INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Medication Adherence Given Individual SystemCHANGE™ in Advancing Nephropathy (MAGICIAN) Pilot Study
Indiana University School of Nursing

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Indiana University, IU Health, Eskenzai, or IU Health Physicians.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to try new ways to improve the way that people with chronic kidney disease manage their health. We are interested in learning more about the ways that you take care of yourself, including information about the medication that you take for your kidney care and blood pressure.

You were selected as a possible participant because you are receiving kidney and blood pressure care services from a healthcare provider at IU Health or Eskenazi Health.

The study is being conducted by Rebecca Ellis, PhD, RN, ACNS-BC at the Indiana University School of Nursing at Indiana University, Dr. Arjun Sinha, MD, IU Health, and IU School of Medicine; Susan Perkins, PhD, Department of Biostatistics at Indiana University and James Hill, PhD, Computer Science. It is funded by the IU School of Nursing and the National Institute of Nursing Research.

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 150 participants from IU Health or Eskenazi Health taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

This study has 3 phases- the screening phase, the intervention phase, and the maintenance phase. Before being invited to participate in this study, you will be asked questions from the 6-item cognitive screening survey to make sure you qualify for the study.

Screening Phase

If you are eligible to take part in the study, we will begin by reviewing your medical records for medications you take, what level of renal impairment you have, and may periodically review your records throughout the study if you have medication changes or visits with your doctor or hospital. After this review, with the study nurse, we will ask you to fill out a demographics form. We will monitor how you take your medication by giving you a pill bottle to use that has an electronic cap that will let us know when and how often you open the pill bottle to take a pill. For two months, you will use this special pill bottle and remove the cap when you normally take your medication. After you take your medication, you will put the cap back on the bottle. You will also be given a discrepancy log to make notes on your medication and instances where the cap was removed but medication was not taken. The first and the fourth week the study nurse will call you to ask survey questions about how you are using the pill bottle and cap to make sure you are not having any problems using it. At the end of the two-months, someone from our study team will call you and tell you how to mail the empty bottle and cap back to the study team as well as perform the Patient Activation Measure (PAM-13) survey. The study team will give you a pre-paid envelope to return the discrepancy log and cap. Then you can mail it back to us by putting the sealed envelope in a US postal mailbox. The study investigator will then look at the information from the cap and if you have a medication score less than 0.85, we will ask you to continue in the study. If your score is 0.85 or greater, we will thank you for your participation and you will end the study.

If you are invited to participate in the next phase of the study, we will randomly assign you to treatment group 1 or treatment group 2. Random assignment is like flipping a coin-heads puts you in one group and tails puts you in the other group. Both groups will get an intervention for improving kidney health.

Intervention Phase

The intervention phase is next. If you are invited to continue the study, we will arrange a time to "visit" with you using Zoom, a video conferencing that can take place on a computer or your phone. Your electronic cap and bottle will be returned to you by mail. You will be asked to use the electronic bottle for 12 more weeks.

You will also be asked to complete additional surveys. These surveys include 1) Acceptability Scale, 2) Outcome Expectancy, 3) Treatment Credibility Questionnaire.

You will again use a special bottle and cap to keep and take your medication. You will also be given a special mobile phone for this study. Each week for 6 weeks, you will place the phone near the bottle to send data to the study team. After the data is received, you will get one text message on the provided mobile phone each week for 6 weeks. These text messages are education about your disease and disease process.

A member of our study team will call you each week to ask you questions and make sure the equipment is working correctly. The study team member will also discuss information from the first visit with you. We will also ask you about any healthcare visits that you have with your healthcare provider. This might include a visit to your providers for a checkup and any time spent in the hospital or a visit to the emergency room.

Treatment group 1 will receive education that will help you to learn more about caring for your chronic kidney disease. You will receive your first materials by mail before the research nurse's video visit. You will receive a text on your study phone from the research nurse to review the educational materials throughout the study. In addition, the research nurse will call you to review the education and ask if you have had any changes to your medications and what healthcare providers you have seen recently.

Treatment group 2 will receive training by a research nurse who will work with you to learn about SystemCHANGE™. Part of this intervention involves completing time worksheets together with the study nurse (Important People Form, Life Routine Form, Solutions Form). This helps you identify people who are important in helping you with taking your medicines, and identify your daily routines, specifically the routines around the times that you are scheduled to take your medicines. The research nurse will ask you to think about possible changes in your routines that may make it easier for you to take your medicines every day on time without having to remember. The research nurse will call you to discuss the important people you marked on the Important People Form and which solutions you have decided to use from the Solution Form. Throughout the study, the research nurse will send your personal medication taking report to your phone. The research nurse will telephone you to discuss how you are doing with taking your medicine every day on time and using the forms. Together, you will discuss possible solutions for improving your medication taking. You will try out the ideas and then see if your medication taking is getting better from your personal medication taking report. In addition, the research nurse will ask you if you have had any changes to your medications and what healthcare providers you have seen.

Maintenance Phase

In both groups, at 8 weeks, someone from the study staff will call you and ask you some of the same questions as before about your medication and your kidney health, as well as repeat the previous surveys. They will also ask you some questions about participating in the study. In this final phase, you will continue to use the electronic cap and bottle to take your medications.

At the end of the twelve weeks, you will once again take the surveys as before. You will receive a postage paid envelope to return the cap and phone to the study nurse. At this time, you will also take part in a semi-structured interview. We will arrange a time to call you for this interview.

At the completion of the twelve weeks, those in treatment group 1 will have a chance to enroll in treatment group 2 as described above.

In both groups, all the interactions that you have with the study nurse over the telephone and by video visit will be audiotaped so that the investigator can make sure the study nurse is following the research study steps.

At the completion of the intervention(s), you will have no additional testing in the study, and you will continue to follow-up with your providers.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

While participating in the study, the risks, side effects, and/or discomforts include:

- Possible frustration when using the electronic medication monitoring (EMM) cap
- Fatigue (physical or mental) during answering the questions
- Possible loss of confidentiality
- Uncomfortable answering personal questions

We will minimize these risks by:

- Hiring Research Assistants and Nurse Intervenors who have education and experience working with people with health conditions
- Making sure you are comfortable using the EEM cap before starting this study and checking on you weekly for issues.
- To minimize possible fatigue, you will be asked every 20 minutes during the interviews if you would like to take a break.
- Keeping all files in a locked, secure, location available only to the research team.
- If uncomfortable with questions, tell the researcher you do not want to answer that question.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

The information learned from this study may be useful to help other people, like you, learn ways to better care for themselves in the future. There may or may not be a direct benefit to you; however, as a result of participating in this study, you may pay more attention to how you manage your kidney health, which could result in you changing your behavior to improve your kidney health.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. Audio recordings will be monitored by the primary investigator and project coordinator. These recordings will be used for quality assurance and monitoring intervention fidelity. Audio recordings will be maintained until the study is closed.

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.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and state or federal agencies who may need to access the research records (as allowed by law). State and federal agencies may include the “Office for Human Research Protections (OHRP)” for federally funded research, and/or “National Institutes of Health (NIH)” for research funded or supported by NIH.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent. If information is used in future research, it will be de-identified before sharing.

WILL I BE PAID FOR PARTICIPATION?

To thank you for your time and use of the devices in this study, you will receive compensation in the form of gift cards. A subject can receive a total of $50.00 but only if they participate in BOTH the Screening and the Intervention phase. The Subject must be invited to participate in the Intervention phase, which will be based on the Electronic Medication Monitoring Screening phase.

In the Screening phase of the study, you must complete all the activities including interviews with study staff via phone or in person, and confirmed use of the study devices. After the receipt of all materials including the Electronic Medication Monitoring cap and discrepancy log (in a prepaid envelope), you will receive a $20 honorarium in the form of a gift card. This will be mailed to you within 10 days of receipt of the study materials.

At the conclusion of the study, those in treatment group 1 and treatment group 2 will mail back the study devices, and after completed surveys and interviews, a $30 honorarium in the form of a gift card, will be mailed to you as a thank you. This will be mailed to you within 10 days of receipt of the study materials.

For those who participate in both treatment groups. As a thank you, you will receive $30 at the completion of the 12-week educational intervention as well as $30 at the completion of the 12-week

SystemCHANGE™ intervention. The final $30 will be mailed to you within 10 days of receipt of the study materials.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study. You or your insurance company will be responsible for the prescribed medications that you already take.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Rebecca Bartlett Ellis at (317) 274-0047. Feel free to leave a message if no answer and the primary investigator or the project coordinator will return your call within 24 hours.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 317-278-3458 or 800-696-2949.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, contact the researcher, Rebecca Ellis at 317-274-0047.

PARTICIPANT'S CONSENT

In consideration of all the above, I give my consent to participate in this research study. I will keep the above portion and send this signed sheet to the primary investigator for documentation of my consent. The research nurse will also call me to go over this document with me.

I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____ **Date**:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____