Certification of Completion of the Informed Consent

IRB #

Title:

I have discussed the "Informed Consent for Participation in Research Activities" in its entirety for the above referenced research study, with the research participant listed below (or the research participant's legally authorized representative). During the review of the consent form, the possible benefits, risks and discomforts involved in his/her participation on the study, as well as potential alternatives were reviewed.

The research participant has been encouraged to ask questions, and all questions asked by the participant have been answered. The research participant affirmed that he/she has received all information that he/she desires at this time, and a copy of the signed consent form has been provided to the participant.

PRINTED NAME of Person Obtaining Informed (Consenter)	SIGNATURE	TITLE	DATE	TIME

ADULT INFORMED CONSENT

COH Protocol # 19424
TITLE: Cardiovascular Reserve Evaluation in Survivors of Transplantation (CREST)
Version date: 04/24/2023

PRINCIPAL INVESTIGATOR: Saro Armenian, DO, MPH

DAY TIME TELEPHONE NUMBER FROM THE HOURS OF 8:00 AM TO 5:00 PM: DR. ARMENIAN AT (626) 218-7320

EXPERIMENTAL PARTICIPANT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study, also known as an experiment or clinical trial. As a research participant, you have the following rights:

1. To be told what the research study is trying to find out.
2. To be told what will happen to you and whether any of the procedures to be used are different from what would be used in standard practice.
3. To be told about the discomforts, side effects and risks of the things that will happen to you as part of the research study.
4. To be told if you can expect any benefit from participating in the research study.
5. To be told of the other choices you have and how they may be better or worse than being in the research study.
6. To be told what medical treatment is available if any complications arise.
7. To be allowed to ask any questions concerning the research study, both before agreeing to be in the study and during the course of the study.
8. To refuse to participate in the research study or to change your mind about participation after the study is started. To be informed that this decision will not affect your right to receive the care you would receive if you were not in the study.
9. To receive a copy of the signed and dated research study consent form.
10. To be free of pressure when considering whether you wish to agree to be in the research study.

ADULT INFORMED CONSENT

COH Protocol #19424
TITLE: Cardiovascular Reserve Evaluation in Survivors of Transplantation

PRINCIPAL INVESTIGATOR: Saro Armenian, DO, MPH

KEY INFORMATION
You are invited to participate in a research study because you will be receiving a hematopoietic stem cell transplant (HCT). The purpose of this research study is to see how well your heart, lungs and muscles are working individually, and how these systems are working together. The information we learn by doing this research study may help us understand why HCT survivors are at higher risk for developing cardiovascular disease.

Participants in this study will be asked to perform cardiopulmonary exercise tests (test of heart and lung function), physical ability tests, echocardiograms and lower extremity ultrasound. Participation is expected to last about two years following HCT.

The very rare, but major risks associated with study include severe chest pain, heart rhythm disturbance, heart attack, death due to a heart condition and/or stroke. The benefits associated with the study include notification of any incidental findings and a comprehensive assessment of your cardiovascular system, which may not be done as part of standard of care.

You do not have to join this research study. If you are interested in learning more about this study, please continue to read below.

INTRODUCTION
With ongoing improvements in transplant strategies, the number of patients surviving transplant continues to increase. However, long-term survivors have a higher risk of developing health problems after transplant, such as a diagnosis of cardiovascular disease (CVD). Cardiovascular disease refers to conditions that involve narrowed or blocked blood vessels that can lead to heart attack, chest pain (angina) or stroke. Other heart conditions affect the heart muscle, valves or rhythm. Cardiovascular complications in transplant patients are more common and often occur earlier than expected when compared to the general population. Patients who received a transplant are at an especially high risk for CVD in part because of treatments they received (chemotherapy and/or radiation therapy).

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future. Please take as much time as you need to read the consent form. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. We will give you a copy so

that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

In this study we will utilize blood tests and non-invasive testing to determine information about a person's cardiovascular reserve capacity (the difference between the rate the heart pumps blood at a particular time and its maximum capability for pumping blood) which may help us understand the high risk of CVD in the HCT population. This study will measure cardiovascular reserve capacity over time by utilizing the six tests discussed in section B and blood testing. Participants will be asked to complete four visits for this study which includes a pre-transplant visit, a 6 month post-transplant visit, a one-year post-transplant visit and a two-year post-transplant visit. Each visit is expected to last approximately 5 hours: 5-10 minutes for screening purposes and another 4 hours to complete the study procedures including tests that are used to determine your cardiovascular reserve capacity (these tests are discussed below).

About 350 people will take part in this research study.

B. WHAT IS INVOLVED IN THE STUDY?

Screening Procedures:

After signing this consent form, the study staff will make sure that it is safe for you to participate in the research study by asking you a few questions about your health

If these tests show that you are eligible to participate in the research study, you will be enrolled to the study to undergo the study procedures. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

Study Procedures:

After study enrollment, you will have a four-hour visit to perform the following study procedures:

Blood Draw: About 4 teaspoons (20mL) of your blood will be taken from a vein in your arm for a complete blood count (CBC) and to screen for other aging biomarkers (substances in the blood that may be associated with aging).

Echocardiogram: This test is an ultrasound of the heart muscle. You will lie on a bed while a technician uses an ultrasound wand, pressed against your chest, to take images of your heart.

Musculoskeletal Ultrasound Evaluation: This test is an ultrasound that will look at the amount of muscle in your leg.

Bioelectrical Impedance Analysis (BIA): This test will look at the amount of body fat and muscle you have throughout your body using completely safe electrical signals. This is measured by stepping on a machine, very similar to a scale, with bare feet and placing your hands on mental sensors. The test will last a few minutes. If you have an implantable defibrillator or pacemaker you will not participate in this procedure.

Pulmonary Function Test (PFT): This is a breathing test that looks at how well your lungs are working by measuring the amount of air taken into your lungs and exhaled as you breathe.

Electrocardiogram (ECG): An ECG requires attaching small pads to your skin to record the electrical activity of your heart. The ECG itself is painless and is not associated with risks. However, the places where the pads are placed could become red and slightly irritated. Occasionally it may be necessary to shave small areas of the chest (males) for the attachment of electrodes.

Vital Signs and Physical Examination: Vital signs include the measurement of your heart rate, respiratory rate, blood pressure, blood oxygen levels, height and weight. Your heart rate and respiratory rate will be evaluated by the electrocardiogram. Your blood pressure will be measured using an automated blood pressure cuff. A blood pressure cuff will be placed over your upper arm about one inch above the bend of your elbow then the cuff will inflate and slowly deflate so that the machine can take your measurement. The blood oxygen level is measured using a small machine that is placed around your fingertip for a few minutes. Your designated primary hematologist or a clinician from the research team will review these vital signs before testing continues.

Cardiopulmonary Exercise Test: This test measures how well you use oxygen while you exercise. You will be asked to pedal a stationary bicycle while a device measures how much oxygen you consume. The exercise level will be increased a little at a time. This test will be performed under the supervision of a pulmonary physician.

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Functional Testing: These are an additional set of tests that measure your ability to exercise using everyday activities. These tests include the 30 second sit to stand (STS) test, 2-minute step in place test (2MSPT), and the timed up and go (TUG) test. The 30 second STS test measures how many times you can go from a seated position to a standing position in 30 seconds. The 2MSPT measures how many times you can step in place, much like walking up steps, in 2 minutes. Finally, the TUG test measures how ling it take you to stand up from a chair, walk a few steps and return to the same chair.

Hemoglobin Test (Visit 1 only): This test measures patient's Hemoglobin (Hgb) level and tells us if you are anemic (not having enough red blood cells to carry adequate oxygen to your body). If PI requested, prior to beginning the cardiopulmonary exercise test (CPET), your Hgb level will be checked using Germaine Hb Hemoglobin (Hb) Test system analyzer. A small amount of blood will be collected via a finger stick. The study staff will clean your finger, then prick the tip of it with a tiny needle (or lancet) to collect the blood.

Questionnaires: You will also be asked to complete questionnaires about your daily life, your quality of life, fatigue, pain, and exercise routine. Completing these questionnaires is expected to take about 40 minutes.

The post-transplant visits are expected to last approximately five hours: 5-10 minutes for screening purposes and another 4 hours to complete the study procedures discussed above.

Research Study Calendar:

		Visit 1	Visit 2	Visit 3	Visit 4
	Screening*	Pre-HCT	6 mo Post-HCT	1 yr Post-HCT	2 yr Post-HCT
Sign Consent	X	-	-	-	-
Screening Questions	X	X	X	X	X
Pulse Oximeter Reading		X	X	X	X
Blood Test		X	X	X	X
Echocardiogram		X	X	X	X
Musculoskeletal Ultrasound		X	X	X	X
Bioelectrical Impedance Analysis		X	X	X	X
Pulmonary Function Test		X	X	X	X
Electrocardiogram		X	X	X	X
Vitals and Physical Examination**		X	X	X	X
Cardiopulmonary Exercise Test (CPET)****		X***	X	X	X
Functional Testing		X	X	X	X
Questionnaires-Overall health, fatigue and physical activity		X	X	X	X

*****Screening procedures may be completed on the same day as Visit 1 Pre-HCT.

** Physical examination will be completed by the patient's primary oncologist.

*** If PI requested, Hemoglobin Test will be done prior to beginning the CPET.

**** If PI requested, any study procedure may be repeated within a timepoint for screening purposes prior to the CPET.

C. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be in this research study for about 2 years.

D. WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Possible Risks Associated with Blood Draw

Risks of blood draws include mild pain or discomfort, bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).

Possible Risks Associated with Finger stick
Risk of finger prick is you may feel a sharp poke, but only last for a second.

Possible Risks Associated with Echocardiogram:
In this test, ultrasound (sound waves) is used to examine the heart. A colorless gel (sometimes cold) is first applied to the chest. An ultrasound wand is placed on the gel and is moved around to different parts of the chest. You may be asked to move slowly from side to side, to breathe slowly, or to hold your breath. This helps in obtaining higher quality pictures. The echocardiogram is non-invasive and is not associated with any health risks.

Possible Risks Associated with Musculoskeletal Ultrasound:
In this test, ultrasound (sound waves) is used to produce pictures of muscle. Occasionally, an ultrasound exam may be temporarily uncomfortable, but it should not be painful. The ultrasound is non-invasive and is not associated with any health risks.

Possible Risks Associated with Bioelectrical Impedance Analysis:
In this test a weak electric current flows through the body and the voltage is measured in order to calculate impedance (resistance) of the body. This is a safe, simple and noninvasive procedure. However, Bioelectrical Impedance Analysis should not be used by participants with an electronic medical implant, such as a heart pacemaker.

Possible Risks Associated with Pulmonary Function Test:
In this test, your lungs will be evaluated by measuring the amount of air taken into your lungs and exhaled as you breathe. Risks with this test are minimal. However, some people become lightheaded or faint. The test may also trigger an asthma attack in individuals with asthma.

Possible Risks Associated with Electrocardiogram:
An ECG requires attaching small pads to your skin to record the electrical activity of your heart. The ECG itself is painless and is not associated with risks. However, the places where the pads are placed could become red and slightly irritated. Occasionally it may be necessary to shave small areas of the chest (males) for the attachment of electrodes.

Possible Risks Associated with Cardiopulmonary Exercise Test
In this test, you will be asked to pedal a stationary bicycle while a device monitors how much oxygen you consume. Details of the risks are listed below.

Occasional Side Effects (occurring in greater than 5 out of 100 research participants):

- Fatigue
- Muscle soreness
- Joint pain

- Lower back pain
- Leg cramps

Very rare, but serious, Side Effects (occurring in less than 1 out of 1000 research participants):

- Angina (severe chest pain)
- Arrhythmias (heart rhythm disturbances)
- Myocardial ischemia (heart attack)
- Sudden cardiac death (death due to a heart condition)
- Cerebrovascular accident (stroke)

Possible Risks Associated with Functional Testing

You may become tired from repetitive exercise. If you do, please inform the technician or study staff and the test will be altered for stopped as appropriate.

Possible Risks Associated with Questionnaires: You may become tired from the amount of time needed to fill out the questionnaire. You are free to skip any question that makes you feel uncomfortable.

Incidental Findings:

It is possible the research procedures could find a medical problem unrelated to the purpose of this study that you did not know about before. If during the research procedures we learn information that may be important for you to know about, such as the possibility of a previously unknown medical condition, we will tell you. You may authorize the release and communication of the findings to your personal doctor. These findings may require additional testing or treatment. You will be responsible for the cost of any additional tests or related treatment.

E. HOW WILL YOUR INFORMATION BE KEPT CONFIDENTIAL?

Any information learned from this study in which you might be identified will be confidential and disclosed only with your permission. Every effort will be made to keep any information collected about you confidential. However, it is impossible to guarantee that information about you will not be mistakenly released. If, despite our best efforts, identifying information about you is released, it could negatively impact you or your family members. This risk is small.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.

- Regulatory agencies such as the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and the National Cancer Institute (NCI) in the U.S., and similar ones if other countries are involved in the study as required by law.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The Certificate protects against the release of information, documents or biospecimens that may identify you that was collected during the period the Certificate is in effect to individuals not connected with the research. For example, the researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you choose to voluntarily disclose the protected information under certain circumstances (for example, if you request the release of information in writing), the Certificate does not protect against that voluntary disclosure. Additionally, the Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, for other scientific research, as allowed by federal regulations protecting research subjects, or for your medical treatment.

F. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS RESEARCH STUDY?

We do not expect you to benefit directly from participation in this study. However, if we detect clinically meaningful abnormalities during the testing process, you and/or your physician will be notified of them. In addition, you will have the opportunity to meet with a study clinician to discuss these findings. The knowledge gained from the current study may be used to improve screening in patients who plan to receive a transplant.

G. WHAT OTHER OPTIONS ARE THERE?

Your alternative is to not participate in this study. Choosing not to participate will not affect your ability to receive care at City of Hope.

H. ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

You will receive modest compensation for your time and effort spent on the study. You will receive a $200 gift card at the following 4 time points:

1. Pre-Transplant Visit
2. 6M Post Transplant Visit

3. 1Y Post Transplant Visit
4. 2Y Post Transplant Visit (A total of $800 for all 4 time points)

At each time point, a $25 gas card will be provided to participants who live greater than 30 miles from the Duarte campus. In the event that a participant is asked to repeat study procedures for a specific time point, they will receive an additional $200 as compensation for their time and effort.

If you receive more than $600 per year for taking part in one or more research studies, you may be required to pay taxes on that money. This does not include any payments you receive to pay you back for expenses like parking fees. You may receive an Internal Revenue Service (IRS) Form 1099 if you receive more than $600 in one year for taking part in one or more research studies.

I. WHAT ARE THE COSTS?

Neither you nor your insurance carrier will be charged for participation in this study.

J. WHAT HAPPENS IF YOU GET INJURED AS A RESULT OF THIS STUDY?

If you think you have been hurt by taking part in this study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form. City of Hope will offer you the care needed to treat injuries directly resulting from taking part in this research. However, financial compensation will not be available.

You do not give up your legal rights by signing this form.

K. WHAT ARE YOUR RIGHTS IF YOU TAKE PART IN THIS STUDY AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this research study is voluntary. You are free to withdraw your consent for participation in this study without any loss of benefits, penalty, or interference with any future treatment at City of Hope.

L. WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

The principal investigator, Dr. Saro Armenian, or a member of their research staff has offered to and has answered any and all questions regarding your participation in this research study. If you have any further questions or in the event of a research related injury, you can contact Dr. Saro Armenian at (626) 218-7320.

This study has been reviewed and approved by the Institutional Review Board (IRB). If you have any questions regarding your rights as a research participant, you may contact a representative of that Board, from the Office of Human Research Subjects Protection, at (626) 256-HOPE (4673) ext. 62700.

M. SIGNATURE SECTION

SIGNATURE FOR CONSENT: By signing this consent form, you are making a decision to participate in this research study. Your signature on this informed consent form indicates that you:

1. Have read and understood the information in this form.
2. Have had the information in this form explained to you.
3. Have had a chance to ask questions and these questions were answered to your satisfaction.
4. Have been informed that you will receive a copy of this signed consent form, which includes the "Experimental Subject's Bill of Rights."

I hereby agree to be a research participant in this research study:

_____ _____ _____

Research Participant's Signature Date Time

(For paper consent only, date and time must be in research participant's handwriting)

_____

Print Research Participant's Name

INDIVIDUAL OBTAINING CONSENT SIGNATURE

_____ _____ _____

Signature of Individual Obtaining Consent Date Time

_____

Print Name of Individual Obtaining Consent

FOR USE WITH IRB APPROVED TRANSLATED SHORT/LONG CONSENT FORMS FOR NON ENGLISH SPEAKING PARTICIPANTS ONLY

NOTE: To determine who should sign below, review the guidance document, *Consenting Non English Speaking Research Participants (Pediatric or Adult) – Who Signs What?*

Interpreter: By signing here, I attest that I have acted as interpreter and facilitated this consent process.

_____ _____ _____

Interpreter's Signature Date Time

_____

Print Interpreter's Name

FOR USE WHEN A WITNESS IS REQUIRED:

Witness: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name

COH Protocol # 19424 - Cardiovascular Reserve Evaluation in Survivors of Transplantation

AUTHORIZATION TO USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI) FOR PURPOSES OF THIS STUDY:

I. **Purpose of this Authorization**: The information about your health is something that is protected by law and cannot, except for certain purposes, be disclosed (shared) without your permission. As part of this research, you are agreeing to allow City of Hope, its affiliated research doctors, healthcare providers, and physician network to use and share with others your protected health information ("PHI"), as needed for the research. If you agree to participate in the study named above (called the "Study"), you must sign this authorization in addition to the *Study Consent Form*.

II. **The Information About You that is Covered By this Authorization**: PHI refers to information that we maintain about you that identifies you and includes the information contained in your medical record. Your medical record consists of information related to your health and the treatment we provide to you, such as your medical history, the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures. If you sign this authorization, you are allowing City of Hope and the individuals indicated below to use and share any PHI we maintain about you that is required for your participation in the Study.

III. **Purposes for Uses and Sharing of your PHI; Who Will Use, Share and Receive your PHI**: Your PHI will be used and shared with others for the purpose of doing this research as described in the *Study Consent Form*. Your PHI will also be used to keep the research sponsor informed about this Study, for reporting to those individuals and authorities responsible for overseeing our research activities to make sure that the activities are properly conducted, and to report to regulatory agencies as required by the Study.

The people authorized to use and share your PHI for purposes of the Study include the Principal Investigator and the research staff supporting the Study; your City of Hope physicians and the health care team; the Health Information

Management Services Department (i.e., Medical Records Department), and affiliated research doctors and other medical centers participating in the research, if applicable. This also includes any agents or contractors used by these individuals or groups for purposes of conducting or managing this Study. At the City of Hope, the Institutional Review Board ("IRB"), and other City of Hope research regulatory committees will have access to your PHI as necessary to monitor research.

You are also allowing your PHI to be shared with the Office for Human Research Protections ("OHRP") and with any person or agency as required by law. In addition, certain other regulatory agencies, including, the National Cancer Institute ("NCI"), the National Institute of Health ("NIH") will have access to your PHI.

This authorization will allow us to use and share your PHI for the Study. No other additional uses and disclosures other than for the purposes of the Study is included in this authorization. City of Hope's Notice of Privacy Practices will continue to protect your non-Study information. If necessary, another separate permission will be obtained from you for any non-Study uses or sharing of your PHI.

IV. **Expiration of this Authorization**: This authorization to use and share your PHI will expire twenty-five (25) years from the date that you sign this authorization.

V. **Further Sharing of Your PHI**: Your privacy is important and this is the reason for having rules which control who can use or see your PHI. City of Hope maintains control over your PHI at present, but once we share this information with a third party (for example, an individual or agency outside of the City of Hope), then it is no longer possible to maintain the same level of protection. The persons outside our control may not be governed by federal or state privacy laws and it is possible that they could share your PHI with others for whom you have not given permission.

The information from this Study may be published in scientific journals or presented at scientific meetings but your identity will be kept confidential.

VI. **<u>Your Rights Under this Authorization</u>**: You may cancel this permission to use and share your PHI at any time by contacting City of Hope's Privacy Officer at (626) 256-HOPE (4673) ext. 64025. You should ask for the form, *Revocation (Cancellation) of Authorization for Use of Protected Health Information for Research*. Fill this form out and return it as the form instructs. Your cancellation begins when the Health Information Management Department of City of Hope receives this form. If you cancel this authorization to use and share your PHI, you will no longer be able to participate in the Study. This is because the research under this Study cannot be conducted without your PHI.

Once you cancel your permission to use and share your PHI, the researchers and others involved in conducting the Study will no longer be able to use or share your PHI for this research. PHI already used and shared up to this point as part of this Study will continue to be used for purposes of this research. This means that any uses of your PHI and any PHI shared about you by City of Hope prior to receiving your cancellation (revocation) form cannot be taken back. While no further PHI about you will be shared for the Study, your PHI already shared will continue to be used in the overall Study.

VII. **<u>Signing this Authorization is Your Choice</u>:** Your ability to obtain care at the City of Hope will not be affected by your decision to sign this authorization form. You will be able to continue to receive health care at City of Hope if you choose not to sign this authorization form or if you sign this form and later cancel your permission to use and share your PHI.

If you agree to the use and sharing of your PHI, please sign below. You will be given a copy of this authorization form.

_____ _____ _____

Research Participant's Signature Date Time

(For paper consent only date and time must be in research participant's handwriting)

_____

Print Research Participant's Name

INDIVIDUAL OBTAINING CONSENT SIGNATURE

_____ _____ _____

Signature of Individual Obtaining Consent Date Time

_____

Print Name of Individual Obtaining Consent

FOR USE WITH IRB APPROVED TRANSLATED SHORT/LONG CONSENT FORMS FOR NON ENGLISH SPEAKING PARTICIPANTS ONLY

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Interpreter: By signing here, I attest that I have acted as interpreter and facilitated this consent process.

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Interpreter's Signature Date Time

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Print Interpreter's Name

FOR USE WHEN A WITNESS IS REQUIRED:

Witness: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name