TranS1 Incorporated, Wilmington, North Carolina, United States
PR-0018
20101715

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	Prospective, Multicenter Clinical Study Comparing Axial Lumbar Interbody Fusion (AxiaLIF®) and Transforaminal Lumbar Interbody Fusion (TLIF) Spinal Procedures

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

 Subject Initials: _____

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Prospective, Randomized, Multicenter Clinical Study Comparing Axial Lumbar Interbody Fusion (AxiaLIF®) and Transforaminal Lumbar Interbody Fusion (TLIF) Spinal Procedures

PROTOCOL NO.: PR-0018

SPONSOR:
TranS1 Incorporated
Wilmington, North Carolina
United States

INVESTIGATOR:
Kevin McCarthy, M.D.
3rd Floor
7301 Hennessey Boulevard
Baton Rouge, Louisiana 70808
United States

SITE(S):
Bone and Joint Clinic of Baton Rouge
3rd Floor
7301 Hennessey Boulevard
Baton Rouge, Louisiana 70808
United States

Baton Rouge General Medical Center
8585 Picardy Avenue
Baton Rouge, Louisiana 70809
United States

Our Lady of the Lake Regional Medical Center
5000 Hennessy Boulevard
Baton Rouge, Louisiana 70808
United States

The NeuroMedical Center Surgical Hospital
10105 Park Rowe Circle
Baton Rouge, Louisiana 70810
United States

STUDY-RELATED PHONE NUMBER(S):
Kevin McCarthy, M.D.
225-766-0050
225-346-4290 (24 Hours)

Adaire O'Brien
225-766-0050, ext. 5096

Subject Initials: _____

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

A person who takes part in a research study is called a *research* or *study subject*.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this consent form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form
- Having the study doctor or staff explain the research study to you
- Asking questions about anything that you do not understand, and
- Taking home an unsigned copy of this consent form if you would like to. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things that may help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve *standard medical care*. Standard medical care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at, and/or copied, by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for all procedures that are part of a research study.

After reading and discussing the information in this consent form, you should know:

- Why this research study is being done;
- What will happen during the research;
- What device(s) and procedures will be used;
- Any possible benefits to you;
- The possible risks to you;
- The other medical procedures, drugs or devices that could be used instead of being in this research study; and
- How problems will be treated during the study and after the study is over, if there are any problems.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at anytime.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

STUDY PURPOSE
You are being invited to participate in this research study because you need surgery to fuse the bones in your lower back, or spine. The purpose of this study is to compare two surgical options that fuse the spine: AxiaLIF® (axial lumbar interbody fusion) and TLIF (transforaminal lumbar interbody fusion). By comparing the two surgical options, AxiaLIF® and TLIF, we aim to prove that the safety and usefulness of both surgical procedures are similar to each other.

Both AxiaLIF® and TLIF have been cleared for use in the United States by the Food and Drug Administration (FDA) and will be used according to approved guidelines. This means that both AxiaLIF® and TLIF are already available to patients on the commercial market, and neither procedure is considered experimental.

If you are eligible and you decide to participate in this study, you will be in the study for about 24 months. There will be about 200 subjects from approximately 15 clinic sites in the United States in this study.

STUDY PROCEDURES
If you participate in this research study, you will be asked to take part in some or all of the tests/procedures listed below. All of the procedures listed below are considered standard of care for receiving a spinal fusion, and are not experimental (investigational).

If you are interested in participating in this study, your study doctor will decide if you meet all the requirements necessary to enter the study.

Informed Consent Form
Before you are examined to determine whether you meet all the requirements, someone at the clinic will explain the purpose of this research study to you, and provide this consent form for you to read. If you understand this consent form, and agree to participate in this research study, you will be asked to sign it. Your review and signing of this consent form will take place at the first visit, also called the *Screening visit*.

Visit 1 (Screening/Pre-Operative Visit)

There are a total of 8 clinic visits in this study. A Screening visit will be performed to determine if you meet the requirements to participate in this study. During this visit, the study doctor or designated clinic personnel will complete the following procedures:

- Explain the purpose of this research study and, if you are willing to participate in this study, ask you to read and sign this research subject information and consent form.
- Ask you to complete health questionnaires about back and leg pain and quality of life.
- Ask you about any medication or therapy you are using, and your medical histories; including history about your back condition(s).
- Perform a physical examination, to make sure that you do not have any physical or medical problems that would prevent you from safely participating in this study. This examination will also evaluate the different possible causes of your back pain.
- Perform a neurological (nervous system) examination involving simple tests and questions.
- Collect x-rays and magnetic resonance imaging (MRI - use of a magnetic field to produce an image) of your lower back.

At some point during the Screening visit, it may be determined that you are not qualified to continue into the study. If you are not able to continue in the study, the reason will be explained to you.

If you are qualified to continue in the study, you will be randomly assigned to receive one of the two study operations, and will return for Visit 2 (Operative Visit). Random assignment means that you will be assigned to one of the two surgery groups by chance, similar to tossing a coin. If you choose to participate in this study, you will be randomly assigned to receive either the AxiaLIF® surgical procedure, or the TLIF surgical procedure. You have a 50% chance of receiving the AxiaLIF® procedure and a 50% chance of receiving the TLIF procedure.

Visit 2 (Operative Visit)
During Visit 2, your ability to continue in the study will be determined. If it is determined that you are no longer able to continue in the study, you will be informed of the reason, and your participation will end. If you meet all the study criteria and qualify to continue participation in this study, you will receive one of the following study surgeries listed below (as was determined at the Screening visit by you and your study doctor together):

- AxiaLIF® Spinal Fusion Procedure (surgery with implantable device).
- TLIF Spinal Fusion Procedure (surgery with implantable device).

You will also be asked about any medical problems or complaints, and any new medications or therapies you are taking.

Visit 3 (Hospital Discharge)
During Visit 3 the following procedures will be completed:

- Collect x-rays of your lower back;
- You will be asked to complete health questionnaires about back and leg pain and quality of life;
- You will be asked about any medical problems or complaints, and any new medications or therapies you are taking.
- Perform a neurological (nervous system) examination involving simple tests and questions.

Visits 4, 5, 6, & 7
At Visits 4, 5, 6, and 7, the following procedures will be done:

- You will be asked to complete health questionnaires about back and leg pain and quality of life.

- Collect x-rays of your lower back;
- You will be asked about any medical problems or complaints, and any new medications or therapies you are taking.
- Perform both a physical and neurological (nervous system) examination involving simple tests and questions.

Visit 8 (End of Study Visit)
At Visit 8, the following will procedures will be done:

- You will be asked to complete health questionnaires about back and leg pain and quality of life.
- Computed Tomography (CT – test that produces a picture of your body using radiation) scans will be taken of your lower back.
- You will be asked about any medical problems or complaints, and any new medications or therapies you are taking.
- Perform both a physical and neurological (nervous system) examination involving simple tests and questions.

This will be your final visit in the study.

Unscheduled Visits (when required)
If you or your study doctor feel it is necessary, you may be asked to come in for an unscheduled or unplanned visit. One or more of the following procedures may be done:

- You will be asked to complete health questionnaires about back and leg pain and quality of life.
- X-rays and/or computed tomography (CT) scans will be taken of your lower back.

- You will be asked about any medical problems or complaints, and any new medications or therapies you are taking.
- Perform both a physical and neurological (nervous system) examination involving simple tests and questions.

Subject Responsibilities

As a subject in a research study, you have certain responsibilities. Your responsibilities are to:

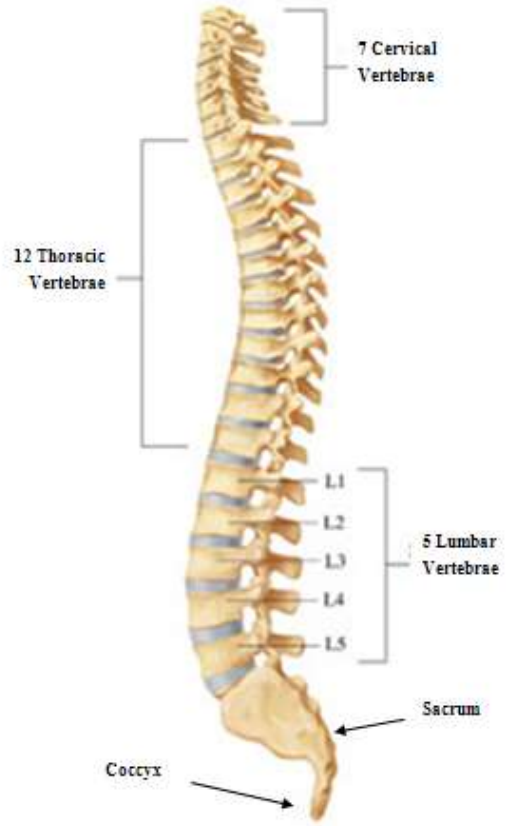
- Return for scheduled visits and procedures.
- Follow procedures as instructed by research staff.
- Complete all study questionnaires as directed.
- Report all changes in your physical or mental condition to research staff during the course of the study, whether or not you feel they are related to the study operations or procedures.
- <u>You have the responsibility to tell your study doctor immediately if you have:</u>
    - Any side effect
    - Any injury, and/or
    - Any symptom or complaint.

      Bone and Joint Clinic of Baton Rouge
      Kevin McCarthy, M.D.
      225-766-0050 or 225-346-4290 (24 Hours)

Surgical Procedures

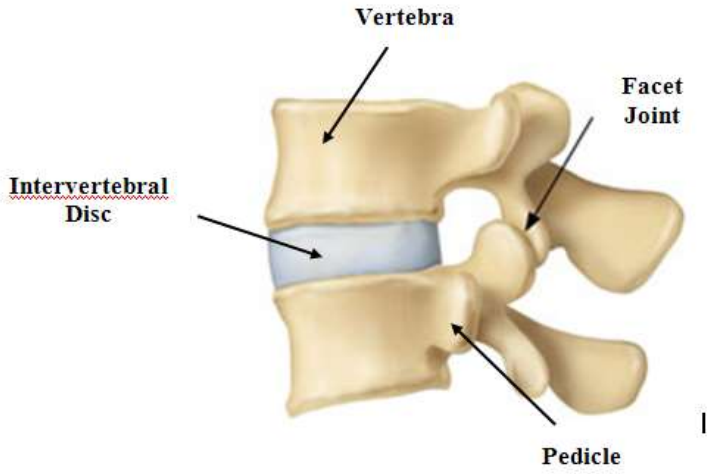
Spine Anatomy

Spinal Column



Vertebra (Spine Bone) and Disc

Please refer to these pictures as the spine fusion procedures are reviewed below. This will help give you an idea about what part of your back and spine will be affected during each type of surgery.



AxiaLIF® Surgery

AxiaLIF® (axial lumbar interbody fusion) is a surgical procedure where the doctor places a small tube under the tailbone (coccyx) and into the unhealthy area of your lower back. Then, a metal rod will be placed in to the unhealthy area to stabilize the spine bones, also called vertebrae. If you consent to the study and are randomized to receive AxiaLIF®, you will be instructed on how to prepare for the surgery. You will be asked to fast the day before the procedure, and you will be instructed by your surgeon to drink a mixture that will help cleanse your bowel. This is to make the surgery easier and lessen the risk of infection.

You will be positioned on your stomach and the area around your tailbone will be thoroughly cleaned. The procedure will be performed under general anesthesia. The tube will be placed by making a small slit next to your tailbone. The surgeon will then use an x-ray machine to view the unhealthy area of your spine. The center of the diseased disc will be removed, and bone graft material will be put in its place. This material will help new bone to grow over time in order to "fuse" the vertebrae, or spine bones. Bone graft material can be taken from bone or bone

marrow from other healthy areas of your body, or can come from an outside source. Your study doctor will be able to tell you what he/she plans to use for your surgery. The potential risks of this part of procedure are outlined below in the section titled "Risks and Discomforts."

The AxiaLIF® rod is then inserted in between the two vertebrae. If any height was lost between the vertebrae when the spine was unhealthy, the AxiaLIF rod may be used to help restore this height. After completing the AxiaLIF® procedure, your surgeon will add pedicle screws, a type of screw that will help further stabilize your spine. Your surgeon will then close the slit by your tailbone, which usually leaves behind only a small scar or scars.

TLIF Surgery

TLIF (transforaminal lumbar interbody fusion) is a type of spine surgery where the doctor approaches the lower spine through a small opening in the back. If you consent to the study and are randomized to receive TLIF, you will be instructed on how to prepare for the surgery.

If you receive the TLIF procedure, you will be positioned on your stomach. The surgeon will then use an X-ray machine to view the unhealthy area of your spine, and make a small incision in your back over the vertebra(e) to be treated. Surgical instruments are used to gently move the skin, muscles, and soft tissues to the side so the surgeon can reach the spine. A tube-like instrument, called a tubular retractor, is placed through the slit in the skin so the surgeon can reach the effected part of the lower spine. The unhealthy bone is removed, and a metal or plastic cage, or spacer, is then placed in between the discs to widen the space between them. This means that any height lost between the vertebrae when the spine was unhealthy can be restored to the original, healthy disc height. Bone graft material is then put inside and around the spacer. This material can be taken from bone or bone marrow from other healthy areas of your body, or can come from an outside source. Your study doctor will be able to tell you what he/she plans to use for your surgery and the potential risks of this part of procedure are outlined below in the section titled "Risks and Discomforts."

The surgeon will then place pedicle screws on either side of the spine. This is a type of screw that will help further stabilize your spine. After the surgical procedure has been completed, the surgeon will close the opening in your back, which usually leaves behind only a small scar or scars.

RISKS AND DISCOMFORTS

The possible risks to subjects receiving an AxiaLIF® or TLIF surgical procedure are similar to those that can result from receiving any other spinal fusion procedure. The possible negative effects may include, but are not limited to:

- Bleeding (including hidden internal bleeding during and after surgery).
- Fracture or crack in the sacrum (the lowest part of the spine).
- Damage to the nerves or soft tissue.
- Pressure on, or damage to the spinal cord.
- Puncture of, or damage to the bowel.
- Injury to veins or arteries.

- Loss of bowel or bladder function.
- Loss of erectile or ejaculatory function.
- Meningitis (swelling of the area around the brain and/or spinal cord, usually due to an infection).
- Infection.
- Pain.

AxiaLIF® device

The possible risks associated with the AxiaLIF® device include, but are not limited to:

- Breaking of the device.
- Loosening of, or movement of, the device from the location the surgeon placed it in. This can possibly cause delayed pressure on the nerve roots, or damage to the nerve roots.
- Fractures or cracks in the surrounding spinal bones.
- Bursitis (swelling of the one of the small sacs of fluid surrounding joints).
- Pain, discomfort or abnormal feelings due to the presence of the device.
- Bowel injury.

Bone graft

There may be risks associated with collecting bone graft (pieces of bone) from the patient's own bone structure(s). The following risks are problems that could occur at the donor bone site (the bone structure that the surgeon may remove bone from):

- Pain at the donor site.
- Infection.
- Herniation (bone moving out of place; moving abnormally).
- Fracture or splitting.
- Non-union or delay in the growing together (fusion) of bone.

TLIF device

The possible risks associated with the TLIF device(s) include, but are not limited to:

- Breaking of the device(s).
- Loosening of, or movement of, the device(s) from the location the surgeon placed it in. This can possibly cause delayed pressure on the nerve roots, or damage the nerve roots.
- Fracture or cracks in the surrounding spinal bones.
- Bursitis (swelling of the one of the small sacs of fluid surrounding joints).
- Pain, discomfort or abnormal feelings due to the presence of the device(s).

Anesthesia Risks

There are potential negative effects associated with receiving general anesthesia:

- Negative reaction to anesthesia (headache, muscle pain, nausea).
- Myocardial infarction (heart attack).
- Cardiac arrest (stopping of the heart).
- Hypoxemia (lowered oxygen levels in blood).
- Anaphylaxis (difficulty breathing).
- Hypotension (lowered blood pressure).

Subject Initials: _____

- Thrombophlebitis (inflammation of the veins, related to a blood clot).
- Pulmonary embolism (blood clot in the lungs).
- Respiratory distress (difficulty breathing).
- Pneumonia.
- Fever.
- Death.

CT Scan, MRI and x-rays risks
Procedures such as CT Scans, MRIs, and x-rays will be used during this research study to see how you are healing after surgery. The total radiation exposure from these tests is considered small and is not likely to negatively affect you or your back condition.

The contact with radiation in this study is thought to be small. However, the effects of radiation can add up over a lifetime. It is possible that having several of these tests may add to your general risk of injury or disease. When deciding whether to enter this study, think about your past and future contact with radiation. Examples of contact with radiation include x-rays taken for any reason or radiation therapy for cancer treatment.

Pregnancy
The surgical options used in this study may be unsafe for an unborn baby, a nursing infant, sperm or eggs. Therefore, women who participate in this study must agree to avoid becoming pregnant and men who participate in this study must agree to avoid fathering a child, throughout the study and for up to four weeks after the study. If you are a woman of childbearing potential, you will be given a pregnancy test before beginning this study. During this study, if you suspect that you have become pregnant, you must notify the study doctor immediately.

Abstinence is not listed as a method of pregnancy prevention by the Sponsor, per the protocol. Our Lady of the Lake Regional Medical Center is a Roman Catholic Healthcare institution, whose religious tenets do not endorse methods of pregnancy prevention other than abstinence. Becoming pregnant during this research study could significantly harm your baby and yourself. Only abstinence is 100% effective in preventing pregnancy. If you are a woman who is able to become pregnant, the study doctor will discuss medically acceptable methods of pregnancy prevention with you. You must discuss with the study doctor whether abstinence is or is not an acceptable method of pregnancy prevention. You should also discuss methods of pregnancy prevention with your regular/primary care doctor before deciding to participate or not participate in the study. The study doctor cannot serve as your attending physician for this purpose because doing so puts him or her into a professional conflict of interest. Additionally, the study doctor may not write prescriptions for, or otherwise in any way provide you with, means of artificial pregnancy prevention.

Other Risks
As noted above, these possible negative effects are similar to those you might face if you had a different type of spinal fusion procedure. Nevertheless, as with any procedure, unexpected issues could result which cannot be corrected and which could be permanent, or require additional surgery for correction. You should carefully consider the risks before agreeing to participate in the study. We encourage you to discuss these risks with your study doctor. There

may be side effects that are not known at this time. Please keep in mind that your condition may not get better, or may get worse during this study.

NEW INFORMATION
If any information regarding the study design changes, you will be told about these changes in case it might change your decision to be in this study. You may be asked to sign a new consent form if new information arises that impacts the study.

EXPECTED BENEFITS
Your back condition may improve while you are in this study, however, this is not for certain. The results of this study may help people with back problems similar to yours, and you may have an operation that takes less time, a faster recovery or improved outcome compared to continued conservative care therapies, other spinal fusion procedures or disc replacement techniques.

COSTS TO SUBJECTS
Procedures that are done only for the study, such as extra x-rays or CT scans, will not be billed to you or your insurance company. You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay for certain procedures, you may be billed for those charges.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor of this study. This discussion should include who will pay the costs of treating possible side effects that result from the study surgery.

PAYMENT FOR PARTICIPATION
You will be paid by the Sponsor as follows:

- $50 for completing the 1 Month Visit;
- $50 for completing the 3 Month Visit;
- $50 for completing the 6 Month Visit;
- $100 for completing the 12 Month Visit; and
- $100 for completing the 24 Month Visit.

Your compensation for completing the study will be a total of $350 if all study visits are completed.

If all study visits are not completed, you will be paid only for the visits that were attended.

ALTERNATIVE TREATMENTS
You may choose not to participate in this study. Your decision to participate or not participate in the study will in no way affect your current or future treatment by your physician. You may choose to receive alternative, possibly beneficial treatments such as continued conservative therapy (e.g., physical therapy, acupuncture, manipulation, bed rest, traction, injections into your spine, back bracing, electrotherapy, pharmaceuticals) or a surgical procedure to fuse your vertebrae. You could also have either one of the study procedures done without participating in the study. The study doctor will discuss these treatment options with you. You do not have to be in this study to receive treatment for your back condition.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records.
- Research records.
- Records about phone calls made as part of this research.
- Records about your study visits.
- Information gathered for this research about:
  - Physical exams.
  - X-rays and other imaging.
  - Laboratory tests.
  - Questionnaires.
- Records about the study device(s).

Who may use and give out information about you?

The study doctor and the study staff.

Who might get this information?

The Sponsor of this research. "Sponsor" means any persons or companies that are:

- Working for or with the Sponsor, or
- Owned by the Sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA).
- Department of Health and Human Services (DHHS) agencies.
- Governmental agencies in other countries.
- Our Lady of the Lake Hospital, Inc.
- Western Institutional Review Board® (WIRB®).

Why will this information be used and/or given to others?

- To do the research,
- To study the results, and
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research study is over.

May I withdraw or revoke (cancel) my permission?

- You may withdraw, or take away your permission, to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.
- When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.
- Your authorization for use and disclosure of your medical record information will not expire.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

CONFIDENTIALITY
Study information collected about you will be given to the Sponsor. "Sponsor" means any persons or companies that are working for or with the Sponsor, or owned by the Sponsor.

It may also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study device(s) may be considered for approval. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by the Sponsor of this research. "Sponsor" means any persons or companies that are:

- Working for or with the Sponsor, or
- Owned by the Sponsor.

These may also be looked at and/or copied for research or regulatory purposes by:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries, and
- Western Institutional Review Board® (WIRB®).

Total confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be given out during those presentations.

COMPENSATION FOR INJURY
If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide necessary emergency medical treatment. You or your insurance will be billed for this treatment. The sponsor does not intend to pay for the treatment of any injuries resulting from your participation in this study. No other payment is routinely available from the study doctor or sponsor.

By signing this consent form, I have not given up any of my legal rights.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- If it is in your best interest;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- Or for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.

SOURCE OF FUNDING FOR THE STUDY

The Sponsor, TranS1®, Inc. will compensate the research institution for participating in this study.

QUESTIONS

If you have any questions concerning your participation in this study or if you have questions, concerns or complaints about the research, contact:

Adaire O'Brien at 225-766-0050, ext. 5096.

If at any time you feel you have experienced a research-related injury, contact:

Kevin McCarthy, M.D. at 225-766-0050 or 225-346-4290 (24 Hours).

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

Western Institutional Review Board® (WIRB®) is a group of people who independently review research.

Western Institutional Review Board® (WIRB®) will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB® if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent form for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name (printed)

CONSENT SIGNATURES AND DATES:

_____ _____
Signature of Subject (18 years and older) Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

_____AM or PM
Time of Consent *Circle one*

Subject Initials: _____

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

_____	_____
Printed Name of Person Conducting the Informed Consent Discussion	Position
_____	_____
Signature of Person Conducting the Informed Consent Discussion	Date

Subject Initials: _____