Informed Consent Form

TITLE: The Kidney Genomics Research and Discovery (GRAND) Initiative

PROTOCOL NO.: FRRGPM20-001
IRB Protocol #20203346

SPONSOR: Frenova Renal Research

INVESTIGATOR: Michael Scott Anger, MD
SITE(S): Fresenius Medical Care920 Winter Street
Waltham, MA 02451

PROGRAM RELATED TELEPHONE NUMBER: (855) 4MY-RESN | (855) 469-7376
e-Mail: MyReason@Frenova.com

You are invited to take part in the My Reason research program,. Participation is completely optional and there is no direct benefit (financial or otherwise) to individuals for participating. You can choose not to take part and there will be no penalty or loss of benefits to which you are otherwise entitled.

If you choose to take part in this study, you need to sign and date this document. We will give you a fully signed and dated copy of this document.

This signature will permit My Reason to collect and analyze your blood or saliva sample and to contact your healthcare providers to collect your medical records. My Reason will remove information that can identify you, like your name and date or birth, before any records are shared with researchers. This information is then considered to be deidentified.

Are there benefits to being a part of My Reason?

The benefit of participating in My Reason is helping researchers learn more about human health and disease, including kidney disease and potentially associated conditions. This may lead to better ways to detect and treat disease and keep people healthy in the future.

In order to do this, samples and medical information about you may be licensed to or shared with researchers. These researchers may develop products or inventions (such as medicines or therapies) that result in commercial profit. Frenova also may charge researchers for access to information collected by My Reason. Participants in My Reason, their families or their heirs will not share in any possible future profits.

What does participation in My Reason involve?

You will be asked to donate a blood or saliva sample (approximately 3 tablespoons of blood or less than a teaspoon of saliva). If you receive dialysis treatment, we may be able to collect leftover blood from your routine blood draws in certain situations.

1. We will request information about you and your health. My Reason will collect information from your health records that is relevant to researchers. We will store your

identifiable health information, including your name and contact information, in a different database from your deidentified genetic and medical information that is shared with researchers.

a. Please review the separate "HIPAA Authorization Form" for more information on how we collect and use your health records.

2. We may contact you in the future for reasons including but not limited to:
   - Opportunities to participate in other research or clinical trials.
     Note: You may be eligible for other research studies or clinical trials that are not presented to you by Frenova
   - Updating you about My Reason, kidney disease and potentially associated conditions, or other relevant information

   Any future opportunities or requests are completely optional and will not impact your participation in My Reason.

3. Your deidentified samples, health information, and genetic information may be shared with approved scientific research communities, including universities or commercial companies. We will not give researchers your name or any other information that could directly identify you without your permission.

Why does My Reason want to collect and store my blood/saliva samples and health information?

Your samples contain DNA, which are instructions for how your body works. Everyone's DNA is different. By studying the DNA of many different people and comparing it to information in their medical records, we hope to find differences that explain why some people stay healthy and others get sick. Testing on your sample may include whole genome sequencing, which means we will test all of your DNA. If you have questions about how your genetic information will be used, ask the study staff.

How will My Reason collect my samples?

There are several ways we might collect your samples:

- Personnel may collect leftover blood from your routine blood tests.
- A qualified medical professional may collect an additional blood sample when you are having blood drawn for routine tests
- We may provide you with a spit kit (saliva collection kit)
- We may request a blood sample even if you are not already having blood drawn

Will My Reason share my name or other information that identifies me?

Your privacy is very important to us, and we will use appropriate safeguards to protect your personal information. We must collect personal identifying information like your name, address, or phone number so that we can record your consent to participate, collect your medical information and manage the research program. To help protect your identity, we will assign a unique code to your samples, medical information and any genetic information collected from your sample. We will remove personal identifiers such as your name, date of birth, and address. We will use appropriate safeguards to limit access to approved personnel and help prevent unauthorized access, use, alteration, and disclosure. These safeguards make it very hard for someone to identify you based on your samples or medical information. However, there is a chance that your information could be re-identified in the future.

We will not share information that identifies you like your name, address or phone number with researchers or anyone else without your consent or unless required by law. Under this consent, we may provide your deidentified information and samples to researchers for future studies without additional consent from you.

- The information and samples we collect you may be shared with approved researchers who are conducting research studies, such as researchers affiliated with universities, government agencies such as the National Institutes of Health (NIH) or Food and Drug Administration (FDA), the Institutional Review Board that oversees My Reason, or companies developing new drugs or devices, such as pharmaceutical companies or Fresenius Medical Care North America.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action or suit unless you say it is okay or as required by law. They also cannot provide them as evidence. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.
Even with the Certificate of Confidentiality, we may be required to disclose your information if required by law, such as to report child abuse or certain communicable diseases. The Certificate does not prevent a government agency from checking records or evaluating programs if allowed by law, such as disclosures required by the Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations or if you consent.

Does participating in My Reason cost me anything?
There is no cost to you (or to your insurance company) for participating in My Reason.

Will I be paid for taking part in this research?
Participants will not be compensated for participating in My Reason.

Will I be informed of the results from my DNA sequence or analysis of my medical information?
My Reason will not provide you with information collected or generated in this research program, including your DNA sequence, information about your individual genetic results or health, or the results of any studies using your information. If this does become a possibility in the future, you may be contacted by the research team with more details.

Are there any risks to being a part of My Reason?
If you give a blood sample, there is a small risk of bleeding, bruising, infection at the needle site, or fainting (just as with any blood draw).

There is some risk that your samples and information may be used inappropriately or could be used to identify you. There is a small risk that someone could re-identify you based on information provided to researchers, or that someone could get access to information we have stored about you in some unexpected situations (such as unauthorized access to our electronic systems), even with the protections My Reason has in place..

We also do not know every possible risk that might come up in the future.

Can my genetic information be used against me?
A federal law, called the Genetic Information Non-discrimination Act (GINA), states that individuals cannot be discriminated against by most employers or health insurance companies based on their genetic information.

However, GINA does not protect against discrimination by companies that sell life, disability or long-term care insurance, or for conditions for which you have already been diagnosed.

These laws may change over time and therefore the protections may change. Additionally, military personnel are not protected under GINA as the Department of Defense has their own policies protecting genetic information.

What if I change my mind later and don't want to participate in My Reason?
Being a part of My Reason is your choice. If you decide to participate in My Reason now, but change your mind at a later time, then you can withdraw (quit) as described in this Informed Consent Form. Your decision will have no effect on medical care you receive from Fresenius Medical Care North America or affiliated clinical centers. There will be no penalty or loss of benefits to which you are otherwise entitled.

If you choose to withdraw from My Reason, we will not collect any new samples or medical information from you. Your existing samples and information will not be released to any new researchers.

However, My Reason cannot withdraw your samples or information from researchers that already received them prior to your withdrawal. We also may keep your samples and any information that we have already collected or generated from your samples for research integrity and quality control purposes.

You may request to withdraw from the study by phone, email, or through the My Reason website.
Phone: (855) 4MY-RESN or E-mail: MyReason@Frenova.com

If you have questions, concerns, or complaints, or think this research has harmed you or made you sick, talk to the research team at the phone number listed above on the first page or email: MyReason@Frenova.com

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-855-818-2289 (toll-free), researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

How long will My Reason last?
There is no planned end date for My Reason although Frenova may decide to stop My Reason at any time. Unless you choose to withdraw, your samples and information will be kept until My Reason ends or the samples and information are no longer useful for research.

Consent to be in the My Reason research program:
By signing your name below, based on all of the information provided above and in the attached HIPAA Authorization Form, you agree to participate in My Reason and acknowledge and agree to the following. If you do not sign, you will not be able to participate in My Reason.

1. My genetic and medical information will be collected and stored by Frenova as described in this Informed Consent Form and the attached HIPAA Authorization Form.

2. Researchers may conduct studies using information about me collected or maintained by Frenova as part of My Reason. Their research may be related to kidney disease or potentially associated conditions.

3. If I give a blood or saliva sample, it will be stored in a laboratory facility that is associated with My Reason. This sample includes my DNA and other chemical.

4. To collect my sample, the research program may use my leftover blood from my routine blood draws (such as when my blood is drawn for dialysis care), if available. My Reason may also collect my blood or saliva sample in another way.

5. I also may be asked to give additional blood or saliva samples after my initial sample. I can say yes or no to each request for a new sample.

6. Frenova may contact me for the purposes described in this Informed Consent Form.

7. I am otherwise entitled. If I agree to participate, I can withdraw (quit) at any time and revoke my consent to participate in new studies, subject to the limitations described in this Informed Consent Form.

8. I will be asked to sign a separate form (HIPAA Authorization Form) authorizing my health care providers to disclose my protected health information to Frenova for the purpose of My Reason.

9. To the extent required by law, I agree that information and samples collected and deidentified by My Reason may be shared and used for future research purposes as described in this Informed Consent Form.

If I have any questions, I may contact the program at the available phone number and email address before signing this form.

Phone: (855) 4MY-RESN
Email: MyReason@Frenova.com

_____
Participant Name (Please print)

_____ _____
Participant Signature Today's Date (Date of consent)

_____
Name of Person Witnessing Consent (Please print)

_____ _____
Name of Person Witnessing Consent Signature Today's Date (Date of consent)

(If no witness signature is required, this witness signature section of the consent form may be left blank)

_____
Name of Person Obtaining Consent (Please print)

_____ _____
Name of Person Obtaining Consent Signature Today's Date (Date of consent)

HIPAA Authorization Form

Kidney Genomics Research and Discovery Initiative
Permission to Use Personal Health Information

Title of Research Program: My Reason Research Program
Principal Investigator(s): Michael Scott Anger, MD

A. What is the purpose of this HIPAA Authorization Form?
State and federal privacy laws limit the use and disclosure of your protected health information (called "PHI") by your health care providers. The purpose of this HIPAA Authorization Form is to allow your health care providers to disclose certain medical information about you to Frenova for the My Reason research program.

B. What Protected Health Information will be released to Frenova?
By signing this HIPAA Authorization, you authorize your current, former, or future health care providers to disclose all health information pertaining to your medical history, mental or physical condition, treatment received, and the other types of sensitive information discussed in the next paragraph. This may include PHI collected from your dialysis facility, nephrologist, primary care provider, cardiologist, or other health care specialists relevant to research.

C. Will my Protected Health Information include sensitive information about me?

Possibly. By signing this Authorization Form and initialing below, you agree that your health care providers may disclose sensitive information if contained in your health record.

For example, the sensitive information listed below may be reflected in your diagnoses or medications.

- ✓ Information about drug or alcohol abuse, diagnosis, or treatment.
- ✓ HIV/AIDS or sexually transmitted disease testing or diagnoses.
- ✓ Genetic information, including prior genetic test results.
- ✓ Mental health diagnosis or treatment.

I understand that the sensitive information listed above may be reflected in information collected by My Reason	*INITIAL HERE* ☞

D. How will my information be used or disclosed?
Your healthcare provider will disclose your protected health information to Frenova in order to administer My Reason. As described in the Informed Consent Form, Frenova will remove identifiable information about you (such as your name and contact information) before disclosing your genetic and health information to others, although Frenova may disclose your identifiable information (such as your name) if required by law or with your additional consent.

E. Am I required to sign this Authorization?
No, you are not required to sign if you do not wish to participate in My Reason. Your participation is entirely voluntary. There is no consequence to your treatment, payment, enrollment or eligibility for healthcare benefits if you choose not to participate. However, if you do not sign this Authorization, you will not be able to participate in My Reason.

F. Does this HIPAA Authorization expire?
Yes, this Authorization to use or disclose your PHI expires when the My Reason research program ends, and all required monitoring is complete. In the state of California this authorization expires on October 20, 2070.

G. Can I cancel or revoke this Authorization?
Yes, you can cancel or revoke this Authorization at any time by contacting the research team by phone or email.

Phone: (855) 4MY-RESN
Email: MyReason@Frenova.com

If you cancel or revoke this HIPAA Authorization or the Informed Consent Form, Frenova will stop collecting your PHI from your health care providers. The cancellation will be effective immediately upon Frenova's receipt of your written notice, except it will not have any effect on any prior action taken by Frenova or your health care providers in reliance on this Authorization.

May I review or copy my information in my medical record?
Yes, you have a right to see and copy information in your medical records maintained by your health care providers. Your health care providers may document your enrollment or store this HIPAA Authorization in your medical record. However, any results or analyses arising from the My Reason research program will not be entered in your medical record.

Is my health information protected after it has been given to Frenova?
Once your PHI is released to Frenova, it may not be protected by HIPAA or other state and federal privacy laws that your health care providers must follow. Frenova describes how it will use and disclose your PHI for My Reason in the Informed Consent Form.

H. Questions
If you have any questions about My Reason, The GRAND Initiative, this Authorization, or the use or disclosure of your information, please use the contact information below:
Phone: (855) 4MY-RESN
Email: MyReason@Frenova.com

I. Signature

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____

Participant Name (Please print)

_____

Participant Signature Today's Date (Date of consent)