MAYO CLINIC

Name and Clinic Number

Approval Date: December 14, 2021

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: AKI in Care Transitions (ACT) Trial

IRB#: 21-011055

Principal Investigator: Erin Barreto, PharmD and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	You have been asked to take part in this research because you have been diagnosed with Acute Kidney Injury (AKI) during your hospital stay. Mayo Clinic in Rochester, Minnesota has developed the **A**cute Kidney Injury (AKI) in **C**are **T**ransitions (ACT) program, to provide education and care coordination for AKI survivors. The purpose of the study is to compare the knowledge gained and outcomes of patients who are part of the ACT program compared to those who receive standard care.

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What's Involved	As a part of this study you will be asked to ~~complete questionnaires~~ about general physical, mental, and emotional health. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. If you feel you need assistance related to your physical or mental health while speaking with study staff you are encouraged to ask for help. The questionnaires will take 10-15 minutes to complete and will be given to you while you are in the hospital and approximately 1 month after you have been discharged. You will be assigned to 1 of 2 study groups using a process called randomization, which is like the flip of the coin. If you are assigned to the group participating in the ACT program, the study team will provide standardized education and assist with coordinating your follow-up care when you leave the hospital. You may be asked to allow us to observe your visit with your clinician. If you are assigned to the group receiving standard care, your inpatient care team will provide education and coordinate your follow-up care. For participants in both groups, we will review your medical record regarding your kidney health history and care.
Key Information	We are testing a process that may help improve patient outcomes and the approach to care for AKI survivors. This research requires investment of your time to completing questionnaires and answering questions. What we learn in this research study will benefit patients with AKI that need follow-up care in the future. As with all research, there is a chance that confidentiality could be compromised; however, we take many precautions to minimize this risk.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator(s):** Erin Barreto **Phone:** (507) 284-2511 ext. 55866 **Institution Name and Address:** Mayo Clinic 200 1st St. SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have been diagnosed with Acute Kidney Injury (AKI) during your hospital stay. The plan is to have about 50 people take part in this study at Mayo Clinic.

Why is this research study being done?

This research is being done to develop materials and processes that will help facilitate education and kidney care coordination for AKI survivors.

Information you should know

Who is Funding the Study?

This study is supported by the Agency for Healthcare Research and Quality (AHRQ). The AHRQ will pay the institution to cover costs related to running the study.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

Your active participation will last for approximately 30 days after you leave the hospital, when your last follow-up survey is completed, but investigators may follow your care using information available in your electronic medical record for up to 1 year.

What will happen to you while you are in this research study?

If you chose to participate in this research and sign this informed consent form, you will be asked to participate in the following:

- You will be asked to complete a questionnaire that may take 10-15 minutes while you are in the hospital and another questionnaire that can be completed over the phone one month after your hospital discharge.
- You will be assigned to 1 of 2 study groups using a process called randomization, which is like the flip of a coin.
- If you are assigned to the group participating in the ACT program, the study team will provide standardized education and assist with coordinating your follow-up care when you leave the hospital. You may be asked to allow us to observe your visit with your clinician. This may be done by having a study team member present in the room during the appointment, by video-recording the visit with a small camera, or both. You, your clinician, and any visitors can turn off the recorder at any time. If there is a physical examination, the study team observing will step out of the room, and the recording device will be shut off. If you choose to participate in the study and are randomized to the intervention group, you can choose to decline observation of the visit at that time.
- If you are assigned to the group receiving standard care, your inpatient care team will provide education and coordinate your follow-up care.
- We will review your medical record regarding your kidney health history and care.

Questionnaires and surveys are done only for research purposes and will not be incorporated into the medical record. The results are only important for research. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible risks or discomforts from being in this research study?

The risks to participating in this research study are minimal, which means that we do not believe they will be any different than what you would experience at a routine clinical encounter or during your daily life. Sometimes having a conversation observed or recorded can be distressing. If you wish to no longer be observed or recorded, you may ask the study team member observing to exit the room or turn off the recording device. Additionally, you may choose not to answer any questions you are uncomfortable answering on the post-visit survey. As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

Access to educational resources about acute kidney injury will be available for all patients. This may help increase your familiarity with kidney health considerations. We also expect that the results of this study will help benefit others with acute kidney injury in the future.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Questionnaires
- Focused education on AKI care

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will not be paid for taking part in this study.

Will your information or samples be used for future research?

I permit the research team to keep the collected study data (including audio and video recordings) in a registry to conduct further analyses, future un-identified and IRB approved research, trainings, quality improvement and educational purposes.

☐ Yes ☐ No Please initial here: _____Date: _____

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How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Data collected for research is de-identified by use of a coded number in place of the subjects' name or medical number. All research materials are stored in locked cabinets and on password-protected computers. If the results of the research are made public, information that identifies you will not be used.

Representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential. Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The Mayo Clinic Institutional Review Board that oversees the research.

- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media) information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

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You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature