Document Coversheet

Study Title: A Randomized Clinical Trial of Continuous vs. Intermittent Infusion Vancomycin: Effects on Measured GFR and Kidney Injury Biomarkers

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KEY INFORMATION FOR A RANDOMIZED CLINICAL TRIAL OF CONTINUOUS VS. INTERMITTENT INFUSION VANCOMYCIN: EFFECTS ON MEASURED GFR AND KIDNEY INJURY BIOMARKERS

We are asking you to choose whether or not to volunteer for a research study about how different vancomycin infusion strategies may affect kidney function. We are asking you because your doctor has prescribed vancomycin to treat an infection. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn about the best way to give this medication (vancomycin): several times throughout the day or a slow (continuous) infusion. Your direct participation in this research (measurement of kidney function, blood draws, and urine collection) will last until your doctor decides you no longer need this antibiotic (vancomycin). The research team will monitor you until hospital discharge.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If one method of infusion strategy turns out to be better than the other, there is a 50% chance that you will receive vancomycin in the method that is least harmful to your kidney. Participation in this study will help to inform other healthcare professionals about the safest way to give this medication to future patients. By participating in the study, the research team will carefully monitor your blood levels of vancomycin to make sure they are in the appropriate range.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Regardless of which way vancomycin is given to you, participation in this study includes measuring your kidney function using a very small dose of dye (known as iohexol). We will be taking very small samples of blood and urine, which may not be acceptable to you.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Aaron Cook, PharmD of the University of Kentucky, Department of Pharmacy Practice and Science ataaron.cook@uky.edu. If you believe you are hurt or if you get sick because of something that is due to the study, you should call Juan-Carlos Aycinena, M.D. during regular office hours at 859-323-2663. At other times, you may page him via calling 859-257-1000.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You are not qualified for the study if you are younger than 18 years of age or have any of the following: chronic or end-stage kidney disease, currently have acute kidney injury, recently received vancomycin, allergy to iohexol, uroepithelial tumors (grown on your bladder or pelvis), are pregnant, or prisoner status.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at UK Medical Center. The total amount of time you will receive vancomycin is determined by your doctor. The total amount of time you will be asked to volunteer for this study in terms of blood draws and urine collection is 5 days, but we will follow your outcomes until hospital discharge.

WHAT WILL YOU BE ASKED TO DO?

If you are enrolled in the study, you will be randomly assigned (like the flip of a coin) to receive the vancomycin prescribed by your doctor either via intermittent infusion (multiple doses per day) or continuous infusion (a slow infusion that lasts 24 hours).

In order to measure your kidney function, a small amount of iohexol will be given by your nurse. This agent is commonly used in imaging procedures, but this is a much smaller dose. In order to measure kidney function, we measure levels of iohexol as it disappears from your body by drawing small amounts of blood twice that day. These procedures will occur the day that you are enrolled in the study, as well as 2 and 3 days later. Each blood draw will take approximately 1 teaspoonful of blood. We will also ask you to contribute urine (30 ml or about 3 teaspoons) at the start of the study and on days 1, 2, 3, and 5 of the study. The study team will coordinate this collection with nursing staff as appropriate in order to try and perform all laboratory tests at the same time if possible.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Loss of Confidentiality- Any time information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks of Blood Draw- Risks associated with drawing blood from the intravenous line you already have are minimal, but may include discomfort, bruising, soreness, infection, excess bleeding, clotting, light headedness, or fainting. You will have up to 6 teaspoons of blood collected because you are in this study.

Risks of Urine Collection- There are no known risks for urine collection.

Risks of Iohexol Administration- In the dose used to measure kidney function, treatment-related events are rare (<0.01%) and may include: nausea, vomiting, flushing and itching.

Risks of Vancomycin Infusion Strategy- The standard of care in most cases in this hospital is to give vancomycin multiple times per day, or intermittent infusion. In comparison to continuous infusion, risks from this strategy may include an increased risk of kidney injury and more out of range vancomycin levels. While continuous infusion may reduce your risk of injury to the kidney (why we are performing this study), it may cause irritation to your vein as well as require you to be connected to your IV pole for longer periods of time, which could impact your mobility while hospitalized.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

If you participate in the study, you may receive the benefit of increased monitoring and closer attention to your vancomycin dosing. Our researchers will ensure that your dose is correct and that your vancomycin levels are being monitored very closely, even more so than normal.

If you are randomized to intermittent infusion (multiple doses per day), you may not get any personal benefit from taking part in this study aside from increased monitoring.

If you are randomized to continuous infusion, we do not know if you will get any benefit from taking part in this study. However, some patients receiving continuous infusion have developed kidney injury less than patients

receiving intermittent infusion. Regardless of which infusion strategy you receive, if you take part in this study, information learned may help influence how other patients in the future receive vancomycin in the safest way possible.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, you will simply receive vancomycin as prescribed by the judgement of your medical team and any hospital protocol. At UK, the most common method of giving vancomycin has been intermittent infusions. There have been more clinicians choosing to do continuous infusions in the recent past.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

Therefore, these costs (iohexol, additional laboratory tests) will be paid for by the study.

Your insurer, Medicare, or Medicaid, may agree to pay for the costs. However, a co-payment or deductible may be needed from you. The amount of this co-payment or deductible may be costly.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information from all participants. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Any paper records will be kept in locked file cabinets in locked offices and you will be given a unique subject identifier number in our electronic databases that cannot identify you.

You should know that in some cases we may have to show your information to other people.

For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, if you report information about a child being abused; or if you pose a danger to yourself or someone else.

  To ensure the study is conducted properly, officials of the Food and Drug Administration and the University of Kentucky, may look at or copy pertinent portions of records that identify you.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, we cannot guarantee the security of data obtained by way of the Internet.

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 cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. 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.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator and your doctor know if you are in another research study. You should discuss this with the investigator and your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Juan-Carlos Aycinena, M.D. during regular office hours at 859-323-2663. At other times, you may page him via calling 859-257-1000.

Dr. Aycinena, in collaboration with your medical team, will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility. You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will not provide you with individual research results.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 50 people to do so at the University of Kentucky.

The National Institutes of Health are providing financial support and/or material for this study.

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

STORING AND SHARING YOUR INFORMATION OR SPECIMEN SAMPLES FOR FUTURE USE:

The researchers would like to store, use, and share your identifiable information and samples for future research. Having information and samples from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. Researchers can use the stored information and samples to learn more about the safest way that we can give vancomycin to patients.

Researchers would like to have permission to look at your medical records from now until December 31, 2029. Researchers would collect general information related to your health such as test results, treatments, and doctor's notes. The confidentiality section below provides details about how we will keep your information private.

WHERE WILL INFORMATION OR SPECIMEN SAMPLES BE STORED AND FOR HOW LONG?

The information will be stored in Dr. Cook's research laboratory in the University of Kentucky College of Pharmacy for no longer than six years. All of your samples will be coded with a unique identifier and accessible only to the study investigators. This means that your sample will not have your name on the labels but will have an identification number.

ARE THERE RISKS FROM ALLOWING YOUR INFORMATION OR SPECIMEN SAMPLES TO BE STORED FOR FUTURE RESEARCH?

Privacy and Social/Psychological:

There is a risk that someone could get access to the stored information or samples. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known.

Unknown:

There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now.

HOW WILL YOUR PRIVACY AND CONFIDENTIALITY BE PROTECTED?

Researchers will take careful steps to keep your information confidential.

Researchers will store your identifiable information or samples in a freezer in a locked laboratory and data in a password protected database.

Researchers will remove your name or other direct identifiers from your information or samples. We will label your information or samples with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to you.

HOW WILL WE SHARE YOUR INFORMATION OR SPECIMEN SAMPLES WITH OTHER RESEARCHERS?

Your information or samples with their unique code may be shared with other researchers without your additional informed consent, provided an Institutional Review Board (IRB) has approved this action. An IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human participants. If a researcher requests your information or samples with identifiable information, an IRB will decide if the research may be conducted with or without your additional consent.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR INFORMATION OR SPECIMEN SAMPLES?

You may withdraw your permission to allow your information or samples to be used for future research. To do so, you must send a written withdraw request to:

Aaron Cook, Pharm D.
Department of Pharmacy Practice and Science
University of Kentucky College of Pharmacy
789 S. Limestone Street TODD 275
Lexington, KY 40536

Any remaining information and samples will be destroyed. In addition, it may be possible to destroy the code that links you with your information and specimen samples. However, the information and samples that have already been used or shared may not be withdrawn.

WILL YOU RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?

The information and samples that you provide will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives should this occur.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE FUTURE RESEARCH TESTS?

Tests done for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. 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.

OPTIONAL FUTURE USE:

Do you give permission for your identifiable blood samples to be stored, used, and shared for future research?

☐ Yes ☐ No Initials _____

Remember, you can still be in the main study even if you even if you do not wish to allow your information and/or specimens stored or shared for future research.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic information (name, initials, gender, race, ethnicity, age, study number, mailing address, telephone number)
- Dates including date of birth, hospital admissions/discharges, dates of medical events, study visits
- Social Security Number
- Medical and medication history as they relate to your enrollment and participation in this study
- Ongoing medication use
- Health status
- Hospital / medical records (both inpatient and outpatient) which relate to this study: age, baseline kidney function, comorbidity, surgical history, medication history, hospitalization history.
- Results of physical exams, x-rays, blood tests, and other diagnostic and medical procedures related to the study
- Results of laboratory tests (blood, urine)
- Hospital and clinic notes related to the study

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- UK Hospital
- Investigational Drug Service (IDS)
- Food & Drug Administration
- Center for Clinical & Translational Science
- National Institutes of Health

- Other doctors, healthcare professionals and scientists who are involved in the study
- Health systems outside of UK for which you have a patient relationship

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: Aaron Cook, PharmD, PhD, 789 S. Limestone Street, TODD 275,Lexington, KY 40536 to inform him of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

You will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you may have the right to access the information.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ **Signature of research subject** *or, if applicable, *research subject's legal representative*	_____ **Date**
_____ **Printed name of research subject**	
**Printed name of research subject's legal representative*	
**If applicable, please explain Representative's relationship to subject and include a description of representative's authority to act on behalf of subject:* _____ _____	
_____ Printed name of [authorized] person obtaining informed consent and HIPAA authorization	_____ Date