	Human Research Protection Program Institutional Review Board **Consent to Participate in a Research Project and Authorization to to use and Disclose Protected Health Information (PHI)**	

STUDY TITLE: *Comparison of Lumenis Pulse 120H Moses 2.0 holmium laser versus Olympus Soltive thulium fiber laser for mini-percutaneous nephrolithotomy*

PROTOCOL NUMBER: *IRBNet 2072488*

CONSENT VERSION DATE: *13 December 2023*

HOSPITAL OR INSTITUTION: *Maine Medical Center, Portland, ME*

INVESTIGATOR: *David Sobel, MD*

SUBJECT'S NAME (printed):_____

For italicized areas below, either remove italics if not applicable, OR insert study specific information.

Throughout this consent form "you/your" will be used to refer to either you or your child/the participant.

Part I: Key Information About this Research Study

You are being asked to volunteer in a research study.
You do not have be in this study. Even if you do agree, you can still leave the study at any time without any penalty, without giving a reason, and will still be able to continue your medical care at MaineHealth. Withdrawal or refusing to be in the study will not affect your relationship with MaineHealth in anyway.

Why is this study being done?
Lasers have been used in the treatment of kidney stones since the 1990s, but the most effective type of laser has not been determined. At Maine Medical Center, we use two lasers interchangeably for the treatment of kidney stones, a Holmium laser and a Thulium laser. They are very similar but use different types of crystals to create the laser energy. Both of these lasers are FDA approved for the treatment of kidney stones in the surgery that you will be undergoing. What is not known is whether one laser is more effective than the other, or if there are

differences in other outcomes after kidney stone surgery. This study aims to evaluate these two lasers.

Why are you being asked to be in this research study?
You are being asked to take part in this study because you have a kidney stone(s) that will be treated using a minimally invasive surgery called percutaneous nephrolithotomy using laser energy. As part of the study, we will collect information related to your procedure and experience during recovery. We may also review and collect information from your medical records. The surgery itself will be no different if you participate in the study or not. The care after surgery will be no different either.

How many people will take part in this study and how long will it take?
This study will include approximately 52 study participants at MaineHealth.

How long will you be in the study and how much time will it take up?
The study activity period lasts from the start of your surgery until approximately 90 days after your surgery. There are no additional visits for research purposes outside of your normal care after surgery.

What will you be asked to do?
If you agree to be in this study, you will be asked to:

- During surgery, you will undergo treatment of your kidney stone(s) with either the holmium laser or the thulium laser. You will not know which laser was used until your participation in the study is complete (90 days after surgery). We will collect information about how efficient the laser is at treating kidney stones, and your posteroperative experience. You will be asked to complete a questionnaire at your postoperative visit when your stent is removed. You will undergo follow up imaging as per the standard of care after surgery.
- A more complete and detailed description of the study procedures is included later in Part II of this document (Additional Information and Details).

What are the risks or discomforts that are possible from being in this study?
As both these laser machines are FDA approved for treatment of kidney stones and considered standard of care, there is no additional surgical risk to participating in the study. The surgery itself will not be any different than if you did not participate. The follow up plan will not be any different either.

The only additional risk to you as a participant is that of having your protected health information (PHI) that could identify you be seen by individuals who are not involved with the study. The study takes this risk very seriously and minimal protected health information will be collected as part of the study, such as medical record number and date of surgery. We have protocols in place for secure collection and management of your information.

What benefits to you are possible if you participate in this study?
The possible benefits of taking part in the research study are the same as undergoing your procedure to treat your kidney stone(s) without being in the research study. Additionally, the

information we receive may help us understand which laser machine is preferable or more efficacious for the treatment of kidney stones and may help us better treat kidney stones in the future.

If you say no to being in this study, do you have other options for your condition?
You will receive the same care and undergo the same procedure for your kidney stone(s) even if you do not take part in the study.

Will being in this study cost you anything?
As the surgery and follow up itself are no different if you participate in this study or not, you or your insurance company will not be charged for any tests or services specifically required by this research study. You will still be responsible for the cost of your usual ongoing medical care, including procedures, non-study medications, and tests that your study doctor or regular doctor requires during this study as part of your usual medical care.

Will you be paid for being in this study?
You will not be compensated for participating in this study.

If you were injured or harmed as a result of being in the study, who would pay for the necessary medical treatment and/or hospitalization?
Please see Part II regarding details concerning payment for injury or harm.

If you decide to be in the study, the researchers will tell you about any important new information that is learned during the course of this study, which might affect your condition or your willingness to continue participation in this study.

Part II. Additional Information and Details

WHAT IS INVOLVED IN THE STUDY?
If you decide to be in this study, your part will involve:

- Following enrollment in the study, you will undergo mini percutaneous nephrolithotomy (Mini PCNL) for your kidney stones(s). Your surgeon will have gone over the surgery as well as the risks, benefits and alternatives to this procedure. There is no change to the way the surgery is performed except for which laser machine is used.
- At time of surgery you will be randomized to using either the holmium laser machine or the thulium laser machine. Both of these lasers are used interchangeably in our operating room at any given time. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by computer. You will not know what laser was used during your surgery until 90 days after your surgery. You will have an equal chance of being placed in the group undergoing surgery with the Holmium laser or the group undergoing surgery with the Thulium laser.

- After surgery, you will undergo the usual ("standard-of-care") postoperative treatment, and when meeting discharge criteria will be discharged to home.
- Your stent removal will be in the office as usual 7-10 days after surgery and we will have you complete a questionnaire about your recovery.
- A follow-up imaging study (low-dose CT scan) will be performed approximately 8-12 weeks after surgery to determine whether there are any residual stones unless this was performed before this time.
- You will be followed for approximately 90 days after surgery to capture any subsequent kidney stone events, emergency department visits, need for additional procedures, refills for pain medications, or telephone calls to clinic.
- After the study is completed (anticipated January 2027), all relevant findings from our research will be shared with you if you would like.

WHAT ARE THE *(OTHER)* RISKS OF THE STUDY?
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. Please let a member of this study team know if you are taking part in another research study.

We collect a minimum amount of Protected Health Information (PHI) about you during the study, namely medical your record number (MRN) and date of surgery (DOS). These items will be stored in an encrypted database accessed only by study personnel. Despite our best protocols, there is always a small risk of breach of confidentiality. This is essentially the only risk of the study.

For more information about risks, ask Dr. David Sobel, the principal investigator, or contact the MMP Urology office at 1 (207) 773-1728.

WHAT ABOUT CONFIDENTIALITY?
At MaineHealth, we will take steps to help make sure that all the information we get about you is kept confidential. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used.

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will share the data we get from you in this study with the study team, the sponsor of the study (and those who work for them), MaineHealth's Institutional Review Board, applicable Institutional officials, and certain federal offices, including the Office for Human Research Protections (OHRP), and, where applicable, the Food and Drug Administration (FDA). However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this. In a lawsuit, a judge can make us give them the information we collected about you.

A description of this research study will be available on http://www.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.

This study is supported by Boston Scientific Corporation, which has acquired Lumenis, Ltd., the manufacturer of one of the lasers. This study was developed by the research team at Maine Medical Center and Boston Scientific Corporation is not involved in how the study is run or your care as a patient or study participant. The information we get from your participation in the study without any of your personal identifying information will be shared with them.

WHAT IF I AM INJURED DUE TO MY PARTICIPATION IN THIS STUDY?
We do not expect you to become injured or ill as a participant in this research. However, if you feel you have been harmed or suffered from your participation please contact Dr. Sobel, the principal investigator who will be available to answer your questions before, during and after the study. Medical treatment is available and will be provided at the usual charge.

MaineHealth has no policy or plan to pay for any injuries that you might receive as a result of your participation in this study. However, this does not take away your rights to seek or collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.

You or your insurance company will be responsible for any costs resulting from underlying disease or treatments provided to you outside of this research study.

HOW CAN I WITHDRAW FROM THIS STUDY?
It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study, the researcher will share this information with you as soon as possible.

If you want to withdraw, please contact Dr. Sobel, the principal investigator.

For the information collected prior to your withdrawal, the information will continue to be part of the data and included in the final analysis for this research. No new information will be collected.

HOW WILL MY INFORMATION/SAMPLES BE SHARED?
Information obtained during this study may become the property of MaineHealth. When your involvement with the study ends, the information you provided will be stripped of identifiers so that no link can be made to your identity and may be used for other research purposes, including research conducted by other investigators. Because there will be no identifiers associated with the information/samples additional consent from you will not be sought.

Permission for the research team to obtain and use your patient health information

How will the privacy of my patient health information be protected?

There are state and federal privacy laws that protect the use and sharing of your patient health information. By signing this form, you provide your permission, called your "authorization," for the use and sharing of patient health information protected by the Privacy Rule. Authorization includes allowing:

- Your health care providers to share your health information for this research study
- The research team to use and share your health information for this research study.

Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at MaineHealth. Specifically, this will include medical record number (MRN) and date of surgery (DOS). This may also include any new health information about you that comes from the research tests or procedures described in this consent form. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

The research team and people within MaineHealth who oversee and help administer research may see, use or share your information as needed for the research.

People outside of MaineHealth may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors and companies that sponsor the study.

We cannot do this study without your authorization to use and share your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and share your information only as described in this form; however, people outside MaineHealth who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and sharing of your information has no time limit. You may revoke (cancel) your permission to use and share your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. Send your request to: *Dr. David Sobel at Maine Medical Partners Urology (100 Brickhill Avenue, South Portland, ME 04106)*.

If you do cancel your authorization to use and share your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we shared before you wrote to the Principal Investigator to cancel your authorization.

Your decision to not sign this authorization will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records at MaineHealth.

Signing this authorization also means that you maynot be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury contact Dr. David Sobel at MMP Urology offices - 1 (207) 773-1728.

For questions about your rights as a research participant, or to provide input, contact the MaineHealth Institutional Review Board (which is a group of people who review the research to protect your rights) at (207) 661-4474. Alternatively, you may provide comments or ask questions in the Human Research Protection Program Feedback section on our website at https://mhir.org/?page_id=1373 .

I have read, or have had read to me, the above information before signing this consent form. I agree to take part in this research study. I also give permission to use or share my personal health information for the purpose of this research. I have had the chance to ask questions. I have received answers that fully satisfy those questions.

_____ _____
Signature of Subject Date/Time

_____
Printed Name of Subject

Study representative statement
I have fully explained to the subject all of the following: the purpose of this research, the study procedures, the possible risks and discomforts and the possible benefits. I have answered all of the subjects and his/her authorized representative(s) question to the best of my ability. I will inform the subject of any changes in the procedure or the risks and benefits if any should occur during or after the course of the study.

_____ _____
Signature of the Person Obtaining Consent Date/Time

_____
Printed Name of the Person Obtaining Consent

A signed copy of this consent form must be given to each subject entering the study.