



Johns Hopkins
CONSENT to Participate in Research and AUTHORIZATION to Use and/or
Disclose Identifiable Health information for Research

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

Lead Researcher: Deidra Crews MD, SCM
410-550-2820
dcrews1@jhmi.edu

Mailing Address: Johns Hopkins University School of Medicine
301 Mason F. Lord Drive, Suite 2500
Baltimore, MD 21224

Funder: National Institute on Aging

Research Project Lead

At UW-Madison: Margaret Schwarze, MD
UW–Madison, School of Medicine and Public Health
Department of Vascular Surgery

Key Information

The purpose of this research is to study the effects of the Best Case/Worst Case Communication tool for older adults discussing end-stage renal disease (ESRD) with their nephrologists. Patients making a dialysis decision receive nephrologist communication using the Best Case/Worst Case tool, or usual standard of care communication.

At the start of the study, we will randomly assign nephrologists from each site to the training group and teach them to use the Best Case/Worst Case communication tool. Patients in this study will receive care from their nephrologist using the Best Case/Worst Case communication tool or usual care. Palliative care will be available to all patients. Over a two year period patients, nephrologists, and caregivers will be asked to complete questionnaires to help us collect information on the Best Case/Worst Case Communication tool effects. Clinical information will also be collected from Patient charts.

The aims of this study are considered of minimal risk and will be discussed in detail later in this document.

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 Johns Hopkins 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 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.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed \$600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

STUDY ACTIVITY	Today	In a few days	YEAR 1 (every three months)				YEAR 2 (every three months)				TOTAL	
			3	6	9	12	3	6	9	12		
You  <i>take a short survey</i> Payment:	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	\$100
A loved one (Optional)  <i>take a short survey</i> Payment:	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	\$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.

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, 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.

What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

Who at Johns Hopkins can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

Who outside the Johns Hopkins may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor, the National Institute on Aging
- Collaborating researchers outside Johns Hopkins, specifically researchers at University of Wisconsin-Madison who are coordinating this study
- The Palliative Care Research Cooperative Group (PCRC) will use or share your de-identified protected health information (PHI) in compliance with the PCRC Data Sharing

Policy. Data from this study also will be transferred and stored on a server maintained by the 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 Johns Hopkins, 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.

Your authorization for researchers to use your protected health information (PHI) collected for this study does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.

- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher:
Deidra Crews MD, SCM
Johns Hopkins University School of Medicine
301 Mason F. Lord Drive, Suite 2500
Baltimore, MD 21224.

Who should I contact if I have questions?

If you have any questions about this study at any time, contact the Principal Investigator Deidra Crews MD, SCM at 410-550-2820.

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

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 Johns Hopkins 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 Deidra Crews MD, SCM, 410-550-2820. 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 & Time