A Decision Aid for Patients Considering Participating in a Pig Kidney Xenotransplant Clinical Trial

- Karen J. Maschke, PhD
  The Hastings Center for Bioethics
- Michael K. Gusmano, PhD
  Lehigh University
- Elisa J. Gordon, PhD, MPH
  Vanderbilt University Medical Center

The Hastings Center for Bioethics

LEHIGH UNIVERSITY | College of Health

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What is the purpose of this document?

This document is called a **decision aid**. You are receiving this decision aid because a transplant research team has offered you the opportunity to participate in a pig kidney xenotransplant clinical trial, which is a human research study.

The purpose of this decision aid is to help you decide whether to participate in the clinical trial.

This decision aid offers information about each of your options, asks questions to help you reflect on your values and treatment goals, and lists some articles and websites that you can review for more information.

How you use this decision aid is up to you. You might start by reviewing the decision aid and talking to family members and/or others who can help you think about what decision to make.

What is the purpose of this document? (continued)

This is not an informed consent form. If you decide that you want to learn more about participating in the clinical trial, you can talk to the research team. By using this decision aid, you are **not** providing informed consent or agreeing to participate in the clinical trial.

This document might not answer all your questions about a pig kidney xenotransplant clinical trial. You can ask your doctor or transplant team questions at any time.

Asking your doctor or the transplant team questions does **not** mean that you are participating in an informed consent discussion.

If you choose to participate in a pig kidney xenotransplant clinical trial, you will have an informed consent discussion with the transplant research team. During the informed consent discussion, you can ask any questions about the clinical trial.

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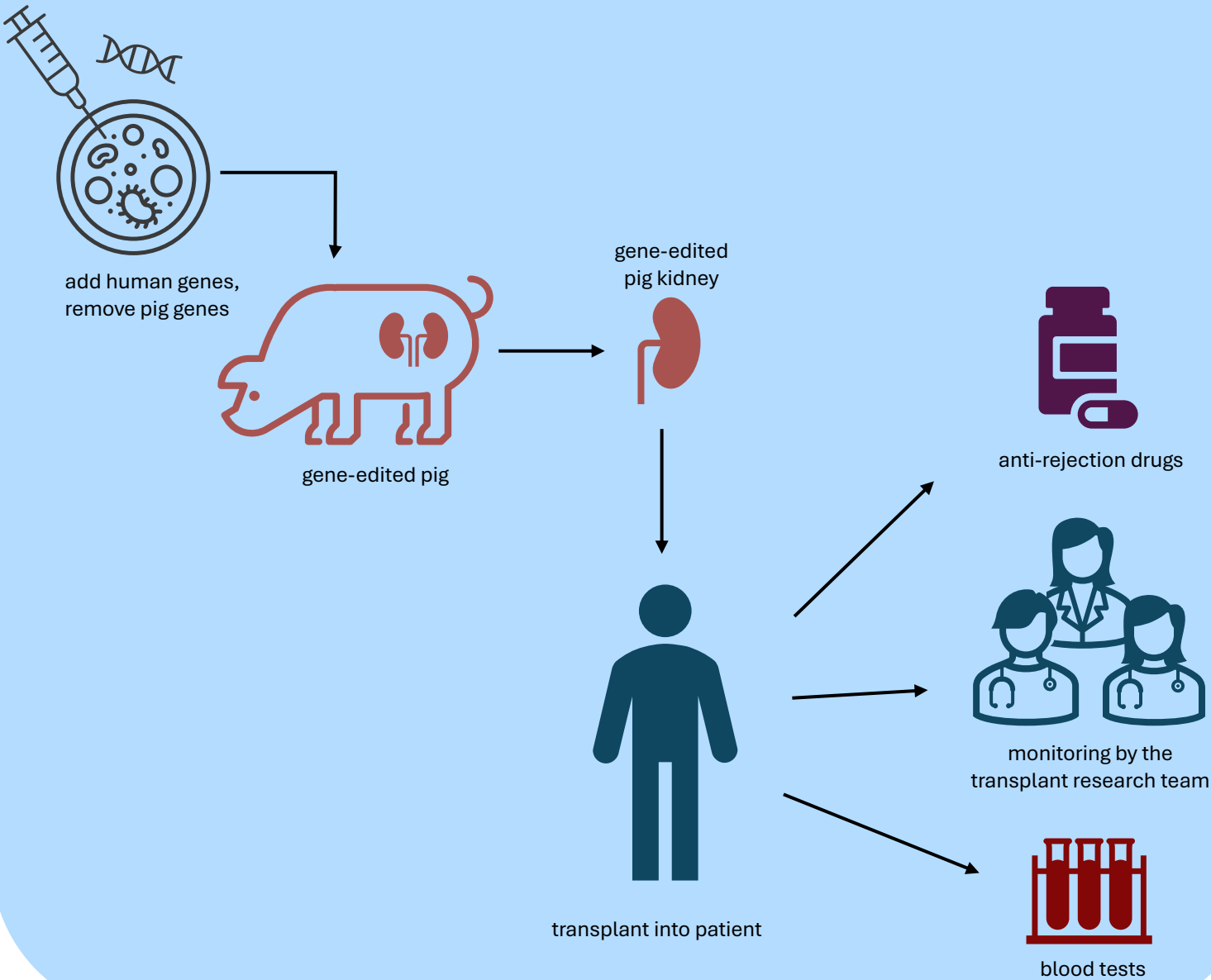
What is pig kidney xenotransplantation?

Xenotransplantation transfers an organ from an animal into a human recipient.

Pig kidney xenotransplantation transfers a kidney from a gene-edited pig into a human recipient.



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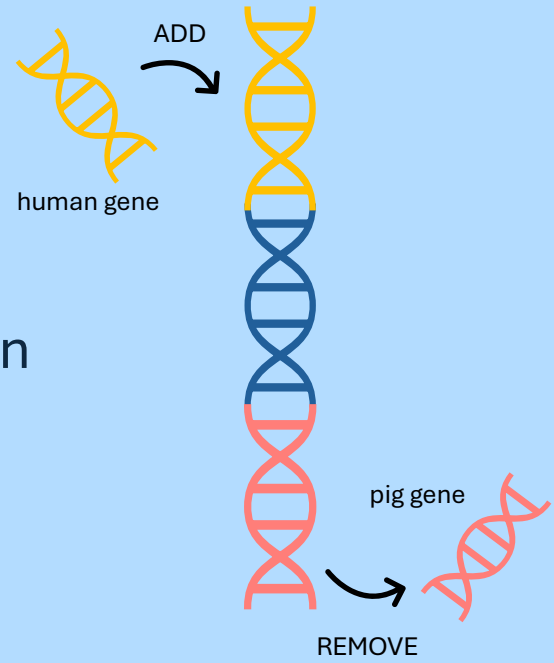
What is a ‘gene-edited’ pig kidney?

• The kidneys used in xenotransplant clinical trials come from pigs that have been **gene-edited.**

• Gene-edited pigs have some human genes added and some pig genes removed.



• Gene editing helps make the human body less likely to reject the pig kidney.

• There might be other gene edits made to the pig. The research team can explain which edits were made and why.

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Facts about pig kidney xenotransplantation

• Some early research studies have transplanted pig kidneys into monkeys and baboons (non-human primates), and into deceased humans whose families agreed to the xenotransplant to see how well the pig kidneys work.

• Some living people in the U.S. have received a gene-edited pig kidney under the U.S. Food and Drug Administration's (FDA's) Expanded Access/Compassionate Use pathway.

• The FDA's Expanded Access/Compassionate Use pathway is different from a clinical trial.

• Xenotransplants approved under this pathway are not done as part of a research study. Research studies are needed to provide more information about whether these transplants are safe and work.

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What is a pig kidney xenotransplant clinical trial?

A pig kidney xenotransplant clinical trial is one kind of research study.

The purpose of the clinical trial is to find out whether:

- The pig kidney is **safe** for human recipients
- The pig kidney **works** when transplanted into a human

Patients who meet eligibility requirements (e.g., their age and medical condition) may be offered the opportunity to participate in the clinical trial.

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Deciding whether to participate in a pig kidney xenotransplant clinical trial*

You would undergo multiple discussions with the transplant research team to make an informed decision about whether to participate in the clinical trial.

Research team members will explain:

- The purpose and procedures of the clinical trial
- The risks of participating in the clinical trial
- The potential benefits of participating in the clinical trial
- The alternatives to being in the clinical trial
- Other details about the clinical trial

You can ask the research team any questions about the clinical trial.

If you decide to participate, you will sign an **informed consent form,** which states that you voluntarily agree to take part in the trial.

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*Reminder: This decision aid is **not** an informed consent form. This decision aid aims to help you decide whether you want to learn more. By using this decision aid, you are **not** agreeing to participate in a clinical trial.

7 What are your options?

Should You Participate in a Pig Kidney Xenotransplant Clinical Trial?

OPTION 1

Do not participate in the clinical trial

↓

Continue your current treatment plan

OPTION 2

Participate in the clinical trial

↓

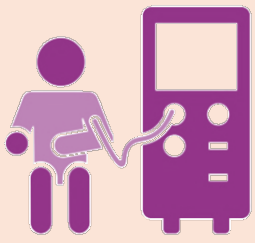
Receive a gene-edited pig kidney

Note: You can stay on the human waitlist while waiting for a pig kidney for participation in a clinical trial.

Continuing your current treatment plan may involve:

- Waiting for a human kidney transplant

- Dialysis



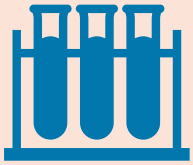
- No treatment: conservative kidney management

Participating in the clinical trial may involve:

- Possibly taking non-FDA-approved anti-rejection drugs

- Being closely monitored by the transplant team, before and after transplant

- Having your clinical data and blood, urine, and tissue samples collected by researchers



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Possible advantages and disadvantages of each option

Participating in a pig kidney xenotransplant clinical trial

Possible Advantages	Possible Disadvantages
• You might receive a kidney transplant from a pig sooner than if you waited for a human kidney transplant. • The pig kidney might be safe for you and might work. This information could help other kidney patients decide in the future. • If you get a pig kidney transplant, you would come off dialysis. • Taking part in this clinical trial will help researchers learn if a pig kidney is safe and if it works in humans.	• The pig kidney might not be safe in a human body. • The pig kidney might not work and might have to be removed. • You might get sicker after the pig kidney transplant or die from it. • You might get an infectious disease from the pig kidney. • You might transmit a pig infectious disease to your intimate partner or household members. • The duration of post-transplant monitoring for a pig kidney will likely be longer than regular monitoring for a human kidney transplant. • Local public health officials may also monitor you if you get an infectious disease from the pig. • Monitoring for pig kidney infectious diseases might include your intimate partner and household members. • The media might want to do a news story about your pig kidney transplant. If you agree, this story might violate your privacy.

- Your body might make more antibodies after receiving a pig kidney. This could make it harder to match with a human kidney if you need a human kidney in the future.
- If the pig kidney does not work, it is unknown if you would be able to return to dialysis.
- Little is known whether human viruses could infect, cause problems, or make changes in the pig kidney that could affect your survival and kidney function.
- It is unknown how long you could live with a pig kidney.
- The same risks of a human kidney transplant would also apply to a pig kidney transplant.
- You may feel distress from knowing that you have an animal organ in your body and knowing that a pig's life ended to give a kidney to you.
- Your family or friends may not approve of your decision to seek a xenotransplant.

Waiting for a human kidney transplant

Possible Advantages	Possible Disadvantages
• Kidney transplant recipients live longer than if they were on dialysis. • On average, kidney transplants last 10 years. • Kidney transplant recipients usually have a reasonable quality of life. • Kidney transplant recipients may feel well enough to work and travel. • Kidney transplant recipients have few dietary restrictions.	• It can take many years of waiting before getting a human kidney. • **Possible health complications:** – An infectious disease from the human kidney donor. – Bleeding, infections (e.g., a bladder infection), hernia, and pain/numbness. – Problems to the heart, blood vessels, or urinary system. – High blood pressure, bone damage, high cholesterol, weight gain, infection, or kidney failure from anti-rejection medicines. – Weakened immune system due to anti-rejection medicines, which can increase your risk of cancer and make it harder to fight off infections. – Changes in how you look due to anti-rejection medicines (e.g., your face may get fuller, you may gain weight, or develop acne or facial hair). – A greater chance of getting cataracts, diabetes, extra stomach acid, and bone disease. – Kidney recipients may have sleep disorders, anxiety, and depression after transplant.

Dialysis

Possible Advantages	Possible Disadvantages
• Patients can stay alive on dialysis for many years. • Patients may start dialysis sooner than they could get a human or pig kidney. • Dialysis can give you a regular routine. • Dialysis improves your health by removing wastes from your blood. • Many patients on dialysis can still go to work.	• Many dialysis patients feel sick and have problems with sleep, muscle cramps, and feeling tired. • Most adults on dialysis suffer from chronic pain. • Patients on dialysis usually live shorter lives than patients who receive a human kidney transplant. • Dialysis patients generally experience a very low quality of life because of the large amount of time needed to do treatment, and limits placed on diet and fluid intake. • Treatment time may interrupt your daily routine. • Patients can feel fatigued after the treatment. • Patients who have physically active jobs may need to find other jobs. • In addition, dialysis can: – Lead to circulatory problems, like poor blood flow or blood clotting. – Cause sudden changes in body water and chemical balance. These changes can lead to muscle cramping and low blood pressure, which can make you feel weak, dizzy, or sick. – Require dietary limits on salt intake, fluids, and high-phosphorus foods (e.g., poultry, fish, nuts, peanut butter, dried beans, cola, tea, and dairy products).

No treatment: conservative kidney management

Possible Advantages	Possible Disadvantages
• Patients usually go to few doctor visits. • Patients usually need few blood tests. • Patients usually take less medication. • Reduced treatment procedures may improve quality of life.	• Patients usually live for a much shorter amount of time than patients on dialysis or patients who receive a transplant. • Patients usually die within a few weeks after stopping dialysis treatment. • As waste builds up in your blood, you may feel less alert and a loss of appetite.

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What is most important to you?

Taking time to reflect on your values, priorities, and treatment goals can help you make a decision that is personally right for you. Identifying the factors that are most important to you may make it easier to decide whether to enroll in a pig kidney xenotransplant clinical trial or stay with your current treatment plan.

Write down each value and priority that is guiding you. Next, rank how important each value and priority is on a scale of **1** (*not important*) to **5** (*very important*).

Values	**Importance**
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5

Priorities	**Importance**
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5

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Reflecting on your values*

Now that you have identified what is most important to you, it may be easier to find **specific reasons** why you might or might not want to participate in this pig kidney xenotransplant clinical trial. You can use the space below to write out your reasons for or against participating in the clinical trial. Or, you can write your ideas down on a separate piece of paper or talk about your reasons with family members or others who support you.

First, write down the reasons for and against participating in the clinical trial. Next, rank how important each reason is on a scale of **1** (*not important*) to **5** (*very important*).

Reasons **to** participate in the clinical trial:	**Importance**
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5

Reasons **not to** participate in the clinical trial:	**Importance**
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5
_____	1 2 3 4 5

*There are no right or wrong reasons. Your transplant team will understand and accept whatever you choose to do. They will not try to change your mind.

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What are the next steps?

• This page is meant to help you focus your thoughts and note down your preferences at this point in time.

• This page is meant for your use only.

• After you fill out this page, it will be up to you to pursue your options.

• No one from the research team will reach out to you.

• This page is **not** an informed consent form.

☑ Check what you want to do next (check all that apply).

☐ I want to continue with my current treatment plan.

☐ I want to discuss the options with my kidney doctor.

☐ I want to discuss the options with my family.

☐ I want to learn more about the pig kidney clinical trial.

☐ I want to participate in the pig kidney clinical trial.

☐ I do not want to participate in the pig kidney clinical trial.

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For more information about the NIH-funded Xenotransplantation study, visit: https://www.thehastingscenter.org/who-we-are/our-research/current-projects/ethical-and-policy-guidance-for-translational-xenotransplantation-clinical-trials/

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