INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

MOSES Lithotripsy Technology Applied to Stone Fragmentation during Ureteroscopy

About this research

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

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

Taking part in this study is voluntary

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

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine if new laser technology can improve the safety and effectiveness of laser stone breakup during ureteroscopy. Sometimes a laser is used to break up kidney stones. This study will determine if the new laser technology will result in decreased laser time along with decreased time in the operating room and decreased surgery related injury.

You were selected as a possible participant because you or your doctor has decided to treat your kidney stones with ureteroscopy.

The study is being conducted by Marcelino Rivera, MD with IU Health Physicians Urology.

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 116 participants taking part in this research.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, you will do the following things:

Information about your health and treatment of your kidney stones will be collected before, during and after your ureteroscopy procedure. During the surgery, the MOSES lithotripsy technology or standard laser will be used to break up your kidney stone(s). The surgeon will not be told which laser will be used. After the laser is used, the stone(s) will be removed using basket extraction and a stent will be placed.

Stone analysis (make up of your kidney stones) data will also be collected.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
While participating in the study, the risks, side effects, and/or discomforts include:

Loss of confidentiality

Risks related to Ureteroscopy surgery and not related to taking part in the research include but are not limited to:

- Bleeding
- Infection
- Ureteral stricture/obstruction
- Other adverse events associated with anesthesia depends on overall health status and varies

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
We don't expect you to receive any benefit from taking part in this study, but we hope to learn things which will help scientists in the future.

WHAT ARE THE OTHER TREATMENT OPTIONS?
There may be other options for treatment of your kidney stones. You may choose not to take part in the study and have ureteroscopy to remove your kidney stones where you surgeon will use standard laser to break up the stone.

WILL I RECEIVE MY RESULTS?
We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. This includes information like what your kidney stone is made of and any tests that may help the doctor decide how to prevent you from forming kidney stones in the future. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

HOW WILL MY INFORMATION BE PROTECTED?
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications and databases in which results may be about this study.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal

agencies, specifically the Food and Drug Administration (FDA), etc., who may need to access your medical and/or research records.

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.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information or specimens collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?

You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?

You or your insurance company will be responsible for the following standard of care costs: clinical visits to the doctor both before and after surgery, your surgery and all associated costs such as the hospital and doctors' fees and aby lab tests or films (x-rays or CT scans) taken to help guide the treatment and prevention of your kidney stones.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHAT FINANCIAL INTEREST DOES THE RESEARCHER HAVE?

Dr. Rivera may benefit financially from this study. The Institutional Review Board (an ethics committee that helps protect people involved in research) has reviewed the possibility of financial benefit. The Board believes that the possible financial benefit is not likely to affect your safety and/or the scientific integrity of the study. If you would like more information, please ask the researchers or study staff.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study contact the researcher Dr. Marcelino Rivera at 317-962-3700. After business hours, please call 317-962-3700 and ask for the Urologist on call.

In the event of an emergency, you may contact Dr. Marcelino Rivera at 317-962-3700.

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

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, please contact Dr. Marcelino Rivera at 317-962-3700.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances: you do not have surgery as planned to treat your kidney stones

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

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

Printed Name of Person Obtaining Consent:_____

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