Walter Reed National Military Medical Center
CONSENT TO PARTICIPATE IN RESEARCH
Title: A randomized trial of bladder instillations versus onabotulinumtoxinA for treatment of interstitial cystitis/bladder pain syndrome
Principal Investigator: Capt Eva Kwong Welch, MD

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

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You are being asked to take part in this research study because you likely have interstitial cystitis (IC)/bladder pain syndrome (BPS). We recommend either bladder instillations or bladder Botox® for treatment of your IC/BPS. A bladder instillation is a procedure where a flexible tube (catheter) is placed into the structure that drains the bladder (urethra), and medications are given through the catheter to fill the bladder. Bladder Botox® is a procedure that involves inserting a thin, tube-like instrument, with a light and lens for viewing, through the urethra into the bladder, then injecting the Botox® medication into the bladder muscle. Both forms of treatment have been shown to be better than placebo (a treatment that has no therapeutic effect), have excellent safety profiles, but just have not been compared head-to-head. Therefore, the purpose of this study is to compare bladder instillation therapy to bladder Botox® and see which one is more effective or improves symptoms the most.

Additionally, we would like to learn more about the natural environment (microbiome) of the bladder and vagina in patients who have IC/BPS and are getting bladder instillations. Seeing if there is a difference may lead to a better understanding of the underlying disease process of IC/BPS and also help develop new treatments in the future. We would like to collect urine and vaginal specimens now to be used in future research.

If you agree to participate, you will be randomly selected to be in the bladder instillation or bladder Botox® group. Randomization is a process like flipping a coin and means you will have a chance of being assigned to either, and the groups will be evenly split. If you are placed in the bladder instillation group, you will receive 6 weekly instillations (standard at our facility). Each bladder instillation procedure should take no more than 5 minutes each time. At your first visit, we will collect the vaginal and urine specimens and perform the bladder instillation. Between your 4th and 6th instillations, we will collect vaginal and urine specimens again. If you are randomized to the bladder Botox® group, you will undergo a one-time procedure.

Regardless of the group you are in, you will complete a couple of short questionnaires (which should take no more than 15 minutes) and a 1-day bladder diary (where you use a measuring hat

to measure the amount you urinate) before you start treatment, and again at your 1 and 2 month post-treatment visits. We will follow-up with you by telephone 6-9 months after treatment to complete one short questionnaire (which should take no more than 5 minutes) and get feedback about your study experience. This will conclude your participation in the study.

The potential risks of participating in this study include bladder/urethral irritation, urinary tract infection, inability to urinate normally, and blood in the urine (hematuria).

Your alternative is not to participate in this research, and you can undergo either bladder instillation or bladder Botox® therapy if desired. There may also be other options for treating your condition. Alternative treatments and/or procedures that may be available to you include: oral medications, pain management, and surgical management (hydrodistension, a procedure that fills your bladder with water, and sacral neuromodulation, a type of electrical stimulation therapy).

Your participation is completely voluntary, and if you were not to participate, you can choose to proceed with either treatment. Your decision will not affect your future care at Walter Reed National Military Medical Center. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

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

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you likely have IC/BPS, for which we recommend either treatment with bladder instillations or bladder Botox®. The purpose of this study is to compare bladder instillation to bladder Botox® therapy and see which therapy improves symptoms the most. We would also like to learn more about the bladder and vaginal microbiome in IC/BPS patients who are getting bladder instillations. This can help us understand the underlying disease process of IC/BPS and also develop new future treatments.

If you agree to participate, you will be randomized to receive either bladder instillations or bladder Botox®. If you are placed in the bladder instillation group, you will receive 6 weekly instillations. If you are placed in the bladder Botox® group, you will undergo a one-time procedure. We will follow-up with you 1 and 2 months post-treatment, with a telephone visit at 6-9 months post-treatment. This will then conclude your participation in the study.

There will be about 58 people taking part in the study at Walter Reed National Military Medical Center, over a period of 2 years.

The healthcare provider will provide the participant with relevant clinical information. Research data will not be shared with the patient while the study is ongoing.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process". This information may be collected as a part of your regular medical care.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

We will ask a couple of questions to ensure you can safely participate in the study. If you meet any of the following criteria, unfortunately you will not be able to participate in this study:

- Symptoms or conditions in your medical history that suggest that this research might be harmful to you and/or allergies to medications used in the research
- Known alternative diagnosis explaining bladder pain symptoms
- Bladder instillation within the past 3 months
- Use of intradetrusor onabotulinumtoxin A within the past 6 months. Intradetrusor onabotulinumtoxin A is an injectable agent used in the treatment of overactive bladder syndrome
- Use of ≥ 400 units of onabotulinumtoxinA in any part of the body in the last 3 months
- Inability or unwillingness to insert a urinary catheter into your bladder yourself
- The amount of urine left in your bladder following urination is 200 mL or more
- Receiving other medical procedures as treatment for your bladder at the same time as this research. This would include such things as hydrodistension, which is a procedure that fills your bladder with water, and sacral neuromodulation, which is a type of medical electrical stimulation therapy
- Current use of a vaginal pessary, which is a prosthetic device inserted into the vagina, or another similar device
- Untreated symptomatic prolapse > POP-Q stage 2 (a centimeter inside or outside of the hymen)
- Females who are pregnant or planning a pregnancy during the study and who are unable or unwilling to use a reliable form of contraception during the study
- Inability to speak/read English

You will be randomly assigned to receive bladder instillation or bladder Botox®. Randomization is a process like flipping a coin and means you will have a chance of being assigned to either.

If you are placed in the bladder instillation group, you will receive 6 weekly instillations. At your first bladder instillation visit, we will collect the vaginal and urine specimens and perform the bladder instillation. A catheter will be placed via the urethra into the bladder, the instillation allowed to drain into the bladder, then the catheter removed. You will be advised to let the instillation dwell for at least 30 minutes, or until you feel the urge to void. This will be repeated weekly. Between your 4th and 6th instillations, we will collect a vaginal and urine specimen again.

If you are placed in the bladder Botox® group, you will undergo a one-time treatment at our outpatient clinic. You will take a pregnancy test before the procedure. Per standard of care, you will take an antibiotic immediately before the procedure to decrease risk of infection. An anti-anxiety medication can be prescribed to be taken before the procedure per your preference. We will place anesthetic medications in your bladder before the procedure. We will perform a cystoscopy, which involves inserting a thin-tube like instrument with a light and lens for viewing, through the urethra into the bladder. 100 units of Botox® will be given in 20 small injections in the bladder. If abnormal findings are found on cystoscopy, the clinician will take the appropriate steps to diagnose and treat the abnormality, as possible.

If at any point you are experiencing symptoms concerning for a urinary tract infection, we will obtain a urine specimen to send to the lab to look for signs of infection. If an infection is found, you will be treated with antibiotics and a culture will be obtained to ensure you are on appropriate antibiotics.

If your symptoms are not controlled at any point after treatment, you can follow-up with the Urogynecology or Urology clinic for further evaluation and discussion of treatment options.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of:

- Bladder/urethral irritation, which is inherent in the catheterization and/or bladder instillation and Botox® procedures.
- Urinary tract infection, however this risk is decreased by cleaning the area in question prior to instrumentation and using sterile technique; this risk is inherent in the bladder instillation and Botox® procedure.
- Urinary retention (inability of the bladder to empty normally), which is a potential side effect of the Botox® medication. This occurs in approximately 20% of patients, with 5% needing to temporarily self-catheterize.
- Hematuria (blood in the urine), which is a side effect of the Botox® procedure, generally self-limited and subsides within a couple of days.
- Breach of confidentiality, however all data collected will be coded and stored in a locked, secure location either in the Urogynecology clinic or Urogynecology network drive.

If you are ABLE TO BECOME PREGNANT and you want to take part in this study, you should know that there are no adequate, well-controlled studies regarding safety of bladder instillations and Botox® use in pregnant and/or breastfeeding women. We therefore recommend that you should not get pregnant or breastfeed during the bladder instillation therapy or 3 months after receiving Botox®. Reliable (greater than 80% effective) methods include abstinence, previous hysterectomy, intrauterine device, male or female sterilization, hormonal contraceptives (injectables, implant, oral contraceptive pills, dermal patch, intravaginal ring), diaphragm, and male condom.

If you become pregnant or feel you might be pregnant, contact your personal physician and the principal investigator of this study listed in the Contact Information section at the end of this document. If your pregnancy is confirmed, you will be withdrawn from the study.

There may also be other risks of taking part in this study that we do not yet know about.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

The possible benefit to you as a research participant in this research study and if you have IC/BPS is improved symptom relief from either bladder instillations or Botox®. However, there is no guarantee that you will benefit from being in this research. Others may benefit in the future from the information learned during this study. The possible benefits to others are learning whether bladder instillations or bladder Botox® is superior, so that we can maximize therapeutic effect for patients with IC/BPS. This can also potentially decrease progression of the disease, decrease the number of patients seeking more invasive and costly treatment, and overall translate to lower healthcare cost. Additionally, future research regarding the female urinary and vaginal microbiome in patients with IC/BPS may have implications for understanding the underlying etiology for IC/BPS and guide further treatment.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research, and you can undergo either bladder instillation or bladder Botox® therapy if desired. There may also be other options for treating your condition. Alternative treatments and/or procedures that may be available to you include: oral medications, pain management, surgical management (cystoscopy with hydrodistension, sacral neuromodulation). You should talk with your personal physician (if applicable) about these options.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Eva Kwong Welch, MD
Capt, MC, USAF
Contact information: (301) 400-2468

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Department of Urogynecology
Walter Reed National Military Medical Center
Building 9
Bethesda, MD 20889

12. SOURCE OF FUNDING:

None

13. LOCATION OF THE RESEARCH:

Department of Urogynecology
Walter Reed National Military Medical Center
Building 9
Bethesda, MD 20889

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

None

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. These records may be looked at by staff from the Urogynecology department, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: All study data will be collected by the PI, AIs, or approved members of the research team. The vaginal/urine specimens will be identified with subject ID number and specimen content only. They will be stored in a secure location within the Biomedical Research Laboratory at WRNMMC. All physical data will be coded with the subject assigned a subject identifier. The data will be kept in a locked cabinet within the Urogynecology Clinic. A master code will be used to store the patient names, patient study ID numbers, DOD ID numbers, date of birth, phone numbers, and email addresses for reference; this will be password protected on the secure Urogynecology network drive, to which only the Urogynecology research team has access and

doubly secured when not under review. In a separate electronic data file, the information from all questionnaire data will be organized and stored under the same aforementioned security constraints.

The biological specimens may be maintained for a maximum of three years after study completion and will be disposed of per WRNMMC protocol. The data sheets, files, and master code will be maintained for a minimum of three years after study completion, then shredded and disposed of in a HIPAA compliant receptacle per WRNMMC protocol. Any HIPAA documents will be held for a minimum of six years after study completion, then shredded and disposed of in a HIPAA compliant receptacle per WRNMMC protocol. The PI will be responsible for destroying and disposing of the information.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, 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 results. You can search this Web site at any time.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

The principal investigator and research team will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will coded.

16. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. Identifiers will be removed, and coded information may be used for future research. You have a number of options with regard to this request. If the stored data has an identifying link you can request to be contacted and sign a separate consent form to allow the use or available of this data in another study. You may also choose either to not allow any further use of your data, allow use of only coded data, or give consent now for the use of your identifiable data to be used in future studies. This future research may be in the same area as the original study or it may be for a different kind of study. You will be provided choices at the end of this consent form to allow or deny use in future research studies.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

Future Use of Biologic Specimens: The investigators in this study are asking for your permission to store your samples described above for future use in other research studies. The specifics of these future research studies are unknown at this time, but these studies will frequently be in the area of interstitial cystitis/bladder pain syndrome.

Your samples would be stored with the following information: participant study ID number. This is considered identifying information and can be traced back to you as the donor.

The storage (bank) area is maintained at Biomedical Research Laboratory, Department of Research Programs WRNMMC, Bldg 17B, Rm 4006, 4650 Taylor Road, Bethesda MD 20889. The storage bank Manager, Yaling Zhou. Ph.D, Supervisor/Scientific Director, is responsible for the storage bank. The Manager's phone number is: (301) 295-8287. Future research investigators requesting portions of your samples from the bank must have the approval of the bank Manager and also must have a research protocol for their newly proposed research study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants). It is possible these other researchers will request approval from an IRB to contact you in the future. The specimens will be destroyed per the WRNMMC lab protocol after three years.

Some future research studies may include genetic testing of your samples stored at the bank. Since storage (banking) of biologic specimens for future genetic testing is still undergoing development, the benefits and risks of genetic testing are not fully known at this time. It is believed that the risks are very low. Using new technology, information about your DNA structure (genetic information) gained from your banked samples can be used to indicate risk for developing certain diseases. This genetic information is unique to you and may indicate changes in your future health status or life expectancy, or that of your children and other relatives. These discoveries could be stressful and cause psychological difficulties or family problems. It is also possible that during future research, people of your ethnic background may be found to be at more risk for certain diseases. This could stigmatize your ethnic or cultural group.

Release of personally identifiable genetic information may pose a possible risk of discrimination or increased difficulty in obtaining certain types of insurance for you and your family members. The Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110-233) also known as "GINA" is a federal law that prohibits discrimination in health insurance coverage and employment based on genetic information. However, GINA does not apply to employers with fewer than 15 employees. GINA's protections in employment do not extend to the US military. Nor does it apply to health insurance through the TRICARE military health system, the Indian Health Service, the Veterans Health Administration, or the Federal Employees Health Benefits Program. Lastly, the law does not cover long term care insurance, life insurance or disability insurance.

Potential risk would occur if the confidentiality of your data is breached. Because of the consequences of a breach of confidentiality, every effort will be made by the bank to protect your privacy. The storage bank's procedures to protect the confidentiality of your data include: standard security measures within the laboratory storage location, removal of all personal information from the specimens with the only identifiers on the specimen being patient study ID number and specimen content.

Your samples will be stored for three years maximum at this bank. The storage timeframe begins at the conclusion of the study. Generally, you will not be provided with the results of the future studies using your samples from this bank. This is typically the case because the research results at that early point will not have a clear meaning for or direct clinical benefit to you.

You may request that your specimen be withdrawn from the bank at any time if you decide you no longer want to participate. This can be done by notifying the Principal Investigator as well as the bank Manager listed above.

Your biospecimens will not be used for commercial profit.

17. USE OF INFORMATION AND SPECIMENS

During this research study, you will be asked to provide the following types of samples (biological specimens): urine and vaginal specimens. These specimens will be identified via a participant subject number only.

While this study is on-going, your samples will be handled in accordance with this study's protocol and applicable regulations at the following laboratory: Biomedical Research Laboratory, Department of Research Programs WRNMMC, Bldg 17B, Rm 4006, 4650 Taylor Road, Bethesda MD 20889. Your samples may be maintained for a maximum of three years after study completion and thereafter, will be disposed of as per WRNMMC protocol.

Coded information may be used for future research. You have a number of options with regard to this request. If the stored data has an identifying link you can request to be contacted and sign a separate consent form to allow the use or available of this data in another study. You may also choose either to not allow any further use of your data, allow use of only coded data, or give consent now for the use of your identifiable data to be used in future studies.

18. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away. You do not have the option of opting out of incidental finding notification.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

1. An incidental finding may cause you to feel anxious
2. Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

19. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

20. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must contact the PI by phone, in writing or electronic mail, or in person. If you decide to no longer participate in this research study, the researcher will include the data already collected in the final analysis to maintain the integrity of the research. If you wish to have all of your data withdrawn from the study, please notify the PI in writing.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

21. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately using the contact information in the section below.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

22. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Eva Kwong Welch, MD
Phone: (301) 400-2468
Mailing Address: Walter Reed National Military Medical Center
Department of Obstetrics and Gynecology, Urogynecology division
8901 Wisconsin Avenue
Building 9
Bethesda, MD 20889

Walter Reed National Military Medical Center Human Research Protection Program (HRPP) Office
The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator/HRPP POC: Phone: (301) 295-8239

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

Walter Reed National Military Medical Center
Department of Research Programs
Building 17B
8901 Wisconsin Ave
Bethesda, MD 20889
(301) 295-8239

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

Please initial the sentences that reflect your choices, and then sign below:

_____ I do not authorize the storage of data collected as a part of this study for future use in research studies.

_____ I authorize the storage of data collected as a part of this study for future use in research studies.

With regard to future research studies done on stored data that has a link to my personal identity

_____ I do not wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

_____ I wish to be notified by investigators in the event of research findings of potential impact to my family members or myself. I agree that the investigators conducting this study may use my social security number to locate me in the future.

Please initial the sentences that reflect your choices, and then sign below:

_____ I do not authorize the storage of my biological specimens for future use in research studies.

_____ I authorize the storage of my biological specimens for future use in research studies

With regard to future research studies done on my biological specimens kept at the storage bank:

_____ I do not wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

_____ I wish to be notified by investigators in the event of research findings of potential impact to my family members or myself. I agree that the investigators conducting this study may use my social security number to locate me in the future.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date & Time

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date & Time