INFORMED CONSENT

Cardiovascular Outcomes in Renal Atherosclerotic Lesions Randomized and Multi-Center Two-Group Clinical Trial To Assess The Best Treatment for Patients with High Blood Pressure and Renal Artery Stenosis: Stenting with Anti-Hypertensive Medical Therapy, Compared to Medical Therapy Alone

Principal Investigator:
Co-Investigators:
Telephone No:

WHAT YOU SHOULD KNOW ABOUT A RESEARCH STUDY:

- We give you this consent/authorization form so that you may read about the purpose, risks, and benefits of this research study. All information in this form will be communicated to you verbally by the research staff as well.
- Routine clinical care is based upon the best known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.
- We cannot promise that this research will benefit you. Just like routine care, this research can have side effects that can be serious or minor.
- You have the right to refuse to take part in this research, or agree to take part now and change your mind later.
- If you decide to take part in this research or not, or if you decide to take part now but change your mind later, your decision will not affect your routine care.
- Please review this form carefully. Ask any questions before you make a decision about whether or not you want to take part in this research. If you decide to take part in this research, you may ask any additional questions that you may have at any time.
- Your participation in this research is voluntary.

INTRODUCTION

We invite you to take part in a research study involving over 900 patients at approximately 100 hospitals in the United States and 100 hospitals outside the United States. The study is extending the follow-up period out until March 31, 2014. The minimum follow-up required for the study will be 4 years and some patients will have a maximum follow-up of 9 years.

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PURPOSE (WHY THIS RESEARCH IS BEING DONE)

You are being asked to participate in this research study because you have a history of high blood pressure while on 2 or more blood pressure medications and a known or suspected renal artery stenosis (narrowing of the blood vessel that supplies blood to your kidney). The purpose of this study is to answer the question - What is the best treatment for patients who have high blood pressure and renal artery stenosis? Currently there is no agreement on diagnosis (identifying the cause or nature of an illness or disease), the method of treatment, or follow-up for patients with blockage (narrowing) in the kidney artery.

DESCRIPTION OF THE RESEARCH PROCEDURES AND DURATION OF YOUR INVOLVEMENT:

This is a randomized study, which means that the volunteers participating in the study will have a 50:50 chance of being assigned to one of two groups (stent plus medical therapy [blood pressure medication], or medical therapy alone). This random assignment is made by chance, (like the result of flipping a coin).

Volunteers assigned to one group will be taking medication only, and will not receive a stent. Volunteers assigned to the stent group will be taking medication and receive the PALMAZ GENESIS Stent. Both the groups will be followed with medications (including blood pressure medications), tests and doctor visits in the same way. Your doctor will be able to decide what type of blood pressure medications you should take, although you may be provided with one or more of those medications free of charge. Your doctor can also change these medications as often as he/she thinks they should be changed.

This study is designed to compare the safety and effectiveness of treating your renal artery stenosis with the use of an investigational device and blood pressure medication as compared to blood pressure medication alone. The device is called the PALMAZ GENESIS Stent (a stainless steel mesh tube that is permanently implanted) to keep your kidney artery open allowing more blood to flow to your kidney.

Current standards of care for patients with your condition can be to either take medications for your high blood pressure or have a renal angiogram (procedure to evaluate with X-ray photographs the narrowing in your kidney artery) and possibly have the artery dilated (opened) with a balloon (angioplasty) with or without the placement of a stent. Stents are commonly used in the treatment of narrowings in blood vessels. Within three to four weeks after a stent is permanently implanted, the inner lining of the artery will grow over the stent surface and the stent will become part of the artery. Metal stents are often placed in other blood vessels, including those of the heart and legs.

During stent placement an embolic protection device may or may not be used, depending on your specific anatomy and the judgment of your doctor. These devices are placed in the kidney artery beyond the narrowing, and before the stent is placed. These devices might collect particles that break off during the procedure and may or may not prevent kidney damage. At completion of the stent procedure the device is removed from the body. No embolic protection device is approved for use in kidney arteries, but these devices have been used for this type of procedure.

Study Entry:

Your doctor may recommend one or more tests to diagnose your renal artery stenosis as part of your standard of care. These tests may include an ultrasound examination, MRA (magnetic resonance angiography), CTA (computed tomography angiography) or an angiogram of your kidney artery.

If your doctor performs a renal angiogram, the doctor will advance a sheath through a very small incision in an artery in your groin or arm. With the aid of fluoroscopy (special x-rays), the catheter will be advanced through the artery leading to your kidney. The doctor will fill your kidney arteries with contrast dye to take pictures of them with X-rays to determine the degree to which kidney arteries are blocked. If a narrowing is discovered you will then be randomized (like flipping a coin) to either receive a stent or not. If the blockage is mild (<60%) or the blood vessel is completely blocked (100%) in your kidney artery then you will not be able to participate in the study.

Baseline Procedures:
If you decide to participate, we will collect information about your medical history (blood pressure, kidney function, past illnesses, etc.) and perform a physical exam. We will obtain blood and urine samples to look at your kidney function. Some of this blood and urine will be sent to a central laboratory to determine whether you are anemic (low red blood cell count), diabetic, have high cholesterol, or you have kidney disease. Samples may be stored for later use. Please see the information on the last page of this consent form for specific information about the storage of your blood and urine for future testing.

In order to understand how your health changes over time, another part of the study will be to have you/your proxy (a person that you authorize to substitute for you) complete a questionnaire called a Quality of Life Survey. You will answer questions about your general health, and symptoms that you may or may not have (chest pain, shortness of breath, sleep problems, etc). All of your responses to the questions will remain completely confidential and you may choose not to answer any question. Completion of the Quality of Life Survey will take approximately 15-20 minutes.

This study contains a health economics review that will be done to compare the medical care costs for patients with renal artery stenosis, treated with renal artery stenting or aggressive medical therapy. As part of this study, you will be asked to sign a Medical Billing Release Form. This form will be used by the Economic and Quality of Life Assessments Group to collect hospital bills from the patient accounting department at any hospital to which you are admitted, from the time of your enrollment in CORAL through the study follow-up period. This information will be kept strictly confidential and be used solely to assess the medical expenses which occur as a direct result of participating in the CORAL trial.

You will also have a test to check how your heart is functioning. This test is an ECG. This test requires you to lie still while a technician attaches some patches to your chest and then connects wires. These wires are connected to a machine that makes a tracing to look at the beats of your heart.

After all the preliminary tests are done, and you are eligible for the study (meaning that no other diagnosis has been discovered that would prevent you from receiving a stent or that your high blood pressure is due to another health problem), you will be assigned to receive a stent + medical therapy or medical therapy alone.

Randomization:
If you are randomized to receive a stent + medical therapy, your doctor will determine at that time, whether or not the narrowing in your kidney artery will allow for the placement of the Genesis Stent.

If your doctor feels that the narrowing of your kidney artery does not allow for the placement of this device, alternative treatments may be provided.

After randomization your doctor may recommend additional medication(s) for your blood pressure. A medication has been donated from AstraZeneca and is being provided to you free of charge. The name of the blood pressure medication is Candesartan (Atacand) or Candesartan (Atacand)/HCT (Hydrochlorothiazide). This medication is one of several types of medication that can be prescribed for blood pressure control. This medication may be used alone or in combination with other blood pressure medications.

Another recommended medication that has been donated by Pfizer is Caduet, a combination drug made up of Amlodopine (Norvasc) and Atorvastatin (Lipitor). If your doctor feels that you would benefit from this medication it will be provided free of charge. Amlodipine (Norvasc) is used to treat high blood pressure and works by blocking calcium which relaxes and widens the blood vessels. Atorvastatin (Lipitor) is used to help lower cholesterol and fats (triglycerides) in the blood.

If you are unable to take the provided recommended medications, then your doctor will prescribe other blood pressure medications at his/her discretion although this medication will not be provided by the study. After the test and procedures are complete and the doctor determines your blood pressure medication, you will be discharged to go home. All patients in the study will need to have blood and a urine sample taken before going home after randomization. These will look at your kidney function.

Follow-Up Visits:
You will be followed closely throughout the course of the study. You will return for follow-up visits at 2 weeks, 3 months and 6 months after randomization. After the first year, you will see your study doctor or study nurse twice a year (every six months) until the study is completed. The study related office visits are detailed below with what to expect at each visit.

Two Week Office Visit:
You will be scheduled for your first follow-up visit two weeks after randomization. You will have your blood pressure measured, blood samples obtained and questions regarding your medications and how you are feeling will be asked. You may need to return to the office every two weeks for 2 months until your blood pressure is properly controlled.

3 & 6 Month Visit:
You will have your blood pressure measured, blood samples obtained and questions regarding your medications and how you are feeling will be asked. During the 6-month follow-up you will have a repeat ECG performed and the Quality of Life survey will be repeated. You/your proxy will either receive a packet of questions in the mail two weeks prior to your scheduled appointment or a phone call from a person at the Economics & Quality Of Life Core Lab.

Annual Visits:
You will have your blood pressure measured, a physical exam performed, blood & urine samples obtained and questions regarding your medications and how you are feeling will be asked. You will have a repeat ECG performed and the Quality of Life survey will be repeated at years 1, 2 & 3 only. You/your proxy will either receive a packet of questions in the mail two weeks prior to your scheduled appointment or a phone call from a person at the Economics & Quality Of Life Core Lab.

Semi-Annual Visits (after the 1st year):

You will have your blood pressure measured, blood samples obtained and questions regarding your medications and how you are feeling will be asked.

Study Completion Visit:

You will be scheduled for a final visit called the study completion visit. At this visit all of the tests that were done prior to randomization will be repeated. These tests will include a physical exam, blood and urine samples, an ECG and a Quality of Life survey. If you have a serious medical problem during the study (heart attack, stroke, kidney failure, or uncontrollable blood pressure problems), your study doctor may recommend that this visit be performed earlier, although you will continue to be seen until the study is completed.

RISKS AND DISCOMFORTS YOU MAY EXPERIENCE IF YOU TAKE PART IN THIS RESEARCH

Risks of hypertension (high blood pressure) include: heart attack, heart damage, stroke, congestive heart failure, kidney damage, kidney failure requiring the need for dialysis, and death. You are at risk of all of the above whether or not you participate in this study. Our aim of the study is to reduce the chances of you developing any of the above complications of high blood pressure and answer the question of what is the best way to treat your high blood pressure and renal artery stenosis.

A risk of the angiogram and stent procedure, renal failure, may be increased if you have renal insufficiency (decreased kidney function). The pain will be minimized by local anesthesia (numbing medicine) and intravenous medication for sedation. The risks and complications in this study are the same as those associated with an angiogram and angioplasty of the renal artery and include:

Potential Adverse Effects	Seriousness	Likelihood of Complications
Bleeding	High	5%
Permanent Renal Failure (kidney failure)	High	5%
Permanent renal insufficiency (decreased kidney function)	High	10%
Renal infarction (decreased blood supply)	High	1%
Death	High	0.1%
Loss of arm or leg function	High	0.1%
Quadriplegia (paralysis of arms and legs)	High	0.1%
Paraplegia (paralysis of both legs)	High	0.1%
Stroke (a sudden blockage or rupture of a blood vessel in the brain resulting in, for example, loss of consciousness, partial loss of movement or loss of speech)	High	0.1%
Renal artery perforation or rupture (tear in vessel)	High	1%
Blood vessel injury	Moderate	1%
Pseudoanuerysm (ballooning out of a vessel)	Moderate	5%
Need for Surgery	Moderate	1%
Allergic reaction to dye (symptoms can include a rash or trouble breathing)	Moderate	1%
Failure to deliver stent	Moderate	1%
Renal artery aneurysm (ballooning out of vessel)	Moderate	1%
Restenosis (reclotting or closure of the vessel)	Moderate	30%
Vessel dissection (tearing)	Moderate	10%
Embolization of stent (movement of stent)	Moderate	5%
Atheroembolism (dislodgement of plaque in the blood vessel)_	Moderate	5%
Hypertension (high blood pressure)	Moderate	5%
Infection (symptoms can include fever, redness, swelling,	Moderate	1%

fatigue)		
Transient Renal Failure (Temporary decreased kidney function)	Low	5%
Vessel Thrombosis (clotting in the vessel)	Low	1%
Renal artery spasm	Low	10%
Fever (symptoms can include shivering, headaches and increased heart rate)	Low	1%
Hypotension (low blood pressure)	Low	1%
Bleeding from access site	Low	5%

The discomforts from participating in this study are similar to your normal health care. You may experience temporary pain when a blood sample is taken. When you enter any blood vessel you have the risk of causing injury to the blood vessel, an infection, or an inflammation in the area of the vein called phlebitis.

The ECG has minimal discomfort when the adhesive patches are removed.

The Quality of Life questionnaire or phone call contains sensitive questions about your quality of life. If you are unable to, or do not wish to answer any question, you may leave it blank or state you do not wish to answer. When you are finished answering the questions, you will place the questionnaire packet in a secure envelope that you will seal with a label marked “Confidential”. All responses to the questions are completely confidential and if the results of this study are published, your identity will not be disclosed.

We will recommend that you take medications to thin your blood such as aspirin, or, if you are allergic or intolerant to aspirin, other such medications. If you receive a stent we will strongly recommend that you take aspirin or other such medications for a minimum of 1 month. You will have an increased tendency to bruise easily or bleed from any site with these medications.

The side effects of the study medication(s) Atacand or Atacand/HCT or Caduet (Norvasc) which are all blood pressure medications and/or other blood pressure medications that may be prescribed by your doctor will be the same whether or not you are participating in this study since you have high blood pressure that requires treatment with these medications. In general, medication to reduce your blood pressure can cause low blood pressure, rash, fever, chest pain, heart attack, cough, changes in blood sugar, muscle pain, difficulty sleeping, changes in kidney and liver function, blood disorders, itching, stomach pain, fast heart rate, anxiety, depression, changes in sexual function, headache, frequent urination and urgency, dizziness, and fatigue. Certain classes of medications used to treat your high blood pressure may cause kidney damage or kidney failure after prolonged use. This risk is increased if you do not have adequate fluid intake. As with any medications, you may have an allergic reaction that can be fatal or cause any of the above symptoms.

If your doctor prescribes the combination drug Caduet, Lipitor (one of the drugs in Caduet) has these possible side effects: constipation, flatulence (gas), indigestion, stomach ache, nausea, vomiting, diarrhea, headache, lightheadedness, dizziness, difficulty sleeping, swelling – especially of the arms and legs, abdominal pain, back pain, chest pain, stomach pain, muscle cramps, muscle aches, muscle pain, joint pain, arthritis, allergic reaction, rash, urinary tract infection, and bladder infection. Rare side effects that may occur are an elevation in the liver enzymes which may indicate liver disease or liver damage, inflammation of the pancreas (pancreatitis), duodenal or stomach ulcer, gallstones, decreased bowel function and angioedema. Angioedema is a possibly life-threatening swelling of the face, lips, tongue, and throat which could make breathing difficult. If you experience

this side effect, you should seek emergency medical treatment immediately and also contact the study doctor.

Rhabdomyolysis is a very rare side effect of the statin drugs (such as LIPITOR) that lower cholesterol. The condition results from severe inflammation of muscles leading to muscle breakdown and the elimination of muscle protein in the blood stream and urine. The excess protein in the urine can cause kidney failure. The key symptoms of rhabdomyolysis are muscle pain and weakness, fever, and dark urine. If you experience these symptoms, stop taking the study drug and call the study doctor immediately.

Your doctor will explain the side effects of the medications you are taking and monitor you closely throughout for possible side effects of any of the above mentioned study medication.

RISKS TO UNBORN CHILDREN

This research represents a significant risk to unborn children. Therefore, all women of childbearing age will be screened for pregnancy. This screening is standard procedure for all women of childbearing age prior to undergoing an angiogram. This screening may include a blood or urine pregnancy test. If you think that you may be pregnant or plan to become pregnant you should not participate in this study. If you become pregnant during this study, immediately contact your study doctor.

POSSIBLE BENEFIT TO YOU IF YOU DECIDE TO TAKE PART IN THIS RESEARCH

We cannot guarantee or promise you that you will benefit from participating in this study. Participating in this study may benefit others in the future by providing scientific information about high blood pressure and if renal artery stenosis should be treated with a stent and medical therapy, or just medical therapy alone. This study will also answer the important question of what is the effect of renal artery stenosis and high blood pressure.

COST TO YOU FOR TAKING PART IN THIS STUDY

If you decide to participate in this study, you will not be billed for any research costs including additional visits and x-rays. You or your insurance company will be billed for standard procedures, which will take place as part of this study. Any routine related procedures will be billed to you or your insurance company. Non-routine costs required by the study protocol will be paid by the study sponsor. You understand that in the event of related injury resulting from the research procedure, medical treatment, including hospitalizations if necessary, for injuries or illness is available. This medical treatment is not provided free of charge. Monetary compensation is not available for lost wages because of injury, nor is any other financial compensation available. You understand that there are no financial incentives for participating in this study.

PAYMENT OR OTHER COMPENSATION TO YOU FOR TAKING PART IN THIS RESEARH

You will be compensated for your time and gas by payment of a stipend of $50.00 for your baseline evaluation and $100.00 for your end-of-study visit and $30.00 for study-required follow-up visits. This stipend will be paid after each visit.

ALTERNATIVES TO TAKING PART IN THIS RESEARCH

There are other non-investigational stents approved for the treatment of failed angioplasty of renal artery stenosis. Besides renal artery stenting, other therapies are available to treat blockage of the renal artery, which include: medical therapy (medications, risks factor management), balloon angioplasty, and renal artery bypass graft surgery. If, after consideration of these potential benefits

and risks, you do not wish to participate in this study, you and your doctor will decide which standard treatment may be appropriate for you.

CONFIDENTIALITY- (USE(S) AND DISCLOSURE(S) OF YOUR PERSONAL INFORMATION)

By agreeing to participate in this research study, you give to _____, the Principal Investigator and all personnel associated with this research study your permission to use or disclose health information that can be identified with you that we obtain in connection with this study. We will use this information for the purpose of conducting the research study as described in the research consent form.

The information that we will use or disclose includes past medical history, present medical history, vital signs, laboratory results, diagnostic test results, interventional test results, and outcomes data. We may use this information ourselves, or we may disclose or provide access to the information to The Food and Drug Administration (FDA), and other government agencies, and the Data Safety Monitoring Board (DSMB) as part of the research study. Under some circumstances, the Institutional Review Board and Research and Grants Administration of _____may review your information for compliance audits.

The _____is required by law to protect the privacy of your health information, and to use or disclose the information we obtain about you in connection with this research study only as authorized by you in this form. There is a possibility that the information we disclose may be re-disclosed by the persons we give it to, and no longer protected. However, please note that this research is funded and supported by the National Heart, Lung and Blood Institute which follows federal guidelines for confidentiality and privacy.

Your permission for us to use or disclose your personal health information as described in this section is voluntary. However, you will not be allowed to participate in the research study unless you give us your permission to use or disclose your personal health information by signing this document.

Access to your personal health information obtained specifically for the purposes of this research study, may be denied.

You have the right to revoke (cancel) the permission you have given to us to use or disclose your personal health information at any time by giving written notice to _____, MD. However, a cancellation will not apply if we have acted with your permission, for example, information that already has been used or disclosed prior to the cancellation. Also, a cancellation will not prevent us from continuing to use and disclose information that was obtained prior to the cancellation as necessary to maintain the integrity of the research study.

Except as noted in the above paragraph, your permission for us to use and disclose personal health information has no expiration date.

A more complete statement of _____ Privacy Practices are set forth in its Joint Notice of Privacy Practice. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the person identified in the Notice.

Your participation in this study will be confidential. When results of a study such as this are reported in medical journals or at meetings, the identification of those who took part in the study are withheld. A copy of the informed consent document will be given to you, included in your medical record, and

maintained by your treating doctor or hospital, as applicable, and will be subject to state and federal regulations concerning confidentiality of medical records.

IN THE EVENT OF A RESEARCH RELATED INJURY

By signing this consent form, you have not waived any of your legal rights or released this institution from liability for negligence. You may revoke your consent and withdraw from this study at any time without prejudice.

In the event that you should be injured as a result of this study, you will be provided with the necessary care. This care does not imply negligence on the part of the Hospital or any of the doctor's involved. Where applicable, the Hospital reserves the right to bill third party payers for the services rendered**.**

The Investigator reserves the right to terminate this study at any point if he/she believes that important adverse events might result from its continuation. Should problems arise during the study, you should contact the Responsible Investigator,_____, MD or his associates by calling _____.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. If you decide not to participate in this study, your decision will not affect your future relations with your doctor. If you decide to participate you are free to withdraw your consent and to discontinue participation at any time without penalty.

NEW FINDINGS

You will be told of any new findings that may influence your willingness to continue to participate in the research. The study doctor or study Sponsor may terminate your participation in this study if it is determined that it is not in your best medical interest to continue your study participation.

OFFER TO ANSWER QUESTIONS

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

SIGNATURE SECTION (please read carefully)

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS STUDY. YOUR SIGNATURE INDICATES THAT YOU HAVE READ THE INFORMATION PROVIDED ABOVE, YOU HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND HAVE DECIDED TO TAKE PART IN THIS RESEARCH.

BY SIGNING THIS DOCUMENT YOU AUTHORIZE US TO USE OR DISCLOSE YOUR PERSONAL HEALTH INFORMATION AS DESCRIBED IN THIS FORM.

The date you sign this document to enroll in this study, that is, today's date, MUST fall between the dates indicated on the approval stamp affixed to the bottom of each page. The dates indicate that this form is valid when you enroll in the study but do not reflect how long you may participate in the study. Each page of this Consent/Authorization Form is stamped to indicate the form's validity as approved by _____Institutional Review Board (IRB).

_____	_____/_____/_____	_____:_____
Signature of Participant	Date	Time (24 hour clock)
_____		
Printed Name		
_____	_____/_____/_____	_____:_____
Signature of Person Obtaining Consent	Date	Time (24 hour clock)
_____		
Printed Name		
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Signature of Witness	Date	Time (24 hour clock)
_____		
Printed Name		
_____	_____/_____/_____	_____:_____
Signature of Investigator	Date	Time (24 hour clock)
_____		
Printed Name		

YOU WILL BE GIVEN A COPY OF THIS SIGNED FORM TO KEEP.

If you have any questions concerning this study or consent/authorization form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research-related

injuries, please feel free to contact the Chairperson of _____Institutional Review Board at _____.

COLLECTION, STORAGE AND USE OF BLOOD AND URINE SAMPLES FOR FUTURE RESEARCH (INCLUDING GENETIC RESEARCH)

A sample of the blood and urine taken during the study may be frozen in the event that the investigators decide to use it for future research. Any such research will be approved by an Institutional Review Board, like the one that has approved this study. When such research is done, the investigators using these samples will not receive any information that would identify you (like your name, medical record number, or social security number). You can change your mind about the use of these samples at any time. **Some of these samples, the DNA, may be used for genetic testing.** However, the results will not be told to you and will not be placed into your medical record, unless you agree. Your samples will only be used for research and will not be sold.

The potential benefit of the use of the stored samples is to identify new information about your conditions, including high blood pressure or renal artery stenosis, that may improve the care of patients in the future. We can offer no guarantee of benefit to you. The greatest risk associated with the storage of these samples is a possible loss of confidential information that you may not want disclosed. However, your samples will be identified only by code and the codes will remain private. Investigators utilizing the stored samples will not have access to the codes.

Please answer the following three questions by circling the response at the right:

1. Samples of my blood and urine may be stored for future testing? **Yes / No**
2. Samples of my DNA may be stored for future **genetic** testing? **Yes / No**
3. I wish to be contacted about information pertaining to my health if genetic information is obtained and if my study doctor believes it would alter my care. **Yes / No**

_____	_____/_____/_____	_____:_____
Signature of Participant	Date	Time (24 hour clock)
_____		
Printed Name		
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Signature of Person Obtaining Consent	Date	Time (24 hour clock)
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Printed Name		
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Signature of Witness	Date	Time (24 hour clock)
_____		
Printed Name		
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Signature of Investigator	Date	Time (24 hour clock)

Printed Name