

BOICE-WILLIS CLINIC, PA

Patient Name: _____ DOB: _____ MRN: _____



Informed Consent Otoplasty Surgery

Patient Name: _____ DOB: _____ MRN: _____

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you about otoplasty surgery, its 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

Otoplasty is a surgical process to reshape the ear. A variety of different techniques and approaches may be used to reshape congenital prominence in the ears or to restore damaged ears. Each individual seeking otoplasty is unique, both in terms of the appearance of their ears and the expectations for results following otoplasty surgery. It is important that you fully discuss your expectations with your plastic surgeon prior to surgery.

ALTERNATIVE TREATMENTS

Otoplasty is usually an elective surgical operation. Alternative forms of management consist of not undergoing the otoplasty operation.

INHERENT RISKS OF OTOPLASTY SURGERY

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 risks with potential benefits. 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 possible consequences of otoplasty surgery.

SPECIFIC RISKS OF OTOPLASTY SURGERY

Ear Trauma:

Physical injury after the otoplasty procedure could disrupt the results of surgery. Care must be given to protect the ear(s) from injury during the healing process. Additional surgery may be necessary to correct damage.

Asymmetry:

The human face is normally asymmetric. There can be normal differences between ears in terms of shape and size. There can be variations from one side to the other in the results obtained from an otoplasty procedure. Additional surgery may be necessary to correct postoperative asymmetry.

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. Patients with significant skin laxity (patients seeking facelifts, breast lifts, abdominoplasty, and body lifts) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and the recurrence of skin looseness will occur at some time in the future, more quickly for some patients than others. There are nerve endings that may become involved with healing scars from surgeries such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, small nerve endings may become too active during the healing period producing a painful or oversensitive area due to the small sensory nerves

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involved with scar tissue. Often, massage and early nonsurgical intervention resolve 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 under your skin that can occur 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. Nonprescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Hematomas can occur at any time, usually in the first three weeks following injury to the operative area. You could require a blood transfusion. 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 the patient to revision surgery.

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 by 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 aspiration pneumonia and respiratory failure. It is essential to have regular bowel function after your surgery.

Scarring:

All surgeries leave 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 a 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, which are prominent, raised, red scars that do not settle. Further treatments with medications and/or surgery may be required.

Firmness:

Excessive firmness can occur after surgery 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 high or low temperatures may occur after surgery. Usually this resolves during healing, but in rare situations, it may be chronic.

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Major Wound Separation:

Wounds may separate after surgery. Should this occur, additional treatment including surgery may be necessary.

Sutures:

Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible, or produce irritation that requires suture removal.

Damage to Deeper Structures:

There is the potential for injury to deeper structures including nerves, blood vessels, lymphatics, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

Fat Necrosis:

Fatty tissue found deep to the skin might die. This may produce areas of firmness under 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.

Surgical Anesthesia:

Both local and general anesthesia involve risk. There is a possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Shock:

In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Pain:

You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. If you are a chronic pain patient followed by a pain therapy practitioner, you may be asked to see this practitioner preoperatively to assist you in the management of your pain disorder in the postoperative period. Chronic pain may occur very infrequently because of nerves becoming trapped in scar tissue or due to tissue stretching.

There are nerve endings that may become involved with healing scars from surgery. While there may not be a major nerve injury, small nerve endings may become too active during the healing period producing a painful or oversensitive area due to the small sensory nerves involved with scar tissue. Often, massage and early nonsurgical intervention resolve this. It is important to discuss postsurgical pain with your surgeon.

Cardiac and Pulmonary Complications:

Pulmonary complications may occur secondarily to blood clots (pulmonary emboli), fat deposits (fat emboli), pneumonia, or partial collapse of the lungs after general anesthesia. 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 surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heartbeats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

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Venous Thrombosis (Clot) and Sequelae:

Thrombosed veins, which resemble cords, occasionally develop in the area of the breast or around IV sites 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, suture material and glues, blood products, topical preparations, or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur in response to drugs used during surgery 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 medication, prescribed or over the counter, as well as medications you now regularly take. Provide your surgeon with a list of medications and supplements you are currently taking.

Surgical Wetting Solutions:

There is a possibility that large volumes of fluid containing diluted local anesthetic drugs and epinephrine that is injected into fatty deposits during surgery may contribute to fluid overload or systemic reaction to these medications. Additional treatment including hospitalization may be necessary.

Fat/Air Embolism:

In rare cases, fat particles or air can enter the vascular system and can travel to the heart, lungs, or brain. This can result in significant complications including death.

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, which may not be recognized in advance. One side of the face may be slightly larger, while one side of the face may be droopier. The breast and trunk area exhibits the same possibilities. Many such issues cannot be fully corrected with surgery. 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 or surgery. You may be disappointed with the results of surgery. Asymmetry, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Size may be incorrect. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery to improve your results. Unsatisfactory results may NOT improve with each additional treatment.

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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 the formation of blood clots, and therefore, may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, 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 surgery 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 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 the 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 to travel via air. Medications may be required should you have a long flight/trip to prevent deep vein thrombosis (DVT)/pulmonary embolism (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.

Body Piercing:

Individuals who currently wear body-piercing jewelry in the surgical region are advised that an infection could develop from this activity. Body-piercing jewelry should be removed prior to your surgical procedure.

Nails:

To determine your vitals during surgery your anesthesia provider may require access to your fingernails for monitoring. Make sure to have at least two fingernails free of nail polish or acrylic nails on the date of your surgery.

Jewelry:

Jewelry should not be brought with you at the time of your surgical procedure. Items such as earrings, wedding rings, and necklaces should be removed and placed in a safe place. Do not bring your jewelry with you for your surgery.

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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 Surgery:

Surgery involves the coagulation of blood vessels and increased activity of any kind may open these vessels leading to a bleed or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery to control bleeding. 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 surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery, and are often stressful. Please openly discuss with your surgeon, prior to surgery, 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 surgery, the effects on mental health cannot be accurately predicted.

ADDITIONAL SURGERY NECESSARY (Reoperations)

There are many variable conditions that may influence the long-term result of surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of body structures. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are associated with this surgery. 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 surgical procedure. You and your surgeon will discuss the options available should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, and pathology and lab testing fees.

PATIENT COMPLIANCE

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

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ATTESTATIONS

Smoking, Secondhand 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 secondhand 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 nonsmoker and do not use nicotine products. I understand the potential risk of secondhand 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 6 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 fee, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking to your surgeon.

Sleep Apnea/CPAP:

Individuals who have breathing disorders such as obstructive sleep apnea and who may rely upon continuous positive airway pressure (CPAP) devices 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 surgery. This is an important consideration when evaluating the safety of surgical procedures in terms of very serious complications, including death, that relate to preexisting medical conditions. Surgery may be considered only with monitoring afterwards in a hospital setting in order to reduce risk of potential respiratory complications and to safely manage pain following surgery.

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.

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DVT/PE Risks and Advisory:

There is a risk of blood clots, DVT, and PE with every surgical procedure. The risk varies with the risk factors below. The more numerous the 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
- _____ Use of Birth Control Pills
- _____ Use of Hormone Stimulating Drugs
- _____ Swollen Legs
- _____ History of Cancer
- _____ Use of 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 surgery is elective and you're a high-risk patient, it's best to consider with not proceeding with the elective surgery.

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

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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 no surgery. 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, which 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.



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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 **Otoplasty Surgery**.

I have received the following information sheet: **Otoplasty Surgery**.

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 the 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 _____