Informed Consent Form

Multicenter Assessment of the Pancreas in Type 1 Diabetes (MAP-T1D)

Date: 10/27/2021

NCT03585153

Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Al Powers, M.D. **Version Date: October 15, 2021**
Study Title: Multicenter Assessment of the Pancreas in Type 1 Diabetes (MAP-T1D)
Institution/Hospital: Vanderbilt University Medical Center

This informed consent applies to adults (age 18+) with diabetes-related autoantibodies

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 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.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have been diagnosed with autoantibodies related to diabetes. We are trying to find the best ways to obtain clear pictures of the pancreas. Magnetic resonance imaging (MRI) is a way to take pictures of organs inside the body. We will scan you in a number of ways using this MRI scanner and compare the results. The purpose of this study is to use advanced tools and MRI to study the pancreas. We will use these findings to help us learn more about the pancreas of healthy individuals and individuals with diabetes. We will use the best approach in future studies that may involve people with specific diseases, such as diabetes. No medical decisions will be made based on the results of the scan. We expect to scan approximately 250 people at Vanderbilt.

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

Participants will undergo at least three MRI scans over the course of one year, at intervals ranging from one week to six months apart. We would like to determine if there are changes to the pancreas that occur over this time. If the participant approves, additional MRI scans may be performed after the initial three scans have been completed.

If the results from your oral glucose tolerance tests performed through TrialNet are abnormal, we may scan you at a more frequent interval of 1-2 months until you are either diagnosed with diabetes or until results from repeated oral glucose tolerance tests return normal. If you are diagnosed with diabetes, you may re-enroll in the study as part of the diabetic cohort and be scanned additional times.

The MRI scan will take about 60 minutes. During the scans you will need to stay still. An MRI scan is taken in a large machine that is shaped like a tunnel. This scan does not use x-rays. Instead, it uses a strong magnet and radio waves, like those used in an AM/FM radio to make pictures of your body.

You may not be able to have this scan if you have a device in your body such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear implants. Also, you may not be able to have this scan if you have iron-based tattoos, pieces of metal (bullet, BB, shrapnel) in your body. Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body when you are getting the scan. For this reason, you will be asked to remove these objects before going into the room for the scan. You will complete a survey to make sure it is safe for you to enter the MRI scanner.

You will hear “hammering”, clicking, or squealing noises during the scan. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them. During the scan, the MRI staff is able to hear and talk to you. You will also be able to hear the staff. You will be asked to lie very still throughout the scan. They will be talking to you during your scan and may ask you to hold your breath, not move, or other simple tasks. Breath hold

length will not exceed 20 seconds. Participants will be allowed to breathe normally before and after breath holds to fully recover between breath holds. The total number of breath holds during the scan will not exceed 12 total breath holds. You may be asked to lie very still throughout the scan. In some subjects, physiological data such as heart rate and breathing will be monitored using non-invasive equipment comprised of a pulse oximeter attached to your finger and a pneumatic belt, a belt that is sensitive to your chest movement associated with breathing, placed around your chest. In this study, the MRI scan will be used for research purposes only. However, if we see something that is not normal, you will be told and asked to consult your doctor and withdrawn from the study.

We may share de-identified study results with other participants and, in some cases, offer group or family sessions to discuss results and follow-up testing. For example, you can choose to provide urine for additional testing. We may also take a swab from the inside of your mouth for genetic testing.

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:

There are no known major risks with an MRI scan. But, it is possible that harmful effects could be found in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off during the MRI scan. Transdermal patches slowly deliver medicines through the skin. Some patches have metal in the layer of the patch that is not in contact with the skin (the backing). You may not be able to see the metal in the backing of these patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate area of the patch. Tell the study doctor that you are using a patch and why you are using it (such as, for pain, smoking cessation, hormones). Ask your doctor for guidance about removing and disposing of the patch before having an MRI scan and replacing it after the procedure. Tell the MRI facility that you are using a patch. You should do this when making your appointment and during the health history questions you are asked when you arrive for your appointment.

There are no known risks of having non-contrast MRI scans while pregnant. However, there may be risks that are unknown.

The MRI used in this study has been used in human research for several years and no risks have been identified. However, some people may experience discomforts such as nausea, dizziness, flashing lights in the eyes, and a metal taste in the mouth. These discomforts are most likely to occur as a result of rapid head movement in or near the MRI machine. For this reason, you should try not to move, especially your head, while you are inside the MRI.

5. Risks that are not known:

There are no known side effects of having an MRI without contrast. However, there may be risks that are unknown at this time.

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 are: development of MRI methods to measure changes in the pancreas accompanying diabetes that may be useful for diagnosis and therapeutic monitoring.
b) The benefits you might get from being in this study are: you will be alerted if any abnormal results are detected during the MRI scan.

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

This is not a treatment study and you do not have to take part if you do not want to.

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

You will be compensated $50 for each MRI visit. If you are recruited from more than 100 miles from Vanderbilt, we will pay for your flights to and from Nashville. We may ask you for your Social Security number and address before you are compensated for taking part in this study.

In the event abnormal results are detected during the MRI scan, Vanderbilt will not be financially liable for any follow-up imaging or testing.

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

If you feel claustrophobic, we will stop the study. If you cannot remain still during the exam you may be taken out of the study. If you are taken out of 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. Deciding to not be part of the study will not change your regular medical care in any way.

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 Jon Williams, Ph.D. at 615-875-9200**.**

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:

If the information from this study is presented publicly or published in a medical journal, you will not be identified by name, picture, or any other personally identifying information. All efforts, within reason, will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Your medical records will be kept by your doctor in locked cabinets behind locked doors and will only be accessible to the treating physicians and study staff. The MRI data that we obtain will be de-identified and replaced with a code number. All MRI data will be secured in a computer database behind a password-protected firewall. Only study staff will have access to the MRI data. Image data will be acquired by the 3 Tesla scanners and will be stored both on digital media (which will not leave the secured scanner area) and on the Institute of Imaging Science server, which is protected by institutional firewalls and is password protected. Investigators may archive these data for their own use, in which case they will be kept in the relevant investigator's locked office. Ten years after the study is concluded, the image data will be destroyed.

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

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.

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. Powers and his study team may share the results of your study and/or non-study linked MRI images as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and National Institutes of Health. 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. Williams in writing and let him know that you withdraw your consent. His mailing address is T-3113 Medical Center North, 1161 21st Ave. South, Nashville, TN 37212. 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. 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

Consent obtained by:

Date	Signature
	Printed Name and Title

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Consent for Genetic Research

The purpose of this study 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 blood sample 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.

A single blood sample of 1 teaspoon will be drawn from a vein in your arm using a needle. We may also collect a urine sample and/or take a swab of the inside of your mouth. This will take about 5 minutes of your time.

Blood samples – You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only the principal investigator, Alvin Powers, and other key personnel involved in this study will have access to your name.

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 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 Jon Williams at 615-875-9200 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.

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Please check 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 studies of diabetes.

☐ 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

Signature: _____ Date: _____