shingles. It is not known for certain that there will be a benefit in oncology patients, and it is the purpose of the study to help determine this. It is possible that no therapeutic or other direct health benefits may result during or following completion of this study. You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help other people in the future.

VI. ALTERNATIVE PROCEDURE(S) / TREATMENT(S):

Your other option is to not take part in the study. Participation in research is entirely voluntary. The alternative to participating in this study is that you do not participate. If you choose not to participate, and you are eligible as determined by your VA primary provider, they may order the vaccine and you could receive it.

The study doctor or staff can discuss these options with you.

VII. PRIVACY, CONFIDENTIALITY, AND USE OF RESEARCH RESULTS:

Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974.

Participation in this study will involve a loss of privacy to the study staff team, but information about you will be handled as confidentially as possible. Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. The research records will be kept in a password-protected computer file that only the study team

has access to. Your information will be combined with information from other people taking part in the study. We will write about the combined information we have gathered. Any presentations or publications from this information will not identify you.

When your information is given to other researchers working with this study, your information will be labeled with a unique code. Only the VA approved direct study team will be able to identify you. The paper research records will be kept in a locked filing cabinet in a locked office. The electronic research records will be kept on a password-protected computer.

When your information is given to the sponsor, your information will be labeled with a unique code. Only the VA research team will be able to identify you.

VA policy requires us to keep study records indefinitely. However, protections will be put in place to be sure that this information is kept confidential.

By joining this study, you give the investigators your permission for them to collect data from your medical records to determine if you are eligible and if you remain eligible to participate in the study.

In order to comply with federal regulations, research records identifying you may be reviewed by the following:

- Representatives of the sponsor Merck of this study
- Authorized representatives of the LSCDVAMC Institutional Review Board and VA
- Federal Agencies such as the Government Accounting Office (GAO), the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP)
- The Medical Research and Education Foundation

Because this research involves articles regulated by the FDA, the FDA may choose to inspect and copy medical or research records that identify individual research participants.



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VIII. SPECIAL CIRCUMSTANCES:

**Permission to Contact You for Future Research Studies**

~~The purpose of future research will be to do additional, or more detailed, studies on~~ issues related to aging: immune status and function, vaccines, new treatments, mental status and function, and/or activities of daily living. If you answer 'NO' below, then you will not be contacted for future research studies. Your choice to give permission to be re-contacted or not to give permission to be re-contacted will not affect your enrollment in the current study, nor your access to care at the LSCDVAMC.

**I give permission to be contacted in the future for follow-up research studies.**

**(Circle one: )** YES NO Initials: _____ Date:_____

New Findings:

You will be told by the study doctor of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

Financial Considerations

You will be paid for your time and effort for being in this research project. You will be paid $20.00 with cash or a VISA gift card for each blood draw that you complete. The total amount a subject could receive from the 4 blood draws is 4x$20 =$80. If the final visit is on a day that is not a routine clinic day or if there is any other study visits that arise on days that are not part of routine care you will receive additionally $20 for travel expenses.

Ending Participation

The investigators may stop your participation in this study without your consent, for example, if they think that it will be in your best interest, if you do not follow the study plan, if you experience a study-related injury, or for any other reason.



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Compensation for Research-Related Injury

If you sustain injury as a direct result of your study participation, medical care will be provided by the LSCDVAMC at no cost to you. Financial compensation for such things as lost wages, disability, or discomfort due to an injury may not be available.

VIII. CONTACT INFORMATION

**To answer questions about the research or if you sustain a research related injury contact the following:**

- During the Day: Dr. David Canaday, 216-368-8901 or have VA operator 216-791-3800 page him.
- After Hours: have VA operator 216-791-3800 page Dr. David Canaday.

**For answers to questions about rights as a research participant or to voice a concern or complaint contact the following:**

- The Research Administrative Officer at (216) 791-3800 ext. 4657
- The LSCDVAMC Patient Representative at (216) 791-3800 ext. 4026

**If you wish to speak with someone other than study staff to provide input concerning the research process, check whether a study is being conducted at the LSCDVAMC, and if study staff are permitted to represent the study contact :**

- The LSCDVAMC Institutional Review Board Office at (216) 791-3800 ext. 4658



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Subject Name: _____ Date:

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Consent Version Date: 10-9-14

**RESEARCH SUBJECTS' RIGHTS**: I have read or have had read to me all of the preceding information.

Dr. Canaday or his staff _____has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

**I understand that I do not have to take part in this study, and my refusal to participate will involve no penalt or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss o VA or other benefits to which I am entitled.**

The results of this study may be published, but I will not be identified in publications by name, photograph, or other identifiers. My records, including my name and results of my participation, may be revealed as required by laws and regulations of state and federal agencies.

I understand my rights as a subject, and I voluntarily consent to participate in this study. I understand what the study about and how and why it is being done. I will receive a signed consent form or a photocopy of it. I understand that in signing this consent form I do not waive my legal rights nor release the LSCDVAMC from liability for negligence.

Subject's Signature_____ Date __ /__/__

Signature of Person Obtaining Consent_____ Date __ /__/__



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