

Consent to join the Kidney Precision Medicine Project

Person in charge of this study (Principal Investigator):

[PI Name]

Person organizing this study (Contact Person):

[Research Team Contact Name and Phone Number]

The sponsor of this study: National Institutes of Health (NIH)

This form tells about the Kidney Precision Medicine Project (KPMP). KPMP is a research study. It is not medical care. Joining KPMP is voluntary. You can choose to join or not. No matter what you decide, you will still get the best care possible.

Review this form carefully. It tells all about KPMP so you can decide if you want to join. We will give you a copy of it to keep. If you have questions, please ask us.

Here are some key points about KPMP:

- If you join, we will take a biopsy (a few small pieces) of your kidney.
 - The most common risk of the biopsy is bleeding.
 - Rarely, bleeding may lead to loss of your kidney or death.
 - If you are hurt due to the biopsy, we will pay for the cost of your care.
- If you join, we will ask you to:
 - Give blood and other samples
 - Talk to the study team 2 to 3 times a year for up to 10 years. These visits may be by phone or in person.
- You will be helping researchers make discoveries. This may help people with kidney problems in the future. Also, we will give you the result of your kidney biopsy. This may or may not help your doctors take better care of you.

To learn more, please read the rest of this form.

What is KPMP?

KPMP is a research study. It is not medical care. Our goal is to learn more about kidney injury and kidney disease. We hope the discoveries we make will help healthcare providers take better care of people in the future.

Why are you asking me to join KPMP?

You have a condition that can make your kidneys not work as well as they should. This is called chronic kidney disease. By studying your kidneys, we may learn more about why chronic kidney disease happens. We may learn how to treat it more effectively or even how to prevent it.

How long will KPMP last?

KPMP will last for at least 10 years. We will do some study visits by phone and some in person. We will contact you 3 to 4 times in the first month after your biopsy. After that, we will contact you two times a year for the length of the study. We hope that at least 1000 people will take part in KPMP.

What will you ask me to do?

There are four main parts to KPMP:

1. We will biopsy your kidney

We will take a biopsy (a few small pieces) of your kidney. This is a medical procedure. You will spend most of the day at the hospital. After the biopsy, you will have to rest at the hospital for several hours. You will not be able to drive yourself home. You may need to take a few days off of work.

First, the care team will place an IV line (a small tube placed in your vein using a needle). Then a specially trained care provider will perform the biopsy. The provider will locate your kidney using an

ultrasound (machine used to see inside your body) and/or CT scan (special type of x-ray). Once the provider locates your kidney, they will numb the skin above it on your back. Then the provider will use a needle to biopsy your kidney. The provider will insert the needle into your back three, four, or five times. You may feel a pinch or pressure when this happens. You may hear a clicking sound. The provider will ask you to hold your breath when they take the biopsy.

After the biopsy, you will have to rest for several hours. If your blood pressure is high before or after the biopsy, the care team may prescribe medications to lower it. The care team may ask you for a urine (pee) sample or a blood sample before you go home.

If necessary, you may be asked to stay in the hospital overnight.

2. We will gather samples from you.

- a. We will ask you for a urine sample at least once a year. Most of the time we will ask for a regular urine sample (pee in a cup). At least one time we will ask you to collect all of your urine for 24 hours. We will give you instructions for how to do this. We will give you a special container for your urine.
- b. We will ask you for a stool (poo) sample. We will give you instructions for how to do this. We will give you a special container for your stool.
- c. We will ask you for a blood sample at least once a year. Each time, we will take 3 tablespoons of blood. We will take blood from your arm using a needle.

3. We will gather information about you.

- a. We will ask you for permission to study your health records including highly sensitive items such as HIV status, substance abuse, and mental health history.
- b. We will ask you lots of questions and ask that you complete some questionnaires.

- We will ask what medicines you are taking.
- We will ask you about your health including asking you to complete a PROMIS Global Health Questionnaire and a Personal History Questionnaire.

We will ask you about your understanding of your health using a questionnaire called a Health Literacy questionnaire.

- We will ask you about how you are feeling.
 - We will ask you about parts of your life like your job.
 - After your biopsy, we will ask you about how you feel about it.
- c. We will measure your height and weight.
- d. We will measure your blood pressure and temperature.
- e. We will examine you for swelling caused by kidney problems.
- f. You can't join KPMP if you are pregnant. We will ask you if you are pregnant before we do your kidney biopsy. We might also do a pregnancy test.
- g. We may take other measurements or gather other data that tell us about your health. For example, we may get data from places like United States Renal Data System (USRDS), which tracks kidney disease, Centers for Medicare and Medicaid Services (CMS), the National Death Index (NDI), the Scientific Registry of Transplant Recipients (SRTR), [\[insert site specific registries and databases\]](#) and other registries, and electronic health records (EHR). We may gather this data from these places even if you stop coming to your follow-up visits, stop responding to us and/or withdraw from the study. If you do not want us to gather this data, you must directly tell us by calling [\[phone number\]](#) or by writing to us at [\[email\]](#) or by mail at [\[address\]](#).
- h. Members of our study coordinating center at the University of Washington may contact you to follow-up if you have study concerns.

4. We will tell you about other studies

We will tell you about other research studies. For example, we might ask you to answer more questions or give more samples. You can say yes or no to any study and still be part of KPMP.

What will you do with my samples and biopsy?

We will study your samples and biopsy. If there is extra, we will store it. It will be stored by the study outside of [study site]. We will share it with other researchers.

DNA and proteins are found naturally in samples and kidney biopsies. DNA is the genetic information that tells the cells in your body how to behave. It is helpful to study DNA because it can tell us more about different diseases and help discover new ways to treat them. We will study your DNA and proteins. We will use many methods to study your DNA. For example, we may study your DNA by whole genome sequencing. Every person's whole genome sequence is different. It is unique to them, like a fingerprint. We will add all of this information to your KPMP record.

We may isolate cells from your blood to make a cell line. A cell line is a group of cells that live in a lab. Cell lines live for as long as researchers care for them. For this reason, cell lines are often called "immortal." Cell lines are used to make more DNA and proteins for research.

Your samples and cell line will be part of your KPMP record. We are responsible for your samples and cell lines. We will care for them and make decisions about how they are used. When the KPMP is done, the US National Institutes of Health (NIH) will be responsible for your samples and cells. They will care for them and make decisions about how they are used. Your samples and cell lines will be used for research long into the future.

You will not get any profit that is made from your samples or cell lines.

What will you do with my KPMP record?

Your KPMP record will have all the samples we collect from you. It will have your kidney biopsy. It will include your DNA, which is found naturally in samples and kidney biopsies.

Your KPMP record will not have your name. We will replace your name with a code. We will limit who has the key that links codes to names.

We will keep your KPMP record with the records from all of the people who join KPMP. We will store all of these records securely.

We will put a copy of your KPMP record in databases managed by the NIH. Researchers use these databases to make discoveries about health. The NIH will store your KPMP records securely.

The researchers who use your KPMP record may be from anywhere in the world. They may or may not be part of the KPMP team. They may work at universities or hospitals. They may work for a government. They may work for companies to make new medicines or products.

Researchers will use many methods to study your KPMP record. Because KPMP will last for ten or more years, some of these methods may not even be invented yet. If you sign this form, you consent to these future uses of your data.

There will be an approval process for researchers who want to work with KPMP records that might identify you. They will have to tell KPMP about the research they want to do. They will have to have ethics training. They will have to sign an agreement stating they will not try to find out who you are.

If you sign this form, you consent to future researchers using your data.

There is no limit on the length of time we or the NIH will store your KPMP record. Researchers will use your KPMP record for research long into the future.

Are there any risks to joining KPMP?

Yes, there are risks to joining KPMP. Review these risks carefully. Ask any questions you have.

Risk from kidney biopsy: The main risk of joining KPMP is from the kidney biopsy.

- If the doctor uses a CT scan to locate your kidney, you will be exposed to radiation. The CT scan is about three times as much radiation as you are naturally exposed to in a year.
- You may have bruising or pain in your back after the biopsy.
- People often have bleeding after a kidney biopsy. This can be mild, moderate, or severe. Please be sure to pay attention to what the biopsy team tells you about what to expect after the biopsy and contact the study team if you have worsening symptoms.
 - If the bleeding is mild, your urine may look pink or red for 1 to 2 days. You usually have no other problems. This is common. It happens to about 100 in 1000 people.
 - If the bleeding is moderate, you may need a blood transfusion. Your urine may be red for up to 7 to 10 days. This is less common. It happens to about 10 in 1000 people.
 - In rare cases, the bleeding is severe. You may need additional medical procedures to stop it. This happens to about 1 in 1000 people.
- In very rare cases (fewer than 1 in 1000 people):
 - You may get a kidney infection.
 - You may get a urinary block. You may not be able to urinate (pee) until the block clears.
 - Other organs near your kidney may be damaged.
 - Your kidney may need to be removed.
 - You may die.

Risk from IV placement: The most common risks of having an IV are brief

pain and bruising. Some people may feel dizzy or faint. There is also a small risk of infection.

Risk from giving a blood sample: The most common risks of giving a blood sample are brief pain and bruising. Some people may feel dizzy or faint. There is also a small risk of infection.

Risk to your privacy: Participating in KPMP may be a risk to your privacy.

First, DNA is in your samples. Every person's DNA is unique. Someone might find out who you are just from your DNA.

Second, if there is a data breach, someone could see or use your KPMP record without permission. There is a chance they could figure out who you are. They could use information from your KPMP record against you. It could impact your employment, insurance, or family relationships.

Your privacy is very important to us. We will take great care to protect it. We believe the risk to your privacy is low, but it is not zero.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). It protects your privacy because it says employers can't treat people differently because of their DNA. This law does not apply to employers with fewer than 15 people. It does not apply to the federal government or the military. It also says that health insurers cannot use DNA information against people. They cannot use it to change your coverage, drop you, or charge you more. This law does not apply to three types of health insurance. It does not cover people who get their care through the military (Tricare or the VA). It does not apply to the Indian Health Service. It does not apply to federal employee health benefit plans. These groups have their own policies about DNA information.

Also, KPMP has a Certificate of Confidentiality. This is another way to protect your privacy. It will help us fight most legal demands to give out information that could identify you. This means researchers can refuse to give out information that identifies you except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;

- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

Other risks: There may be other risks that we don't know about yet. We will tell you if we learn anything that might change your decision to be part of KPMP.

Will you ever give out my name or other information that identifies me?

There are a few times when we might need to give out your name or other information that identifies you.

- We will give out information about you to protect your health or the health of others.
 - If we learn or suspect that you are being abused.
 - If we learn or suspect you are abusing, neglecting, or have abandoned someone who depends on you for care, like a child or dependent adult.
 - If we learn that you plan to harm yourself or someone else.
 - If we learn that you have a disease that is a risk to public health, like measles.
 - If we learn that you have a condition that is urgent.
- We will give out any data that the people who oversee U.S. research laws and regulations need to make sure we are following the law. This may include information that identifies you. The people who oversee research are from:
 - The Office for Human Research Protections
 - The U.S. Food and Drug Administration
 - The National Institutes of Health (NIH)
 - Other sites involved in this study including the University of Washington, and the University of Michigan
 - Washington University's Institutional Review Board (a committee that oversees the conduct for research involving human participants) and

the Washington University Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

Are there any benefits?

KPMP is not medical treatment. It is a research study. If you join, you will be helping researchers make discoveries. This may help people with kidney problems in the future.

We will give you and your healthcare team results from your kidney biopsy. We will also give you and your healthcare team results that are important to your immediate care, like your blood pressure. This may or may not help your doctors take better care of you.

Does it cost anything to participate in KPMP?

You do not have to pay any money to participate in KPMP. That said, if you have complications because of participating, your hospital stay or recovery may be longer. This could mean more time off work. If you have to take extra time off work, you may lose wages.

Will I be paid?

[Insert Site Specific Payment amount, schedule and method here.]

Researchers will use your data, kidney biopsy, and samples to make discoveries. If these studies lead to new tests, medicines or products, they could make a profit. You will not get any of these profits.

Will I find out the results of the research?

As we have told you, we will give you and your healthcare team results from your kidney biopsy. We will also give you and your healthcare team results that are important to your immediate care, like your blood pressure.

We may have other results for you over time. We will ask your permission before we give them to you or your healthcare team. For example, we will ask if you would like results about your DNA. These results could tell about your risk of developing specific diseases. You will be able to say yes or no to finding out this information. You can say no and still be part of KPMP.

If you want to know about the scientific discoveries we make, visit our website www.kpmp.org.

What if I get hurt?

If you get hurt because of participating in KPMP, we will pay for your care.

If you are hurt and get care at another hospital, you can file a claim with KPMP to pay for those costs.

We and KPMP will only pay if you are hurt because of participating in KPMP. We and KPMP will not pay for care for any health condition you had before taking part in KPMP.

For further information contact [PI Name and Phone Number].

What about my family?

We encourage you to talk to your family before you decide to join KPMP.

If you join KPMP, you are giving researchers permission to study your DNA. DNA is passed from generation to generation. For this reason, your DNA tells about you and it tells about the people who are related to you by blood. You might learn something about your health that will also be important to your blood relatives to know. Think about if and how you might share this type of information.

Also, when researchers study your DNA, they may find out that family relationships are different than expected, for example that someone is adopted. We will not give out this type of information.

Do I have to join?

Joining KPMP is voluntary. You can choose to join or not. No matter what you decide, now or in the future, it will not affect your care. You will not lose any benefits or rights. You will not be penalized.

If you decide to join KPMP, you can change your mind at any time. You won't be penalized or lose any benefits for which you otherwise qualify. If you decide you want to withdraw (quit), we ask that you tell us. Failure to attend study visits does not qualify as withdrawing. You can tell us by calling [phone number] or by writing to us at [email] or by mail at [address].

If you withdraw, we will ask you what we are allowed to do with your record moving forward. Unless you tell us otherwise, we will handle your withdrawal this way:

- We will stop contacting you.
- You will not be asked to attend study visits, answer questionnaires, or provide more samples.

Your record will not be used for new studies. However, if researchers already have your KPMP record, we will not be able to get it back. Also, we will let researchers check the results of past studies. If they need your KPMP record to do this work, we will give it to them. We will continue gathering data from places like the United States Renal Data System (USRDS), Centers for Medicare and Medicaid Services (CMS), National Death Index (NDI), the Scientific Registry of Transplant Recipients (SRTR), [Insert site specific registries and databases] and other registries, and electronic health records (EHR) even if you withdraw from the study. As we have told you, you must directly tell us that you do not want us to gather this data. You may tell us by calling [phone number] or by writing to us at [email] or by mail at [address].

Even if you withdraw, we will keep your name and contact information. We keep this information so we can follow U.S. research laws and regulations.

Can I be taken out of KPMP?

Yes, the KPMP team can take you out of KPMP. They could remove you if they are unable to complete your kidney biopsy. They could remove you if they think it is necessary for your safety. The KPMP team will tell you if they remove you from KPMP.

What if I have questions?

We encourage you to ask questions. If you have any questions about KPMP, please contact: **[name(s), phone number(s)]**.

If you have questions, concerns or complaints or would like to talk to someone outside of KPMP about your rights as a research participant or about your experience in KPMP contact the Washington University Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu.

If you experience a research-related injury, please contact: **[name(s), phone number(s). Include 24/7 phone number, instructions about who to ask for (e.g., research fellow on call, resident on call, etc.)]**,

[SITE SPECIFIC HIPAA INFORMATION CAN BE INSERTED HERE]

This form is not a contract. It tells what will happen if you decide to join KPMP. You are not waiving any legal rights by agreeing to participate in this study.

Remember:

- You have the right to as much time as you need to decide if you want to join. Nobody is allowed to pressure you.
- You have the right to understand all of the information in this form.
- You have the right to ask questions and get answers you can understand.

If you decide to join KPMP,

- You have the responsibility to participate as best you can.
- You have the responsibility to tell us if you want to stop participating.
- You have the responsibility to follow directions as best you can.
- You have the responsibility to tell us accurate and complete information.
- You have the responsibility to tell us right away if you are having any problems related to KPMP.

Informed consent:

I have read this consent form. This research study has been explained to me and all of my questions have been answered. I choose to take part in KPMP.

Do not sign this form if today's date is after EXPIRATION DATE: 11/22/23.

(Signature of Participant)

(Date)

(Participant's name – printed)

Statement of Person Who Obtained Consent

I reviewed this form with the person who has signed above. They have told me that they understand the risks and benefits of taking part in KPMP. They have told me they understand what is involved with taking part in KPMP. I have made sure that all of their questions have been answered.

(Signature of Person who Obtained Consent)

(Date)

(Name of Person who Obtained Consent - printed)