Single Cell Molecular Analysis of Influenza Vaccine Induced T Cell Responses in Adults 65 Years of Age or Older

NCT04077424

November 25, 2019

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Single cell molecular analysis of influenza vaccine induced T cell responses in adults 65 years of age or older
Version Date:	11.11.2019
PI:	Spyros Kalams, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key information about this study:
You are being asked to take part in this research study because you are 65 years old or older, and you are planning on receiving the flu vaccine as part of your standard medical care.

Purpose of this study
In the United States, annual flu vaccination is currently recommended for people 65 years of age and older. However, as people get older, they tend to respond less well to flu vaccine. Other factors besides age, such as frailty (measures of strength, balance, walking performance) are also likely to be important for predicting who will respond to the flu vaccine. The purpose of this study is to test how your immune cells respond to flu vaccine, and see how this is related to age and measures of frailty. The goal is to enroll 120 people.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
Risks of Blood Draw: Pain, redness, soreness, bruising, or infection may occur at the needle stick site. Rarely some people faint.
Risks associated with health information review: As with any study that involves collection of data, there is the potential risk of loss of confidentiality. Every effort will be made to protect your confidentiality and we take this very seriously.
Measurement of handgrip strength using a handheld device can be associated with muscle strain. The physical activities a short walk could result in falls. For these reasons, all physical activities will be closely monitored by research nurses. If any activity results in physical discomfort or is deemed by the study nurses to be unsafe, the activity will be immediately stopped.

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Risks that are not known:
There may be risks that we do not know about at this time, but unlikely since we are just drawing blood.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study:
The information learned in this study may be helpful in the further understand how people respond to flu vaccine.
The benefits you might get from being in this study:
Apart from the benefit of routine influenza vaccination, this study does not offer immediate benefit for study participants

Procedures to be followed:

You will be randomized to the egg-based high-dose inactivated influenza, the egg-based adjuvanted influenza vaccine, or the recombinant influenza vaccine. Each of these vaccines has been approved by the Food and Drug Administration (FDA) for prevention of influenza infection in adults 65 years of age or older.

We will obtain blood on the day of vaccination, 5-9 days, 24-40 days, and optional 6 months (166-194 days) after you get your flu vaccine as part of standard of care.

VISIT 1 (day 0)

- We will review to make sure you qualify to be in the study.
- We will ask about your medical history, ask about what medications you are taking, and whether or not you drink alcohol
- Height and weight measurements
- Answer a questionnaire about symptoms of depression
- Answer questions about daily functioning, energy, and weight loss
- Measurement of grip strength using a hand-held device
- Perform a 15-foot walking test
- A short memory and cognition exercise
- Five-times Sit-to-Stand Test
- Blood (about 3-4 tablespoons) will be drawn with a needle to test for antibodies (which help the body fight off infection) to the flu vaccine and which immune cells are responding.

All answers to questions and questionnaires as well as all measurements will be recorded confidentially Your samples and de-identified information about you may be made available to others to use for research. To protect your privacy, we will not release your name or any identifying information such as birthdate or address. You will not receive any benefit as a result of the tests done on your samples.

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These tests may help us learn more about the causes, risks, treatments, or how to prevent frailty and other health problems.
Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, and/or others. If this happens, there are no plans to provide money to you.
VISIT 2 (5-9 days after vaccine)

- Blood (about 3-4 tablespoons) will be drawn with a needle to test for which immune cells are responding to flu vaccine.

VISIT 3 (4-6 weeks, or 24-42 days after vaccine)

- Blood (about 3-4 tablespoons) will be drawn with a needle to test for antibodies (which help the body fight off infection) to the flu vaccine and which immune cells are responding.

VISIT 4 (Optional visit, 6 months or 166-194 days after vaccine):

- Blood (about 3-4 tablespoons) will be drawn with a needle to test for antibodies (which help the body fight off infection) to the flu vaccine and which immune cells are still responding.

	Visit 1 (Day 0)	Visit 2 (5-9 days)	Visit 3 (24-42 days)	Visit 4 (optional 6 month visit) (166-194 days)
Flu Vaccine	X			
Baseline Data Collection	X			
Blood (approximately 45-60 mLs (3-4 tablespoons))	X	X	X	X

Payments for your time spent taking part in this study or expenses:
You will receive $75 if you complete the study.
We may ask you for your Social Security number and address before you are compensated for taking part in this study.
You will receive an additional $25 for the optional blood draw.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for

paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact **Dr. Kalams at** [redacted] or **Joan Eason at** [redacted] If you cannot reach the research staff, please page the study doctor at [redacted]

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at [redacted] or toll free at [redacted]

Other treatments you could get if you decide not to be in this study:
There are no treatments as part of this study.

Reasons why the study doctor may take you out of this study:
The study doctor may decide that it is best for you to leave the study. If you are taken out of the study for any reason, you will be told why.

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What will happen if you decide to stop being in this study?
Joining the study is voluntary (that is, you decide). If you join the study, you have the right to stop the study at any time and for any reason. You should tell your study doctor or nurse right away. Deciding to not be part of the study will not change your regular medical care in any way.

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

Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Information from this study, including your identifying information may be provided to the United States Food and Drug Administration (FDA), and other regulatory agencies.
Your identity and medical records and data related to this study will be kept confidential, except as required by the law, and except for inspections by Agencies that regulate experimental drug studies (including the FDA), auditors, members of Vanderbilt University Institutional Review Board (IRB), NIH, and/or Sanofi Pasteur, the company that is providing the vaccine. By signing this consent form, you consent to the study doctor and his or her staff to collect and use personal data about you for the study ("study data"). This includes your date of birth, your sex, your ethnic origin, personal data on your physical or mental health or condition, and blood collected in the course of this study.
Your study data is protected by the use of a study subject code ("subject identification number"), which is a number specific to you. The study doctor is in control of the code key, which is needed to connect study data to you.
Vanderbilt may share information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Kalams, and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.
During the research, if we learn you are having thoughts about suicide or hurting yourself or others as part of the depression symptom questionnaire, the research staff will ask you more questions about your thoughts. Based on your response, the staff may provide you with help to get treatment. This may include:

- working with you to contact your doctor,
- contact a trusted family member, or a therapist to discuss your thoughts,
- or work with you on a plan that may include getting you to a hospital for safety.

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This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and

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contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.
If you change your mind, we ask that you contact Dr. Spyros Kalams in writing and let him know that you withdraw your consent. His mailing address is *VUMC,* [redacted] *Nashville, TN* [redacted]. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality. You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds the data. To ensure the scientific quality of the research study, you will not be able to review some of your data until after the research study is finished.

Consent for Genetic Research

The purpose of genetic testing is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment. You are being asked to give a sample of blood for genetic research. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision

to hire, promote, or fire you or when setting the terms of your employment. Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.
Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.
You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.
Giving samples for research is your free choice and you may be in the study even if you do not want your samples used or stored for gene research.
At any time, you may ask to have your sample destroyed. You should contact Dr. Kalams at 6[redacted] or Joan Eason at [redacted] to have your sample destroyed and no longer used for research.
We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.
There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.
Please **initial** Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

_____ Yes _____No

My blood/tissue sample may be stored/shared for future gene research in _____.

_____ Yes _____ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

_____ Yes _____ No

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Leftover Blood Samples

After all study tests are done, we would like to keep any remaining blood to use in possible future research studies. These studies may test for antibodies against other bacteria or viruses. Your samples will be labeled only by a code—the study subject number –and will not be labeled with your name or initials. If these stored samples are tested in the future, no identifying information will be used in the reporting or publication of any results. Results from this future research would not be reported to you or your doctor. These coded specimens may be shared with other institutions and researchers. You can decide if you want your samples to be used for future research. Your decision can be changed at any time by notifying the study doctors or study personnel in writing. Your decision about your samples will not affect their participation in this study or other studies or their medical care.

Please **initial** your choice:

_____ YES, you may store my unused coded (identified as described above) samples for an indefinite period of time for future research.

_____ YES, you may store my unused samples for an indefinite period of time for future research as described above, but you must remove any information that could identify it as theirs (labeling it only by study and dose group).

_____ NO, you may not use my samples for other future research. Destroy my unused samples at the end of this study.

Future Contact

We may want to contact you in the future to see if you would be interested to have your take part in future studies. This will not affect the status of this study.

Please **initial** your choice:

_____ YES, you can contact me about future studies.

_____ NO, I may not be contacted about future studies.

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If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____

Date Signature of patient/volunteer

Consent obtained by:

_____ _____

Date Signature

_____

Printed Name and Title

Time: _____