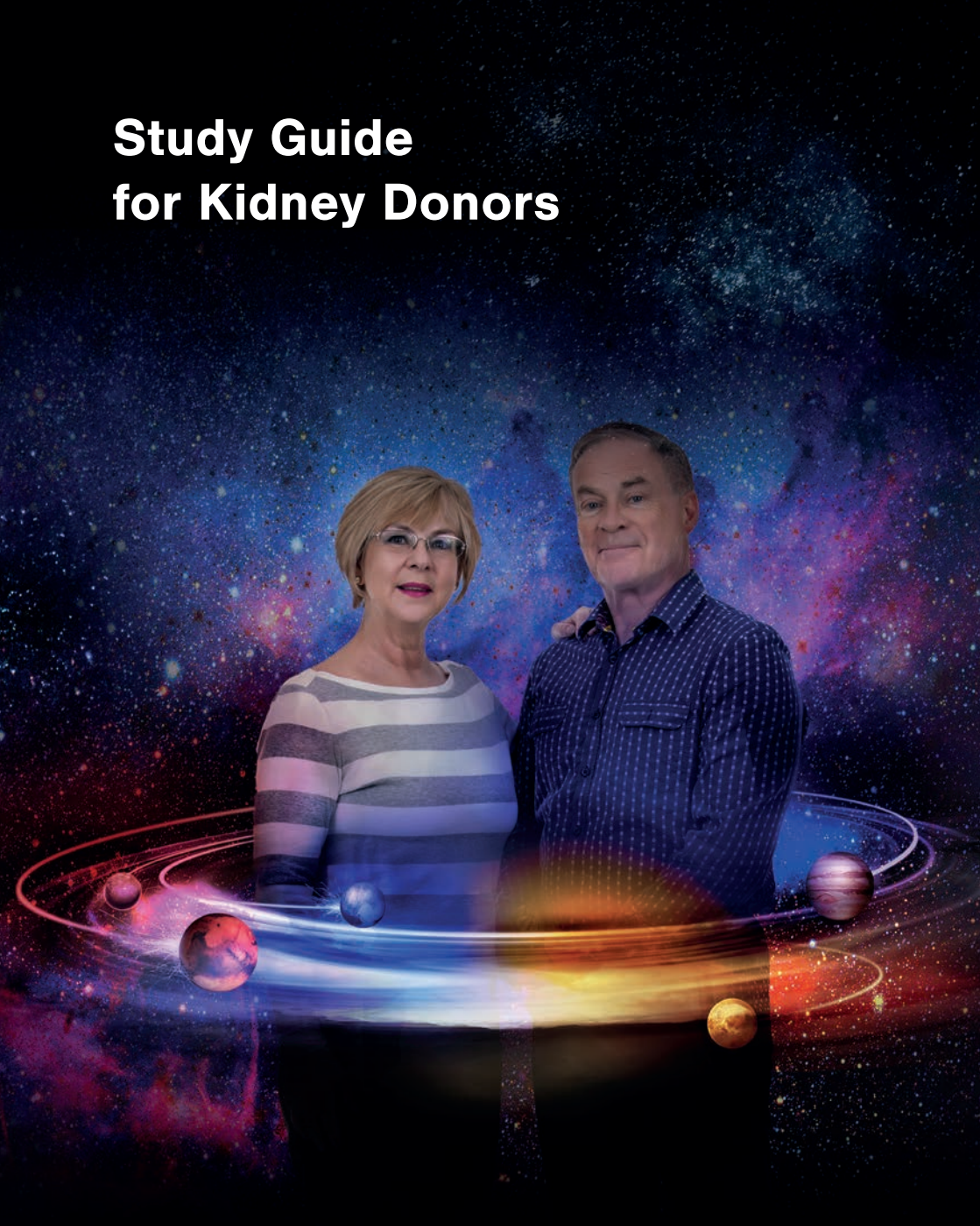


# Study Guide for Kidney Donors







## Welcome to the Mercury Study

Thank you for choosing to take part in the Mercury Study – we greatly appreciate your involvement! We are grateful for your commitment to become a kidney donor and for helping us learn more about a potential new treatment for people receiving a kidney transplant (kidney recipients).

You will be part of a group of up to 75 pairs of kidney recipients and their matched kidney donors participating in this study at about 40 study centers in the United States.

This guide contains information to help you understand what to expect during study visits and throughout the entire study. Your safety and well-being are important to us, so if you have any questions or concerns about the study, please contact the study team using the information provided on the back of this guide.

## About the Mercury Study

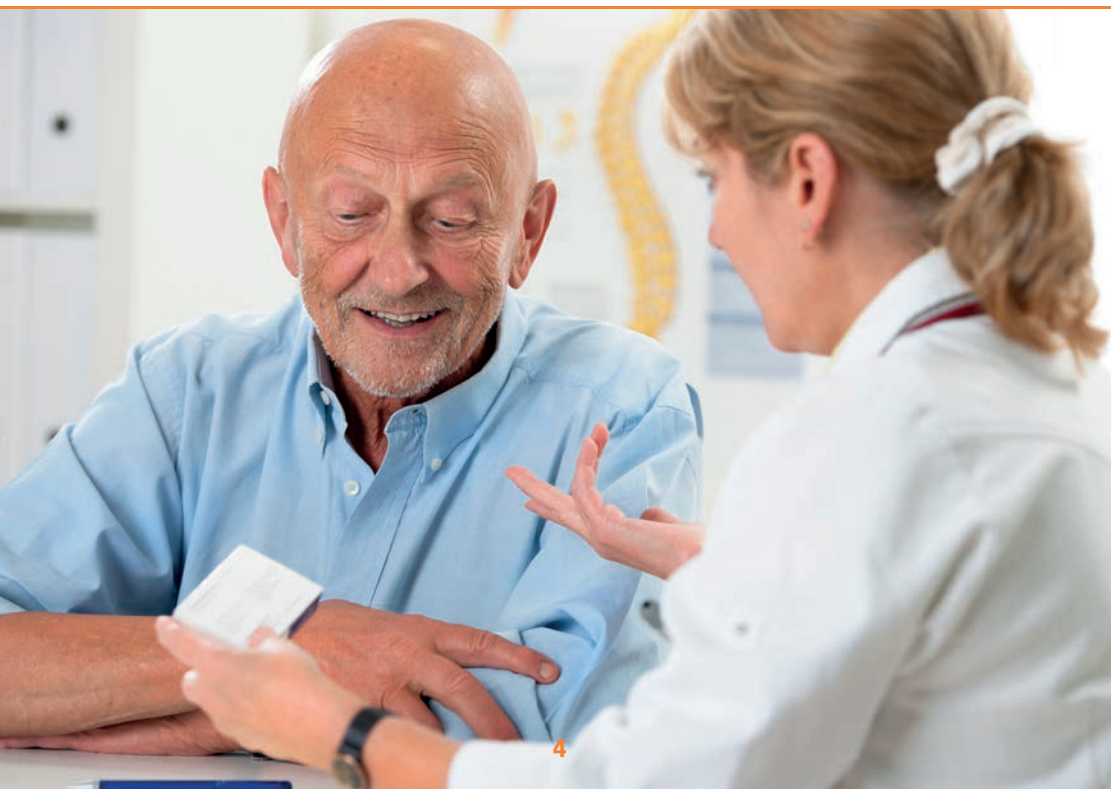
When a person receives a donor kidney, there is always the risk of rejection because their immune system might see the kidney as “foreign” and attack it. To help stop this, the recipient usually receives high doses of anti-rejection medications.

The Mercury Study will look at how safe an investigational therapy (a potential new treatment that is still under development) is and whether it can help kidney recipients to avoid the need for anti-rejection medications.

The investigational therapy is a preparation of stem cells isolated from your blood, as the matched donor for the kidney recipient. Stem cells can develop into all of the different types of blood cells in the body, including those of the immune system. Researchers believe that an infusion of your stem cells into the kidney recipient may help the recipient’s immune system accept the kidney transplant without the need for anti-rejection medications.

## What will happen during the Mercury Study?

- Your participation in the Mercury Study will begin about 2 months before the kidney transplant surgery and will last until about 1 month after the surgery.
- Now that you have agreed to take part in the study and have been matched with a kidney recipient, you will be randomly (by chance) placed in 1 of 2 groups. About 50 donor/recipient pairs will join the investigational group and 25 donor/recipient pairs will join the control group.
- You will be asked to attend up to 6 study visits before the surgery if you are assigned to the investigational group, and up to 2 study visits if you are assigned to the control group.
- During the follow-up period after the surgery, the study team will continue to check your health as needed for 4 weeks.



## What will happen to you during the study?

### Investigational group

- At least 6 weeks before the kidney transplant surgery, you will receive under-the-skin (subcutaneous) injections of a medication called G-CSF (granulocyte-colony stimulating factor) once or twice daily for at least 5 days in a row. This medication will cause your bone marrow to release stem cells into your bloodstream. You will be taught how to do the injections yourself at home.
- On Day 5, you will have an apheresis procedure (explained later in this guide) approximately 2 hours after the morning injection of G-CSF.
- The collected cells will be processed in a laboratory to create the investigational therapy that will be given to the kidney recipient.
- If not enough stem cells are collected from the first apheresis procedure, you may need a second procedure the next day after another morning injection of G-CSF. If still not enough stem cells are collected, you may need up to 2 more procedures approximately 3 weeks later.



6 weeks

### 6 weeks before kidney transplant

5–6 days in a row of G-CSF injections at home

May be repeated 11–16 days before the surgery if not enough stem cells were collected during the first round

### Day 5 (and maybe Day 6)

Apheresis procedure after morning G-CSF injection

### Kidney transplant surgery

### Follow-up period

Study team to check your health as needed

### Control group

- You will receive standard medical care for kidney donors.















## What will happen during the apheresis procedure?

- During the apheresis procedure, you will sit in a chair and a needle will be placed in a vein in each of your arms.
- From one arm, your blood will pass through a tube into a machine. Your blood will be returned to you through the other arm.
- The machine separates and collects some of the stem cells and white blood cells (including immune cells) from your blood.
- Almost all of the other parts of your blood will be returned to you. However, at the end of each procedure, a small amount of red blood cells (the cells transporting oxygen in your blood) and plasma (the clear yellowish fluid part of the blood) may also have been removed.
- This procedure allows the investigational therapy to be prepared **specifically for the matched kidney transplant recipient.**



# Health assessments and procedures at the study visits

This table shows the health assessments and medical procedures you can expect during the study periods.



Icon key		
 G-CSF injections at home	 Questions about changes in your health	 Pregnancy test
		 Apheresis procedure
	Investigational group	Control group
<b>Period before the kidney transplant</b> (1 day to 6 weeks before the transplant)	 (G-CSF injections for 5–6 days, starting 6 weeks before the kidney transplant surgery)	Standard medical care for kidney donors
	 (5 weeks before the kidney transplant surgery)	 (1 week before the kidney transplant surgery)
	 (1 week before the kidney transplant surgery)	 (please report all changes in your health [even minor ones] to the study team)
	 (please report all changes in your health [even minor ones] to the study team)	
<b>Follow-up period</b> (4 weeks after the transplant)	 (please report all changes in your health [even minor ones] to the study team)	 (please report all changes in your health [even minor ones] to the study team)





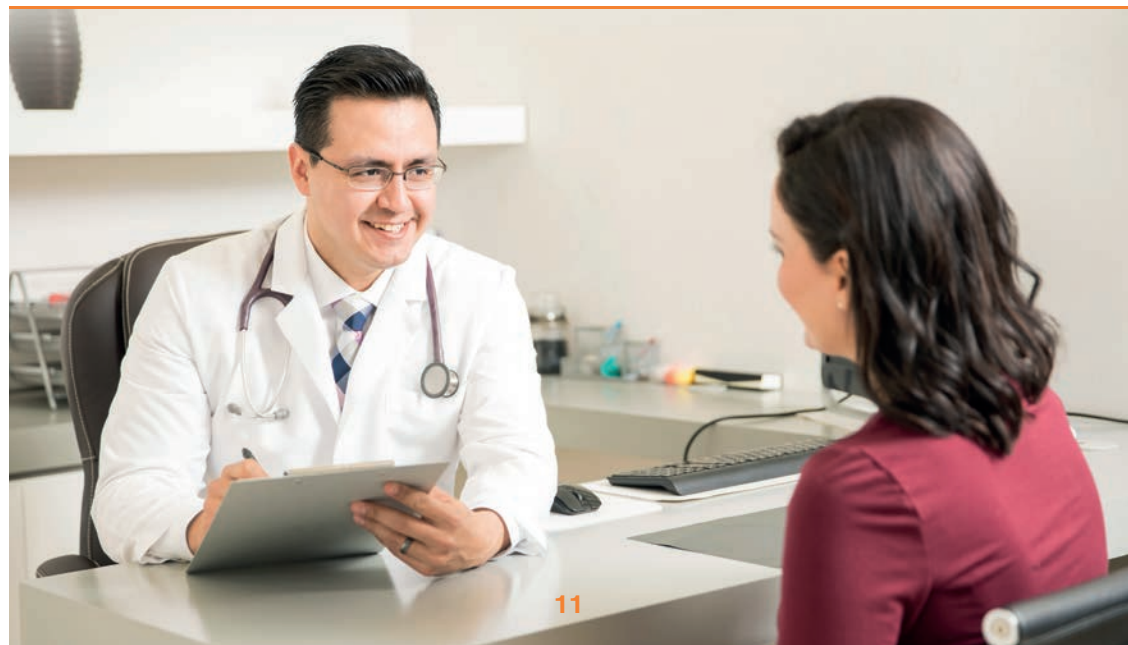
## What health assessments should you expect at the study visits?

The study team will do the following health tests and assessments during study visits:

Assessment	Description
 Pregnancy tests	If you are a woman who is able to have children, you will have a pregnancy test (from either a blood or a urine sample) within the week before the kidney transplant.
 Questions about changes in your health	You will be asked if you have experienced any side effects or changes in your health, and if you have had any visits to the doctor's office or hospital. Please report any changes in your health, even minor ones, to the study team immediately.

## What are your responsibilities during the study?

- Please attend all study center visits and follow the instructions the study team gives you. Let the study team know if you need to reschedule an appointment.
- Do not take part in any other clinical research studies while you are in this study.
- Inform the study team immediately of any changes in your health, even minor ones. Tell the study team if you have had any doctor visits or have been to the hospital for any reason.
- Tell the study team about all medications you are taking and any medical procedures you have had.
- Inform the study team if you have made, or are planning to make, any changes to your medications or are planning to have any medical procedures.
- If you are a woman who is able to have children, you must agree to have a pregnancy test within 1 week of the kidney transplant surgery.





## Contact information

If you have any questions or concerns about the study, or you notice a change in your health, please contact the study team immediately.



*Thank you for taking part in the  
Mercury Study!*