

BOICE-WILLIS CLINIC, PA

Patient Name: _____ DOB: _____ MRN: _____



Informed Consent **Sclerotherapy**

Patient Name: _____ DOB: _____ MRN: _____

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about sclerotherapy potential risks, as well as alternative treatment(s).

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page, and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

Sclerotherapy has been performed by plastic surgeons as a surgical instrument for many years. Sclerotherapy is a method of removing superficial veins and telangiectasias (spider veins) in which a solution, called a sclerosing agent, is injected into the vein. Conditions such as small varicosities, superficial veins, and spider veins may be treated with sclerotherapy. In some situations, laser treatments may be performed at the time of the sclerotherapy.

Skin treatment programs may be used both before and after sclerotherapy treatments in order to enhance the results.

ALTERNATIVE TREATMENTS

Alternative forms of treatment include not undergoing the proposed sclerotherapy procedure. Other forms of treatment, including laser ablation, intravascular or endovenous radiofrequency, or laser treatments, may be substituted for surgical varicose vein stripping. In certain situations, sclerotherapy may offer a specific therapeutic advantage over other forms of treatment. Alternatively, laser procedures in some situations may not represent a better alternative to other forms of treatment when indicated. Risks and potential complications are associated with alternative forms of treatment that involve lasers or surgical procedures.

INHERENT RISKS OF SCLEROTHERAPY

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand all relevant consequences of sclerotherapy.

SPECIFIC RISKS OF SCLEROTHERAPY

Color Change- Hyperpigmentation:

Sclerotherapy may potentially change the natural color of your skin. The most common change is hyperpigmentation or darkening of your skin. Chronic veins can deposit hemosiderin or iron into your skin that may not be obvious until your vein is ablated. These deposits can make your skin appear browner or darker in color once the overlying vein is gone. Bruising or ecchymosis can last on the order of several days to weeks after your procedure depending on the veins treated, but may occasionally persist for 6 months or longer following sclerotherapy. Hyperpigmentation usually resolves with time. Later treatments with lasers can be of benefit in improving areas of hyperpigmentation. Be sure to discuss the likely duration of bruising and skin discoloration with your plastic surgeon. There is a possibility of irregular color variations within the skin, including areas that are both lighter and darker

Damaged Skin:

Sclerosing solutions may cause skin loss. Most areas are usually small. Should this occur, wound care may be required to allow the area to heal. While unusual, large areas of tissue damage can occur from extravasations, arterial injection, etc. Should this occur, more definite procedures such as debridement and skin grafting could be required. Fortunately, major skin loss is very unusual with sclerotherapy.

Allergic Reactions:

A systemic or localized allergic reaction can occur from the injection of a sclerosing agent. Most allergic reactions are localized areas of urticaria that may be treated with medications or topical agents. Major allergic

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reactions can affect your lungs, heart, or kidneys and even cause death. Fortunately, severe allergic reactions with sclerosing solutions are very rare.

Telangiectatic Matting:

Sclerotherapy treatment of your veins may result in more areas of small veins appearing. This referred to as telangiectatic matting. These areas of new very small veins can usually be treated with either repeat sclerotherapy or laser ablation.

Superficial Thrombophlebitis:

Sclerotherapy results in occlusion of the superficial cutaneous veins. Infections of these veins can occur. The superficial infection of a cutaneous vein is referred to as superficial thrombophlebitis. Treatment can involve medications, local drainage, or surgical intervention to curtail and stop the infectious process. You could be left with scars if surgical treatment is required. Additional treatment may be necessary. Fortunately, superficial thrombophlebitis is very unusual with sclerotherapy.

GENERAL RISKS OF SURGERY

Healing Issues:

Certain medical conditions, dietary supplements, and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes resulting in the need for additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. There may also be a longer recovery due to the length of surgery and anesthesia. There are nerve endings that may become involved with healing. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active, producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early non-surgical intervention resolves this. It is important to discuss postsurgical pain with your surgeon.

Bleeding:

It is possible, though unusual, to experience a bleeding episode during or after surgery. Should postoperative bleeding occur, it may require emergency treatment to drain accumulated blood or you may require a blood transfusion, though such occurrences are rare. The collection of blood that can occur under your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time, usually in the first three weeks following injury to the operative area. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Your surgeon may provide medications after your surgery to prevent blood clots. Medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

Infection:

Infection, although uncommon, can occur after surgery. Should an infection occur, additional treatment, including antibiotics, hospitalization, or additional surgery, may be necessary. It is important to tell your surgeon of any other infections, such as a history of methicillin-resistant Staphylococcus aureus (MRSA) infections, an open wound, recent upper respiratory infection/pneumonia, ingrown toenail, insect bite, tooth abscess, or urinary tract infection. Infections in other parts of the body, may lead to an infection in the operated area. Postoperative infections often result in more extensive scarring and predispose to revision surgery.

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Ileus:

The return of bowel function following surgery is important. An ileus is a disruption in bowel function caused by the failure of peristalsis or hypomobility of your bowels/gut, resulting in a lack of defecation and, possibly, repeated vomiting. Anesthetics and medications like pain medications given to you at the time of surgery can contribute to the development of an ileus in the postoperative period. An ileus can result in abdominal distention, vomiting, inability to absorb oral medications, and possibly hospitalization. Repeated vomiting could result in an aspiration pneumonia and respiratory failure. It can be essential to have regular bowel function after your surgery.

Scarring:

All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, this surgery will result in long, prominent scars that are permanent. Abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is a possibility of visible marks in the skin from sutures. These scars may become raised, red, or discolored in the first few weeks/months, but usually settle down over time. However, some patients are prone to “hypertrophic” or “keloid” scars (i.e., prominent, raised, red scars that do not settle). Further treatments with medications and/or surgery may be required.

Firmness:

Excessive firmness can occur after sclerotherapy due to internal scarring. The occurrence of this is not predictable. Additional treatment, including surgery, may be necessary.

Skin Sensitivity:

Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after sclerotherapy. Usually this resolves during healing, but in rare situations, it may be chronic.

Damage to Deeper Structures:

There is the potential for injury to deeper structures, including nerves, blood vessels, lymphatics, muscles, heart, kidneys, and lungs, during sclerotherapy. The potential for this to occur varies according to the area being treated. Injury to deeper structures may be temporary or permanent.

Fat Necrosis:

Fatty tissue found deep in the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is a possibility of contour irregularities in the skin that may result from fat necrosis.

Shock:

In rare circumstances, your sclerotherapy procedure can cause severe allergic reaction. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If anaphylactic shock occurs, hospitalization and additional treatment would be necessary.

Pain:

You can experience pain during or after your sclerotherapy procedure. Persistent unresolved pain or burning can be a sign of extravasation of the sclerosing solution and impending tissue necrosis. Make sure to tell your surgeon if have persistent pain and burning after your sclerotherapy procedure. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

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Cardiac and Pulmonary Complications:

Pulmonary complications may occur secondarily to blood clots (pulmonary emboli), fat deposits (fat emboli), pneumonia, or damage to your lungs after sclerotherapy. Pulmonary emboli can be life-threatening or fatal, in some circumstances. Inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of swelling in your legs or blood clots that may contribute to this condition. Cardiac complications are a risk with any sclerotherapy procedure, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

Venous Thrombosis (Clot) and Sequelae:

Thrombosed veins, which resemble cords, occasionally develop in the area of sclerotherapy treatment and usually resolve without medical or surgical treatment. It is important to discuss with your surgeon any birth control pills you are taking. Certain high-estrogen pills may increase your risk of thrombosed veins. A personal history of bleeding and clotting problems may also increase your risk of thrombosed veins.

Allergic Reactions:

In rare cases, local allergies to tape, wraps, or sclerosing agents have been reported. Serious systemic reactions, including shock (anaphylaxis), may occur in response to drugs used during your procedure and prescription medicines. Allergic reactions may require additional treatment. It is important to notify your physician of any previous allergic reactions.

Drug Reactions:

Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important for you to inform your physician of any problems you have had with any medication or allergies to prescribed or over-the counter medications, as well as medications you now regularly take. Provide your surgeon with a list of medications and supplements you are currently taking.

Persistent Swelling (Lymphedema):

Persistent swelling can occur following surgery.

Unsatisfactory Result:

Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. The body is not symmetric and almost everyone has some degree of unevenness that may not be recognized in advance. The more realistic your expectations as to results, the better your results will appear to you. Some patients never achieve their desired goals or results, at no fault of the surgeon. You may be disappointed with the results of sclerotherapy. Asymmetry, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after sclerotherapy. It may be necessary to perform additional procedures or surgery to improve your results. Unsatisfactory results may NOT improve with each additional treatment.

ADDITIONAL ADVISORIES

Medications and Herbal Dietary Supplements:

There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with forming blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition, such as heart arrhythmia, heart stents, blood vessels with blockages, or blood clots, and are taking medications to thin your blood and prevent clotting such as Plavix®, Xarelto®, Coumadin®, Effient® or Pradaxa®, discuss management of these medications around the time of your sclerotherapy with your plastic surgeon. Your plastic surgeon may sometimes coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a medical condition, do not stop them without discussing it first with your plastic surgeon. Stopping these medications abruptly may result in a heart attack, stroke, or death. Be sure to check with your physician about any drug interactions that may exist with medications that you are already taking. If you have an adverse reaction, stop the drugs

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immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room.

When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions, and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Sun Exposure – Direct or Tanning Salon:

The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use of sunblock or clothing coverage.

Travel Plans:

Any surgery holds the risk of complications that may delay healing and your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame. Allow at least 10-14 days after surgery before traveling via airplane. Medications may be required should you have a long flight/trip to prevent DVT/PE in the immediate postoperative period.

Long-Term Results:

Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your surgery.

Female Patient Information:

It is important to inform your plastic surgeon if you use birth control pills or estrogen replacement, or if you suspect you may be pregnant. Many medications, including antibiotics, may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Intimate Relations After Sclerotherapy:

Sclerotherapy involves coagulating of blood vessels. Increased activity of any kind may open these vessels, leading to recurrence of your veins or telangiectasias. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for additional procedures or surgery. It is wise to refrain from intimate physical activities until your physician states it is safe.

Mental Health Disorders and Elective Surgery:

It is important that all patients seeking to undergo elective sclerotherapy have realistic expectations that focus on improvement, rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional sclerotherapy or laser treatments, and often are stressful. Please openly discuss with your surgeon, prior to sclerotherapy, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective sclerotherapy, effects on mental health cannot be accurately predicted.

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ADDITIONAL SURGERY NECESSARY (Re-Operations)

There are many variable conditions that may influence the long-term result of sclerotherapy. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary procedures and/or surgery may be necessary. Should complications occur, additional procedures or surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are associated with sclerotherapy. Other complications and risks can occur, but are less common. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single sclerotherapy procedure. You and your surgeon will discuss the options available should additional sclerotherapy be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology, and lab testing.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the treated areas are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity need to be restricted. Protective dressings should not be removed unless instructed by your plastic surgeon. Successful postoperative function depends on subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation, and the need for surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after sclerotherapy.

ATTESTATIONS:

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):

Patients who are currently smoking or use tobacco or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin loss and delayed healing and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing, and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of these types of complications. Please indicate your current status regarding these items below:

___ I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing surgical complications.

___ I am a smoker or use tobacco/nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

___ I have smoked and stopped approximately _____ ago. I understand I may still have the effects and therefore risks from smoking in my system if not enough time has lapsed.

___ I have been advised to stop smoking immediately and have been informed of the risks, benefits, expectations, and alternatives to my surgery if I continue smoking.

It is important to refrain from smoking at least ___ weeks before surgery and until your physician states it is safe to return, if desired. I acknowledge that I will inform my physician if I continue to smoke within this time frame, and understand that for my safety, the surgery, if possible, may be delayed.

Smoking may have such a negative effect on your surgery that a urine or blood test just before surgery may be done, which will prove the presence of nicotine. If positive, your surgery may be cancelled and your surgery, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking to your surgeon.

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Sleep Apnea/CPAP:

Individuals who have breathing disorders such as “obstructive sleep apnea” and who may rely upon CPAP devices (continuous positive airway pressure) or utilize nighttime oxygen are advised that they are at a substantive risk for respiratory arrest and death when they take narcotic pain medications following any procedure. This is an important consideration when evaluating the safety of surgical procedures in terms of very serious complications, including death, that relate to pre-existing medical conditions.

Please consider the following symptoms of sleep apnea:

- I am frequently tired upon waking and throughout the day
- I have trouble staying asleep at night
- I have been told that I snore or stop breathing during sleep
- I wake up throughout the night or constantly turn from side to side
- I have been told that my legs or arms jerk while I’m sleeping
- I make abrupt snorting noises during sleep
- I feel tired or fall asleep during the day

It is important for you to inform and discuss any of the above symptoms that you have experienced with your surgeon.

DVT/PE Risks and Advisory:

There is a risk of blood clots, deep vein thrombosis (DVT), and pulmonary embolus (PE) with every invasive procedure. It varies with the risk factors below. The higher the number of risk factors, the greater the risk and the more involved you must be in both understanding these risks and, when permitted by your physician, walking and moving your legs. There may also be leg stockings, squeezing active leg devices, and possibly medicines to help lower your risk.

There are many conditions that may increase or affect risks of clotting. Inform your doctor about any past or present history of any of the following:

- Past History of Blood Clots
- Family History of Blood Clots
- Birth Control Pills
- Hormone Stimulating Drugs
- Swollen Legs
- History of Cancer
- Large Dose Vitamins
- Varicose Veins
- Past Illnesses of the Heart, Liver, Lung, or Gastrointestinal Tract.
- History of Multiple Spontaneous Abortions or Miscarriages

I understand the risks relating to DVT/PE and how important it is to comply with therapy as discussed with my surgeon. The methods of preventative therapy include:

- Early ambulation when allowed
- Compression devices (SCD/ICD)
- Anticoagulation Protocols when Allowed

For high-risk patients, the risks of VTE are still high, even in the setting of appropriate chemoprophylaxis. If your sclerotherapy is elective and you’re a high-risk patient, it’s best to consider not proceeding with such elective sclerotherapy.

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COMMUNICATION ACKNOWLEDGEMENT – CONSENT

There are many ways to communicate with you. It is important to keep appointments and let us know if problems or issues arise. Methods of communicating are by telephone, text, pager, answering service if available, email, and regular mail. If an emergency arises, keep us alerted to your progress so we may aid in any necessary treatments. Please do not leave a message after hours or on weekends on the office answering machine if any urgent or emergent situation exists, as there is a delay in retrieving such messages. All attempts will be made to preserve your privacy in accordance with HIPAA rules.

Please confirm below all acceptable ways of communicating with you:

____ Telephone

____ Home (- -)
____ Work (- -)
____ Cell (- -)

____ Text

____ Pager – Answering Service if available

____ Email – with up to date email address (_____ @ _____)

____ Regular Mail and Delivery

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including a decision not to proceed with surgery. This document is based on a thorough evaluation of scientific literature and relevant clinical practices to describe a range of generally acceptable risks and alternative forms of management of a particular disease or condition. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information that is based on all the facts in your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

This form is for reference purposes only. It is a general guideline and not a statement of standard of care. Rather, this form should be edited and amended to reflect policy requirements of your practice site(s), CMS and Joint Commission requirements, if applicable, and legal requirements of your individual states. The ASPS does not certify that this form, or any modified version of this form, meets the requirements to obtain informed consent for this particular procedure in the jurisdiction of your practice.



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CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Karen Szymanski, DO, MPT and such assistants as may be selected to perform **Sclerotherapy**.

I have received the following information sheet: **Sclerotherapy**.

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are, in the exercise of his or her professional judgment, necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or specific, about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices, or body parts that may be removed.
8. I am aware that there are potential significant risks to my health with the utilization of blood products, and I consent to their utilization should they be deemed necessary by my surgeon and/or his/her appointees.
9. I authorize the release of my social security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. I realize that not having the operation is an option. I opt out of having this procedure _____.
12. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12).
I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date/Time _____ Witness _____