

BERNSTEIN MEDICAL

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Consent for Follicular Unit Extraction

I, _____, hereby grant permission for physicians of Bernstein Medical, P.C. (BMPC), and their assistants, to perform a Follicular Unit Hair Transplantation procedure that includes harvesting the hair via Follicular Unit Extraction (FUE), the administration of anesthetics and sedatives, by oral, intramuscular, or inhalation as may be necessary or desirable to do this procedure for the treatment of hair loss. FUE may be performed manually and/or by robotic control, using the ARTAS™ system manufactured by Restoration Robotics. I consent for the doctors to use the ARTAS™ robot to create recipient sites and/or make the sites by hand.

Bernstein Medical is a beta-testing site for the ARTAS robotic system. New capabilities, such as follicular unit graft selection, smaller punch sizes, and other advances may be used to improve the outcome of your procedure. As individual responses may vary, at the beginning of your procedure the doctor may use several different techniques to see which is more appropriate for your specific case. The doctor will then proceed with the method that gives you the most clinical benefit. Data collected from procedures performed at Bernstein Medical may be used anonymously in clinical studies. FUE procedures are performed over one or two consecutive days.

Your procedure will be performed with the ARTAS robotic system. In the event of mechanical or technical delays, your surgery may need to be postponed and/or rescheduled.

I understand that the ability to harvest grafts through FUE is patient dependent and may vary in different parts of a patient's scalp. If, in the doctor's judgment, the yield from extraction is, or becomes, too low during the procedure, the doctor may decide not to proceed with FUE. In this case the harvesting may be terminated or, with the patient's permission switched to FUT (strip harvesting) which will leave a linear scar.

Please initial A or B:

___ A: If, in the doctor's opinion, the yield from donor extraction becomes unacceptably low, I consent to FUT (strip harvesting).

___ B: If, in the doctor's opinion, the yield from donor extraction becomes unacceptably low, I prefer to stop the procedure.

The FUE procedure has been thoroughly explained to me by the physician, and I fully understand the nature and consequences of the procedure.

I understand that the procedure of hair transplantation is cosmetic in nature and that I have the option of doing nothing at all, wearing a hairpiece, using medications, or having another form of hair restoration surgery. I understand that there are different ways to perform hair transplants and various harvesting methods including strip harvesting and follicular unit extraction, both manually and robotic. These options have been discussed with me and have also been explained in the numerous informational materials made available to me by BMPC.

I understand that there are risks involved in any surgical procedure or treatment and that it is not possible to guarantee or to give assurance of a successful result or to assure an outcome that will meet my goals. This document describes the most common risks associated with hair transplantation surgery. Other risks, though rare, may exist. I recognize that I have been given every opportunity to ask questions and I have made the decision to go forward with the surgery. I clearly understand and agree to the planned surgical procedure. I have been told that hair

transplantation is a generally safe procedure; however, I realize that the following are possible events or complications that may occur:

- **SCARRING:** Every time an incision is made in the human body, a scar will occur, although every effort will be made to make any scarring as inconspicuous as possible. Thickened or raised scars (hypertrophic/keloids). Significant scarring is more likely to occur in people who have had a history of excessive scarring or who have had previous transplants taken from the donor area. _____ (Please initial)

Additional information for patients who select option A FUT/Strip Harvesting:

The donor incision for FUT will be closed with staples and/or sutures. Both absorbable and non-absorbable sutures may be used. Superficial crusting, pinkness, or redness of the incision area may occur, but these effects are usually temporary. Rarely, some area of skin around the suture edges may be lost and this will cause deep crusting which will take longer to heal. A stretched, widened scar is possible, as is a thickened or raised scar (hypertrophic/keloid). Significant scarring is more likely to occur in people who have had a history of the above type of scarring or who have had previous transplants taken from the donor area. Please note that post-op instructions for FUE and FUT/Strip are different. _____ (Please initial)

- **ANESTHESIA REACTIONS:** Local anesthetics (lidocaine, bupivacaine) with Adrenaline (epinephrine) may have effects on many of the body's organ systems, including the heart. Such effects may include allergic reactions, irregular heartbeats, or even, in unusual circumstances, a heart attack. Such risks are uncommon with surgical procedures performed under local anesthesia. Patients on the type of heart or blood pressure medications called "beta-blockers" may be particularly sensitive to epinephrine. Some patients may experience a temporary light-headed episode as a nervous reaction to injections. This reaction may cause a drop in blood pressure and lead to fainting. This condition is easily and relatively rapidly treated. If you are on any heart or blood pressure medication please list below.

I am currently taking _____
I am not on any heart or blood pressure medication _____ (Please initial)

- **SEDATIVES:** You may be given sedatives during your procedure to relax you and make you more comfortable. The sedatives may include Valium or Xanax given orally and Versed administered intra-muscularly. These medications can depress respiration in some patients. Your oxygen levels will be monitored during the procedure. If you are sensitive to these medications or have any respiratory problems, please let the doctor know.
- **ALLERGIC REACTIONS:** I understand that there may be unusual, unexpected or allergic responses to drugs, medications, suture materials, or foods, prescribed or used during the surgical procedure. I recognize that it is important for the physician to be informed of any problem I, or any member of my family, have had with reactions to drugs and also the medications I have taken in the past six months, including over-the-counter drugs, especially aspirin and any street drugs.
I am allergic to _____
I am not allergic to any drugs, medications, suture materials, or foods. _____
(Please initial)

- **STEROIDS:** As discussed, oral corticosteroids (prednisone) will be used to minimize swelling after the hair transplant. I understand the slightly increased risk of this treatment, including the rare complication of degeneration (aseptic necrosis) of the hip joint. I understand the nature of the cortisone treatment and agree to this preventative treatment. _____
(Please initial)
- **FOLLICULITIS:** Folliculitis is an uncommon problem in which hair follicles become infected with bacteria. Folliculitis usually appears in the postoperative period. The

associated symptoms include redness around the grafts, pustules around emerging hairs, and itching. There may be some associated loss of hair in the involved follicles, but since the problem is localized to individual hair follicles, the loss is rarely significant from a cosmetic standpoint. The treatment consists of oral antibiotics that may be given for an extended period of time.

- **HAIR LOSS:** There may be temporary hair loss in the back of the scalp in the area of the harvested hair. This hair will generally grow back. In the transplanted area, you may experience shedding of your existing hair following the surgery (a process called telogen effluvium). If this hair is at or near the end of its normal life span (miniaturized hair), it may not return. Because genetic balding is a continuous process, you may continue to lose more hair over time. If this occurs, a subsequent hair transplant procedure may be desired.
- **HAIR TEXTURE CHANGES:** When your new hair begins to grow it may be more kinked or wavier than your original hair. Over time the hair generally resumes its normal character. It is possible that these hair texture changes may persist.
- **FAILURE OF TRANSPLANTED HAIR TO GROW:** As in all surgical procedures results cannot be guaranteed. It is possible that some or all of the transplanted hair may fail to grow. This may be of particular risk in areas where the scalp has pre-existing scarring. In all cases, every effort will be made to give you the maximum yield from your transplanted hair.
- **NUMBNESS AND PAIN:** Numbness of the scalp/face may occur due to necessary cutting of fine nerve fibers in the skin. This is expected to gradually disappear over several months, but it is possible that all of the sensations may not return. Rarely nerve injury may occur, resulting in long term or possibly permanent numbness and/or pain in the scalp.
- **SMOKING:** Smoking causes constriction of blood vessels and decreased blood flow to the scalp, predominantly due to its nicotine content. The carbon monoxide in smoke decreases the oxygen carrying capacity of the blood. These factors may contribute to poor wound healing after a hair transplant and can increase the chance of a wound infection and scarring. Smoking may also contribute to poor hair growth. The deleterious effects of smoking wear off slowly when one abstains, particularly in chronic smokers, so that smoking puts one at risk to poor healing even after smoking is stopped for weeks or even months. Although it is not known exactly how long one should avoid smoking before and after a hair transplant a common recommendation is to abstain from 1 week prior to surgery to 2 weeks after the procedure.
- **SUN DAMAGED SKIN:** After your transplant, you must still protect your scalp from the damaging rays of the sun. Your new hair makes close observation of your scalp important because unusual new skin growths, or skin changes, may be more difficult to see. In addition, if you have a history of skin cancer or sun damaged skin, you should be followed by your dermatologist. It is possible that significantly sun damaged skin may hinder hair growth.
- **INFECTION:** The symptoms of infection include swelling, redness, tenderness or puss at the surgical site and may be associated with fever or chills. If you experience any of these symptoms, contact us at once.
- **OTHER:** There may be temporary swelling, discoloration, or bruising associated with the procedure. There may be the formation of a cyst at a graft site, ingrown or buried hairs, hematoma (localized blood clot), or rejection of a graft. In areas of scar tissue, grafts may grow poorly or not at all.

For patients who have had prior hair restoration surgery at another institution:

_____ I acknowledge that prior to contacting Bernstein Medical, P.C., I received Hair Transplants/Scalp Reductions from another physician and the results of these procedures were below my expectations. I further acknowledge that Bernstein Medical, P.C., its physicians and employees, bear no responsibility for my present condition. I also acknowledge that I have been informed that Bernstein Medical, P.C. physician(s) may not be able to correct my condition, although they will attempt to do so. (Please initial)

Consent for an in-house peer review of my medical record:

_____ In the ongoing pursuit of quality patient care, BMPC selects a number of patient medical records for periodic review. I hereby give my consent for BMPC physicians to review my medical record should it be selected. I understand that the information contained in my medical record will be kept strictly confidential at all times. (Please initial)

Photography:

_____ I understand that routine full face and scalp photographs will be taken for my office files. This consent does not include the use of photographs for advertising. (Please initial)

Driving Caution:

_____ I am aware that I will be given medications during and after the surgical procedure that may cause drowsiness and/or impair my judgment. I understand that I will not operate a motor vehicle, or dangerous machinery, the day of surgery or at any time while I am under the influence of these medications. (Please initial)

Consent:

_____ I have had the opportunity, in advance of my procedure, to read the contents of material made available to me by Bernstein Medical, P.C. including the information on the company website www.BernsteinMedical.com, Dr. Bernstein's medical publications, the surgical consent form, and pre-operative instructions. (Please initial)

_____ I am aware that the practice of medicine and surgery is not an exact science and that knowledgeable practitioners sometimes disagree as to the best methods of treatment to achieve desired results. I certify that no one has made any guarantee or warranty as to the final outcome or appearance that may be expected. (Please initial)

_____ I understand that during the procedure transplanted follicles are taken from the part of the scalp that is most resistant to the progression of baldness. The transplanted hair can last for a lifetime; however, unrelated conditions may arise that can damage hair follicles including the hair that is transplanted. This may be caused by a variety of medical disorders, dermatologic conditions, progression of balding beyond the norm, and changes related to aging. Treatment for these conditions can mitigate related hair loss, but may not always be successful. (Please initial)

_____ The procedure, its indications, risks and alternatives have been explained to me by my physician, and through the inquiry package, and the preoperative instructions. I recognize that during surgery unforeseen conditions can occur that may alter the course of surgery and necessitate deviating from the original plan. This may include the transplantation of more or fewer grafts than scheduled. I hereby authorize and request the surgeon to use his/her professional judgment to complete the surgery in a manner that will produce the best results in the safest way possible. I have read and understand this consent for surgery. I have been given the opportunity, by my physician, to ask questions, and all of my questions have been answered to my full satisfaction. Any objections have been noted or stricken and initialed by me. (Please initial)

_____ I understand that Bernstein Medical, P.C. does NOT adhere to advance directives (living wills). (Please initial)

_____ This consent was read and signed by me while I was not under the influence of medications or other substances that can cause drowsiness or impair judgment. (Please initial)

Signature of patient

Date

Signature of physician

Date

I certify that on this date I have observed this patient carefully read and sign this consent form of his/her own free will.

Witness for BMPC

Date

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