# A Communication Tool to Assist Older Adults Facing Dialysis Choices

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# University of Washington
# CONSENT to Participate in Research

**Title of the Study:** Effective Communication between Kidney Specialists and Their Patients

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**Invitation**

We invite you to participate in a research study on communication between kidney specialists and patients. Your kidney specialist has identified you as a possible research participant because you are an older adult with treatment options for kidney disease. Up to 340 patients will participate in this study at sites across the United States.

The purpose of this consent form is to give you the information you need to decide whether to participate in the study. It also explains how your health information will be used for this study and requests your permission to use your health information. As we go through this consent, please ask questions about anything that seems unclear or confusing. I'm here to answer any questions you have. *Your participation in this research study is voluntary. If you decide not to participate, the health care provided to you by the University of Washington will not be affected in any way.*

**Why are researchers doing this study?**

The purpose of this study is to evaluate a new training program to support communication between kidney specialists and their patients. The goal of our research is to help patients get the information they need to make treatment decisions that are right for them.

**What will happen in this study?**

If you decide to participate in this research study, we will ask you to:

Complete a brief survey today, including questions on your physical health and well-being and how much help you may or may not need when reading materials from your doctor or pharmacy. You may skip any questions you do not wish to answer.

Complete a survey 1-2 days after today's appointment. We will call you to complete this survey by phone and it takes just 10-15 minutes. The survey will include questions on how well you think your kidney doctor/clinician communicates with you. We will also ask you a few questions about yourself, such as your race and level of education. You may skip any questions you do not wish to answer.

Complete a follow up survey every 3 months, for up to 2 years. You can do these surveys in the way best for you: on the phone, on your computer, or on a paper copy mailed to you. These surveys take 10-15 minutes each. The surveys will include questions about your physical health and well-being. You may skip any questions you do not wish to answer.

Allow study staff to review your medical chart for up to 2 years after you enroll in the study. We are doing this to collect:

- Information about you such as age, gender and race
- Information related to the evaluation, treatment and outcomes of your kidney disease and general health

Pick a family member or loved one to participate in the study with you. This is someone who knows you well and is involved in your care with the kidney doctor/clinician you are



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seeing today. They will also complete brief surveys. However, this is optional and you are not required to have anyone participate in the study with you.

**How is being in this study different from my regular health care?**

This study is not part of your health care. Your kidney doctor/clinician and his/her team will know that you are participating in this research, but they will not be able to see any individual results from this study.

**Will being in this study help me in any way?**

There are no direct benefits to you. However, since the purpose of the study is to improve communication, you may benefit from having better conversations with your kidney specialist. Your participation can make a difference in the future by helping to improve care for others with kidney disease.

**Will I be paid for my participation?**

You will be paid for participating in this study. If you complete all of the surveys over two years, you will receive a total of $100. If your loved one chooses to participate with you, they will receive up to $55 over two years.

| STUDY ACTIVITY | Today | In a few days | YEAR 1 (every three months) 3 6 9 12 | YEAR 2 (every three months) 3 6 9 12 | TOTAL |
|---|---|---|---|---|---|
| **You**   *take a short survey* | ☑ | ☑ | ☐ ☐ ☐ ☐ | ☐ ☐ ☐ ☐ | |
| Payment: | *$20* | | $10 $10 $10 $10 | $10 $10 $10 $10 | $100 |
| **A loved one** *(Optional)*   *take a short survey* | ☑ | ☑ | ☐ ☐ ☐ ☐ | ☐ ☐ ☐ ☐ | |
| Payment: | *$15* | | $5 $5 $5 $5 | $5 $5 $5 $5 | $55 |

**What are the risks?**

Participating in this study involves few risks for you. The risks include:

- You may feel confused or conflicted about the kidney treatment options presented to you
- You may feel some distress when answering the survey questions about your health and kidney treatment decisions
- There is a very small chance that study information could become known to someone who is not involved in the study

We don't expect any of these things to happen. We will explain how we protect the confidentiality of your information in the next section.

**How will researchers keep my research information confidential?**

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Things you tell the researchers about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study
- This information could include information related to the evaluation and treatment of your kidney health and other related medical conditions

We have strict rules to protect your personal information and PHI. Only trained study staff will access your medical chart for study purposes. We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. This study has a Certificate of Confidentiality from the National Institute on Aging. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent. Researchers might use information from this study in scientific journal articles or in presentations. None of this information will identify you personally.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials (including the National Institute on Aging) responsible for monitoring the safety of this study.

With appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Data from this study also will be transferred and stored on a server maintained by the Palliative Care Research Cooperative Group (PCRC) at the University of Colorado. This data will not contain information which could identify you and will be carefully protected. This data will be

stored for at least 10 years after the study is completed. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

**Will information from this study go in my medical record?**

None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**Can I be removed from the research without my agreement?**

The person in charge of the research study or the sponsor can remove you from the research study without your approval if you no longer meet the requirements to be in the study.

**Do I have to be in the study? What if I say "yes" now and change my mind later?**

No, you do not have to be in this study. Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you do not sign this form, however, you cannot take part in this research study. You may completely withdraw from the study at any time. You also may choose to skip any questions that you do not feel comfortable answering. Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at the University of Washington, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

**Who should I contact if I have questions?**

If you have any questions about this study at any time, contact the Principal Investigator, Dr. Daniel Lam at (206) 744-8998; or the Research Coordinator, Lori Linke at 206-720-3835.

If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team, contact the University of Washington Human Subjects Division hsdinfo@uw.edu or at (206) 543-0098 or call collect at (206) 221-5940.

## AGREEMENT TO PARTICIPATE IN THIS STUDY

If you sign the line below, it means that:

- You have read this consent form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.

**Name of Participant (please print):**_____

_____ _____
Signature of Participant Date

**YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.**

**Signature of person obtaining consent:**

_____ _____
Signature Date

**FUTURE RESEARCH**

In the future, other researchers may find it valuable to use the survey data and health information obtained from this study. We would like your permission to let other researchers use this data for future research studies, and to house your de-identified study information in the Palliative Care Research Cooperative Group (PCRC) Data Repository. These researchers would not have any information about who you are or access to your medical records. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed and all data will be de-identified.

I give my permission for the use of the de-identified data for future research:

_____YES

_____NO

## CONSENT TO CONTACT

In order to contact you and to mail you your compensation throughout the research study, study staff would like your preferred U.S. mailing address and phone number(s). **The information you provide on this form will not be used for any other purposes. It will be kept in a locked and secure location, which only study staff can access and use. This information will not be shared with anyone outside of the research team at the University of Washington and will be destroyed at the end of the study.**

By signing this form and providing your contact information, you agree that study staff can contact you for the uses described above.

Your name (please print):_____

Mailing Address: _____

Home phone number**:** _____

Mobile phone number (if applicable)**:** _____

What's the best time of day to call you? _____

Email address (if applicable)**:** _____
*Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact:*

Dr. Daniel Lam at 206-744-8998
Lori Linke at 206-720-3835
Kidney Research institute at 206-616-8574

*You do not have to provide your email address to participate in this study.*

What's the best way to reach you? _____

_____ _____

Signature of Participant Date