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**Informed consent for UVULO-PALATO-PHARYNGOPLASTY (UPPP aka UVPP)**

**SNORING** and **OBSTRUCTIVE SLEEP APNEA (OSA)** are two distinct manifestations of obstruction in the airway during sleep. Although the two conditions usually co-exist, there are some individuals who snore, but do not have apnea, and some quiet sleepers who, nonetheless, obstruct and stop breathing. Whereas a snorer may suffer intense embarrassment and loss of self-esteem, and may be a great annoyance to those who share the night with him, noisy sleeping, per se, does not necessarily pose a threat to one's health or well-being. Thus the choice to treat pure snoring is an **ELECTIVE** decision. On the other hand, Obstructive Sleep Apnea **IS** potentially threatening to the sleeper's health and even his life! Therefore, its treatment is a **MEDICAL NECESSITY**.

**1.** In addition to **OTOLARYNGOLOGISTS**, specialists of various other health disciplines including generalists, pulmonologists, respiratory therapists, neurologists, sleep specialists, psychiatrists, psychologists, oral surgeons and dentists have an interest in and contribute in their own special of ways to the diagnosis and treatment of snoring and OSA.

**2.** Regardless of which type of doctor makes the first contact with the patient, the ultimate evaluation of the snoring patient should consist of each of the following **FIVE ESSENTIAL ELEMENTS**:

**A) The routine ENT exam** looks at all the structures and functions of the head and neck for disease processes of **any and all sorts**, not just those associated with snoring and apnea. Particular attention is focused on the pertinent anatomy of the upper airway and trying to establish the exact cause of the obstructing process.

**B) Fiberoptic Endoscopy** is a hi-tech direct look exam which is done painlessly using a topical anesthetic in the nose. It gives the examiner the unique opportunity to evaluate the pertinent anatomy in its dynamic as well as static states.

**C) The General Physical Exam and Overall Medical History:** Systemic health problems can alter the way people sleep and may have an impact on how sleep pathology is best treated.

**D) The Specific Sleep History** among other things, explores for the presence of sleepiness on awakening, daytime somnolence, headaches, high blood pressure, certain other characteristics of sleep deprivation and esophageal reflux. It also includes observations made by the patient's sleeping partner regarding noise and breathing patterns, body positions, the presence or absence of arousals, apneic events, abnormal body movements and abnormal moods and behavior.

**E) The Polysomnogram or Sleep Study (PSGM)** defines the parameters and magnitude of the obstructive disorder and provides an opportunity for the patient to have a trial with CPAP if indicated. (See section **4A** below.) The results of this exam may have important prognostic implications which can lead the patient and the doctor to a best treatment choice. PSGM also helps to reveal previously unrecognized but potentially dangerous apnea conditions. **Third party insurers and HMO's** rely heavily on the qualitative and quantitative results of such a study in determining whether or not treatment is a medical necessity, and whether

or not they will pay for treatment. Depending on various factors, PSGM's may be done in the privacy of the patient's home, though most are done with an overnight sleep in a specially designed sleep laboratory.

**3a. UVULO-PHARYNGO-PALATOPLASTY (UPPP) AND LASER ASSISTED UVULO-PLASTY (LA-UP)** are perhaps the best known of the many different surgical remedies for snoring and OSA. In these two operations (which are merely minor variations of each other) redundant portions of uvula, palate and sometimes tonsils are removed or reshaped. This effort relieves the obstruction which can develop when these structures relax and collapse inward toward each other during sleep

For a variety of reasons, we no longer recommend the multi-staged "LA-UP operation." Instead, we strongly advocate the time tested **single staged UPPP OPERATION**. This operation is done exclusively in a hospital with general anesthesia.

**3b.** When performing UPPP's in the hospital operating room, we frequently use a cutting instrument called a "**Bovie**". As far as post-operative healing and pain, and the **END RESULT** are concerned, everything is **identical to the results of the Laser procedure.\*\*\***

Although some patients experience an optimal post-treatment status after only one treatment, about 2/3 of patients require two treatments, and an occasional patient needs three or more sessions before the treatment endpoint is reached. It can shrink tonsils if they are not too big. (Incidentally, research is being done to develop a way to remove tonsils with this ablative technology.)

NO ONE pays for **any kind** of treatment for isolated snoring. So, even though the technique has proved itself to be well accepted and effective in eliminating the effects of a uvula and palate that are too long and too close to the posterior pharyngeal wall you probably won't get approval to have it done, and won't get re-imbursed for it if you have it on your own.

What this means is, that if you want to take advantage of this nice, effective procedure, you will have to approach the operation as a **non-covered service**, and pay for it out of your own funds unless you have documented obstructive sleep apnea syndrome by a sleep study.

So HERE ARE YOUR CHOICES:.,

If you are snoring and do not have sleep apnea you may elect to have surgery of the palate and uvula and **PAY FOR IT YOURSELF, OUT OF POCKET** as an uncovered procedure.

If you snore and have mild sleep apnea and the type of anatomy that suggests that remodeling your palate and uvula will help, you can also pay for it yourself

OR

You can have a UPPP done if you have moderate to severe sleep apnea and try to get your insurance company to pay for it.

#### **4. There ARE alternative methods for the PRIMARY treatment of snoring and OSA:**

A. **ASSISTIVE BREATHING DEVICES** such as the so-called **CPAP MACHINE** or one of its many **variations** are effective for almost all degrees of sleep apnea. Their use is particularly attractive because it is non-surgical, and compared to surgery, quite economical. However, the problem with these devices is **POOR PATIENT COMPLIANCE**. Even when successful, many patients find it intolerable to sleep with a mask which is strapped tightly to their face and which, in turn, is connected by a long tube to a noisy pressure generating machine at their bedside.

B. **DENTAL APPLIANCES** of different varieties are highly touted, but they work well only in a small percentage of patients. Compliance and acceptance rates by patients over a long period of time are low.

**5. LOSING WEIGHT IS PROBABLY THE SINGLE BEST THING ANYONE CAN DO TO RELIEVE SNORING AND/OR OSA.** Obviously, not everyone can lose large amounts of weight, and too many of those who do lose it, eventually gain it back. However, **DIETING** is certainly a worthwhile thing to try before undergoing surgery.

**6.** The effects of **NASAL OBSTRUCTION** on snoring and/or OSA are variable. The results from the correction of an existing nasal breathing problem can range from no effect on the snoring and/or apnea at all to complete relief! At any rate, **GOOD NASAL BREATHING IS PHYSIOLOGICALLY NECESSARY FOR THE OVERALL SMOOTH FUNCTION OF THE ENTIRE RESPIRATORY TRACT AND THE HEALTH OF THE INDIVIDUAL, AND IT SHOULD BE RESTORED WHENEVER POSSIBLE WHETHER SNORING AND/OR SLEEP APNEA EXIST OR NOT!** There are many different causes for nasal obstruction. All of them are best evaluated by a **NOSE SPECIALIST**. Once the cause is properly diagnosed, the choice of treatment whether medical, allergic or surgical can be made.

**7.** The **TONSILS** can contribute significantly to snoring and OSA. If they are extremely large, it may be best to operate on them under general anesthesia in an operating room. If large **ADENOIDS** are present, they may have to be removed as an independent procedure. Tonsils and adenoids are expendable. Adults don't need them. **Let us know if YOUR tonsils and/or adenoids are diseased or giving you trouble. If so, we would tend to deal with them more aggressively than if they were healthy!**

**8.** The question of how much redundant tissue to remove is a balance between too little and too much. If not enough is removed, obstruction will not be relieved. On the other hand, if too much tissue were to be removed, the palate might not be able to close the oral cavity off from the nasal cavity during speech and swallowing. If this condition which is called **VELO-PHARYNGEAL INCOMPETENCE** were to occur, the result could be that food and liquids would **regurgitate** through the nose during swallowing, and **speech would be altered**. Since the correction of V-P incompetence is difficult, the best way to deal with it is to avoid it. Thus, it is necessary to place a **definite limit on how much tissue we remove**. We rely on our surgical experience and the presence of some clear anatomical landmarks which indicate to us where lines of resection should be made. Thus, although V-P incompetence is always a possibility, its occurrence is **highly unlikely**.

**9. Physiologists do not fully understand the function of the UVULA.** It is thought to have a role in lubricating the back of the throat and in facilitating the passage of mucus from behind the nasal area to the depths of the throat from where it is eventually swallowed. Although the uvula appears to be completely expendable, and its removal seems to cause no identifiable loss of function, some UPPP patients do complain of a vague throat discomfort which may last several months. In only a very small percentage of patients does this seem to be anything more than a small problem.

**10.** Please note that **people who speak French, Arabic, Hebrew, Yiddish, German, or other languages which roll R's and/or have sounds which rely on vibration of the palate will NOT be able to pronounce these particular sounds after surgery, because the very part of the throat which produces them will have been removed.**

**11.** In a very small percentage of cases of UPPP, post-operative scarring results in a disturbing narrowing of the very passage it was intended to widen! This so-called **stenosis of the naso-pharynx** may require difficult revision surgery.

**12.** It is important that you discuss your **ENTIRE MEDICATION SCHEDULE AND DRUG ALLERGY LIST** with us before you undergo surgery. We especially need to know if you have **ALLERGIES or ANY OTHER TYPES OF INTOLERANCES** to Xylocaine? lidocaine? Marcaine? adrenaline? Valium? atropine? Robinol? Demerol or other pain killers? Penicillin or other antibiotics?

**13.** Although this surgery is usually bloodless, it is important that **drugs which interfere with the ability of blood to clot are avoided.** This includes Aspirin, ibuprofen, and other Non-Steroidal Anti-Inflammatory Drugs (NSAID's) as well as Coumadin, heparin, Persantine and other anticoagulants. Ideally, all of these medications should be avoided for about 2 weeks before and 2 weeks after a laser treatment. Make sure you discontinue them under the **close supervision of the doctor who originally prescribed them!** Do not take it upon yourself to do this on your own.

**14.** Certain drugs used to treat **depression** called **MONOAMINE OXIDASE (MAO) INHIBITORS** are **incompatible with some of the agents we use.** If you take **ANY** drugs of this class, please **discontinue them at least two weeks before surgery, and do this UNDER THE STRICT CONTROL OF THE PRESCRIBING DOCTOR.**

**15.** If you need to take **PROPHYLACTIC ANTIBIOTICS** for **cardiac abnormalities** such as Mitral Valve Prolapse, cardiac pacemaker, valve replacements, rheumatic fever, or because you have **metallic implants** such as teeth or joint replacements, screws, bolts, plates, wires or other orthopedic devices, make sure you follow the prophylactic antibiotic regimen that your **MEDICAL DOCTOR, CARDIOLOGIST, DENTIST OR ORTHOPOD SETS UP FOR YOU.**

**16.** Oral **HERPES SIMPLEX eruptions,** recurrent **aphthous ulcers** or other **viral sores** of the mouth, lips and throat may be aggravated on a temporary or permanent basis by **this** or **any** kind of surgery. If you are prone to such outbreaks, let us know so that we can prescribe an anti-viral medication prophylactically.

**17.** If you expect your insurance company or HMO to pay for your surgery, make sure that you have **obtained the proper PRE-CERTIFICATION,** and that **appropriate CONFIRMATION NUMBERS, ETC., are on record.** (Note that insurance companies are often **CAPRICIOUS,** and that even though approvals might have been granted, it is still possible for them to deny payment on your behalf after the treatment is completed.)

**18. PROPER PATIENT SELECTION IS IMPORTANT.** Surgery is applicable only to those patients who are **in the best of health** and who have no contra-indicating factors. If any doubts exist, medical clearance and special instructions **IN WRITING** should be obtained from your primary care physician.

**19.** During Laser surgery in the office, you may be given **Robinol,** a medication for saliva reduction, **Valium** for relaxation and/or **Demerol** for pain. Any of these drugs can cause sleepiness, mouth dryness, and/or interference with vision and clear thinking. Therefore, it is imperative that you make arrangements for someone **TO DRIVE YOU HOME FROM THE OFFICE AFTER SURGERY.** It is also recommended, especially if any of these medications are given, that you avoid doing anything that requires **GOOD JUDGMENT AND GOOD VISION** for at least **eight (8) hours post-op.**

**20. HOSPITAL SURGERY with or without general anesthesia** is recommended for patients who have an excessively active gag reflex; a preference to be asleep during surgery; excessive anxiety; excessively large tonsils and/or adenoids; a need to have concomitant nasal or other surgery; general poor health and/or excessive risk factors.

**21.** If you **ARE** going into the hospital, you may need a written pre-operative **medical clearance** by your primary care physician. You may also have to have pre-admission **blood tests and possibly an EKG and chest X-ray.** Please, **CALL OUR OFFICE** to confirm the results of these tests as soon as they are reported to us.

**22.** If your surgery is to be in the hospital, we recommend that you arrange a **CONSULTATION WITH THE ANESTHESIA DEPARTMENT** at the medical center to review your special conditions, needs and preferences.

**23.** Except for a few unusual circumstances, it is not necessary to make ANY provisions for **blood transfusions**.

**24.** If your operation is uncomplicated, it is likely that you will be discharged from the hospital late in the day of surgery. If necessary, we CAN keep you overnight. If you are having **concomitant nose or sinus surgery**, it is our **ROUTINE** to admit you to the **special care unit** for **overnight monitoring** of your breathing and vital signs. **IF YOU DO STAY OVERNIGHT, IT IS MANDATORY THAT YOU CALL YOUR INSURANCE COMPANY IN THE MORNING to INFORM THEM OF YOUR EXTENDED STAY AND to TELL THEM TO GET IN TOUCH WITH MY OFFICE STAFF LATER IN THE DAY for details of why you had to stay over.**

**25.** **Post-operative pain after UPPP surgery may be considerable** even when done with a laser. It may be at its worst around the **fourth or fifth day after surgery**. Patients generally are able to maintain adequate caloric and liquid intakes, and though they will hardly feel their best, they nonetheless seem to be able to handle school or work after a few days.

**26.** After surgery you will be given a **POST-OPERATIVE INSTRUCTION SHEET** and **PRESCRIPTIONS** for various medicines. Make sure you are not allergic to anything we give you. Keep in mind that these **drugs may have side effects**. They can make you sleepy, upset your stomach and/or affect your bowel habits in either direction!

**27.** Our experience with UPPP shows little reason to restrict **physical activity**. Nonetheless, we advise **SOME CAUTION**. Moving around is good, but for **TWO WEEKS POST-OPERATIVELY** limit yourself to relatively mild physical exertion and avoid activities and or body positions that tend to raise venous pressures in your face and head, i.e., weight lifting, doing sit-ups and bending over excessively, etc. You should plan either to stay near Princeton, or make sure, **ahead of time**, that if you are **traveling**, you have access to a facility and doctors who have the wherewithal to take care of you should the need arise.

**28.** You must be aware that **UPPP successfully relieves PURE SNORING only in about 80% of cases and relieves OSA only in about 50% of cases**. Proper patient selection improves these statistics, but unexpected failures do occur. UPPP works best when redundancies of the uvula, palate and/or tonsils are the only causes of obstruction. UPPP works least well when other anatomical and/or physiological factors (such as poor jaw projection, small mouths, large tongues, thick cheeks, and flaccid easily collapsing walls of the throat) are contributing significantly to the obstruction process. Try as we may, it is impossible to absolutely predict which patients will profit most from these operations. Therefore, **WHEN EVALUATING THESE NUMBERS, PATIENTS AND DOCTORS ALIKE MUST BE REALISTIC!!!** Not everyone gets a totally perfect result from this surgery. Also note, that for reasons that are not clear, some **patients may be satisfactorily relieved of their snoring problem, but continue to be threatened by a serious obstructive sleep apnea condition**. This is why a post-operative sleep study is sometimes a valuable follow up to surgery.

**29.** **If the UPPP procedure turns out to be UNSUCCESSFUL for you**, there are other surgical and/or non-surgical modalities which, if applied secondarily, might prove beneficial. These include, but are not limited to laser ablation of redundant tissue from the base of the tongue, partial removal of the epiglottis, surgical advancement of the jaw bone, repositioning of the hyoid bone and, as a last resort, tracheostomy. Of course, weight loss regimens, the use of previously considered assistive breathing devices (CPAP, etc.), and/or a variety of oral and dental appliances also might be logical choices.

**A.** My **signature** below attests to the fact that I recognize that each decision one makes in life is a balancing of good against bad, **that there is no such thing as "the perfect operation,"** that surgeons do not always get perfect results, and that patients may not always be satisfied even when a good anatomical and functional result seems to have been achieved.

**B.** I attest that I have been fully **informed** about the rationale, risks, limitations, methodology, unpredictable factors and **alternative treatment** methods for the surgery that I have chosen to have; that I have carefully read and fully understand this **ENTIRE SEVEN PAGE DOCUMENT**. That I have not withheld any facts or information that might indicate a contra-indication to surgery or a need for any special considerations; that I have been given the opportunity to ask questions which have all been answered satisfactorily; that I understand fully the risks of local and/or general anesthesia and any medications that are likely to be used on me; that I have been offered the opportunity to seek a **second opinion** regarding my problem; that I have been offered the opportunity to have my spouse and/or significant others, and/or family members and/or friends present during key discussions.

**C.** I acknowledge that this consent and the entire extensive document is applicable not only to surgery in a generic sense, but also to the specific performance of UPPP and/or total or partial tonsillectomy, and that if other procedures are performed concomitantly, additional and separate informed consents will be given.

**D.** I understand that in addition to the potential dangers and risks previously discussed in this handout, **the list of possible undesirable developments and complications** also includes, **but is not necessarily limited to, the following:** burning feelings; persistent pains; feelings of a lump, or of dryness, or of too much mucus and/or saliva in the throat; changes in the quality of voice and/or speech; difficulty with swallowing; alterations in taste; the regurgitation of food and liquids through the nose when swallowing; infection of any kind in the throat or anywhere else in the body; bleeding, the need for blood transfusion and any or all of its attendant risks; anything and everything inherent in just being in a hospital and/or having any kind of operation in any place; unexpected and/or expected reactions to medications or to the use of a laser; etc. I understand that my surgery may not correct my problems satisfactorily, and that I could even be made worse. I further understand that though complications are rare, they DO occur, and that it is possible that any of them could happen to me.

**E.** I also understand that my designated surgeon -or any of his agents acting in his absence on my behalf- may have to deal with unforeseen situations which may require maneuvers, treatments, diagnostic efforts and **EXPENSES charged to me that are not presently contemplated**. Thus, I hereby ask him/her/them to do whatever he/she/they **judge** at the time to be in my best interest and best for the ultimate resolution of the problem(s) that exists now, or that may develop in the course of time. Also, that he/she/they may have to request and rely on the services of yet other health professionals during the course of treatment. This document shall serve as informed consent for my primary treatment, either in the office or in the hospital, and that many of its provisions may be pertinent for subsequent related treatments and procedures as well.

**F.** I understand the difference between "snoring" and "Obstructive Sleep Apnea (OSA)" and the implications of the terms "non-covered service" and "covered service". I also acknowledge the importance of a **SLEEP STUDY** as an **essential** part of my pre-operative work up and how the results of that study may impact on the decision of my insurance company to "pay" for my treatments. I also indicate that either I have done a sleep study, or that I have decided **on my own volition** to reject the recommendation that I do so. I also acknowledge that for a variety of reasons, a **post-operative SLEEP STUDY may also be in my best interests**.

**G.** I understand that my physician has arrangements with some insurance companies to provide certain approved services at a pre-negotiated price, and that if such an arrangement applies to the services provided to me, I will be covered to the extent that my contract with my insurer provides, and that if there are any deductibles and or co-pays that I am responsible for, I will pay them as soon as it is clear what those charges are, or at the latest, within the **same billing period of the time that my carrier pays my physician**.

**H.** I appreciate that my physician has already expended a great deal of effort getting me through the pre-certification process with my insurance carrier, and I understand that even though PRE-CERTIFICATION and/or PRE-APPROVAL may have been obtained, there is **no guarantee** that my carrier will actually make payment when the time comes to do so! If that happens, I hereby agree to personally assume full responsibility

for the REGULAR fee that my physician charges for these services rather than the NEGOTIATED fee my physician may have arranged as part of its contract with my carrier. Furthermore, **I agree that I will pay a reasonable fee to my physician for whatever additional efforts it may have to expend on my behalf in trying to appeal and/or reverse a possibly unfavorable decision made by my carrier.**

**I.** I understand that there are no guarantees as to exactly what the result of the contemplated surgery will be, and that I am assuming this financial responsibility regardless of how good or bad the outcome of the surgery turns out.

**J.** I understand that the stated fee is to cover the cost of the performance of the intended procedure(s) and sixty (60) days of **ROUTINE** post operative care, and that additional charges may be made for future endoscopies and/or unusual unexpected services that may become necessary. I also agree to assume responsibility for additional fees which may be charged for other related or non-related surgeries or treatments that might become necessary either during or sometime after the defined post-operative period.

I understand that potential risks associated with any surgery could include, among other things, broken teeth, pain, bleeding, infection, need for more surgery, need for more medications, loss of airway and suffocation, stroke and other injury to brain, heart attack, pulmonary embolus (blood clots in lungs and other body parts) and death.

_____	_____	_____
Signature of patient (or parent if a minor)	date	print name and relationship of signer
_____	_____	_____
signature of witness	date	print name and relationship of witness

**Please sign one of these forms and return it to us. Keep another copy along with the rest of this document in your permanent files. Thank you.**

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