BOICE-WILLIS CLINIC, PA

Patient Name: DOB:	MRN:	



Informed Consent

Nipple Reconstruction Surgery

Informed Consent - Nipp	le Reconstruction Surgery
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Patient Name:	DOB:	MRN:

<u>INSTRUCTIONS</u>

This is an informed consent document that has been prepared to help inform you about nipple reconstruction 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

Nipple reconstruction involves the restoration of the nipple or nipple-areolar complex lost due to injury, breast cancer, or other conditions. A variety of different techniques exists for reconstruction of the nipple and its surrounding areolar tissue. These include the use of skin grafts taken from other regions of the body, local flaps of breast skin that are shaped into a nipple, or the sharing of tissue from the opposite nipple-areolar region. Additional techniques such as tattooing may be used to add color to the tissue if needed.

Nipple reconstruction may be performed as a single surgical procedure, or combined with other breast reconstruction procedures.

ALTERNATIVE TREATMENTS

Nipple reconstruction surgery is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure or the use of external nipple-areolar prostheses.

INHERENT RISKS OF NIPPLE RECONSTRUCTION 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 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 possible consequences of nipple reconstruction surgery.

SPECIFIC RISKS OF NIPPLE RECONSTRUCTION SURGERY

Scarring:

All surgeries leave scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may occur in both the nipple reconstruction site and the donor site for tissues used in the nipple reconstruction. Scars may be unattractive or of a different color, texture, or height than the surrounding skin. 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 the possibility of visible marks in the skin from sutures. In some cases, scars may benefit from surgical revision or treatment. Scars may be chronically itchy or painful.

<u>Skin Grafts</u>:
Skin grafts are used in some nipple reconstruction techniques. The location from where the graft is taken may have residual scarring, poor healing, or abnormal color. Chronic itching or pain sensations have been reported. Skin graft loss can occur due to infection or other causes. Additional skin grafts may be needed.

Hair Growth:

Skin grafts used in nipple reconstruction may contain hair follicles. Unattractive hair growth may occur in the reconstructed nipple. Additional treatment may be possible to remove the hair follicles.

Tattoos:

If tattooing is required as an additional procedure, it may be impossible to precisely match the color and texture of the opposite nipple-areolar complex. Tattoos may fade or change over time and require a revisional procedure.

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Change in Nipple Sensation:

Nipple reconstruction cannot restore normal sensation to the breast or nipple. It is common to experience diminished (or loss of) skin sensation in areas that have had surgery. Diminished (or complete loss of) skin sensation may not totally resolve.

Skin Contour Irregularities:

Contour and shape irregularities may occur. Nipple position and shape will not be identical to the other native or reconstructed breast. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility when there is excessive redundant skin. This may improve with time or it may be surgically corrected.

Breast Implant Damage:

Breast implant damage can occur during a nipple reconstruction surgery. A damaged or broken implant will require surgery for replacement or removal.

Damage to Opposite Nipple:

Some nipple reconstruction procedures use a tissue-borrowing technique from the opposite nipple region. It is possible that the donor nipple region may be damaged or loses normal sensation, reactivity, or function.

Breast Disease:

Current medical information does not demonstrate an increased risk of breast cancer in women who have nipple reconstruction surgery. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than an individual with no family history of this disease. It is recommended that all women perform periodic self-examination of their breasts, have mammography according to American Cancer Society guidelines, and seek professional care should a breast lump be detected. In the event that suspicious tissue is identified prior to or during breast surgery, additional tests and therapy with corresponding expenses may be warranted.

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 the skin will not change and recurrence of skin looseness will occur at some time in the future, quicker for some than others. There are nerve endings that may become involved with healing scars from surgery such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, the small nerve endings may become too active during the healing period, thus 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 post-surgical 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 the 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

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to an increased chance of bleeding and additional surgery. It is important to follow post-operative instructions and to limit exercise and strenuous activity for the instructed time. Non-prescription "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. 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. Post-operative infections often result in more extensive scarring and predispose to revision surgery.

lleus:

The return of bowel function following surgery is important. An ileus is a disruption in bowel function caused by failure of peristalsis or hypomobility of your bowels/gut, resulting in lack of defecation and possibly repeated vomiting. Anesthetics and medications such as pain medications given to you at the time of surgery can contribute to the development of an ileus in the post-operative 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 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 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 the 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 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 hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations, it may be chronic.

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.

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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. Injuries 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 the possibility of contour irregularities in the skin that may result from fat necrosis.

Surgical Anesthesia:

Both local and general anesthesia involves risks. There is the 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 pre-operatively to assist you in the management of your pain disorder in the post- operative period. Chronic pain may occur very infrequently from 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, the small nerve endings may become too active during the healing period, thus 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 post-surgical pain with your surgeon.

Cardiac and Pulmonary Complications:

Pulmonary complications may occur subsequent 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 might require hospitalization and additional treatment.

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; 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

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Patient Name:	DOB:	MRN:	

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 regularly take. Provide your surgeon with a list of medications and supplements you are currently taking.

Asymmetry:

Symmetrical body appearance may not result after surgery. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to normal asymmetry in body features. Most patients have differences between the right and left side of their bodies before any surgery is performed. Additional surgery may be necessary to attempt to diminish asymmetry.

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. One side of the face may be slightly larger or one side of the face droopier. The breast and trunk area exhibit the same possibilities. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations are to the 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.

ADDITIONAL ADVISORIES

Medications and Herbal Dietary Supplements:

There are potential adverse reactions that occur as a result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with the forming 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®, Coumadin®, Xarelto®, 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.

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Sun Exposure – Direct or Tanning Salon:

The effects of the sun are damaging to the skin. Exposing the incision 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 sun block 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 timeframe. Allow at least 10-14 days to travel via airplane. Medications may be required should you have a long flight/trip to prevent DVT/PE in the immediate post-operative 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 <u>not</u> related to your surgery.

Interference with Sentinel Lymph Node Mapping Procedures:

Breast surgery procedures that involve cutting through breast tissue, similar to a breast biopsy, can potentially interfere with diagnostic procedures to determine lymph node drainage of breast tissue to stage breast cancer.

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 status 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, necklaces, should be removed and placed in a safe place.

Future Pregnancy and Breastfeeding:

This surgery is not known to interfere with pregnancy. If you are planning a pregnancy, your breast skin may stretch and offset the results of surgery. You may have more difficulty breastfeeding after this operation.

Female Patient Information:

It is important to inform your plastic surgeon if you use birth control pills, 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 coagulating 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

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unavoidable, may require additional surgery, and surgeon, prior to surgery, any history that you may historders. Although many individuals may benefit effects on mental health cannot be accurately predicted.	nave of significant emoti t psychologically from	ional depression or mental health
ADDITIONAL SURGERY NECESSARY (Re-Continuous There are many variable conditions that may influe your tissue may respond or how wound healing necessary to perform additional tightening or repost additional surgery or other treatments may be not infrequently, the risks cited are associated with this are less common. The practice of medicine and surexpected, there is no guarantee or warranty, expressome situations, it may not be possible to achieve of your surgeon will discuss the options available additional costs and expenses for such additional anesthesia fees, pathology, and lab testing.	ence the long-term rest will occur after surge itioning of body structure ecessary. Even though as surgery. Other compargery is not an exact so essed or implied, on the optimal results with a single	ery. Secondary surgery may be cires. Should complications occur, in risks and complications occur lications and risks can occur but cience. Although good results are expressed that may be obtained. In ingle surgical procedure. You and very be advised. There may be
PATIENT COMPLIANCE: Follow all physician instructions carefully; this is essurgical incisions are <u>not</u> subjected to excessive healing. Personal and vocational activities need to be removed unless instructed by your plastic surge surgery and subsequent care. Physical activity that swelling, fluid accumulation, and the need to return up care, return for aftercare, and promote your recommendation.	force, swelling, abrasione restricted. Protective on. Successful post-oper increases your pulse of to surgery. It is import	on, or motion during the time of edressings and drains should not erative function depends on both or heart rate may cause bruising,
ATTESTATIONS		
Smoking, Second-hand Smoke Exposure, I Patients who are currently smoking or use tobacco a greater risk for significant surgical complications Individuals exposed to second-hand smoke are also to nicotine exposure. Additionally, smoking may recovery from anesthesia, with coughing and possification tobacco smoke or nicotine-containing products have Please indicate your current status regarding these	or nicotine products (p of skin loss, delayed so at potential risk for s have a significant neg bly increased bleeding. ave a significantly lower	atch, gum, or nasal spray) are at healing, and additional scarring. similar complications attributable gative effect on anesthesia and Individuals who are not exposed
I am a non-smoker and do not use nicotine promoke exposure causing surgical complications.	oducts. I understand t	he potential risk of second-hand
I am a smoker or use tobacco/nicotine product smoking or use of nicotine products.	s. I understand the risk	of surgical complications due to
I have smoked and stopped approximately and, therefore, risks from smoking in my system, if		

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 timeframe, and understand that for my safety, the surgery, if possible, may be delayed.

___ 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.

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Patient Name:	_ DOB:		MRN:
Smoking may have such a negative effect on your surgery that a urine or blood test may be done just before surgery, 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.			
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 of 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 (- - -)	
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 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 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.



Informed Consent - Nipple Reconstruction Surgery

Pat	tient Name:	DOB:	MRN:
	CONSENT FOR SUR	GERY/PROCEDURE	or TREATMENT
1.	I hereby authorize <u>Karen Szymanski, DO</u> Reconstruction Surgery.	O, MPT and such assistants as	may be selected to perform Nipple
	I have received the following information sh	eet: Nipple Reconstruction Su	ırgery.
2.	I recognize that during the course of the op necessitate different procedures than those designees to perform such other procedure and desirable. The authority granted under not known to my physician at the time the p	e stated above. I therefore author is that are in the exercise of his of this paragraph shall include all of	rize the above physician and assistants or or her professional judgment necessary
3.	I consent to the administration of such anes anesthesia involve risk and the possibility of		
4.	I understand what my surgeon can and can specific, about my outcome. I have had the are realistic and which are not. All of my qu risks to the procedures I seek, as well as th Understanding all of this, I elect to proceed	opportunity to explain my goals estions have been answered, ar ose additional risks and complic	and understand which desired outcomes and I understand the inherent (specific)
5.	I consent to be photographed or televised by including appropriate portions of my body, for revealed by the pictures.		
6.	For purposes of advancing medical educati	on, I consent to the admittance of	of observers to the operating room.
7.	I consent to the disposal of any tissue, med	lical devices, or body parts that r	may be removed.
8.	I am aware that there are potential significato their utilization should they be deemed n		
9.	I authorize the release of my Social Securit registration, if applicable.	y number to appropriate agencie	es for legal reporting and medical-device
10.	I understand that the surgeons' fees are se agreeable to me. If a secondary procedure		
11.	I realize that not having the operation is an	option. I opt out of having this pr	rocedure
12.	IT HAS BEEN EXPLAINED TO ME IN A W a. THE ABOVE TREATMENT OR PROCI b. THERE MAY BE ALTERNATIVE PROC c. THERE ARE RISKS TO THE PROCEC	EDURE TO BE UNDERTAKEN CEDURES OR METHODS OF T	
	I CONSENT TO THE TREATMENT OR PRO I AM SATISFIED WITH THE EXPLANATION		STED ITEMS (1-12).
	Patient or Person Authorized to Sign for Pat	ient	
	Date/Time	Witness	