UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Acute and Chronic Kidney Injury after Nephrectomy and Other Surgeries
Sub-title: Nephrectomy

Consent Version: 1.3

Company or agency sponsoring the study:
There is no sponsor for this study.

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator:
Markus Bitzer, M.D., Principal Investigator, University of Michigan, Division of Nephrology

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research collects health-related information, urine specimens, blood specimens and pieces of kidney tissue to better understand why some people develop acute kidney injury, or a temporary loss of kidney function, or chronic kidney disease, a permanent loss of kidney function after nephrectomy. This research will help us determine why some people are more likely to develop worsening kidney function after having surgery on their kidney.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, we anticipate that the risks will be minimal as we will take pieces of your kidney that would otherwise be discarded after you have completed surgery. We will additionally collect information concerning your health from the medical record. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by allowing us to better identify patients at increased risk of kidney related complications after surgery. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 1 year.

You can decide not to be in this study. Alternatives to joining this study include to receive surgery as recommended by your doctor.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

This study is going to carefully study pieces of kidney tissue with novel techniques to measure structures in the kidney to help us determine who is most likely to have loss of kidney function after having a nephrectomy.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Any adult over the age of 18 who is undergoing a nephrectomy can partake in this study.

You will not be allowed to participate in this study if you have very low kidney function or are >65 years of age when the state of Michigan is in Phases 1-4 of COVID-19 pandemic.

3.2 How many people are expected to take part in this study?

We anticipate that about 100 patients will participate in this arm of the study each year. We are additionally enrolling patients undergoing a different type of surgery. We anticipate that 20 patients from that arm of the study will participate each year.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

- At the first meeting, the research team member will provide information about the study and determine if you are eligible to participate.
- If you are willing and able to participate, we take pieces of your kidney that would normally be discarded for research.
- We will additionally ask you to provide blood and urine specimens.
- Your coded research information and samples will be stored for future research use.
- Details about the study are below.

<u>Recruitment and Enrollment Visit:</u>

If you are undergoing a total nephrectomy, you are eligible to participate in this study. To determine if you are eligible, the study coordinator will review your medical record and discuss with your surgeon. If you are eligible and choose to participate, a study coordinator will access your medical information in your electronic medical record. We will record data including your age, sex, other medical problems, medications and laboratory results.

<u>Surgery:</u>

You will then have your surgery. Once the kidney is removed from your body, we will remove small pieces of kidney tissue from an area that will normally be discarded. These specimens will be used for research purposes.

We will ask you to provide a blood and urine specimen. We would like to collect about 50 mL (about 3 tablespoons) of blood. We will additionally also collect about 50 mL (about 3 tablespoons) of urine. We will also take a blood sample to study your genomic information for our biorepository (see **Consent for Genetic Studies and Future Research** below. If you do not consent to genetic studies, we will only obtain 40 mL of blood). Blood and urine samples are optional at all time points in the study.

Visit 2: 2-4 Weeks after Surgery
You will then see your surgeon for a follow-up visit about 2-4 weeks after your surgery. At this time, we will ask you to provide another blood and urine specimen, if you agree. We will additionally extract information from your electronic medical record.

Visit 3: 3 Months after Surgery
You will then see your surgeon for a follow-up visit about 3 months after your surgery. At this time, we will ask you to provide another blood and urine specimen, if you agree. We will additionally extract information from your electronic medical record.

Visit 4: 12 Months after Surgery
You will then see your surgeon for a follow-up visit about 12 months after your surgery. At this time, we will ask you to provide another blood and urine specimen, if you agree. We will additionally extract information from your electronic medical record.

CONSENT FOR GENETIC STUDIES AND FUTURE RESEARCH:
Besides the information about the main study, the following information is specific to unspecified future use of identifiable data and/or biospecimens. We would also like your permission to keep some of your genomic information and medical information collected in the main study, so that we may study it in future research. Genomic information holds the instructions that your body uses to grow and function, which are called genes. Your genes are responsible for your physical features such as eye color, blood type, and how your body breaks down medications. Genes can also be responsible for some medical conditions.

Genomic information relates to the structure and function of all of the genetic material in the body. We will submit your genomic information to a repository to be used for scientific purposes. A repository contains information from many people. Some repositories are maintained by the University of Michigan, some are maintained by the federal government, and some are maintained by private companies. Researchers all over the world can take information from the repository and use it in their studies. Their studies may be similar to this one or may be completely different.

We will label your genomic information with a code, instead of your name or other information that people could use to directly identify you. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally.
Researchers will have controlled access to your specific genomic information. Controlled access means that researchers will need approval from study principal investigators in order to obtain the genomic information from the repository.

We may share your samples, genomic information and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your samples, genomic information and medical information with other researchers, we will not be able to get it back. Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your genomic information. Allowing us to do future research on your genomic and medical information will not benefit you directly.

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

4.2 How much of my time will be needed to take part in this study?
This study will require 4 separate visits apart from your surgery. All of these visits will be done during regularly scheduled visits with your surgeon, but you may need to spend extra time getting blood drawn or providing a urine specimen (about 30-40 minutes). If your surgeon needs you to have blood drawn, we will draw our samples at the same time.

The first visit (recruitment and enrollment) will take about 60 minutes.

We will ask for a blood and urine specimen at your surgery and when you come for follow-up appointments with your surgeon at 2-4 weeks after surgery, 3 months after surgery and 1 year after surgery.

4.3 When will my participation in the study be over?
The study is expected to last 1 year, although we may check information in your medical chart for up to 5 years.

4.4 What will happen with my information and/or biospecimens used in this study?
Your biospecimens and collected information will be stored for future research use and may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens will be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Temporary pain from blood draw:
Drawing blood causes discomfort when the needle is inserted. A bruise may appear for a few days. There is a slight chance of infection. You may feel dizzy, lightheaded or you may faint. These risks are minimized by the use of trained personnel to draw your blood.

Loss of privacy
Some data obtained for research use will be labeled with your name. An example is a report from a laboratory. Another is information about your medical history. Information on paper will be stored in a locked file cabinet. Other data will be on a computerized research database. This is in the University of Michigan Nephrology research space. Only members of the research team will have access to the files and database.

There is a possible risk of the loss of confidentiality about your medical information. There are laws against misuse of your information, but they may not give full protection. There may be other unforeseen privacy risks. We believe that the chance that these things will happen is very small, but we cannot make guarantees. Your privacy and confidentiality of your data are very important to us and we will make every effort to protect them. We will take all of the following steps to protect your privacy and the confidentiality of your information:

- DNA samples will not be labeled with your name or other direct identifiers (like social security numbers or date of birth).
- All samples will be coded (assigned a unique study number), which will allow the researchers to link or connect your sample to other information that you provide through questionnaires and other study activities.
- The key to the code linking you to your DNA samples will be maintained in a confidential file with tight security precautions. The key will only be used to connect other information we collect to your DNA sample. This key to your code will never leave the University of Michigan.
- Some of the tests performed on your samples may be done by researchers at laboratories outside where the biobank exists, but they will never know who you are nor have access to the code linking the samples to you. Only study staff can access this list and they sign an agreement to keep your identity a secret.
- Researchers who study your sample and information will not know who you are. We will give them only the code number and not any information that directly identifies you. The researchers must sign an agreement that they will not try to find out who you are.

Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, gender, and some medical information from the study. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or gender as you.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You will not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Your participation in this study is voluntary. Therefore, your alternative is *not* to participate in the study. You may refuse to participate without any penalty or loss of any benefits to which you are otherwise entitled and without any effect on your medical care.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No, there is no harm to you if you decide to leave the study. We ask that you please notify the study coordinator so that we know you no longer wish to participate.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.

- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

No. You will not be paid for participating in this study.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Every effort will be made to maintain your privacy. You will be given a unique study identification number. This number will be used to record your study information and will be maintained in a locked area at the clinical site. Your name, medical record or other personal identifiers will not be released or used in any publication or disseminated study information. Study information from all research centers, after removing identifying information, will be stored in secure electronic files located at the University of Michigan. Only authorized members of the research study will have permission to see this data.

If you give us permission to use your DNA, the federal Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under this law:

- Health insurance companies and group health plans may not request your genetic information that we obtain from this research
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums
- Employers with 15 or more employees may not use your genetic information that we obtain from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

GINA does not apply to the following groups; however, these groups have policies in place that provide similar protections against discrimination:

- Members of the US Military receiving care through Tricare
- Veterans receiving care through the Veteran's Administration (VA)
- The Indian Health Service
- Federal employees receiving care through the Federal Employees Health Benefits Plans

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has

been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Markus Bitzer, MD
Mailing Address: 1150 W Medical Center Drive, 1570 MSRB II
Ann Arbor, MI 48109
Telephone: 734-764-3157

Study Coordinator: Linda Drnek
Mailing Address: UH South F7822D, 1150 E Medical Center Drive
Telephone: 734-936-5754
E-mail: lagius@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- Other (specify):_____

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-E

Legally Authorized Representative or Parent Permission
Subject Name:

_____

Parent/Legally Authorized Representative:
Printed Legal Name:
_____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If "Other," explain: _____

Reason subject is unable to consent: _____

Sig-D

Consent/Assent to Collect for Optional Future DNA Research
This project involves the option to allow the study team to keep your identifiable specimens/data for use in future DNA research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my specimens for future DNA research.

_____ No, I do not agree to let the study team keep my specimens for future DNA research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____