Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____ **Medical Record #** _____

Principal Investigator: Cirle Warren, MD
University of Virginia
P. O. Box 801379
Charlottesville, VA 22908 434-924-9676

Study Coordinator: Jennifer White, RN, CCRC
University of Virginia
P.O. Box 801340
Charlottesville, VA 22908
434-982-3649

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you give your permission or consent to be in the study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

The study is being funded by the University of Virginia Health System.

Why is this research being done?

The purpose of this study is to evaluate the effectiveness of Alanyl-Glutamine supplementation in lowering recurrence, duration of diarrhea, and death from *Clostridium difficile* infection.

Alanyl-Glutamine has not been approved by the U.S. Food and Drug Administration (FDA) for treatment of *Clostridium difficile* infection. It has not been proven to be safe or helpful and is therefore considered investigational for the purpose of this study.

Alanyl-Glutamine has been used in several clinical trials in different populations of patients. When given to HIV patients experiencing diarrhea, supplementation improved their symptoms related to diarrhea. This drug has also been given to cancer patients receiving chemotherapy. After supplementation, there was a reduction

in diarrhea caused by chemotherapy. In another study with patients undergoing cardiac surgery, those who received Alanyl-Glutamine supplementation had fewer clinical complications, such as death, irregular heart beats and low blood pressure requiring treatment.

The standard treatments for mild to moderate and severe uncomplicated *Clostridium difficile* infection are the antibiotics metronidazole 500 mg, a pill taken three times a day and vancomycin 125 mg , a pill given four times a day, for 10-14 days.

You are being asked to be in this study, because you currently have an episode of *Clostridium difficile* infection.

While in the study, you will receive the usual standard of treatment for the *Clostridium difficile* infection in addition to the investigational treatment. .

Up to 43 people will be in this study at the University of Virginia Medical Center.

How long will this study take?

Your participation in this study will not require any additional study visits. All study related procedures will take place during the course of your hospitalization or during your clinic visit. If you are in the hospital and are discharged before completing the duration of treatment or if you are enrolled as an outpatient, we shall call you daily until while on the study medication. In addition, you will also be contacted by telephone 3 times over the course of 6 months. Each telephone contact will last about 15 minutes.

What will happen if you are in the study?

SCREENING/BASELINE:

Day 0

If you agree to participate, you will read and sign this consent form before any study related procedures take place. You will have procedures done to make sure you are eligible and it is safe for you to participate. These include the following:

- Review your medical history
- Review results from clinical laboratory test including your stool samples
- Review your current list of medications.
- Perform a pregnancy test, unless you are post-menopausal or surgically sterile, if you are a woman aged 18 to 50 years. The pregnancy test must be negative in order to continue study participation.

If you are eligible to participate, you will proceed with study procedures.

STUDY TREATMENT

**** will take place the same day or the next day as screening/baseline visit**

You will be given the study drug, Alanyl Glutamine, which you will take by mouth or by feeding tube, if applicable, once a day for a total of **10 days**. You will take the study drug in addition to the antibiotics that you are receiving for your *Clostridium difficile* infection.

While taking the study drug, if you are hospitalized a member of our study team will visit you daily. If you are hospitalized and are still taking the study drug when you are discharged or are an outpatient, a member of our study team will call you on a daily basis to check if you took the study agent, had diarrhea and any symptoms (such as nausea, vomiting, and abdominal pain) that you experience during the study treatment period. A symptom diary will be given to you to record recurrence of diarrhea or *C. difficile* infection after the study treatment period. The symptom diary will take less than 10 minutes to complete each day. The follow-up phone calls will last approximately 15 minutes.

You will be asked to provide the following samples on specific days of treatment for research purposes only:

Day 0 – Bloodand stool*
***You will have already provided some of these samples as part of the labs ordered by your primary care team.**

TELEPHONE FOLLOW UP:

You will be asked to participate in 3 follow-up visits during a 6 month period. These "visits" will be conducted by telephone and will last approximately 15 minutes or less. This follow-up is being done specifically for research purposes.

If you are still hospitalized at the time of these visits, a member of our study team will come to see you in the hospital.

Over the course of the follow-up period, you will be contacted (by phone or in person) three times: at 1 month, 2 months, and 6 months after treatment. During these visits, you will be asked about diarrhea or whether you have been diagnosed to have *C. difficile* infection again. You will be provided with a symptom diary to help you keep track of your symptoms on a weekly basis.

Blood Testing

We may need one blood specimen for this study. Whenever possible, we will use the blood drawn during your daily labs while you are in the hospital or blood drawn during your clinic visit. If we cannot use the blood already collected (i.e. not enough blood), we will need to collect an additional tablespoon of blood from you. The total amount of blood for the entire study will be one tablespoon. The blood we draw will be tested to determine whether you are eligible for the study. Any testing done for this purpose will be paid for by the study.

When these tests are done, any leftover samples will be thrown away.. This means there is no information that could be used by anyone to determine who the sample came from.

Stool testing

Any remaining stool from your specimen that was tested for C. difficile will be collected from the Clinical Microbiology Laboratory within 24 hours of collection date. There will be no additional stool collection if specimens are not available from the clinical laboratory. The stool sample will be brought to the Warren Lab, de-identified, coded, and stored in the -80°F freezer until needed for future studies.

WHAT ARE YOUR RESPONSIBILITIES IN THE STUDY?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Ensure that the study drug is taken as instructed, keep the study drug in a safe place away from children, discard any unused study drug after day 10, and report any lost or missed study drug.
- Ensure that the study drug is taken only by you, the person for whom it has been prescribed.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins.

Study Schedule

Visit Activities	Days							
	0	1-4	5	6-9	10±2	40±7d	70±7d	190±7d
Informed Consent	x							
Alanyl-glutamine study treatment		X	X	X	X			
Clinical monitoring and follow-up	X	X	X	X	X	X	X	X
Blood collection*	X							
Stool collection**	X							
Urine collection**								

*Blood collection will be performed for both routine clinical care (as requested by your primary team) and research purposes (if blood test was already performed for routine clinical care, we will not draw blood again unless needed to determine eligibility).
**Stool collection will be for research purposes.

If you want to know about the results before the study is done:

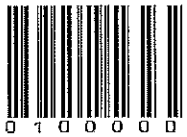
During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

Collection of Samples and Health Information for Research Specimen Bank

What is the purpose of this research specimen bank?

The purpose of collecting specimens for a research specimen bank is to process, and store samples until researchers need them for future research.

The long term goals of the samples collected in this bank will be mainly used for research on *Clostridium difficile*. It is not possible, however, to list every research project that will include the samples because we cannot predict all of the research questions that will be important over the coming years. As we learn more, new research questions and new types of research may be done.



Along with specimens, researchers may need to collect some health information about you for this bank. Combining information from the specimen with information from your health records may be useful for this research. For this research specimen bank, the following types of information could be included: diagnoses and treatment.

What will you have to do to give samples to the specimen bank?

You are also being asked to provide a sample of your stool to be used for research. Certain samples will be collected while you are hospitalized or during your clinic visit. You will not come back to give any more specimens.

How Will Your Sample(s) Be Stored and Labeled?

Your sample(s) will not be labeled with your name or other information that would identify you directly. Instead, it will have a unique code that allows for it to be linked to some of your health information that will be kept on a computer with limited access in the Principal Investigator's office. This link means that your specimen can be identified but only indirectly. We can find out if we need to know which sample is yours.

Which researchers can use your samples and what information about you can they have?

Your sample may be shared with researchers at the University of Virginia. Dr. Cirle Warren will not give your name to other researchers who want to use your sample, but will only give them information like your age and what disease/condition you have. Those who would see the information would include researchers and the others listed under "Who will see your private information?" section of this consent document.

What Are the Benefits of Donating Your Sample(s) to the Specimen Bank for Future Research?

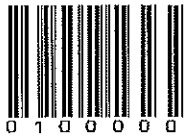
It is very unlikely that any future research performed using your specimen(s) would benefit you directly, but it may provide important medical knowledge that could help other patients with your medical condition or other medical problems in the future.

Will You Find Out the Results of the Research on Your Sample(s)?

Neither you, your health care provider, nor anyone in your family, will receive the results of any research done on your sample(s). The results will <u>not</u> be put in your health records. Therefore, results from any genetic research done on your sample(s) will <u>not</u> affect your medical care. This helps protect you and other members of your family from harm that might be caused by this information.

What Are The Risks of Donating Your Sample(s) For This Study?

The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. One of the risks to you is the release of information from your health records. The University of Virginia will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot *guarantee* it will be safe. To further safeguard your privacy, information obtained from future research will not be placed in your medical record.



There are certain risks of having health information given to other people by mistake. In the unlikely event that this happens, it could cause discrimination or mental harm to you or your family members if others were to see this information. The results could be that you may not be able to get or keep certain kinds of insurance. It could also hurt family relationships.

Except for the additional blood draw, if needed, there will be no other medical procedure required by participating in this study. Your doctor will explain the risks of any other routine medical procedure you are having for your care in the hospital. In some cases, your doctor will ask you to sign a separate clinical consent form that explains the risks of the procedure. Allowing your samples to be placed in the bank for future research will not change the risks of the medical procedure itself.

What If You Change Your Mind About Donating Your Sample(s)?

If you decide now that your sample(s) can be kept for future research, and later change your mind, you can simply withdraw the sample(s) at that time. To withdraw you will need to write to the Principal Investigator listed on the first page of this form. We will then destroy any of your specimens that have not already been used. However, if your sample has been used, the information that we have learned will remain in the study, even if you withdraw. Unless you withdraw from the study, permission for researchers to use your specimen and to use and share your health information for this study will never end.

Will You Be Paid For Donating Your Sample(s)?

You will not be paid to donate your sample(s). Also, the research may lead to the development of a commercial product or new technologies. There are no plans to pay you if this occurs.

Will Donating Your Sample(s) Cost You Any Money?

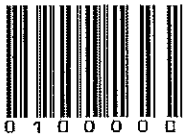
There is no cost to you to have your samples in the bank or for the research conducted using your samples.

What Are Your Other Choices if You Do Not Want To Donate Your Sample(s) for Future Research?

You do not have to participate in the specimen bank to be in the main part of this study. No matter what you decide to do, your decision will not affect your medical care. You can tell us your choice by placing your initials in one of the options below:

SPECIMEN BANKING OPTION:
Please indicate your choice by placing your initials below:

___ **YES** **Your sample(s) may be saved for future research and stored in a specimen**



bank.

___ **NO** **Your sample(s) may not be saved for future research and stored in a specimen bank.**

Could you be helped by being in this study?

We cannot promise that you will be helped by being in this study.
You may benefit from being in this study. Possible benefits include less diarrhea, decreased recurrence of *C. difficile* infection, fewer hospitalizations for *C. difficile* infection, and increased survival and improved quality of life from not having recurrent diarrhea or *C. difficile* infection. In addition, information researchers get from this study may help others in the future.

What are the risks of being in this study?

Risks and side effects related to Alanyl-glutamine include:

Less Likely (between 3 and 20 of every 100 subjects may experience)*

- Abnormal liver tests if you have liver problems at baseline.
- Elevated ammonia levels if you have liver or kidney problems at baseline
- Elevated urea levels

*If you have a known liver or kidney disease, you will not be allowed to be in the study. Abnormal liver tests may present without symptoms, mild symptoms such as nausea or vomiting or abdominal pain, or severe symptoms such as severe abdominal pain. Elevated ammonia levels may be without any symptoms or may present as confusion. Elevated urea levels may also be without symptoms or can present as progressive weakness, loss of appetite, nausea or vomiting, confusion, shallow respiration and in very severe cases can cause coma and death. Liver and kidney function testing will be performed at baseline.

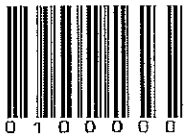
Risks of having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.



You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV, we will tell you the results and help you understand what the results mean for you.

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Risks of Sharing the Drug
Do not share the study drug with anyone. It is prescribed only for you and could hurt someone else. Keep it out of reach of children and people not able to read or understand the label.

Blood Donation
If you participate in this study and are still taking study treatment, it may affect your ability to donate blood. If you have any questions call the organization where you donate blood and talk to one of their nurses.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include the antibiotic therapy that you are currently receiving.

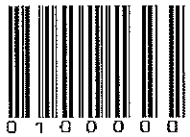
If you are an employee of UVa your job will not be affected if you decide not to participate in this study.
If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will be compensated $50 in for the form of a check for time spent participating in the follow-up phone calls. You should get $25 after completion of study intervention (after Day 10) and another $25 after Day 190 (at 6 month follow-up).

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support.

By agreeing to be in this study, you are donating your blood, bodily fluids, tissue samples for research, and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.



Will being in this study cost you any money?

The study drug, which is being used for research purposes, will be provided at no cost to you or your health insurance. All clinical specimens processed for research purposes will not be charged to the patient or insurance company.
You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask for an estimate of your financial costs. You may also wish to check with your insurance company before the study starts. Ask what they will cover and if they require you to get their permission before you decide to be in the study.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study at any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) Your study physician is concerned about your health
b) Your disease gets worse
c) The side effects of the treatment are too dangerous for you
d) New information shows the treatment will not work or is not safe for you
e) You do not follow your doctor's instructions
f) The study sponsor closes the study for safety, administrative or other reasons

If you decide to stop being in the study, we will ask you to send a letter to the researchers listed on this form stating your intent to withdraw from the study.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. Any information shared will not contain your name or any label that can be traced to you or identified as you. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Your health information. If required for this study, this may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.
- Stool samples if you agree to provide them for future research (specimen banking)

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- People who evaluate study results, including government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. We ask them to protect your privacy. However, they may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

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

Principal Investigator:

Cirle Warren, MD
Department of Medicine, Division of Infectious Diseases and International Health

P.O. Box 801379
Charlottesville, VA 22908
Telephone: 434-924-9676

Study Coordinator/Co-investigator

Jennifer White, RN, CCRC
Department of Medicine, Division of Infectious Diseases and International Health
P. O. Box 801340
Charlottesville, VA 22908
434-982-3649

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908 Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

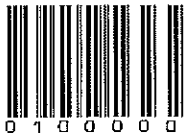
What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.



If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the Short Form written in the language they can understand.

Consent From Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

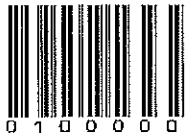
I agree the information in this informed consent form was presented orally in my presence to the subject and the subject had the opportunity to ask any questions he/she had about the study. I also agree that the subject freely gave their informed consent to participate in this trial.

IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE



Interpreter

By signing below you confirm that the study has been fully explained to the potential subject in a language they understand and have answered all their questions.

INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE

If an interpreter was used to explain this study to a potential subject, the interpreter must sign and date the line above.

Surrogate Consent for Adult Participant

In the event the adult participant is unable to give informed consent for participation in this study:

PERSON GIVING CONSENT FOR PARTICIPANT (Signature/ Printed)	DATE

RELATIONSHIP TO PARTICIPANT: *Check one of the options below*

_____Agent under an Advance Directive that authorizes participation in research
_____Court-appointed Guardian
_____Spouse (unless divorce action has been filed)
_____Next of kin

If an interpreter is involved in the consent process because the surrogate does not speak English well or at all, the surrogate should NOT sign on the line above – leave this line blank. Instead, the surrogate should sign the Short Form written in the language they can understand.

Person Obtaining Consent of the Surrogate

By signing below you confirm that you have fully explained this study to the potential subject's surrogate, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Impartial Witness for Consent from Surrogate

If this consent form is read to the subject's surrogate because the subject's surrogate is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject's surrogate may place an X on the "Person giving consent for participant" signature line above.

I agree the information in this informed consent form was presented orally in my presence to the subject's surrogate and the subject's surrogate had the opportunity to ask any questions he/she had about the study. I also agree that the subject's surrogate freely gave their informed consent for the subject to participate in this trial.

IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Attending Physician Approval

I am the doctor that provides medical care for this subject. I believe that his/her health might be helped by being in this study. I approve his/her participation in this research study.

ATTENDING PHYSICIAN (SIGNATURE)	ATTENDING PHYSICIAN (PRINT NAME)	DATE

Note: If the researcher is also the attending physician for the patient, they may also sign here as the attending physician.

INSTRUCTIONS: Delete this section if ALL subjects in the study will be incapable of giving assent (e.g. all subjects in a coma) or if the protocol has a potential for benefit to the subject where assent would not be required.

Person Obtaining Assent of the Adult Subject

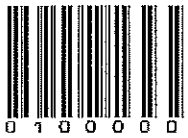
The subject is unable to give assent due to the following reason:

_____

OR

By signing below you confirm that the study has been explained to the adult subject, all questions have been answered and the adult subject has not demonstrated resistance or dissent by word or gesture to enroll in the study. You also confirm that if the subject demonstrates resistance or dissent at any point in the study that they will not be subjected to any additional study interventions.

PERSON OBTAINING ASSENT (SIGNATURE)	PERSON OBTAINING ASSENT (PRINT)	DATE



Interpreter

By signing below you confirm that the study has been fully explained to the potential subject's surrogate in a language they understand and have answered all their questions.

INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE

If an interpreter was used to explain this study the interpreter must sign and date the line above.

Consent of the Participant to Continue to Be in the Study

Your legal representative gave his/her permission for you to be in this research study. This is because you were not able to make your own decision due to your illness. Your condition is now better. You are being asked to decide whether to continue to be in this study. The decision is up to you. Before you sign this form, please ask questions about any part of this study that is not clear to you. When you sign below, you are saying you understand the information we gave you about the study and in this form.

If you sign this form it means that you agree to continue being in the study.

PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

If an interpreter is involved in the consent process because the subject does not speak English well or at all, the subject should NOT sign on the line above – leave this line blank. Instead, the subject should sign the Short Form written in the language they can understand.

Person Obtaining Consent of the Subject

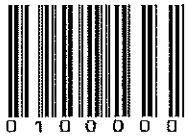
By signing below you confirm that you have fully explained this study to the subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Interpreter

By signing below you confirm that the study has been fully explained to the potential subject in a language they understand and have answered all their questions.

INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE



If an interpreter was used to explain this study to a potential subject, the interpreter must sign and date the line above.

Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the subject and the subject had the opportunity to ask any questions he/she had about the study. I also agree that the subject freely gave their informed consent to participate in this trial.

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE