Lessons on Urethral Lidocaine in Urodynamics ("LULU"): Impact of intraurethral lidocaine on cystometric parameters and discomfort, a RCT

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Lessons on Urethral Lidocaine in Urodynamics ("LULU"): Impact of intraurethral lidocaine on cystometric parameters and discomfort, a RCT

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center

Key Information about this Study

This study is being conducted in order to determine whether use of intraurethral 2% lidocaine jelly meaningfully impacts sensation during filling of the bladder with sterile water for urodynamic bladder testing and to determine whether the use of intraurethral 2% lidocaine jelly meaningfully impacts pain/discomfort, filling metrics, and voiding metrics during urodynamic bladder testing. The only requirement of the study is that you be already scheduled for urodynamic bladder testing. Your participation will only last for approximately 90 minutes or however long it takes to complete the urodynamics bladder test.

There is no guarantee or promise that you will receive any benefit from this study. The investigators have designed this study to learn how well the new treatment (2% lidocaine jelly) compares to commonly accepted treatment (a plain lubricant for catheter insertion). In usual standard of care urodynamic bladder testing, you would not receive any anesthetic for pain relief.

There are risks to taking part in this research study. One risk is that you may have side effects while on the study. Side effects from this study will usually go away soon after the procedure and/or administration of 2% lidocaine jelly. There is a risk that the effectiveness and/or safety of the treatment for the 2% lidocaine jelly group may not be an effective anesthetic for urodynamic bladder testing. You may get a treatment or drug that does not minimize discomfort during the procedure.

We hope the information learned from this study will benefit other patients. If we learn that the use of 2% lidocaine jelly makes this procedure more comfortable for women without affecting test results, this could be very useful for women undergoing urodynamic bladder testing in the future.

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Your provider is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Christina Hegan, MS, APRN, WHNP-BC, Department of Obstetrics & Gynecology, Division of Female Pelvic Medicine & Reconstructive Surgery at The University of Texas Southwestern Medical Center.

Funding
The Society of Urologic Nurses & Associates, a non-profit organization that promotes scientific research, is funding this study. This organization is providing money to The University of Texas Southwestern Medical Center so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

You are being asked to participate in this research study on the use of a numbing cream (called 2% lidocaine jelly) placed in your urethra during urodynamic bladder testing to determine if its use makes any important differences in your ability to sense bladder fullness, empty your bladder effectively, and if it improves discomfort during the testing. Currently, urodynamic bladder testing is not performed with any local anesthetic, such as 2% lidocaine jelly, because it is unknown whether or not it may affect test results or provide meaningful improvement in patient discomfort with testing.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are already being scheduled for urodynamic bladder testing.

This study will enroll approximately 70 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 1 visit with the researchers or study staff.

Screening – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain and which procedures will not have to be repeated. Many of the procedures are described below as "**standard care**" and would be done even if you do not take part in this research study. You will be told which ones are for "**research only**".

Screening Procedures

- If you are capable of becoming pregnant, a pregnancy test will also be done before you receive study treatment.

This visit will take approximately 1.5-2 hours.

Assignment to Study Groups –
When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin to one of two study groups.

- Placebo (Water Based Lubricant Jelly)
- Active Treatment (2% Lidocaine Jelly)

You will have a one in two chance of being in the placebo group. A placebo is an inactive, harmless substance that looks like the other study drugs.

Neither you nor the researchers will know whether you are receiving the study drug or a placebo. In the event of an emergency, there is a way for the researcher to find out which you are receiving.

Study Procedures - as a participant, you will undergo the following procedures:
Urodynamic Bladder Testing

Urodynamic bladder testing is a simple clinical procedure that assesses how well your bladder and urethra are able to store and release urine. This is an outpatient exam and helps your provider better understand and diagnose health issues. It is not a corrective procedure.

What to expect: This is a relatively painless test, although some patients do experience discomfort from the catheter insertion.

Measuring Flow Rate (Uroflometry):

- To begin the test, you will sit on a special procedure chair and urinate into a funnel, which will measure the flow rate of your stream.
- The nurse practitioner will then clean your urethra, the tube that connects our bladder to the outside of the body, and empty your bladder using a catheter (sterile plastic tubing) to ensure the bladder is completely empty and to obtain a sample for infection testing.
- *This is standard care.*

Measuring Bladder and Abdominal Pressure:

- If the urine is free of infection, the nurse practitioner will place a small pediatric catheter into the urethra and use it to fill your bladder with sterile water and, at the same time, measure the pressure inside your bladder.
- The nurse practitioner will place another small pediatric catheter in either your vagina or rectum, depending on the presence of uterovaginal prolapse or vaginal vault prolapse and the degree of prolapse present.

- If there is prolapse present, large cotton swabs called "scopettes" may be placed in the vagina to hold the prolapse up and simulate what surgery would do to provide support to the uterus and/or vagina.
- Two self-adherent wired patches that measure your pelvic floor muscles' electrical activity ("electromyography", or EMG) will be placed on the skin between your thighs near your anus.
- *This is standard care.*

Measuring Urinary Stress Leakage (Cystometrogram, Leak Point Pressure, & Pressure Flow Study):

- The nurse practitioner will attach the catheters and EMG patch electrode wires to the computer and begin filling your bladder with sterile water.
- You will be requested to inform the practitioner when you initially feel the sensation of water in your bladder, the first urge to urinate, a strong urge to urinate, and when you feel you have reached your full bladder capacity.
- During this portion of the test, the nurse practitioner will be asking you to do some exercises by bearing down and coughing at different strengths of force and at different intervals throughout the procedure. This is to assess for urinary stress leakage and the pressure and volume indicated to evoke incontinence.
- After you have reached your bladder capacity, the nurse practitioner will ask you to urinate and empty your bladder. You should be able to void around the pediatric catheters. The computer will capture the amount you void, as well as your maximum flow rate, the electrical activity of your pelvic floor muscles, and the pressure of your abdomen, bladder, and detrusor while you void.
- *This is standard care.*
- For the research study, you will be asked to complete a pain scale (called a "visual analog scale") ranging from 0 to 100 mm during catheter insertion, at maximum bladder capacity, at the time of voiding, and once the procedure is completed.

Research Study

- At this point in the study, you will be randomized to either placebo (water based lubricant) or active treatment (2% lidocaine jelly)
- 5cc of either placebo or active treatment will be placed into the urethra using a plastic soft-tipped syringe (i.e., without a needle).
- You will sit for 5 minutes to allow the medication to take effect, if applicable.
- The small catheter is then replaced, and the cystometrogram & pressure flow study tests are repeated, taking the same measurements as above.
- You will be asked to repeat the pain scale again during catheter insertion, at maximum capacity, during voiding, and after the procedure is complete.

Measuring Closing Pressure of Urethra

- After you empty your bladder, the nurse practitioner will fill your bladder with sterile water again to approximately 200ml and hook the urethral catheter up to another device, which will help measure the closing pressure of your urethra, length of your urethra, and area of continence. The device will gently pull the catheter in and out of the urethra approximately three times to obtain an accurate average of measurements.
- The practitioner will then remove all catheters and scopettes. If you were unable to void at least 200ml of urine on the initial uroflometry test, the nurse practitioner may ask you to void in the procedure chair again to try to obtain another uroflometry test reading.

- *This is standard care.*

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons 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 stopped.

The researchers will discuss your options for medical care when your participation in this study ends.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician.

Risks – "What are the risks of participation in the research?"

Risks from the research

The investigators have designed this study to learn how well the new treatment (2% lidocaine jelly) compares to commonly accepted treatment (a plain lubricant for catheter insertion). In usual standard of care urodynamic bladder testing, you would not receive any anesthetic for pain relief. There is a risk that the effectiveness and/or safety of the treatment for the 2% lidocaine jelly group may not be an effective anesthetic for urodynamic bladder testing. You may get a treatment or drug that does not minimize discomfort during the procedure.

Risks from the specific research procedures (drug(s), interventions, or procedures)

There are risks to taking part in this research study. One risk is that you may have side effects while on the study.

Side effects from this study will usually go away soon after the procedure and/or administration of 2% lidocaine jelly.

Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately about any side effect that you have while taking part in the study.

The following section will describe the risks related to your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Side effects can range from mild to serious. Serious side effects are those that may require hospitalization, are life threatening or fatal (could cause death). The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely).

Risks and side effects for procedure and medication are as follows:

Urodynamic Bladder Testing

Urodynamic bladder testing requires that participants receive a bladder catheterization as standard care. Bladder catheterization involves placing a catheter into the bladder in order to remove urine and fill the bladder with sterile water. A rare and uncommon risk is potential for urinary tract infection. You will receive one dose of oral antibiotic after the procedure in order to prevent an infection. *This is standard care.* If an infection occurs, the infection will be treated with a few days of oral antibiotics. Additionally, you may feel bladder or urethral discomfort, including burning and stinging urethral sensations, and urinary urgency and/or urinary frequency due to irritation from the catheter at the time of placement and with bladder filling. These uncomfortable sensations should not last more than a few hours. You will also be offered one dose of oral bladder analgesic (pain reliever) at the end of the procedure and study. *This is standard care.*

Other rare, but serious risks include the occurrence of autonomic dysreflexia, which is a medical emergency that occurs with uncontrolled blood pressure and heart rate; typically this is only ever seen in patients with spinal injuries and lesions. This study is not planned for patients with neurogenic disease who have this potential risk for occurrence of autonomic dysreflexia. If this occurs, it would occur in the setting of undiagnosed and unknown neurogenic disease. If this occurs, the catheter will be removed, and a larger catheter will be used to immediately drain the bladder, which usually helps resolve the reaction. If needed, nitroglycerin paste will be applied to the chest in order to stabilize vital signs and appropriate critical care will be provided.

2% Lidocaine Jelly

Although 2% lidocaine jelly is poorly absorbed through the urethra and bladder, you may theoretically experience some systemic side effects. Side effects that have been reported by some patients using lidocaine for various medical reasons include lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus (ringing in the ears), blurred or double vision, nausea, vomiting, sensations of heat, cold or numbness, twitching, tremors, low blood pressure, urethral irritation, or tingling sensation. Rare, but serious side effects include unconsciousness, respiratory depression, irregular heart rhythms, heart attack, cardiac arrest, methemoglobinemia (a serious condition where the blood is less able to carry oxygen to the tissues of the body), or seizures. Allergic reactions to lidocaine are incredibly rare but may occur. Allergic reactions may manifest as skin lesions, itching, redness of the skin, swelling, or anaphylaxis, a medical emergency requiring immediate intervention. This is study is contraindicated in patients with known sensitivity or allergy to lidocaine or local anesthetics. If this occurs, it would occur in the setting of an undiagnosed and unknown sensitivity or allergy.

Due to the investigational nature of this study, there may be other risks that are currently unknown.

For more information about risks and side effects, ask one of the researchers or study staff.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit may include answering questions regarding withdrawal and addressing potential reasons for withdrawal, as well as the potential need for physical examination in the event of any adverse event. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Reproductive Risks -
Concerns for sexually active women: If it is possible you could be pregnant, you should not take part in this study because we do not know how the study drugs/procedures could affect a fetus. If you discover later that you were pregnant while taking part in this study, tell one of the study doctors right away so that management of the pregnancy can be discussed.

If you are a woman who is pregnant or could be pregnant, you cannot take part in this study because we do not know how the urodynamic bladder testing and/or 2% lidocaine jelly might affect a developing fetus. We will do a pregnancy test before you start treatment to make sure you are not pregnant.

If you learn that you likely were pregnant during your participation in this research study, the researchers would like to collect follow-up information regarding your pregnancy.

Risks to babies who are being breastfed: Women who are breastfeeding cannot take part in this study because we do not know what effect the drugs/procedures might have on their breast milk.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, or even at different times, may increase the risk 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.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"
There is no guarantee or promise that you will receive any benefit from this study.

We hope the information learned from this study will benefit other patients. If we learn that the use of 2% lidocaine jelly makes this procedure more comfortable for women without affecting test results, this could be very useful for women undergoing urodynamic bladder testing in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"
There are other options available to you. Your other choices may include:
Proceeding with urodynamic bladder testing without participation in the study.

Payments – Will there be any payments for participation?

You will receive a $100.00 stipend for your participation in the study. You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of the study visit. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Costs – Will taking part in this study cost anything?

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as the urodynamic bladder testing, including urine analysis for infection, abdominal pressure test, uroflometry, cystometrogram, leak point pressure test, pressure flow study, and urethral pressure profile test. It is important to understand that some insurance companies do not cover some costs (for example, approved drugs used in a way different from the package instructions). If your insurance company does not cover these treatments or procedures *performed as standard care*, you will still be required to pay for them.

Ask the researchers if you have any questions about what it will cost you to take part in this study (for example bills, fees, or other costs related to the research).

The sponsor will provide the study drug free of charge during this study. There is no cost to you for the repeated cystometrogram and pressure flow study that are completed as research procedures.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Certificate of Confidentiality:
To help us further protect your information, the investigators will obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;

- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- Medical History
- Information that we get from your medical record.
- Information contained in your medical records related to your medical history and treatments prior to the study.
- Information that is collected during your participation in the study including medical and treatment history.
- Information that you give us during your participation in the study, such as continuous pain scales (visual analog scales).
- Demographic information, such as your age, marital status, employment, and level of education, etc.

We will get this information by asking you and looking at your medical records.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the Sponsor, Society of Urologic Nurses & Associates, funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The

sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- the members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at University of Texas Southwestern Medical Center.
- the Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the UT Southwestern Division of Female Pelvic Medicine & Reconstructive Surgery clinic for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.
After you enroll in this study, you may ask the researchers to stop using your health information at any time . However, you need to say this in writing and send your letter to Christina Hicks, MS, APRN, WHNP-BC, UT Southwestern Medical Center, 5323 Harry Hines Blvd. Dallas, TX 75390-8539. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

You will only have access to your PHI until December 31, 2021.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study, please contact: Christina Hicks, MS, APRN, WHNP-BC.

Primary contact:
Christina Hicks, MS, APRN, WHNP-BC can be reached at 214-645-3848.

If primary is not available, contact
Agnes Burris, RN Clinical Research Coordinator, can be reached at 214-645-3833.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

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Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM