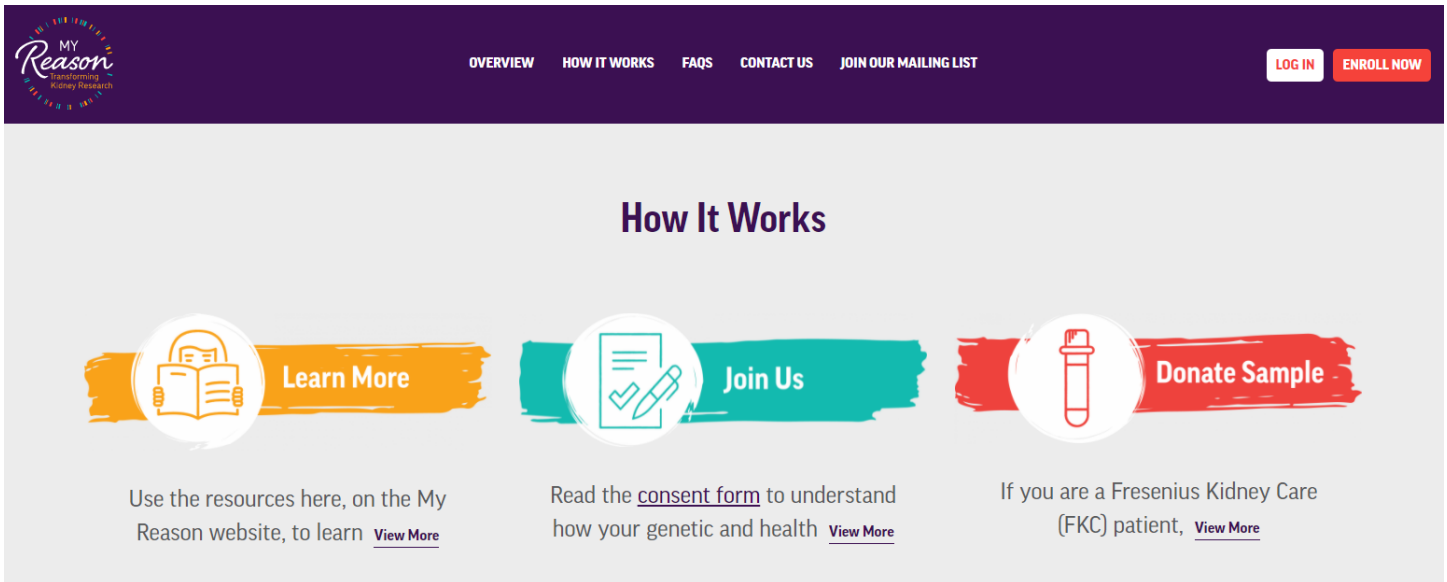
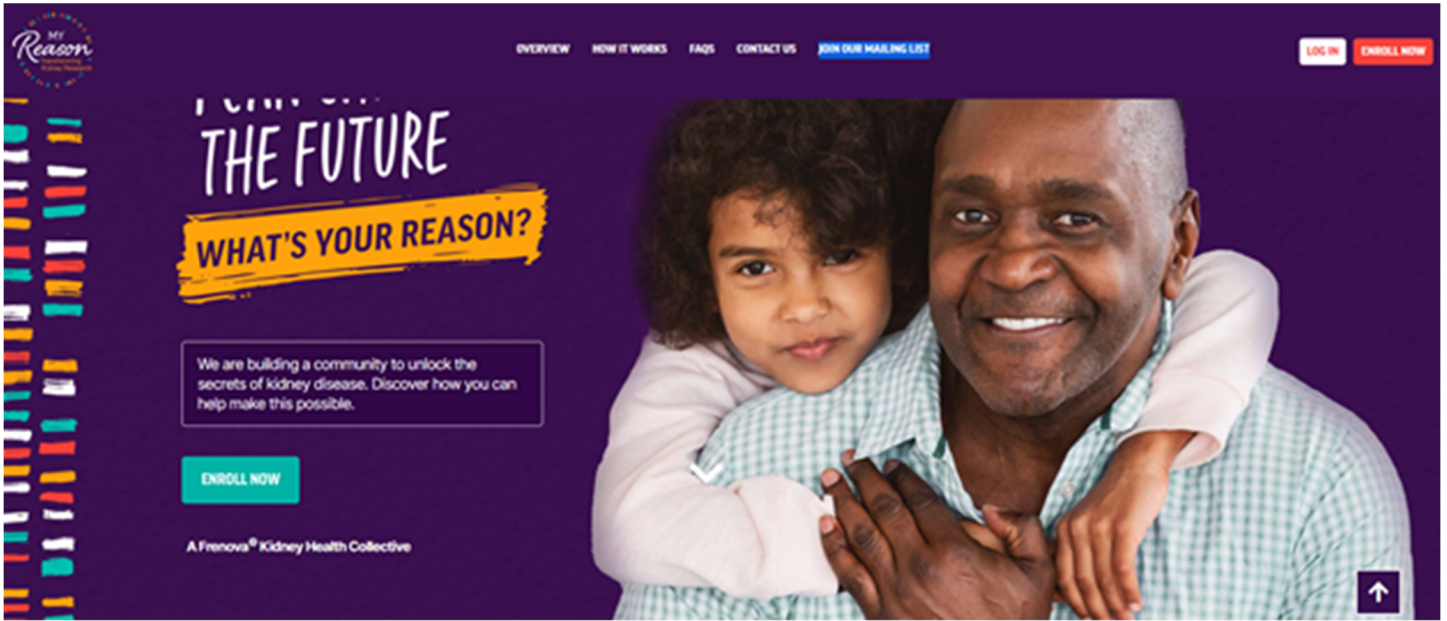



From the My Reason web page, an “Enroll Now” button is presented in two places. 1) At the top, right-hand corner of the page and 2) near the bottom, left of the page.






Clicking the “Enroll Now” button will navigate the person to a new page where the Inclusion / Exclusion Screening form is presented.



**CALL**  
Call us at a time convenient for you.  
[855-4MY-RESN](tel:855-4MY-RESN) (855-469-7376)

**CONTACT US**  
Click here to join the mailing list or send us an email.

**Quick Links to Common Email Providers**  
 [yahoo/mail](#)   [AOL](#)

### Inclusion / Exclusion Screening

Are you eligible to participate in the study?

Welcome! Let's get started. The first step in this process is determining if you are eligible to participate in this research program. Please take a moment to answer the following questions.

#### Qualifying Eligibility Questions

Are you living in the United States or Puerto Rico?\*  Yes  
 No  
[Reset](#)

Can you confirm that you are legally old enough to consent in your state of residence (18 years of age in the U.S. and 21 years of age in Puerto Rico)?\*  Yes  
 No  
[Reset](#)

Are you currently in jail or prison?\*  Yes  
 No  
[Reset](#)

You may have questions. If so, just look to the left for our contact information.

[Submit](#)

The interested person is required to answer each question.

#### Question 1:

Are you living in the United States or Puerto Rico?\*  Yes  
 No  
[Reset](#)

#### Question 2:

Can you confirm that you are legally old enough to consent in your state of residence (18 years of age in the U.S. and 21 years of age in Puerto Rico)?\*  Yes  
 No  
[Reset](#)

#### Question 3:

Are you currently in jail or prison?\*  Yes  
 No  
[Reset](#)

If the answer to a question excludes the person from participating, an appropriate message is displayed for that question.

#### Question 1:

Are you living in the United States or Puerto Rico?\*

Yes

No

[Reset](#)

You must be a **living in the United States or Puerto Rico** to participate in the **My Reason** research program.

Please use the "Contact Us" link to the left to join our email or postal mail list, if you would like to receive updates from us in the future.

### Question 2:

Can you confirm that you are legally old enough to consent in your state of residence (18 years of age in the U.S. and 21 years of age in Puerto Rico)?\*

Yes

No

[Reset](#)

You must be the **legal age in your state of residence** to participate in the **My Reason** research program.

Please use the "Contact Us" link to the left to join our email or postal mail list, if you would like to receive updates from us in the future.

### Question 3:

Are you currently in jail or prison?\*

Yes


No

[Reset](#)

Individuals **currently in jail or prison** are not eligible to join the **My Reason** research program at this time.

Please use the "Contact Us" link to the left to join our email or postal mail list, if you would like to receive updates from us in the future.

After all questions are answered that meet the inclusion criteria, a "Next" button is presented.



**CALL**  
Call us at a time convenient for you.  
855-4MY-RESN (855-469-7376)

**CONTACT US**  
Click here to join the mailing list or send us an email.

**Quick Links to Common Email Providers**  
Gmail, yahoo/mail, Outlook, iCloud, AOL

### Inclusion / Exclusion Screening

Are you eligible to participate in the study?

Welcome! Let's get started. The first step in this process is determining if you are eligible to participate in this research program. Please take a moment to answer the following questions.

#### Qualifying Eligibility Questions

Are you living in the United States or Puerto Rico?  
 Yes  
 No  
[Reset](#)


Can you confirm that you are legally old enough to consent in your state of residence (18 years of age in the U.S. and 21 years of age in Puerto Rico)?  
 Yes  
 No  
[Reset](#)

Are you currently in jail or prison?  
 Yes  
 No  
[Reset](#)

You may have questions. If so, just look to the left for our contact information.

[Next >](#)

Clicking "Next" presents the opportunity to provide the email address of the person providing consent. Also, the person is asked to confirm their email address and provide a primary phone number. The email address and primary phone number are required for the person to continue the process.



**CALL**  
Call us at a time convenient for you.  
855-4MY-RESN (855-469-7376)

**CONTACT US**  
Click here to join the mailing list or send us an email.

**Quick Links to Common Email Providers**  
Gmail, yahoo/mail, Outlook, iCloud, AOL

### Inclusion / Exclusion Screening

Status

Please let us know how we can reach you.

Your email address will be needed for the upcoming steps in the enrollment process. We may use your contact information to see if you have any questions about this registry, if we need additional information in order to complete your enrollment or to invite you to participate in other research studies.

#### CONTACT INFORMATION

Enter your Email address\*

Please confirm your Email address\*

Primary phone number (ex. 3334445555)\*

After clicking "Submit", the next step is to create your My Reason Portal account. You will receive an email message with a link to validate your email address. After clicking the link in the message, you can return here to complete the enrollment and consent process.

Step by step instructions are available below by clicking the "[View Instructions](#)" check box.

[View Instructions](#)

Click Here  
[Reset](#)

[< Prev](#)

[Submit](#)

There is also an option to view instructions for next steps to validate the email address, create a My Reason Participant Portal account and completing the informed consent process.

**View Instructions**

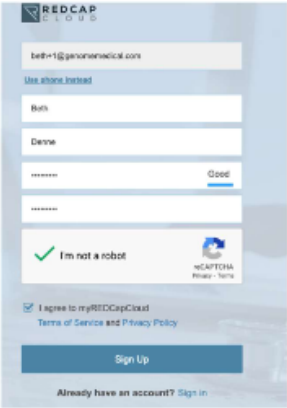
Click Here  
[Reset](#)

## Instructions

+ - Auto 100 1 / 4

Congratulations, you are now eligible to participate in the My Reason research program. The next step in the enrollment process will be to enter your email address so we can send you an invitation link to the My Reason Participant Portal provided by REDCap Cloud.

After you enter your email address on the next page, you will be taken to the My Reason Participant Portal login screen, where your email address will be pre-populated and you will be asked to create a password.



After you enter a password and click Sign Up, you'll see a message, like this one, asking you to check your email to activate your account.

Check your email address at "beth+1@genomemedical.com" to activate your account and ensure your account can be recovered.

Clicking "Submit" after entering the email address redirects the person to the My Reason Participant Portal account creation page.



### CALL

Call us at a time convenient for you.  
[855-4MY-RESN \(855-469-7376\)](tel:855-4MY-RESN)



### CONTACT US

Click here to join the mailing list or send us an email.

### Quick Links to Common Email Providers



[yahoo/mail](#)



[AOL](#)



ehedrick66+08121@gmail.com

[Use phone instead](#)

First Name

Last Name

Password (8 or more characters)

Too short

Confirm your password



I'm not a robot



reCAPTCHA  
[Privacy](#) - [Terms](#)



I agree to myREDCapCloud

[Terms of Service and Privacy Policy](#)

Sign Up

Already have an account? [Sign in](#)

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The email address entered in the previous step is piped to the account creation page and the person is not allowed to edit the email address. The person enters their First Name and Last Name, creates and verifies their password, confirms they are not a robot and agrees to the “myREDCapCloud Terms of Service and Privacy Policy”.

Clicking “Sign Up” presents a message instructing the person to activate their portal account by validating their email address. The person is not able to continue signing in from this page until they visit their email Inbox and proceeding through the email validation link provided in the email message.

Check your email address at "ehedrick66+08121@gmail.com" to activate your account and ensure your account can be recovered.



UAT

ehedrick66+08121@gmail.com

Sign in

[Use phone instead](#)

[Forgot password?](#)

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[Privacy](#) | [Terms](#)

The person receives an email message at the address provided. The message includes a link to validate the email address and proceed to My Reason Participant Portal to continue the informed consent process. The link is specific to the email address and only valid for the given email address.

## UAT - myREDCapCloud Sign Up Inbox x



**REDCap Cloud** <noreply@redcapcloud.com>  
to ehedrick66+08121 ▾

2:16 PM (11 minutes ago)



Hello Dexter Tester, welcome to myREDCapCloud!

Your username is: [ehedrick66+08121@gmail.com](mailto:ehedrick66+08121@gmail.com)

Please click the link below to activate your account

[https://myrcc.uat.redcapcloud.com/#signup=c524c1e7829a42e6afa1076515a7e261&lang=en\\_US](https://myrcc.uat.redcapcloud.com/#signup=c524c1e7829a42e6afa1076515a7e261&lang=en_US)

← Reply

↶ Reply all

➔ Forward

Clicking the link in the email message takes the person to the My Reason Participant Portal login form. The email address provided is piped into the username field and cannot be changed. The user provides the password set in an earlier step.

Your REDCap Cloud myREDCapCloud account has been activated.

**UAT**

[Forgot password?](#)  
Sign in with a different account

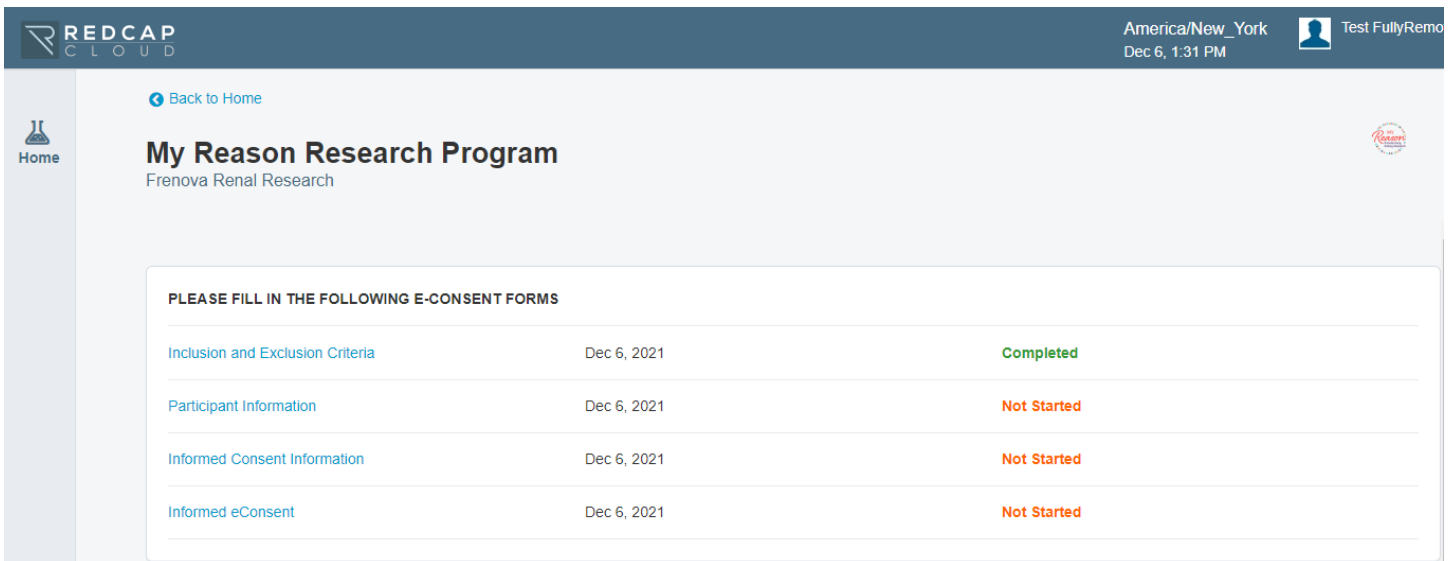
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[Privacy](#) | [Terms](#)



After successful log in, the portal Home page is presented.



Clicking on the My Reason Research Program image navigates the user to their dashboard to continue the informed consent process.



Instructions are also provided under the list of forms to be completed.



## OVERVIEW

---

This is your dashboard for the **My Reason** Research Program Portal (hosted by REDCap Cloud). The dashboard contains forms that will be available for you to complete.

You can easily identify your completed tasks which will be listed with a green “Completed” or “Submitted” status. Tasks that need your attention will have a red “Not Started” or “Data Entry Started” status.

### **STEP 1: Participant Information**

Complete this form to provide general demographic information about yourself.

### **STEP 2: Informed Consent Information**

Review the informed consent information to understand your participation in My Reason.

### **STEP 3: Informed eConsent**

Review and sign the informed consent and HIPAA Authorization to participate in My Reason.

## WITHDRAWALS

If you decide to participate in My Reason now, but change your mind at a later time, then you can withdraw (quit) at anytime by initiating a request to withdraw by phone, email, or through the My Reason website.

Phone: (855) 4MY-RESN or Email: [myreason@frenova.com](mailto:myreason@frenova.com)

At the time of request, please provide your **name and participant ID** which can be found at the top of the **Participant Information** form.

After which, you will receive an email notifying you that a 'Withdrawal' form has become available for you to complete.

## Completing the “Participant Information” form.

What has changed: It is important for us to properly identify participants as ESKD and to correctly identify their dialysis provider. We are adding questions related to dialysis treatment and provider to the “Participant Information” form. These questions are placed in the “PARTICIPANT INFORMATION” section, below the “Race” field.

RED CAP CLOUD America/New\_York Test U  
Mar 10, 3:17 PM

Home

Back to Forms

### My Reason Research Program

Frenova Renal Research

Participant Information

The information we collect here will be used to record your participation and to identify your health records for inclusion in the My Reason registry.

Today's Date\* Mar 10, 2022

Subject ID : \_\_\_\_\_

#### PARTICIPANT INFORMATION

First Name\* Test

Middle Name/Initial

Last Name\* UAT1

Suffix Select

Is there another name that would help identify you?

Maiden Name  
 Married Name  
 Nickname  
 Other  
 Not Applicable

Reset

Date of Birth\*

Are you currently receiving dialysis treatment?\*  Yes  No  
Reset

Select Dialysis Provider\*

Fresenius Kidney Care  
 Davita  
 US Renal Care  
 American Renal Associates  
 Other

Reset

Enter Dialysis Provider Name ACME Dialysis

#### CONTACT INFORMATION

Email sowersc+0311

Home Address Line 1\*

Home Address Line 2 (PO BOX, Apartment, Suite)

City \*

State\* Select

Zip Code\*

Primary Phone Number 9195634000

Alternate Phone Number  
Ex. 3334445555

## Question “Are you currently receiving dialysis treatment?” is required:

Are you currently receiving dialysis treatment?\*  Yes  No  
Reset

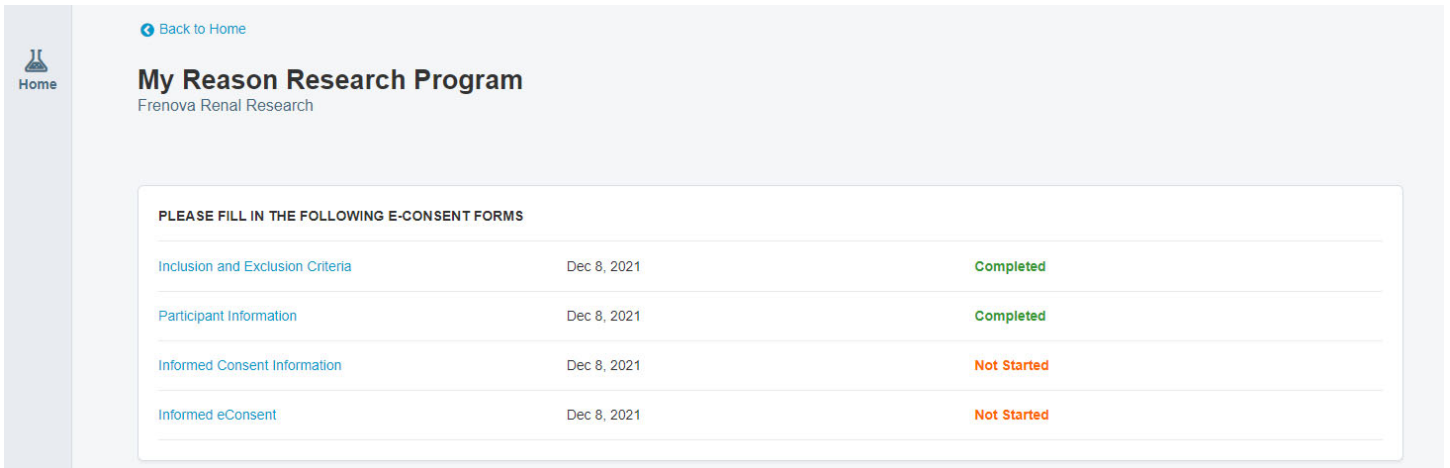
If selecting “Yes”, the interested person is required to select their dialysis provider.

Are you currently receiving dialysis treatment?*	<input checked="" type="radio"/> Yes <input type="radio"/> No <a href="#">Reset</a>
Select Dialysis Provider*	<input checked="" type="radio"/> Fresenius Kidney Care <input type="radio"/> Davita <input type="radio"/> US Renal Care <input type="radio"/> American Renal Associates <input type="radio"/> Other <a href="#">Reset</a>

**If selecting "Other", the interested person may enter their dialysis provider name.**

Are you currently receiving dialysis treatment?*	<input checked="" type="radio"/> Yes <input type="radio"/> No <a href="#">Reset</a>
Select Dialysis Provider*	<input type="radio"/> Fresenius Kidney Care <input type="radio"/> Davita <input type="radio"/> US Renal Care <input type="radio"/> American Renal Associates <input checked="" type="radio"/> Other <a href="#">Reset</a>
Enter Dialysis Provider Name	<input type="text" value="ACME Dialysis"/>

After clicking “Submit”, the participant is returned to their portal dashboard.



Home

Back to Home

## My Reason Research Program

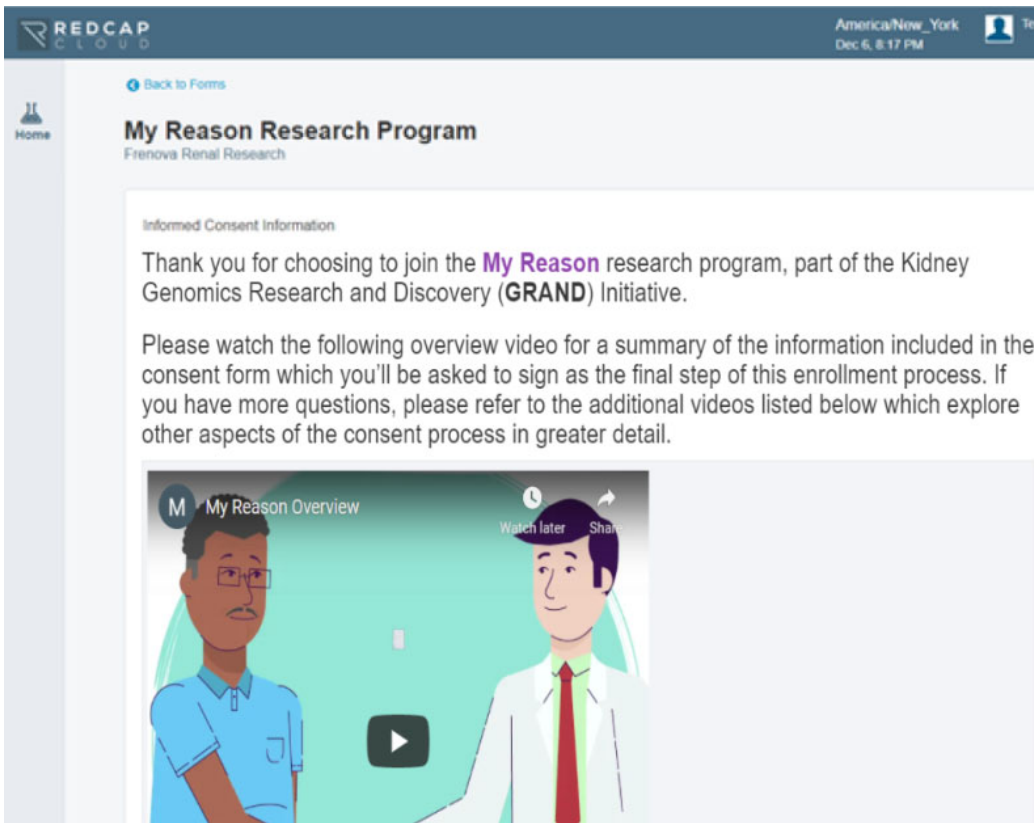
Frenova Renal Research

PLEASE FILL IN THE FOLLOWING E-CONSENT FORMS

<a href="#">Inclusion and Exclusion Criteria</a>	Dec 8, 2021	Completed
<a href="#">Participant Information</a>	Dec 8, 2021	Completed
<a href="#">Informed Consent Information</a>	Dec 8, 2021	Not Started
<a href="#">Informed eConsent</a>	Dec 8, 2021	Not Started

The next step is to view the “Informed Consent Information” form where information is presented to provide appropriate informed knowledge concerning the consent form.

There is an initial video segment that summarizes all the elements of the consent.



REDCAP CLOUD

America/New\_York  
Dec 6, 8:17 PM

Home

Back to Forms

## My Reason Research Program

Frenova Renal Research

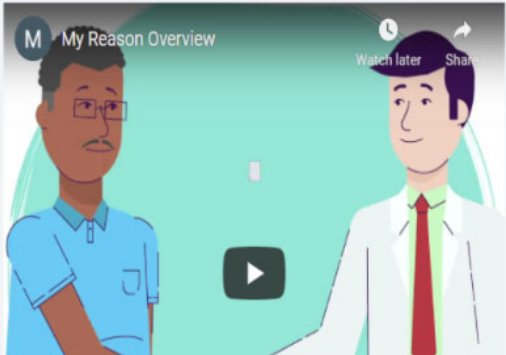
### Informed Consent Information

Thank you for choosing to join the **My Reason** research program, part of the Kidney Genomics Research and Discovery (**GRAND**) Initiative.

Please watch the following overview video for a summary of the information included in the consent form which you'll be asked to sign as the final step of this enrollment process. If you have more questions, please refer to the additional videos listed below which explore other aspects of the consent process in greater detail.

M My Reason Overview

Watch later Share



There is also an option to view the transcript of the summary video.

[Read the video transcript](#)  [View](#)  
[Reset](#)

We are excited to invite you to take part in the My Reason research program, part of the Kidney Genomics Research and Discovery (GRAND) Initiative. Participation is completely optional and there is no direct benefit (financial or otherwise) to individuals for participating. This Initiative is sponsored by Frenova Renal Research, a subsidiary of Fresenius Medical Care.

**Consent to be in the My Reason Research Program, part of the Kidney Genomics Research and Discovery (GRAND) Initiative:**

By providing your electronic signature, based on all of the information provided and in the HIPAA Authorization Form, you agree to participate in My Reason and acknowledge and agree to the following nine points. 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 and the HIPAA Authorization Form.
2. 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, RNA, serum and blood.
3. Researchers may conduct studies using information about me collected or maintained by Frenova. Their research may be related to kidney disease or potentially associated conditions.
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 through other means.
5. I 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.
7. If I decide not to participate, there will be no penalty to me, and I will not lose benefits to which 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.

Following the initial summary video, there are eight (8) additional video segments along with their transcript. The eight additional videos are presented in an FAQ format.

<b>What is the My Reason Research Program?</b>	<input type="checkbox"/> <a href="#">View Video</a> <a href="#">Reset</a>
<b>What does participation in My Reason involve?</b>	<input type="checkbox"/> <a href="#">View Video</a> <a href="#">Reset</a>
<b>Why does My Reason want to collect and store my blood/saliva samples and health information, and how will they be collected?</b>	<input type="checkbox"/> <a href="#">View Video</a> <a href="#">Reset</a>
<b>Will My Reason share my name or other information that identifies me and how will this information be secured?</b>	<input type="checkbox"/> <a href="#">View Video</a> <a href="#">Reset</a>
<b>Does participating in My Reason cost me anything?</b> <b>Will I be paid for taking part in this research?</b> <b>Are there benefits to being a part of My Reason?</b>	<input type="checkbox"/> <a href="#">View Video</a> <a href="#">Reset</a>
<b>Will I be informed of the results from my DNA sequence or analysis of my medical information?</b> <b>Are there any risks to being a part of My Reason?</b> <b>Can my genetic information be used against me?</b>	<input type="checkbox"/> <a href="#">View Video</a> <a href="#">Reset</a>
<b>How long will My Reason last, and what if I change my mind later and don't want to participate?</b>	<input type="checkbox"/> <a href="#">View Video</a> <a href="#">Reset</a>
<b>What is covered in the HIPAA Authorization Form?</b>	<input type="checkbox"/> <a href="#">View Video</a> <a href="#">Reset</a>

Clicking the “View Video” option beside each of the FAQ statements presents the key point of the video, the video segment and the opportunity to view the video transcript.

### Segment 1:

What is the My Reason Research Program?  View Video  
[Reset](#)

My Reason is a research program. The goal of My Reason is to help researchers better understand the potential causes of kidney disease and associated health conditions.

Video length is 2:35.



The video player shows a man in a purple shirt holding a white document. The video title is 'Frenova My Reason Research Progra...'. There are 'Watch later' and 'Share' buttons. A 'Watch on YouTube' button is at the bottom left. Below the video player, there is a link to 'Read the video transcript' and a 'View' button.

We are excited to invite you to take part in the My Reason research program, part of the Kidney Genomics Research and Discovery (GRAND) Initiative. Participation is completely optional and there is no direct benefit (financial or otherwise) to individuals for participating. This Initiative is sponsored by Frenova Renal Research, a subsidiary of Fresenius Medical Care.

My Reason is a research program in which participants provide a biological sample, like blood or saliva, that will be analyzed for genetic information as described in this video Informed Consent. My Reason also will seek permission to collect participants' medical records.

The information we receive from these biological samples and medical records will be deidentified and included in a database that will be shared with qualified researchers. The goal is to combine this information for a large number of participants to help researchers better understand the potential causes of kidney disease and associated health conditions. These researchers also may use the information to help to develop new drugs, treatments or tests.

Please go through all videos carefully before you decide to take part in My Reason.

If you choose to take part, you will be asked to sign and date a consent form electronically. The electronic signature will signal your permission for My Reason to collect and analyze your biological sample and to contact your healthcare providers to collect your clinical records and to include them in the larger program database. We will make available a fully signed and dated copy of the consent form for your records.

This series of videos will tell you:

- The benefits and risks of being a part of My Reason
- How we will collect and use your samples and information
- How we will protect your privacy and the risk that your samples or information could be used inappropriately, which is the main risk under My Reason

## Segment 2:

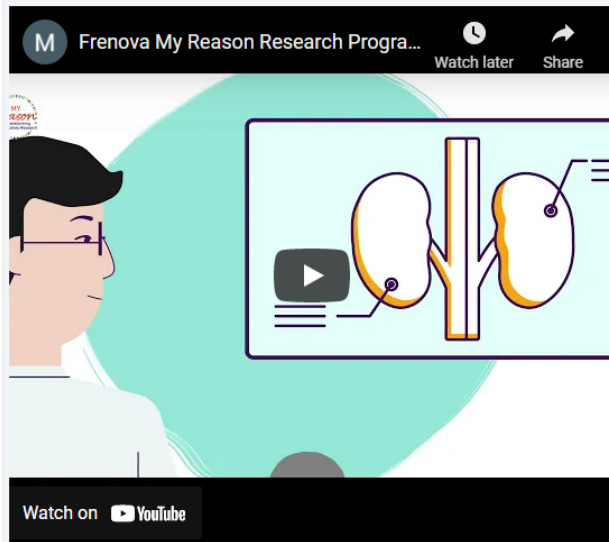
What does participation in My Reason involve?

View Video  
[Reset](#)

Participants will provide consent to share a biological sample (blood or saliva) and medical records.

You may be contacted for updates on My Reason or about future (optional) opportunities.

Video length is 2:17.



### 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 circumstances. If you decline to provide a saliva or blood sample, you will not be eligible to participate in this research program.

We will request information about you and your health. My Reason will periodically 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 database separate from your genetic and medical information that is shared with researchers. Please review the separate "HIPAA Authorization Form" for more information about how we collect and use health records.

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.*

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



### Segment 3:

Why does My Reason want to collect and store my blood/saliva samples and health information, and how will they be collected?

View Video  
[Reset](#)

Your DNA and medical records are unique to you. When this information is provided by hundreds of people, research can begin to better understand the potential causes of kidney disease and associated health conditions.

Your blood or saliva may be collected a few different ways and your medical records will be released by your healthcare providers after your consent is recorded.

Video length is 2:13.



#### 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. Your blood and tissues also contain proteins and other chemicals (such as calcium) that can provide clues about a person's health that may be relevant to researchers. Under My Reason, your sample will be analyzed to collect this DNA, proteins and other chemicals that are part of your genetic information. There have already been many discoveries linking DNA with certain kidney diseases and potentially associated conditions.

#### 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 ordered by your doctor
- A qualified clinical laboratory assistant or a dialysis staff member may collect an additional blood sample when you are having blood drawn for routine tests
- We may provide you a spit kit (saliva collection kit)
- We may request an additional blood sample even if you are not already having blood drawn for tests your doctor has ordered

#### How will My Reason collect my medical information?

- After your consent is recorded, My Reason will send a request for medical information to your healthcare providers
- This request will include the HIPAA authorization (which you will review shortly), allowing your healthcare provider to release your medical information to My Reason
- Your identifiable information will be stored by My Reason in a secure database separate from your deidentified medical and genetic information that is provided to researchers

## Segment 4:

Will My Reason share my name or other information that identifies me and how will this information be secured?  View Video [Reset](#)

My Reason 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.

To help protect your identity, we will assign a unique code to your samples, medical information and any genetic information collected from your sample.

Video length is 4:39.



### 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. If you consent to participate, we will share your identifiable information with Frenova's employees or contractors only to let them perform their jobs for the research program.

However, 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.

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. 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.

The information and samples we collect from you, including genetic and other information collected from your samples, will be combined with information from many other people and may be shared with qualified researchers for research studies. These researchers may work for:

- Fresenius Medical Care North America or its affiliates and subsidiaries, including Frenova Renal Research;
- Universities, medical schools, or other academic research facilities;
- Government agencies like the National Institutes of Health (NIH) and Food and Drug Administration (FDA);
- Public agencies, foundations, consortiums or other non-profit or for-profit groups that conduct or sponsor kidney research;
- Companies that conduct research to develop new therapies or devices, such as pharmaceutical companies; or
- The Institutional Review Board that oversees My Reason

In addition, your health care providers may document your consent to participate and disclose your health information to Frenova as part of My Reason. They may store this documentation in their health record for administrative purposes.

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 by 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.

### How will you secure my private information and the information you collect about me?

As noted above, we will take reasonable precautions to protect the privacy and security of your samples and information collected by My Reason. For example, we will use appropriate safeguards to limit access to approved personnel and help prevent unauthorized access, use, alteration, and disclosure. Although we will provide certain genetic and medical information to researchers, we will not disclose your name or identifiable information about you, unless you specifically consent for us to do so.

## Segment 5:

Does participating in My Reason cost me anything?  
Will I be paid for taking part in this research?  
Are there benefits to being a part of My Reason?

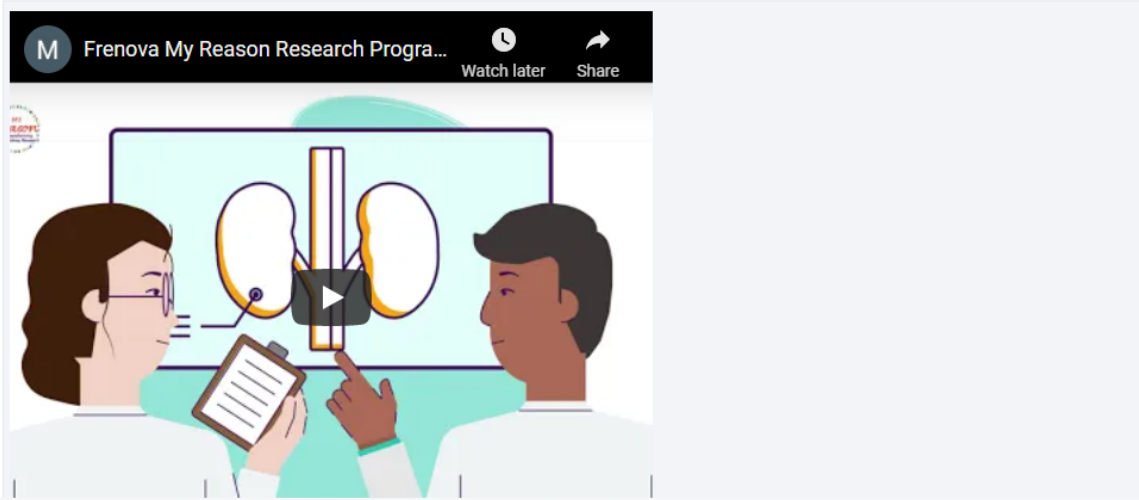
View Video  
[Reset](#)

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

Participants will not be compensated for participating in My Reason.

The main benefit of participating in My Reason is helping researchers learn more about human health and disease, including kidney disease and potentially associated conditions.

Video length is 4:37.



### 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.

### Are there benefits to being a part of My Reason?

There are no known benefits to you from taking part in this research. The main 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 information collected may be licensed or shared with researchers, which may also result in 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.

## Segment 6:

Will I be informed of the results from my DNA sequence or analysis of my medical information?  View Video  
[Reset](#)

Are there any risks to being a part of My Reason?  
Can my genetic information be used against me?

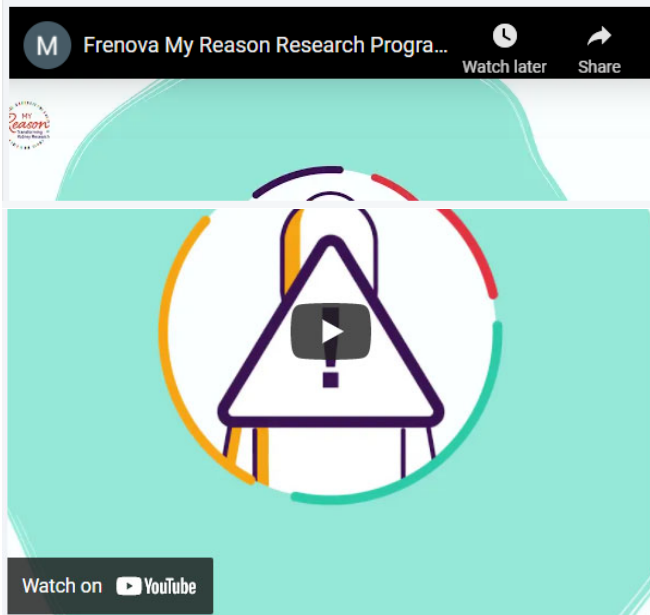
At this time, My Reason will not provide you with information collected or generated in this research program, including your DNA sequence, information about your individual genetic results or health, or the results of any studies using your information.

There are small risks (like bruising) associated with a blood draw, and while very unlikely, there is some risk that your samples and information may be used inappropriately or could be used to identify you; Frenova takes your privacy seriously and will use reasonable safeguards to protect your information.

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. 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.

Video length is 2:21.



### Will I be informed of the results from my DNA sequence or analysis of my medical information?

At this time, 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. As previously mentioned, Frenova takes your privacy seriously and will use reasonable safeguards to protect your information. 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).

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 Dept. of Defense has their own policies protecting genetic information.

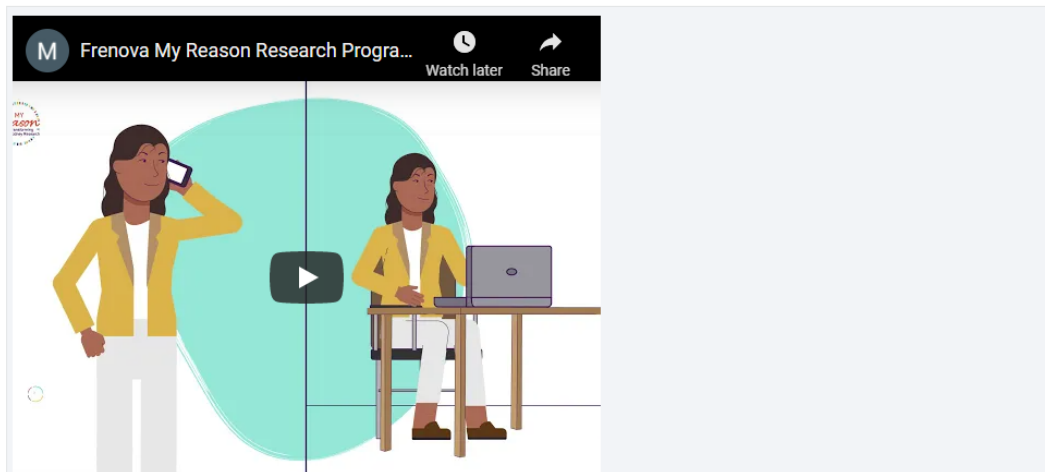
## Segment 7:

How long will My Reason last, and what if I change my mind later and don't want to participate?  View Video [Reset](#)

There is no planned end date for My Reason although Frenova may decide to stop My Reason at any time.

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 the Informed Consent Form.

Video length is 2:49.





### 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 the 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 initiate a request to withdraw by phone, email, or through the My Reason website.

Phone: (855) 4MY-RESN or Email: MyReason@FresnovaRenalResearch.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@FresnovaRenalResearch.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?

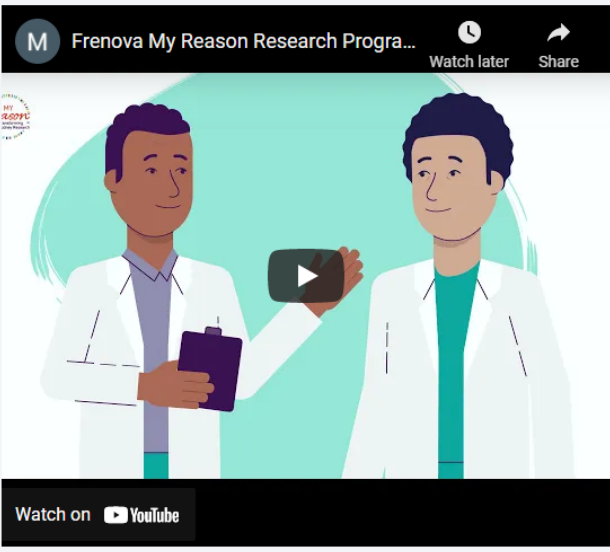
There is no planned end date for My Reason although Fresnova may decide to stop My Reason at any time. Unless you choose to withdraw, your samples and information will be kept until My Reason ends or the samples and information are no longer useful for research.


## Segment 8:

What is covered in the HIPAA Authorization Form?  View Video [Reset](#)

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 the HIPAA Authorization Form is to allow your health care providers to disclose certain medical information about you to Fresnova for My Reason.

Video length is 6:06.



Watch on  YouTube

Finally, we are going to review the HIPAA Authorization Form. In addition to having just provided an electronic signature for the general consent to participate in the My Reason Research Program, you will now provide a separate e-initials and an e-signature for the HIPAA Authorization Form, which will allow My Reason to collect your medical records for this study.

**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, which is part of the Kidney Genomics Research and Discovery (GRAND) Initiative.

**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 section. This may include PHI collected from your dialysis facility, nephrologist, primary care provider, cardiologist, or other health care specialists relevant to research.

**Will my Protected Health Information include sensitive information about me?**

Possibly. By signing this Authorization Form, you agree that your health care providers may disclose sensitive information if contained in your health record. For example, the sensitive information listed here may be reflected in your diagnoses or medications. You will type your electronic initials next to these descriptions when you are providing the electronic signature on the HIPAA Authorization Form:

- \_\_\_ 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.

**How will my health 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 health information to other researchers. Frenova may disclose identifiable information such as your name as required by law or with your consent to the following:

- Fresenius Medical Care North America or its affiliates and subsidiaries, including Frenova Renal Research;
- Universities, medical schools, or other academic research facilities;
- Government agencies like the National Institutes of Health (NIH) and Food and Drug Administration (FDA);
- Public agencies, foundations, consortiums or other non-profit or for-profit groups that conduct or sponsor kidney research; or
- Companies that conduct research to develop new therapies or devices, such as pharmaceutical companies
- The Institutional Review Board that oversees My Reason

**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.

**Does this HIPAA Authorization expire?**

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

**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: My Reason@FrenovaRenalResearch.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. However, researchers can continue to use and share any of the information that they already have.

**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. 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.

**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: My Reason@FrenovaRenalResearch.com



After viewing the video segments, the person is presented with instructions for returning to the dashboard and taking the final step.

Thank you for reviewing this information as part of the consent process.

You're almost there. Your last step will be to return to your portal dashboard, click "Informed eConsent", then review, sign and submit.

Click "Submit" now to return to your portal dashboard.


Cancel    Save and Return Later    Submit


After clicking "Submit", the person is returned to the portal dashboard where they can proceed to the next step in the process.

The screenshot shows the REDCAP Cloud interface. At the top, there is a navigation bar with the REDCAP logo, the location 'America/New\_York', the date 'Dec 6, 1:31 PM', and a user profile icon labeled 'Test FullyRemo'. Below the navigation bar, there is a sidebar with a 'Home' icon and a main content area. The main content area has a 'Back to Home' link and a title 'My Reason Research Program' with the subtitle 'Frenova Renal Research'. Below the title, there is a section titled 'PLEASE FILL IN THE FOLLOWING E-CONSENT FORMS' containing a table with four rows of e-consent forms.

PLEASE FILL IN THE FOLLOWING E-CONSENT FORMS		
<a href="#">Inclusion and Exclusion Criteria</a>	Dec 6, 2021	Completed
<a href="#">Participant Information</a>	Dec 6, 2021	Completed
<a href="#">Informed Consent Information</a>	Dec 6, 2021	Completed
<a href="#">Informed eConsent</a>	Dec 6, 2021	Not Started

The next step is to complete the “Informed eConsent” form. The person is asked if they are a resident of or consenting within the state of California. This is used to determine if the California Research Participants’ Bill of Rights should be provided to the participant.

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## My Reason Research Program

Frenova Renal Research

Informed eConsent

Are you a resident of or consenting within the State of California?\*

Yes  
 No  
[Reset](#)

+ - Auto 100 1 / 9

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### Informed Consent Form

**TITLE:** The Kidney Genomics Research and Discovery (GRAND) Initiative- My Reason research program

**PROTOCOL NO.:** FRRGPM20-001  
ASPIRE® Protocol #20203346


**SPONSOR:** Frenova Renal Research


**INVESTIGATOR:** Michael Scott Anger, MD  
**SITE(S):** Fresenius Medical Care  
920 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.

The actual consent form and the HIPAA Authorization form is presented as a PDF view.

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## My Reason Research Program

Frenova Renal Research

Informed eConsent

Are you a resident of or consenting within the State of California?  Yes  No [Reset](#)

+ - Auto 100 1 / 9

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### Informed Consent Form

**TITLE:** The Kidney Genomics Research and Discovery (GRAND) Initiative- My Reason research program

**PROTOCOL NO.:** FRRGPM20-001  
ASPIRE<sup>®</sup> Protocol #20203346

**SPONSOR:** Frenova Renal Research

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920 Winter Street, Waltham, MA 02451

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+ - Auto 100 7 / 9

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### 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.

The person is required to affirmatively answer each of the consent attestations. Also, the person is required to provide their name, electronic signature, and data of consent.

The final step in the enrollment process is to agree to the following statements and sign this form below. When you are finished and ready, click "Submit" to complete the process and return to your dashboard.

Thank you for joining the My Reason Research Program!

PARTICIPANT CONSENT TO JOIN	
I agree that my health care providers may disclose sensitive information if contained in my health record.*	<input type="checkbox"/> Yes <a href="#">Reset</a>
I have read and understand the information in this consent form. All of my questions have been answered. I freely and willingly choose to take part in the My Reason Research Program. *	<input type="checkbox"/> Yes <a href="#">Reset</a>
I attest that I am physically, mentally, and medically able to provide informed consent.*	<input type="checkbox"/> Yes <a href="#">Reset</a>
Participant Full Name*	<input type="text"/>
Participant Signature*	<a href="#">Add Signature</a>
Date of Consent*	<input type="text" value="Dec 8, 2021"/> 

The electronic signature block:

**Add Signature**

[Save and Exit](#)

[Cancel](#)



[Maximize](#)

[Clear](#)

If appropriate, the participant is provided the California Research Participants' Bill of Rights.

## California Research Participants' Bill of Rights


In accordance with California law, any person who is asked to participate in or consent to research involving ?medical experiments? has the following rights. Medical experiments include collecting a participant?s blood for the purpose of research rather than to provide medical treatment. Research participants have a right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the experiment and any drug or device to be utilized, if applicable.
3. Be given a description of any related discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the participant that are reasonably expected from the experiment, if applicable.
5. Be told about appropriate alternative procedures, drugs or devices that might be helpful to the participant, if applicable, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved, if applicable.
8. Be permitted to withdraw consent for research without any effect on the participant?s healthcare benefits or medical care.
9. Be given a copy of any signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to the experiment without feeling forced or misled.

Please refer to the My Reason Informed Consent Form and HIPAA Authorization for this information, including the procedures to be used in this research program and the risks and benefits of participation.

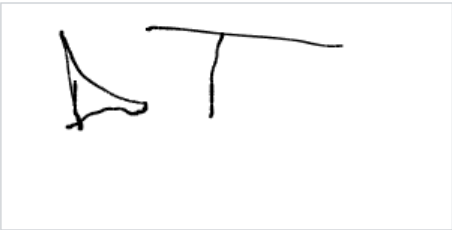
If you have any questions or concerns about information contained in those documents or your rights as a research participant, you are welcome to contact the My Reason team at **(855) 4MY-RESN** or E-mail: [myreason@frenova.com](mailto:myreason@frenova.com)

The participant is required to provide their name, electronic signature, and data of consent.

SIGNATURE	
Participant Full Name *	<input type="text"/>
Participant Signature *	Add Signature
Date*	<input type="text" value="Dec 8, 2021"/> 

The electronic signature block:

**Add Signature**



After clicking “Submit”, the person is returned to the portal dashboard. This completes the consenting process for the participant. There is a welcome message provided and available on their dashboard

The screenshot shows a user interface for a research program. At the top left is the REDCAP CLOUD logo. Below it is a 'Home' button with a flask icon. A 'Back to Home' link is visible. The main heading is 'My Reason Research Program' with the subtitle 'Frenova Renal Research'. A central box titled 'PLEASE FILL IN THE FOLLOWING E-CONSENT FORMS' contains a table with five rows of consent forms, their completion dates, and their status.

PLEASE FILL IN THE FOLLOWING E-CONSENT FORMS		
<a href="#">Inclusion and Exclusion Criteria</a>	Dec 7, 2021	Completed
<a href="#">Participant Information</a>	Dec 7, 2021	Completed
<a href="#">Informed Consent Information</a>	Dec 7, 2021	Completed
<a href="#">Informed eConsent</a>	Dec 7, 2021	Submitted
<a href="#">Welcome</a>	Dec 7, 2021	Not Started

Welcome message:


REDCAP CLOUD

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Home

## My Reason Research Program

Frenova Renal Research



**Thank you for your interest in this research study and for completing the consent process.**

You are making a difference by participating. Everyone has unique differences in their DNA, their medical history, and their life journeys. It is your uniqueness and your story that make your contribution to this type of research so valuable. Just by sharing your DNA and information



The participant receives an email message that contains a link to download a PDF copy of the signed consent, HIPAA Authorization and California Research Participants' Bill of Rights.

## UAT - [REDCap Cloud] eConsent documents Inbox x

**noreply@redcapcloud.com** <noreply@redcapcloud.com> 4:11 PM (3 minutes ago) ☆ ↶ ⋮  
to ehedrick66+08121 ▾

Hello,




eConsent documents "**Informed eConsent.pdf**" (333.5 kB) for study **My Reason Research Program** is available for download. This download will expire on Sep 11, 2021 8:11:15 PM. A second follow-up email will be sent containing the password for retrieving the file at the link below.

Provider: **Frenova Renal Research**

Thank you.

To download the file, follow the link below or copy it into your web browser.  
<https://frenova.uat.redcapcloud.com/sendDownloadPass.jsp?hash=43f0f004-a5a3-42a1-b391-e6040bb15a32>

eConsent Documents

 Reply  Reply all  Forward




A separate email message is sent to the participant that contains the password required to download the PDF copy.

## UAT - Re: [REDCap Cloud] Password for downloading file Inbox x

**noreply@redcapcloud.com** <noreply@redcapcloud.com> 4:11 PM (5 minutes ago) ☆ ↶ ⋮  
to ehedrick66+08121 ▾


Below is the password for downloading the file mentioned in the previous email.





acHmxKjQP6

 Reply  Reply all  Forward


Also, a welcome email is sent to the participant from the My Reason study team. If the participant is a Fresenius Kidney Care patient, they will receive the following message:

## Welcome to My Reason Research Program

 myreason  
To ● Eddie Hedrick

 Reply  Reply All  Forward 

Thu 8/5/2021 2:30 PM

 You replied to this message on 8/11/2021 8:34 AM.



August 5, 2021

Dear Eddie Hedrick,

Thank you for enrolling in the My Reason Research Program. As you have learned from the informed consent, My Reason is enrolling a large number of participants to help build a diverse health database. This health database will help researchers better understand the causes and potential treatments for kidney disease and associated diseases.

As a Fresenius Kidney Care (FKC) patient\*, your next step in the My Reason Research Program is easy! All you need to do is continue with your regular care. A portion of blood from your next routine blood draw will be set aside and stored for the My Reason Research Program, so no extra needle sticks or samples will need to be collected.

Once your sample is collected, your identifying information will be removed from the specimen and your deidentified sample will become part of the research program. As you recently learned in the consent process, this step is integral in safeguarding your protected health information (PHI).

Even though we won't be able to give you specific updates related to your personal contribution to My Reason, we do want to keep you informed about the progress of My Reason. We look forward to continuing to share updates and information about this important research.

If you do have any questions, please contact the My Reason Research Program at [MyReason@fresnova.com](mailto:MyReason@fresnova.com) or 855-4MY-RESN.


Sincerely,

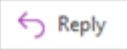



The My Reason Study Team

\*If you believe that we have incorrectly identified you as a Fresenius Kidney Care patient, please contact the My Reason Research Program so that we can address this issue.


If the participant is not a Fresenius Kidney Care patient, they will receive the following message:

## Welcome to My Reason Research Program

 myreason  
To ● Eddie Hedrick

 Reply  Reply All  Forward 

Thu 8/5/2021 2:30 PM

 You replied to this message on 8/11/2021 8:34 AM.



December 8, 2021

Dear «First\_Name» «Last\_Name»,

Thank you for enrolling in the My Reason Research Program. As you have learned from the informed consent, My Reason is enrolling a large number of participants to help build a diverse health database. This health database will help researchers better understand the causes and potential treatments for kidney disease and associated conditions.

Because you are *not* currently a Fresenius Kidney Care (FKC) patient\*, we wanted to provide you with information regarding your next steps in the My Reason Research Program. My Reason is not currently collecting specimens from non-FKC participants, but we do plan to begin specimen collection in the future.

In the meantime, we do want to keep you informed about the progress of My Reason. We look forward to continuing to share updates and information about this important research. We will be notifying you about the timing and details of your sample collection once the program is ready to accept specimens from all participants.

If you do have any questions, please contact the My Reason Research Program at [MyReason@frenova.com](mailto:MyReason@frenova.com) or 855-4MY-RESN.

Sincerely,

The My Reason Study Team

\*If you *are* a current Fresenius Kidney Care patient and believe that we have not correctly identified you as such, please contact the My Reason Research Program so that we can address this issue.