Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Satish R Raj, MD, MSCI Version Date: 6/9/14
Study Title: Assessment of Antibodies and Inflammatory Markers in Postural Tachycardia Syndrome (POTS)
Institution/Hospital: Vanderbilt University Volunteers

This informed consent applies to healthy adults.

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.

You do not have to be in this research study. 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. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you are healthy. The purpose of this study is to study certain chemicals that occur in your blood (antibodies) to see if they are different than the chemicals in the blood of people who have postural tachycardia syndrome (POTS, bad symptoms when standing).

About 200 people will take part in this study.

2. What will happen and how long will you be in the study?

If you agree to be in this study, we will do a physical examination and ask you about your medical history. We will take blood (about 1 tablespoon) from a vein in your arm with a needle. We will ask you to complete a series of questionnaires about your health and symptoms on a computer that is linked to a secure database.

Some people will be asked to have recordings of their heart rate and blood pressure for about 10 minutes while lying down. Would you be willing to have this testing?

☐ No ☐ Yes

Your 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 learn more about the causes, risks, treatments, or how to prevent this 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.

If you wish, we will share with you the antibody results when they are available. However, we cannot provide information for these values or discuss the meaning of these antibody values, as these are unknown. Further these antibody tests will be performed in a non-clinical research lab that is not certified by CLIA (Clinical Laboratory Improvement Amendments, a requirement for clinical testing laboratories.) **You must complete the entire study, including the questionnaire to be eligbile to have the results sent to you.**

3. Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

4. Side effects and risks that you can expect if you take part in this study:

Blood drawing: Drawing blood with a needle may be painful and may cause bruising, bleeding, or rarely, infection. Some people may feel faint when having a needle put in their arm.

Questionnaires: Answering the questionnaires may be boring.

For those who have heart rate testing:

Electrodes: Sticky patches will be put on your chest and your limbs to record electrical activity from the heart or for the body impedance measurements. This might be uncomfortable. This can occasionally cause a rash.

5. Risks that are not known:

None.

6. 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 the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study. We may learn more about POTS and the biochemical differences that may occur in people who have it.

b) The benefits you might get from being in this study. None.

8. Other treatments you could get if you decide not to be in this study:

This is not a treatment study. You may choose not to take part in this study.

9. Payments for your time spent taking part in this study or expenses:

You will not be paid for being in this study.

10. Reasons the study doctor may take you out of this study:

You will be withdrawn from the study if the study doctors decide it is best for you. If the study doctors withdraw you from the study, you will be told the reason.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor.

12. 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. Satish Raj at 615-343-6499 or adcresearch@vanderbilt.edu.

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 Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. The study results will be kept in your research record for at least seven years after the study is over for as long as we need the information for the study. All the information on paper will be kept locked in a secure location. Any information kept in a computer will be through the Vanderbilt CRC data system or the Vanderbilt REDCap system, which has many safeguards. Only members of Dr. Raj's research team will be able to see any of the information that would identify you. Any research data entered into your medical record will be kept as long as it is needed.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Raj 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.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Raj and his study team may share the results of your study and/or non-study linked questionnaire answers to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Raj in writing and let him know that you withdraw your consent. His mailing address is

Dr. Satish Raj
AA3228 Medical Center North
1161 21st Avenue South
Vanderbilt University
Nashville, TN 37232-2195

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.

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.