CLINICAL TRIAL CP-0004

Prospective, Multicenter, Single Arm Safety and Effectiveness Trial of the Endologix Fenestrated Stent Graft System for the Endovascular Repair of Juxtarenal/Pararenal (JAA/PAA) Aneurysms

NCT Number: NCT01491945

Informed Consent Template

Dated: February 7, 2012

Informed Consent Form

Title: Prospective, Multicenter, Single Arm Safety and Effectiveness Trial of the Endologix Fenestrated Stent Graft System for the Endovascular Repair of Juxtarenal/Pararenal (JAA/PAA) Aneurysms

Sponsor: Endologix, Inc.
11 Studebaker
Irvine, CA 92618
United States

Principal Investigator: <INSERT NAME OF PI>

<INSERT ADDRESS OF INSTITUTION>

<INSERT PHONE NUMBER OF INSTITUTION>

INTRODUCTION

You are invited to take part in this clinical research study because you have a condition in a major blood vessel in your body (the aorta) where there is a weakening or ballooning of it, known as an abdominal aortic aneurysm, or AAA. The aneurysm extends near to your renal arteries (juxtarenal) or involves one or more of your renal arteries (pararenal). The renal arteries are the blood vessels that come off of the aorta and supply blood to your kidneys. If left untreated, the aneurysm could break open (rupture), which is life-threatening.

The aim of this research study is to collect information on the safety and effectiveness of a new device system intended to treat juxtarenal or pararenal aortic aneurysms called the Endologix Fenestrated Stent Graft System. Participation in this study will last up to five years. This particular device system has been used in several patients in a clinical study, but is not approved for commercial use.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Should you decide not to participate in the study, you will continue to receive the best possible treatment from your doctor. You may withdraw from the study at any time. Your decision will not affect your future medical care and treatment. If you do agree to take part in the study, you are free to withdraw from the study at any time, without having to give a reason, and this will in no way affect your future healthcare. Your doctor may also stop your participation in the study should he or she determines that this study is not in your best medical interest.

Please read this document carefully before you make a decision about participating in this clinical trial, and ask your doctor or a member of the study team to explain anything that is unclear to you. Your doctor and the Sponsor of the study (Endologix, Inc.) want to make sure you fully understand the study and its requirements.

If you decide to participate in this study, you will be asked to sign this consent form. By signing, you confirm that you have read and understand the information, that you will participate in this study, and that you will follow the study requirements, including the follow-up visits.

GENERAL INFORMATION

You have been diagnosed with an abdominal aortic aneurysm (AAA) - a bulge in a part of the aorta. The aorta is the largest blood vessel in the body and carries blood away from your heart to the rest of your body. The aneurysm is caused by a weakening in the wall of the aorta. If left untreated, the aneurysm may continue to grow to a size that may seriously affect other major arteries in the area. It may even break open (rupture), which is life-threatening.

One of the accepted treatments for an abdominal aortic aneurysm is to place a tube (called a stent graft) inside the aneurysm via an artery in the groin. Stent grafts are made of metal and commonly have a fabric covering. Once the stent graft is in place, blood will flow through the stent graft instead of against the weakened part of the aorta. This technique for treating an abdominal aortic aneurysm is called endovascular aneurysm repair (EVAR). The stent graft is inserted into an artery in the groin and is guided into the aorta. It is positioned so that it covers the entire aneurysm. The stent graft stays there permanently. Endovascular repair of the aneurysm can provide substantial clinical benefits for patients. It is less invasive than standard open surgical repair, it is associated with lower complications rates, and has a faster recovery time. Endovascular devices make it possible to treat patients whose other medical conditions would make open repair difficult or impossible.

In some cases, the aneurysm extends up to or above the renal arteries – the arteries that branch off the aorta to supply blood to the kidneys. Currently in the United Stated, these types of abdominal aortic aneurysms are treated primarily with open surgery. In recent years however, stent grafts are being developed with the hope that they can treat these types of aneurysms without the need for open surgery. These stent grafts are called fenestrated stent grafts. This means that the stent grafts have holes in the fabric covering which are positioned over the renal arteries to allow blood to continue to flow into the kidneys.

You have been asked to participate in this study because you may have the type of abdominal aortic aneurysm that could be treated by a fenestrated stent graft device instead of having to undergo open surgical repair.

THE STUDY DEVICE SYSTEM

The stent graft system that will be used in this study has three components, listed below.

<table>
<tr>
<td>The first component is the lower section of the stent graft system. It is called the Bifurcated Stent Graft (shown to the right) and consists of a metal mesh tube covered with a Teflon cloth type material called PTFE.

These types of metal mesh tube stent grafts have been used for over ten years and PTFE has been used for over 20 years in vascular graft implants.

The Endologix Bifurcated Stent Graft is commercially available and has been implanted in thousands of patients worldwide.</td>
<td>  </td>
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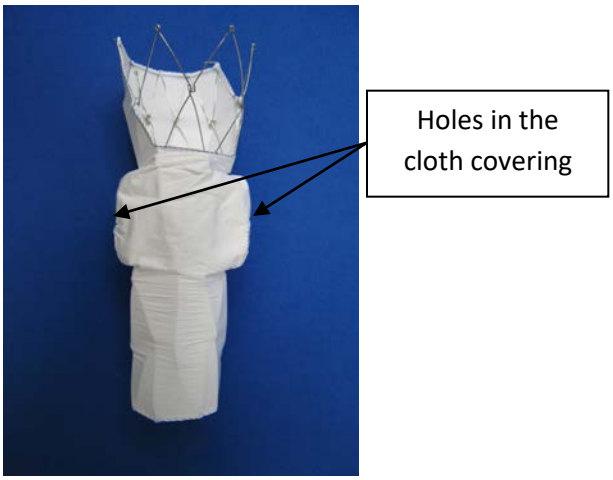
<tr>
<td>The second component is the upper section of stent graft system. It is called the Endologix Fenestrated Stent Graft and it is made of the same metal as the bifurcated device and is covered with the same cloth covering.

It has a hole (“fenestration”) on either side of the mid-section of this device. These holes are approximately 3mm wide and can be positioned over the renal arteries to allow the blood to flow to the kidneys.

It also has an uncovered portion on the top. This uncovered portion can be positioned over other important arteries to allow blood flow to them.</td>
<td> 
</td>
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<tr>
<td>The last component is called the Endologix Renal Stent Graft and it is made of a similar metal as the bifurcated device and is covered with the same cloth covering. It is placed through the hole in the Fenestrated Stent Graft (on each side) and into the renal arteries to assist in maintaining blood flow to these arteries.</td>
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The safety and effectiveness of the Endologix Fenestrated Stent Graft System are what is being investigated in this research study.

STUDY OBJECTIVES

1. **Provide an explanation of the aims of the study:**

   The aim of this study is to evaluate the safety and effectiveness of a new device system (the Endologix Fenestrated Stent Graft System) to treat patients who have a juxtarenal or pararenal aortic aneurysm. This is because a major blood vessel in the body (the aorta) the has a weakening in it that goes up near to the kidneys or may involve one of both of the arteries that provides blood flow to the kidneys.

2. **How will participants be selected for this study and who will select them?** Participants for this study will be selected only if they meet certain requirements and agree to participate. Your doctor will decide whether you can be considered for this study.

   Additional tests will be required prior to and after the procedure. These tests include but are not limited to the following:

   a. Physical Exam to check your health condition
   b. Blood pressure to check your pulses taken at your arms and ankles
   c. Blood drawn to test your kidney function (approximately 1 ½ tablespoonful)
   d. Spiral CT Scan which is a special x-ray that allows your doctor to see your blood vessels at close range
   e. Angiogram which uses a catheter (hollow tube) that is placed into your arteries to see how the blood flows through your aneurysm and the surrounding arteries
   f. Other tests or examinations as ordered by your doctor

   After these tests, a final decision will be made as to your selection for this study. If you are chosen for this study based on your test results and if you decide to participate, your procedure will be scheduled.

3. **How many participants will be involved?** Up to 122 patients at up to 25 institutions will participate. An enrollment rate of one to two patients per institution per month is anticipated.

4. **Where will the study be held?** The study will be held at up to 25 institutions in the United States and internationally.

5. **What will the time span for the study be?** The study requires all patients to be followed after the procedure and to hospital discharge, then again within about one month, six months, 1 year, and annually for up to 5 years. Thereafter your follow-up should be scheduled with your doctor annually per standard of care for patients with endovascular grafts.

6. **What will happen during the course of the study?**
   In preparation for the procedure using the device system, you will have a physical examination by your doctor, blood pressures taken at your arms and ankles and blood drawn for testing. The blood taken from the vein in your arm (approximately 1 ½ tablespoonful) will be used to assess your blood count and to evaluate how well your kidneys work.

The procedure and device implant is generally done in an operating room. The procedure typically takes about two to three hours to complete. At the procedure, you will receive an anesthetic (medication to sedate you and prevent you from feeling discomfort during the procedure). Your doctor will explain which type of anesthetic will be used. Sheaths (hollow tubes) will be inserted into openings that have been made in both groins. The sheaths will be inserted into arteries that go to your legs. A catheter will be placed through the sheath and into these arteries, and then directed to your aorta. Your doctor will take an angiogram (a special x-ray using dye) of your aorta and the arteries that branch from the aorta. This will help your doctor to evaluate the blood flow through these arteries and to position the device.

After the angiogram, the doctor will implant the Bifurcated Stent Graft into the aorta under x-ray guidance. The stent graft itself is mounted on a delivery system that looks like a catheter (a hollow plastic tube). The stent graft is guided into the aorta via the catheter delivery system in the groin and is positioned so that it covers the lower section of the aneurysm. The stent graft will then be released from the delivery system, and the delivery system is removed.

The Endologix Fenestrated Stent Graft will then be implanted, again under x-ray guidance. It is mounted on a separate delivery system and will also be introduced into the aorta via the groin artery. It is carefully positioned so that it covers the upper section of the aneurysm, with the lower part of the stent graft overlapping the upper part of the bifurcated stent graft. The holes on either side of the Endologix Fenestrated Stent Graft will be carefully lined up with the arteries that take blood to the kidneys – the renal arteries. The Endologix Renal Stent Grafts are then implanted through the holes in the fenestrated stent graft and into the renal arteries.

Once your doctor has placed the devices, a final angiogram will be done to look at the device and your arteries. If a leak is identified during the graft placement, your physician will treat it at the time of the procedure. Additional grafts may be placed to seal the attachment sites of the graft if leaks are identified during the procedure. Some leaks may only be seen during follow-up studies. You may require additional endovascular or surgical procedures such as placement of another graft. You may have standard open surgical aneurysm repair or other treatments if complications develop or if the device did not properly treat your aneurysm.

Before you leave the hospital, you will have a physical examination, blood pressures will be taken at your arms and ankles, and blood will be drawn for testing (approximately 1½ tablespoonful).

You will be asked to return to your doctor at regularly scheduled times. At about one month you will have a physical examination, blood pressures taken at your arms and ankles, blood drawn for testing (approximately 1½ tablespoonful), and a CT Scan which is a special x-ray that allows your doctor to see your blood vessels at close range. These same tests will be done at each follow-up interval: 1 month; 6 months; 1 year; and annually to 5 years. Your doctor may also perform other tests as he/she determines is necessary. After 5 years, you will no longer participate in this study; however, your doctor will schedule follow-up visits per the standard of care for patients with endovascular stent grafts.

7. **Who should I contact if I have any queries or concerns regarding my rights as a participant in this study?** You may call <INSERT PI NAME> at <INSERT PI NUMBER> or you can contact the Institutional Review Board at the following address:
<INSERT IRB ADDRESS AND PHONE NUMBER>

BENEFITS, RISKS, AND SAFETY

1. **Potential Benefits of the Study:** There may or may not be direct benefits to you from this research. The potential benefits for participating in this research may be that you may have fewer complications, spend less time in the hospital and recover from the procedure faster than if you had a standard surgical repair of your blood vessel. Furthermore, you will be contributing to the advancement of this technique, which may prove beneficial to you and to future patients. However, no benefit from your participation in this study can be guaranteed.

2. **Risks and/or Inconveniences of the Study:** The frequency of potential complications or risks associated with aortic abdominal aneurysm repair is listed below. These risks or complications may be due to the Endologix devices, the surgical procedure or any pre-existing conditions that you have.

Possible	• Additional procedure to fix aneurysm endoleak or aneurysm enlargement • Bleeding at site of catheter entry in the leg artery at the groin	• Hematoma (clotted blood) at the groin incision site • Post-procedure bleeding at the groin incision site
Less likely	• Allergic reaction, which may be severe • Blood transfusion • Contrast dye reaction • Hemorrhage (excessive bleeding) • Infection • Lymphatic complications (swelling, fluid drainage problems)	• Injury to vessel wall (vessel dissection, vessel perforation or vessel tear) • Stent occlusion (blockage or closure of the stent) • Symptomatic angina (chest pains) • Symptomatic arrhythmia (irregular heart beat)
Rare	• Adynamic Ileus (inability to tolerate oral intake of food) • Anesthesia complications • Aortoenteric fistula (leak between aneurysm and bowel) • Arteriovenous fistula (abnormal connection between an artery and a vein) • Bowel ischemia (poor blood flow to the bowels) • Cardiac arrest • Catheter breakage • Coagulopathy (problems with blood clotting factors)	• Congestive heart failure (weakening of heart muscle) • Conversion to Open Surgical Repair • Coronary Intervention • Death • Edema (swelling) • Emboli (creating new clots downstream of treated area) • Failure to deliver stent graft • Infection requiring intravenous antibiotics • Fever • Gangrene/amputation • Hypotension (low blood pressure) • Impotence (unable to obtain erection)

Rare (cont'd)	• Incontinence (unable to control urination) • Urinary retention (unable to urinate) • Kidney failure • Liver failure • Lower extremity ischemia / claudication (poor blood flow to the legs/cramping or pain in the legs) • Myocardial Infarction (heart attack) • Narrowing of the blood vessel (occlusion) • Nerve injury/damage • Paraplegia (paralysis of the legs) • Partial rupture (pseudoaneurysm) • Pulmonary (lung, breathing) complications • Re-stenosis (re-narrowing of blood vessel)	• Recurrence of portal hypertension (high blood pressure in the liver veins, a liver ailment caused by cirrhosis) in patients who have a history of this condition • Temporary narrowing of the blood vessel (spasm) • Stroke/transient ischemic attack • Respiratory failure (failure of the lungs or breathing) • Rupture (bleeding from aneurysm) • Stent deformity (abnormality) • Stent migration (movement) • Stent thrombosis (blood clot)

Radiation

The risks specific to participating in this clinical study may include, but may not be limited to complications associated with radiation exposure from the x-rays. However, care will be taken to minimize your exposure to the x-rays and the special dye. The follow-up testing has been chosen to decrease the amount of unnecessary exposure to x-rays but at the same time ensure that complete information about how you are progressing is collected. One of the risks associated with radiation exposure is cancer. The natural incidence of fatal cancer in the U.S. is about 1 chance in 5. Everyday radiation exposure from natural occurring background radiation (sun, radon exposure in the home) is approximately 3 mSv per year. CT scans and the stent graft delivery use x-rays as part of the standard of care. In this research study, you will receive a very small amount of extra radiation and extra angiography that might increase your risk of cancer by a very small amount.

Unforeseeable Risks

There may be risks or side effects related to the study device system that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

Most complications can be treated with medication, or conversion to an open surgical repair which will be available as standby at your physician's discretion. The complications could also result in serious injury or death. You understand that a serious complication or injury may require the graft to be removed. In the event of death, you understand that the graft may be removed for analysis. If the graft is removed for any reason, it will be sent to an independent laboratory for analysis. This will provide important information regarding the

performance of the graft in treating patients with your condition. Your decision of not authorizing the removal of the graft for evaluation will not affect your participation in the study.

Additional procedures may be performed at a later follow-up if there are issues noted with the device (for example, blood leaking back into the aneurysm sac known as endoleak). In this case, an additional graft or stent may be placed to correct the leak and stabilize your implanted device. These types of procedures may require hospitalization and overnight monitoring of your condition. You will be on blood thinning medication. Patients on blood thinning medication have been known to have a higher incidence of bleeding complications, such as ulcers, or strokes, both of which can be fatal. Blood thinning medications also increase the risk of bleeding at the site (groin area) where instruments are inserted into the arteries.

All these potential risks are treatable, and if treated timely, your life should not be at risk. Your doctor will discuss with you all the signs and symptoms so that you pay attention to them. If you experience any of the signs and symptoms discussed with your doctor, call him immediately and he will tell you if you should go to a hospital for any treatment.

There may be other device-related problems that are not known yet. If during the study new information becomes available about other problems, every effort will be made to inform you immediately.

3. **Medication:** You may currently be on blood thinning medication. Patients on blood thinning medication have been known to have a higher incidence of bleeding complications, such as ulcers or strokes, both of which can be fatal. Blood thinning medications also increase the risk of bleeding at the site (groin area) where instruments are inserted into the arteries. Your doctor will discuss with you all the necessary medications. If you experience any problems or symptoms, call your doctor immediately.

4. **Cost / Reimbursement:** You or your insurance provider will be responsible for the routine tests and services related to your medical care. These routine tests and services would normally be performed even if you don't participate in the study. You or your third-party payer (such as your insurance carrier) will be responsible for the cost of care associated with your participation in the research study, including the cost of the Study Device and all visits and procedures. You will be responsible for any co-pays and deductibles. You will not be compensated for taking part in this research study, nor will you receive any form of reimbursement for your participation.

   The Sponsor, Endologix, Inc., will be paying the doctors, institution, and clinical study staff for their work related to this study.

5. **Alternatives:** Your participation in this Study is optional. It is understood that open surgical repair of the aneurysm may be one option for patients with a condition like yours. While classical resection and graft placement techniques demonstrate low complications and less chance of death in experienced surgical hands, this procedure may require longer hospital stays and recovery times. Conversion to an open surgical repair may be required if device placement is unsuccessful or if certain complications occur.

GENERAL QUESTIONS

1. **What will happen at the end of the study?** The study results will be submitted for product approval to the United States Food and Drug Administration and to the governing agency of other countries. You can visit the Sponsor's website to request a copy of the final report after it has been published. It is common practice to see the doctor at one month following any procedures such as this. Additional follow-up will be required at six months, one year after implant and annually through 5 years after implant. The tests that were performed at one month after implant will also be performed at the additional follow-up visits. After you complete the study, you will be followed by your doctor annually per standard of care for endovascular grafts.

2. **Where can I get more information about the study?** You can obtain more information about the study by contacting the principal investigator on this trial by contacting the principal investigator at <INSERT PI NAME, ADDRESS AND PHONE NUMBER>.

CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA

All the information collected in this study will be Confidential. The results of the study may be disclosed to contribute to future scientific research and for general scientific purposes subject to the applicable laws and regulations. The information collected in this study (which will not have any data that can identify you) will be disclosed to the study sponsor and affiliated organizations (i.e. core lab) and may be reported to other countries and their respective regulatory agencies. Any information obtained as a result of your participation in this research will be kept as confidential as legally possible. A copy of your signed Informed Consent form and the study data will be part of your permanent medical record, and will be subject to its confidentiality policies. Nevertheless, national laws require that your privacy, security, and unauthorized access to your health information be protected.

You agree to permit ***<insert institution name>***, its agents and subcontractors, your doctors, and your other health care providers (together "Providers"), and ***<insert name>***, MD ("Principal Investigator") and staff to use and disclose health information about you as described below.

1. The health information that may be used and disclosed includes:
    - All information collected during the research described in the Informed Consent Form for this study;
    - Information that can identify you, including, but not limited to your initials, name, age;
    - Health information in your medical records that is relevant to the Research, including, but not limited to the following: a) your entire medical chart; b) health information from other doctors offices or clinics where you have been seen; c) reports from your laboratory or other tests or x-rays; d) your medical history; e) the physical exam done by the study doctor; f) reports from other procedures
2. The Providers may disclose health information in your medical records to:
    - The Researchers;

- The sponsor of the Research, Endologix Inc., and its agents, contractors, designees ("Sponsor"), and third party data administrators; and,
- Representatives of government agencies including the Department of Health and Human Services, the US Food and Drug Administration (FDA), the governing Institutional Review Board (IRB), its agents and subcontractors and other persons who watch over the safety, effectiveness, and conduct of research.

3. The Researchers may use and share your health information:

   - Among themselves and with other participating researchers to conduct the Research;
   - As permitted by the full Informed Consent Form; and,
   - With Endologix Inc., (the Sponsor), its agents, and subcontractors,
   - Representatives of government agencies, including the Department of Health and Human Services, the US Food and Drug Administration (FDA), the governing Institutional Review Board (IRB), its agents and subcontractors; and,
   - With your Providers.

4. Once your health information has been disclosed to a third party by any of the parties above, it may be further disclosed under federal privacy laws and ***<insert institution name>*** and other providers can not promise your privacy will always be protected. Federal privacy laws may no longer protect it from further disclosure.

5. You acknowledge that:

   - You do not have to sign this Authorization, but if you do not, you will not be permitted to participate in the Research.
   - You may change your mind and revoke (take back or withdraw) this Authorization at any time and for any reason. However, if you revoke this Authorization, you will not be allowed to continue taking part in the Research, but you will still be able to continue to receive medical care from your doctor. Also, even if you revoke this Authorization, the Providers, Researchers and Sponsor and other parties above may continue to use and disclose the information they previously collected as permitted by the Informed Consent Form. Health information that has already been sent to the Sponsor cannot be taken back.
   - To maintain the integrity of this research study, you generally will not have access to your health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that is maintained in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at ***<insert institution name>*** to make decisions about individuals.
   - If all information that does or can identify you is removed from my health information, the remaining information will no longer be subject to this Authorization and may be used or disclosed for other purposes.
   - Your health information will be used or disclosed when required by law.
   - If you have questions about the use of your information, you can call ***<insert name>***, MD at (xxx) xxx-xxxx (Principal Investigator phone number).

6. This Authorization does not have an expiration (ending) date.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this clinical research study is completely voluntary and you have the right to revoke this authorization at any time. Should you decide not to participate in the study, you will continue to receive the best possible treatment from your doctor. You may withdraw from the study at any time. Your decision will not affect your future medical care and treatment.

Your doctor may stop your participation in the study should he or she determines that this study is not in your best medical interest. You or your legal representative will be told if any new information is learned that may influence your willingness to continue participation in this study.

If you have any questions or concerns regarding this clinical research you can contact the Principal Investigator who is responsible for this study at <INSERT PI NAME AND PHONE NUMBER>

You can discuss your questions and/or concerns regarding your privacy with a member of the hospital's Institutional Review Board, who has read and approved the Study Protocol. This committee is independent and made up of local community representatives and hospital staff members. You should not sign this form unless all your questions have been answered to your satisfaction.

If the study design or information change, or there are important findings pertaining to this study that may affect your predisposition to take part in it, you will be informed immediately and you will be requested to give another consent.

SOURCE OF FUNDING FOR THIS STUDY

The study doctor and institution are being paid by Endologix, Inc. to conduct this research.
Please feel free to contact the researcher if you have any questions about this study

CONSENT TO TAKE PART IN THIS TRIAL

Patient Acknowledgment:

By signing this Informed and Voluntary Consent Form, I acknowledge that I have read the aforementioned trial-related information. I authorize the disclosure of my medical records to the Sponsor and the Institutional Review Board.

The purpose of this clinical research, the procedures, the risks and benefits and my rights have been explained to me, It was also explained that I can withdraw from the study at any moment.

I sign this Informed and Voluntary Consent Form voluntarily. I am not being coerced by anyone to sign this consent. I understand that I a*m not waiving any of my legal rights.*

Any important findings regarding the study device pertaining to this trial that may affect my health or well being will be told to me immediately.

I am receiving a signed copy of the present Inform Consent Form.

I agree to work together with the doctor and his team and also to participate in all the follow-up visits, as detailed in the information I received.

Participant's (or representative) full name

_____ _____

Participant's (or representative) signature **Date**

Certification:

I have talked with the subject or his/her legal representative about the clinical trial and the Endologix Fenestrated Stent Graft System. I have answered all his/her questions. I strongly believe that the subject (or his/her legal representative) understands the information contained in this document and gives his/her consent to take part in this clinical trial.

Full name of the authorized person explaining the Informed and Voluntary Consent Form

_____ _____

Signature of the person explaining form **Date**