

<<INSERT LOCAL SITE NAME/LOGO/HEADING>>

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Study Title: Caring for OutPatiEnts after Acute Kidney Injury (COPE-AKI) Trial

Principal Investigator: <<INSERT LOCAL PRINCIPAL INVESTIGATOR NAME AND CREDENTIALS>>

Your study contacts:

The researchers involved in this study value patient feedback. Kidney patients were involved in the design of this study, and their insights have been immensely helpful. We want you to be comfortable, so if you have any questions about the study, concerns, or complaints, don't hesitate to get in touch with one or both of the following individuals:

Principal Investigator: Dr. <<INSERT LOCAL PI>>

Phone: <<LOCAL PI PHONE NUMBER>>

Email: <<LOCAL PI EMAIL, OPTIONAL>>

Study Coordinator: <<INSERT LOCAL COORDINATOR>>

Phone: <<LOCAL COORDINATOR PHONE NUMBER>>

Email: <<LOCAL COORDINATOR EMAIL, OPTIONAL>>

Source of Support:

This study is funded by the U.S. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases (NIH/NIDDK)

SUMMARY OF KEY INFORMATION:

- **Purpose:** This study is being conducted to find out if an “enhanced care” team can improve outcomes after hospitalization with acute kidney injury (AKI).
- **Research Activities:** If you enroll in this study, you will be randomly assigned to one of two groups:
 - A group that receives an **enhanced team approach**: This group will receive care recommendations from a team that includes a nurse, pharmacist, and nephrologist (kidney doctor), plus home blood pressure and weight monitoring. This team will work with you for the first 90 days after your hospital discharge.
 - A group that receives a **usual care approach**: This group will receive normal, current standard care that is typical for AKI patients.

Your participation in this study will last one year after your hospital discharge. You will be asked to complete questionnaires and provide a medical history at 4 different time points, as well as provide blood and urine samples at 3 of those time points.

- **Voluntary Participation:** Your participation in this study is voluntary. If you do not participate in this study, you will continue to receive your usual medical care.
- **Risks and Benefits:** The risks of the study are similar to what you experience in your usual medical care and include feeling uncomfortable answering question, confidentiality risks and discomfort from blood draws. It is possible, with enhanced follow-up, that additional

medical evaluation will be recommended for your symptoms or blood pressure, which might also increase your out of pocket costs. More details of the risk are below.

- We cannot guarantee any direct benefit to you by participating in this study. However, you may derive indirect benefit in helping future patients with AKI.
- **Compensation and Costs to You:** You will be compensated up to \$250 for your time. There will be a total of 5 visits, with each payment being \$50. Your parking will be validated for study visits if needed. There will be no direct cost to you to participate. You will, however, be responsible for the cost of any treatment you receive as part of your regular care as you normally would.

If you are interested in learning more about this study, please continue reading below.

1. Why is this study being done?

We are inviting you to take part in this research study to determine if an enhanced care team approach can improve outcomes after hospitalization for patients like you with acute kidney injury (AKI). Approximately 2145 individuals at multiple sites in the U.S. will participate in this study.

AKI is the sudden worsening of kidney function over hours to days. It is a common problem in patients who are in the hospital. After having AKI, your chances are higher for other serious health problems (such as kidney disease and heart failure), rehospitalization or having AKI again. We have heard from patients that recovery from AKI can be difficult. Patients didn't know where to go for answers to questions.

Our goal is to find the best approach to caring for people after hospitalization with AKI to prevent these complications from occurring.

2. What will I be asked to do in this study?

2.1 Initial Study Visit: The initial study visit will happen before hospital discharge:

- The study team will collect information about your vital signs, medical history, medications, demographics, and usual providers.
- You will answer questions about how you are feeling, your quality of life and your knowledge about AKI. The questionnaires are expected to take about 10 minutes; if you are interested in sharing more about how you are feeling, there are questionnaires that are optional that will take an extra 30 minutes. You can do all, some, or none of these questionnaires.
- Blood (two tablespoons) and urine (4 teaspoons) will be collected to measure kidney function and injury proteins.

After the above activities are complete, we will randomly place you (like the flip of a coin) in one of the two groups:

- The **enhanced team intervention group** or
- The **usual care group**.

More information on each group will be discussed under section #3.

2.2 Follow up Activities for BOTH Groups: This chart shows activities during each visit after hospitalization:

	30 days	90 days	6 months	12 months
Review of medications/hospitalizations/medical visits	x	x	x	x
Vitals; blood and urine tests		x	x	x
Questionnaires	x	x	x	x

The 30-day visit will be a phone call to check your medications and medical history.

Follow-up visits may occur in person at the <<SPECIFY LOCAL RESEARCH LOCATION(S)>> **or** remotely. The study staff may talk to you about whether it may be possible to have a study visit at your home instead of the study site to collect your blood, urine, and vital signs. These home visits, if you choose to have them, will be done by a subsidiary of Quest Diagnostics called ExamOne. The company is not affiliated with the study site or COPE AKI.

If you choose to do these visits remotely, a visiting nurse from ExamOne will come to your house, and a research coordinator will talk to you by telephone or video call. The following activities will occur:

- Blood pressure, weight check, and assessment of swelling
- Blood (two teaspoons) and urine (4 teaspoons) collection
- Review of medications and medical history since your last visit.

You will be called by an interviewer from the University of Pittsburgh to answer questions about how you are feeling. It is expected that this telephone visit will take about 10 minutes. This interview can be scheduled at a time that is convenient for you. If you prefer, you can also answer these questions online via a link that is emailed or texted, at your in-person follow-up visit or by phone with your local research coordinator. There are also optional questions that will take up to 30 minutes to answer – you can choose to answer all, some, or none of these questions. Appointment reminders may be sent by email or text message.

3. What is the difference between the two groups to which I could be assigned?

You will be randomly assigned (like the flip of a coin) to one of two groups.

3.1 ENHANCED TEAM INTERVENTION GROUP

The **Enhanced Team Intervention Group** will include the following people in your care: a nurse navigator, a study pharmacist, and a study nephrologist (kidney doctor).

3.1.1 Nurse Navigator: The nurse navigator will be your primary contact and is a resource for you to navigate the medical system and all of your health care – you can bring up any health care concern.

The nurse navigator will meet with you before you are discharged from the hospital. They will provide information and education about AKI and review your medications, as well as conduct an assessment prior to discharge.

Follow-up visits will occur 2-3 days and 7-10 days after you are discharged, and then every 2 weeks for the next 2 months. The primary goal of these visits is to address any health concerns you may have. The nurse navigator will review your weights and blood pressures and discuss with you and your providers any issues with the readings. These visits will be primarily by telehealth, but an in-person option is available if you want.

3.1.2 Study Pharmacist: The study pharmacist will review your current medications, including over-the-counter medications and supplements. They will make sure the medications you are taking match the medications that were prescribed in the hospital and make kidney-specific medication recommendations if needed. They can answer questions you may have about your medications. You will have a telehealth visit with the pharmacist within 7 days of hospital discharge. Additional pharmacist visits can occur at your request or the request of the study team.

3.1.3 Study Nephrologist: The study nephrologist will lead your study care team. Before discharge from the hospital, the nephrologist will make an assessment and recommendations for follow-up care. These recommendations will be communicated to your usual care providers. After discharge, the nephrologist will review your follow-up information with the study care team. As a team, they may make recommendations to your usual providers.

There may be a time when your usual providers disagree with the study team's recommendations. In this case, you and your providers can discuss the best options for your care.

3.1.4 Home Blood Pressure and Weight: You will be given a Bluetooth-enabled scale and blood pressure cuff. The nurse navigator will show you how to use these items. You will be asked to measure your blood pressure and weight daily. The information will be sent to a central computer that can be accessed by the study team. The study team will work with your providers to adjust medications as needed. Your providers (not the study team) will make these adjustments. You can keep these items at the end of the study.

3.2 USUAL CARE GROUP

If you are placed in the Usual Care Group, your follow-up care will be the regular, standard care that you would receive had you not agreed to participate in this study.

In addition, you will receive education about AKI. The study team will communicate with your usual providers to ensure they know you had AKI. From that point on, all of your care will be provided by your usual providers and/or a nephrologist if the team caring for you in the hospital or your usual providers feel this is necessary.

4. Are there any risks involved in participating in this study?

The nurse navigator that draws your blood is highly trained in drawing blood and will work with you to make you as comfortable as possible. When we draw your blood, there is a small chance it may cause pain and/or leave a bruise. You may feel dizzy or faint after a blood draw. There is also a rare risk of infection at the site of the blood draw.

It is possible that you may feel uncomfortable answering personal questions. You do not have to answer any questions that make you uncomfortable, and you may stop participating anytime.

Since private information is collected about you as part of this study, there is a risk of a breach of confidentiality (see “How will my confidentiality be protected” below).

It is possible that if you are in the Enhanced Team Intervention Group that you may have additional medical visits or testing, changes in your medications or other standard care recommendations that result from this enhanced care.

5. Are there any benefits to participating in this study?

You are not guaranteed to benefit from being in this study. You may benefit from the knowledge that you are potentially helping to improve care for future patients with AKI.

If you are in the Enhanced Team Intervention Group, it is possible that being more closely monitored will improve your outcomes after being hospitalized for AKI by improving communication between you and your care providers and decreasing anxiety. This enhanced monitoring may also help to identify any medical issues sooner.

If you are in the Usual Care Group, the study team will give you information about AKI that you can take home. The study team will also communicate with your usual providers so that they are aware that you had AKI. This additional information and communication may help you and your usual providers with your care.

6. Is my participation in the Research study voluntary?

Your participation in this study is completely voluntary. If you chose not to participate in this study, you will continue to receive usual post-hospitalization care for AKI. Whether or not you choose to participate will have no effect on your care or your relationship with your doctor or with <<INSERT SITE HOSPITAL NAME>>.

7. Will you tell me any new information when available?

We will tell you about any new information that we learn during the course of this study that may cause you to change your mind about staying in the study.

8. Can I **withdraw my consent from the study?**

You can withdraw from this research study at any time. Any identifiable research information obtained as part of this study prior to the date that you withdraw your consent will continue to be used by the investigators for the purposes described above unless you specifically ask to have it removed. If you want to withdraw, notify the study contacts on the first page of this form.

9. Will I have access to the study results?

The results will be limited/withheld during the study. We will not be able to communicate the results of blood and urine collection with you during the study, but in some instances, it may be possible for our study team to become aware of issues long after. Because of this, it is important that you communicate all your current and ongoing health concerns to your health provider in charge of your kidney care.

The results of testing performed under this research study will not be included in your medical record. However, you will be notified of any laboratory results that require medical follow-up. At the end of the study, a summary of the study results will be provided to you.

A description of this clinical trial will also be available on <http://www.clinicaltrials.gov>, as required by US 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.

10. Are there any costs to me for participating in this study?

Neither you nor your insurance will be charged for any costs related to the study coordinator, nurse navigator, study pharmacist, or any study nephrologist (kidney doctor) visits or the study-related blood and urine tests.

However, laboratory tests and medical visits that are part of your regular care, including follow-up provider visits to address problems that may be identified through the enhanced care approach, will not be covered by the study and there may be co-payments or additional costs to you.

11. Will I receive any compensation for participating in the study?

You will receive up to \$250 for participating in this study. We will compensate you \$50 for each study visit at enrollment, 30 days, 90 days, 6 months and one year. If the visits are done at the study site, you will also receive reimbursement for parking. You may be required to provide additional personal information for the purpose of payment.

Payment to participants:

<<INSERT ANY LOCAL COMPENSATION LANGUAGE>>

12. Will I receive compensation for any injury from the study?

<<INSERT LOCAL COMPENSATION FOR INJURY LANGUAGE, OR USE STATEMENT BELOW>>

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

13. How will my confidentiality be protected?

Every effort will be made to make sure that the information we collect about you during this research study will be kept strictly confidential. As identifiable information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.

On all research documents outside of this consent form, we will identify you using a study ID rather than your name. A linkage list connecting your name to your study ID will only be accessible to investigator approved members of the study team. All research data stored on paper will be labeled with your study ID and kept in a locked filing cabinet. All research data stored electronically will be coded and stored on password protected computers behind university approved firewall security systems.

In addition to the <<INSERT SITE NAME>> investigators and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

- Authorized representatives of the <<INSERT LOCAL SITE NAME>> Office of Research Protections
- Authorized representatives of the University of Pittsburgh Office of Research Protections who are responsible for the IRB oversight for this study.

- The Study Sponsor, National Institute of Diabetes and Digestive Diseases and Kidney Diseases (NIDDK), for the purposes of monitoring this study.
- Compliance and Safety Monitors (e.g. advises the Sponsor or PI regarding the continuing safety of this study): Data safety monitoring board (DSMB)
- Data Coordinating Center: University of Pittsburgh
- In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law
- If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by <<INSERT SITE NAME>> law, the appropriate agencies.
- ExamOne, a subsidiary of QUEST Diagnostics
- <<INSERT ANY ADDITIONAL LOCAL ENTITIES THAT MAY HAVE ACCESS TO IDENTIFIABLE RESEARCH DATA>>

14. How long will researchers be permitted to use and disclose my research-related data?

At the <<INSERT LOCAL SITE NAME>>, <<INSERT LOCAL DATA RETENTION LANGUAGE>>

The University of Pittsburgh is providing the regulatory oversight for this study and is serving as the data coordinating center. Because of this, investigators and study staff at the University of Pittsburgh will have access to your research-related information. Per University of Pittsburgh policy, all research records will be maintained at this site for at least 7 years following final reporting or publication of a project.

15. Will my research data be used for future research outside of this study?

The data we collect about you throughout this research study may be shared with other investigators interested in future research related to acute kidney disease. Any data that is shared will be de-identified. This means that it will not include your name or anything that could identify you.

We will protect the confidentiality of your records. Because private information is collected about you as part of this study, there is a risk of a breach of confidentiality. To lessen this risk, all of your study information and samples are coded with a study ID and do not contain information that can identify you. A list that links your name and identifiable information to your study ID is only accessible to vital members of the research staff.

By signing this form, you are giving your permission for other researchers to use your de-identified research data for future research purposes (e.g., future studies).

Additionally, your research data will be transferred at regular intervals throughout the study to the NIH/NIDDK (study sponsor) data repository, which will be securely stored. Data stored in the NIH/NIDDK data repository will be available to investigators outside of this study. Before using information that is collected from this study for additional future research studies, direct personal identifiers will be removed, and the investigators will not be able to identify you personally.

15.1 Future use of blood and urine samples: optional

As part of your participation in this study, researchers will collect your blood and urine samples. We would like to use these samples for ongoing research to further understand AKI. You can choose whether or not you agree to allow your samples to be used for future research. If you decline, the use of your blood and urine samples will be limited to the purposes of this study. You can decline and still participate in the study.

In order to allow researchers to share test results, the NIH/NIDDK has developed a special data (information) bank that collects samples. This central bank will store your study information and samples and give them to other researchers to do more studies. We do not think that there will be added risks to your privacy and confidentiality by sharing your samples. The samples and data will be sent with only your code number attached. **Your name or other directly identifiable information will not be given to central banks.** Only the sample material, relevant dates of collection, specific clinical information, and other data about the specimens will be provided. We will store your samples and data indefinitely.

While genetic testing will not be done as part of this study, it is possible that future researchers may conduct genetic testing or whole genome sequencing on your de-identified samples that are stored in this central repository. The risks associated with genetic studies include the potential for a breach of confidentiality, which could affect future insurability, employability, or reproduction plans or have a negative impact on family relationships and/or result in paternity suits or stigmatization. A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies and group health plans to use genetic information in making decisions regarding your eligibility or premiums. GINA also makes it illegal for employers with 15 or more employees to use your genetic information when making decisions regarding hiring, promoting, firing, or setting the terms of employment. This new Federal law does not protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance.

While it is not part of the plans for this study, your data, and specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize. The NIH/NIDDK does not profit from the future use of resources.

15.2 Authorization to use my blood and urine samples

_____ Yes, I agree that my samples can be used for different types of scientific research, including research that is not related to AKI. I acknowledge that the investigators cannot foresee all possible future uses.

_____ No, I do not consent.

16. Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot

provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information. Researchers may release information about you when you say it is okay.

17. HIPAA Authorization:

<<INSERT LOCAL SITE HIPAA language OR keep the below. If your site requires a separate HIPAA authorization form, remove the information below and add a statement that the HIPAA authorization will be separate. >> As part of this research study, we are asking your permission to access and collect information from your medical records to follow your medical condition during the study. This permission does not expire.

All of your past, current, and future medical record information related to your acute kidney injury and other health issues you may experience will be recorded in the study record. Since medical conditions and treatments not related directly to your kidney injury may affect your condition and/or its treatment, it is likely that all of your existing and future medical record information will be placed in the study record. This information will be collected from the center where you receive treatments, including clinic records, hospital records, urgent care/emergency room visits, and, if applicable, private physician records. Laboratory data on chemistry values, kidney function, and urine tests will be collected. If there is a hospitalization at an outside hospital, where the data is not available in the electronic record, a signed HIPAA authorization will be sent in order to obtain information from those centers to both verify your reports on potential events as well as screen for events that you may not recall.

We will protect the confidentiality of your records. This means we will keep your records secure and do all we can to prevent people who have not been given permission to be able to access it. We cannot guarantee the confidentiality of your information from this study, including from your medical records, once people outside <<INSERT LOCAL SITE NAME>> have viewed it. However, the risk is low as we will remove identifiers before giving information to outside individuals.

If you would like to identify another individual(s) who can better provide information about your medical history, including my symptoms, diagnosis, medications, and treatment plan, please provide the name(s) to our study team. Study team members may then contact the individual(s) for that information.

You can withdraw your permission to allow the research team to use your information from your medical records. You can do this by sending a request in writing to the principal investigator listed on the first page. If you do so, you will be withdrawn from this study since your medical information is critical to the study. The research team will continue to use information collected from you or your records up to that point.

CONSENT to PARTICIPATE

The above information has been explained to me, and all my current questions have been answered. I understand that I am encouraged to ask questions and voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

Any questions I have about my rights as a research participant or the research use of my medical information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

<<SITE ADVOCATE INFORMATION (OPTIONAL)>>

You have the option of signing a paper consent or an electronic consent with a research tablet. In the case of electronic signature, then by electronically signing and confirming the consent on the website below, I agree to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be available to me. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed, and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

In case of a paper signature, then by signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

Printed Name of Participant

Date

Signature of Participant

Certification of Individual Obtaining Consent

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual had about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was started until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

Consent for study participants who are unable to read or write are visually impaired, and/or have physical limitations that prevent them from signing the consent form on their own behalf.

The study participant is unable to sign the consent form on their own behalf because he/she has indicated to the study team that he/she is unable to read or write, is visually impaired, and/or has a physical limitation. The consent form has been read to the study participant and to their authorized representative or to an impartial witness (as defined below) if an authorized representative has not been elected by the study participant or is not present by a member of the research study team designated to obtain informed consent, and that member of the study team has discussed the information in the consent form with them. The study participant and their authorized representative, or the impartial witness, have been given an opportunity to ask questions and all of their questions have been answered to the study participant's satisfaction. The study participant has communicated his/her agreement to participate in the research study by making his/her mark on the participant signature line above, by verbally agreeing to join, or by some other means (e.g. nodding, blinking).

I attest that the consent information was explained to the study participant and to myself that the study participant apparently understood the information, and that informed consent was given freely.

THE PARTICIPANT AGREED TO JOIN THE STUDY VERBALLY OR BY SOME OTHER MEANS (E.G. NODDING OR BLINKING)

Signature of Authorized Representative (Print Name) Date/Time

Signature of Impartial Witness* (Print Name) Date/Time

*Impartial Witness: A person who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who, in the absence of an authorized representative for the participant, attends the informed consent process when the participant cannot read or write, is visually impaired, and/or physically cannot sign the form, and who reads the participant

information and informed consent form and any other written information supplied to the participant. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance

Signature of Person Obtaining Consent (Print Name) Date/Time