Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Hand-carried ultrasound for ruling out hydronephrosis in acute kidney injury and acute kidney disease

Principal Investigator: Charbel Khoury
Research Team Contact: **Charbel Khoury, MD 314-362-8351**

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because of an abnormality noted on a blood test that relates to your kidney function (the blood test is called serum creatinine) or because you may not be making normal amounts of urine. A kidney ultrasound was already ordered by your treating team to investigate this further, which makes you eligible to enroll in this research study.

The purpose of this research study is to determine if trainees are able to accurately identify obstruction of the kidneys using a hand-held ultrasound. The ultrasound machine that will be used is the Phillips Lumify portable ultrasound and is approved by the U.S. Food and Drug Administration to perform ultrasound examination of the abdomen**.**

Obstruction of the kidneys (also called hydronephrosis) is a rare but potentially reversible cause of kidney dysfunction. It accounts for about 10% of cases of acute alterations of kidney function. The hand-held ultrasound will not affect your treatment plan. Treatment plan will be dictated solely by a more complete ultrasound performed by a certified radiology technician either 4 hours before or 4 hours after this research hand-held ultrasound. Results from the hand-held ultrasound will eventually be compared to results of the radiology performed renal ultrasound to help determine its accuracy. We will kindly ask you not to share any information related to your health or to your kidneys with the trainee performing the hand-held kidney ultrasound.

WHAT WILL HAPPEN DURING THIS STUDY?

During the study we will ask you to lay on your back in your bed. You may be in the emergency room if the kidney ultrasound study was ordered prior to inpatient admission to the hospital. You may also be in a hospital room at Barnes Jewish Hospital if the kidney ultrasound study was ordered by your primary team after inpatient admission to the hospital.

This study will obtain ultrasound images of both left and right kidneys.

A trainee will use a small hand-held ultrasound machine to examine both kidneys. It should take about 10 minutes to obtain all ultrasound views needed. In case the trainee is having difficulty obtaining the necessary ultrasound images while you are on your back, they will ask you to lay on your side. This will make it easier for the trainee to get the kidney ultrasound images. You have the right to decline laying on your side if you think this will cause you discomfort or pain This will not disqualify you from participation in the study.

The ultrasound images will be stored using your initials only. Data related to your kidney function (blood work, ultrasound images performed by radiology technician) will be obtained from your medical record and be stored on a secure database.

No information from this study will be added to your medical record. The following information will be collected from your medical record for this research study:

- Your past medical history including any history of kidney disease or kidney transplantation, history of kidney cancer and history of obesity.
- Your diagnosis
- Results from today's blood work indicating your kidney function (serum creatinine)
- The amount of urine you made in the past 24 hours
- Results from the kidney ultrasound performed by the radiology technician

No research results will be given to you during this study. No identifiable research results will be given to people who are not involved in the study.

Will you save my research information to use in future research studies?
We might remove identifiers from your private information and then use the information for future research studies or share them with other researchers for their future research. If this occurs we will not ask you for additional consent for these uses of your information.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 170 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for one visit only. The visit is expected to take 30 minutes in average, which includes making sure you are in a comfortable position and then obtaining the ultrasound images. There is NO long-term follow-up needed.

WHAT ARE THE RISKS OF THIS STUDY?

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure.
Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?
You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study, since it will help us understand the role of hand-carried ultrasound in the daily clinical care of patients with kidney dysfunction.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will not have any costs for being in this research study. You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?
You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?
The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?
Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.

- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will store any collected data in an encrypted secure file only accessible to the research team.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue or because the funding for the research study has ended.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact Charbel Khoury, MD 314-362-8351. If you feel that you have been harmed in any way by your participation in this study, please contact Charbel Khoury, MD 314-362-8351.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 12/18/23.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

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(Name of Person who Obtained Consent - printed)