AlloSure for the Monitoring of Antibody Mediated Processes after Kidney Transplantation
NCT04057742

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University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: The All-MAP Study

Formal Study Title: AlloSure and AlloMap for the Monitoring of Antibody Mediated Processes after Kidney Transplantation

Lead Researcher: Sarah Panzer, MD (608) 262-5531 (office hours), (608) 262-2122 (24 hour/pager)

Where Lead Researcher works: University of Wisconsin-Madison, School of Medicine and Public Health, Department of Nephrology

_____

_____ _____
Participant name Medical Record Number

Invitation

We invite you to take part in a research study about antibody-mediated rejection (ABMR). We are inviting you to participate because you have received a kidney transplant and are now being clinically evaluated for possible ABMR, or you have recently been diagnosed with ABMR.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are researchers doing this study?

The purpose of this research study is to find out if blood tests called AlloSure and AlloMap, analysis of your clinical care biopsy samples with a new technology called nCounter® technology, and measuring immune cell phenotypes (characteristics of immune cells) can predict antibody-mediated rejection in kidney transplant recipients. We

Rejection is the most common and important complication that may occur after receiving a transplant. Since you were not born with your transplanted kidney, your body will think this new tissue is “foreign” and will try to protect you by “attacking” it. Rejection is a normal response from your body after any transplant surgery.

We are doing this research because we want to find a way to improve survival and quality of life after kidney transplant by non-invasively monitoring and predicting antibody mediated rejection.

This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of about 69 people will participate in this study.

Funding for this study is provided by CareDX and the National Institutes of Health (NIH). CareDX is the manufacturer of both the AlloSure and AlloMap tests, and a collaborator with NanoString Technologies, the owner of the nCounter® Analysis System.

What will happen in this study?

If you decide to participate in this research study, the researchers will ask you to provide a blood sample (between 4 and 5 teaspoons), a urine sample (up to one cup), and samples will be made from the tissue that is collected from your clinical care biopsy 2 times throughout the normal course of your standard of care treatment for kidney transplant.

Research samples will be collected at the following time points; around the time that you sign this document and at your first follow-up standard of care visit post-treatment. Every effort will be made to collect research samples at the same time that standard of care samples are collected.

Some of the tests we will perform on your samples will be genetic tests, which are done on your DNA. DNA, or deoxyribonucleic acid, carries the genetic instructions for the cells that make up your body. Genes tell your body how to do things like form your spine, or what color your eyes should be.

Your fully identifiable information, such as your name, date of birth, and address will be sent to CareDX along with your blood samples and biopsy slides for the purpose of processing the samples and performing the nCounter analysis and genetic tests. Your urine sample will be coded and sent to a lab at UW for analysis.

After the analyses for this study are complete, we would like to store the remaining urine sample we collected from you, along with your health information we collected for the study, for use in future research about anti-body mediated rejection and transplantation. At the end of this consent form you will have a chance to say whether or not you agree to this invitation to participate in long term storage of your sample and information for future research.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study
- Things you tell the researchers about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history; your diagnosis; and lab test results. We will get this information from your health care providers such as UW Health.

Email Address: We are requesting your email address so we can schedule study visits with you. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Dr. Sarah Panzer at (608) 262-5531 (office hours), (608) 262-2122 (24 hour/pager). You do not have to provide your email address to participate in this study.

How long will I be in this study?

You will be part of the study for about 3 months while you are coming in for your regularly scheduled clinical care visits.

The researchers may take you out of the study, even if you want to continue, if

- your health changes and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or researchers

How is being in this study different from my regular health care?

If you take part in this study, the main difference between your regular care and the study is having an extra two tubes of blood drawn during your routine clinic visits.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study. If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.

- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Dr. Sarah Panzer at the following address: University of Wisconsin Department of Medicine, Division of Nephrology, 1685 Highland Avenue, Suite 5000, Madison, Wisconsin 53705

What are my other choices if I do not take part in this study?

You do not have to be in this research study to receive care after your kidney transplant. If you decide not to take part in the study, you could have standard monitoring for ABMR without the additional tests done for research.

Will being in this study help me in any way?

Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about antibody mediated rejection.

Will I receive the results of research tests?

All of the tests that are part of this study are for research purposes only and their use on the study is considered investigational. Because of this, we will not tell you or your doctors the results of these research tests.

What are the risks?

There is a risk that your information could become known to someone not involved in this study. There is a risk that your information could become known to someone not involved in this study. If this happens, it could affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

The Genetic Information Nondiscrimination Act of 2008 is a Federal law that is supposed to prevent health insurance companies and employers from discriminating against people based on genetic information. There are some limits to this law:

- It does not apply to businesses that employ fewer than 15 people. So, if you work somewhere with fewer than 15 employees, your employer could fire you or make other decisions about employment using genetic information.
- Regardless of where you work, it does not apply to life insurance, disability insurance, or long-term care insurance.
    - This means that if you had an abnormal genetic test result, and that result became known, then you could be denied or pay higher rates for life insurance, disability insurance, or long-term care insurance.

There may be other risks related to genetic testing that we don’t know about right now. This is because the field of genetics is moving forward very quickly.

Blood will be drawn at the time of clinical labs when possible. If an additional needle stick is required, there may be some discomfort, minor bruising, or possible fainting. There is also a very small chance (less than 1%) of infection at the needle puncture site.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures.

Will I be paid or receive anything for being in this study?

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems and to report your sickness or injury, call Dr. Sarah Panzer at (608) 262-5531 (office hours), (608) 262-2122 (24 hour/pager).

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. This includes access to your medical records so that study monitors, auditors, the Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information and samples that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The study sponsors, CareDX, Inc. and National Institutes of Health (NIH)
- Companies or groups performing services for the research study, such as laboratories outside UW-Madison

Will information from this study go in my medical record?

A medical record will be created for you if you do not already have one. None of the information we collect for this study will go in your medical record, but your medical record might say that you participated in this study. A copy of this consent and authorization form might go in your medical record.

A description of this clinical trial will be available on http://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 website at any time.

What if I have questions?

If you have questions about this research, please contact the Lead Researcher, Dr. Sarah Panzer, MD at (608) 262-5531 (office hours), (608) 262-2122 (24 hour/pager). If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

Optional storage of samples and health information for future research

We would like to keep your data and samples for an indefinite period of time, meaning we have no plans of ever destroying your data or samples. Keeping data or samples for future research is called “banking.” The banked data and samples would be kept in a secure location for use by researchers.

This is what will happen with your banked data and samples if you agree to banking:

- We will use the data and samples in future research projects about antibody-mediated rejection and transplantation.
- The data and samples may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- The banked data and samples will be labeled with a code instead of your name. When we give your data and samples to other investigators for research projects, they will not be able to use the code to figure out which data and samples are yours. The research team will maintain a link between your data and samples and your identifiable information kept by the study team. You can request to have your data and samples removed from the bank by contacting the research team at any time.
- Banked data and samples will not be shared with your health care providers or used in your treatment outside this study.

Please initial one of the lines below to indicate whether or not you agree to the optional data and samples banking:

____ Yes, I agree to have my data and samples banked for future research purposes.

____ No, I DO NOT agree to have my data and samples banked for future research purposes.

Agreement to Participate in the Research Study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____

Printed Name of Research Participant

_____

Signature of Research Participant Date

_____

Signature of Person Obtaining Consent and Authorization Date

****You will receive a signed and dated copy of this form****