

A Case Study for a Recommended Informed Consent for Eye Surgeries

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ABSTRACT

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Thesis statement: a comprehensive informed consent standard for eye surgeries can be developed by analyzing emergency surgeries, court decisions, analytical recommendations for informed consent, and practical applications of it.

Using the checklist developed in this paper, ophthalmologists, and vitreous and retina surgeons (in this paper surgeons, physicians, and doctor all refer to a retina and vitreous surgeon) will save time and protect themselves legally by getting detailed informed consent for complex eye surgeries. My real-life experiences with two emergency surgeries, my analysis of court cases, and my research on recommended and required elements of informed consent are presented to provide a workable and efficient informed consent procedure for eye surgeries or any complex surgery. Additionally the checklist will protect patients by providing them with sufficient information required to make an informed decision. Providing the physicians with a legally sound and comprehensive informed consent checklist encourages and expedites the physician-patient dialogue, fully documents patient's informed consent and protects physicians against claims of incomplete or inadequate disclosure of information.

Table of Contents

CHAPTER 1	1
INTRODUCTION	1
1.1 My Story: From pilot to lawyer	3
1.2 An Unexpected Diagnosis	4
1.3 Physical Standards for Pilots.....	5
1.4 Shock and Confusion.....	5
1.5 A Priest’s Help	6
1.6 A Second Opinion	8
1.7 My First Eye Surgery	11
1.8 A Relapse.....	13
1.9 Dr. Lambert and Subretinal Membrane Removal Surgery.....	14
1.10 Problems Encountered with Consent for Surgery.....	16
1.11 Post-Operative Complications	18
1.12 Conclusion	22
CHAPTER 2.....	25
BACKGROUND AND ELEMENTS OF INFORMED CONSENT	25
2.1 Introduction.....	25
2.2 Development of Informed Consent	27
2.3 Elements of Informed Consent.....	30
2.3.1 Diagnosis.....	32
2.3.2 Nature and Purpose of Proposed Treatment.....	35
2.3.3 Risks and Consequences	37
2.3.6 Other Issues	50
CHAPTER 3.....	52
DISCLOSURE STANDARDS AND CAUSES OF ACTION	52
3.1 Introduction.....	52
3.2 Texas Administrative Code (TAC) § 601.2 (2006) § 601.2. Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A.....	54
3.4 Physician Standard	57
3.5 Reasonable Patient Standard.....	59
3.6 Subjective Standard: A standard tailored to the patient	60
3.7 Legal Causes of Action against a Medical Provider	62
3.7.1 Prima Facie Case for Medical Negligence Premised on a Theory of Liability for Lack of Informed Consent	63
3.7.2 Prima Facie Case for Negligence in a Medical Malpractice Action	64
3.7.3 Medical Malpractice Claim.....	64
3.8 Conclusion.....	65
CHAPTER 4.....	67
RECOMMENDATIONS	67
4.1 Introduction.....	67
4.2 Recommendations when presenting the Diagnosis	69
4.3 Recommendations when Presenting the Risks and Consequences	69
4.4 Recommendations when Presenting the Prognosis in the Event Proposed Treatment is Not Undertaken.....	71

4.5	Recommendations when presenting the Disclosure of Alternate Procedures and Risks for Eye Surgeries	73
CHAPTER 5		76
AN INFORMED CONSENT CHECKLIST FOR COMPLEX EYE SURGERIES.....		76
5.1	Introduction.....	76
5.2	Analysis of a Physician’s Informed Consent Form Currently in Use	78
5.3	Analysis of a Hospital Consent Form Currently in Use	79
5.4	Use of Checklists to Speed the Dialogue between Physicians and Eye Patients.....	82
5.5	Informed Consent Checklist for Complex Eye Surgeries.....	84
Informed Consent Checklist for Complex Eye Surgeries		84
Diagnosis		85
Disclosure of Patient’s Disease/Injury		85
Physician		86
Competence.....		86
Comprehension		86
Religious, social or employment barriers.....		87
Voluntary Patient’s Decision		88
Document the patient's understanding of their disease/injury and acceptance of the course of treatment.....		89
Nature and Purpose of the Proposed Treatment.....		89
Risks and Consequences.....		93
Success/failure data		93
Blood transfusions.....		94
Anesthesia		94
Prognosis if Proposed Treatment Not Undertaken.....		95
Alternative Treatments		95
Other Issues for Eye Surgery		97
Completing the informed consent — documentation.....		97
CHAPTER 6.....		99
CONCLUSION.....		99
APPENDIX 1		101
TEXAS MEDICAL DISCLOSURE PANEL		101
APPENDIX 2		104
THE METHODIST HOSPITAL FORM # TMH469 – DONATING TISSUE FOR MEDICAL RESEARCH		104
APPENDIX 3		109
THE METHODIST HOSPITAL		109
DISCLOSURE AND CONSENT; MEDICAL, INVASIVE AND SURGICAL PROCEDURES FORM109		

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CHAPTER 1

Introduction

Any adult who has ever been treated at a doctor's office is familiar with signing paperwork. Hidden somewhere in that stack of paper is a consent allowing the doctor to perform a medical procedure. In fact, a patient could be signing away his or her life, or at least the right to informed consent, if the patient signs the forms blindly.

Informed consent as practiced by doctors and hospitals is an exercise in paperwork and futility. The patients are not informed and the doctors risk liability. The confusion and failure with informed consent is that the doctrine is not uniform, nor is there a standardized disclosure standard. The physician and patients are confronted with differing disclosure standards. There is the minimum state standard, used in Texas that does not inform the patient due to its brevity. Next, the physician standard allows the doctor to disclose information that a reasonable physician would disclose to a patient. The third is the patient standard, requiring the physician to provide the information a reasonable patient would be expected to need to make an informed choice in the treatment. The ultimate disclosure standard is the subjective standard, where the physician and patient tailor the disclosure to the individual patients needs. The problem with obtaining informed consent is there is neither an objective standard nor clear guidance. Doctors focus on having the paperwork complete, to protect against a malpractice lawsuit, while missing the point that informed consent is the patient selecting the best course of treatment for his needs. Informed consent is only obtained by understanding the informed consent elements.

Today, the doctrine of informed consent exists in both the common law and in state statutes and regulations. Informed consent is more than having a patient sign a form. Informed consent is the manifestation of the patient's understanding and decision to select the course of treatment desired. Informed consent can only be obtained by a patient who is provided and understands the six elements of informed consent. Properly obtained informed consent shifts the responsibility, and the decision for treatment, to the person who will ultimately live with, or die because of, the consequences: the patient.

This paper advocates for the development and standardized implementation of informed consent procedures for complex eye surgeries utilizing checklists. Chapter 2 looks at the development of informed consent, and is followed by a discussion of the specific Texas informed consent statute. The paper analyzes a consent form currently in use in a Texas hospital and presents a recommended checklist for complex eye surgeries. The goal of this thesis is to present a flexible and comprehensive informed consent procedure for ophthalmologic patients, enabling them to be truly informed when giving consent. The information presented fulfills the duties of disclosure by ophthalmologists performing these complicated and time-sensitive surgeries.

Instead of reciting only from casebooks or other abstract sources, I hope that by sharing my firsthand experience, I can adequately and realistically depict what a typical patient experiences, address the desire and search for a treatment, and give an objective evaluation of informed consent compliance in ophthalmologic settings. I present my experience as a case study for ophthalmologists to gain understanding of the legal requirements of informed consent for complicated eye surgeries and of patients' concerns. It is my hope that standardized informed consent procedures will be adopted to protect all concerned—both the patients whose

lives are drastically altered by serious eye conditions and the doctors who dedicate themselves to helping them.

1.1 My Story: From pilot to lawyer

In March 1999, I returned from Saudi Arabia after having served as the Mission Director for Operation Desert Fox, where I directed combat operations against Iraq and flew my last operational mission. My duties placed me in charge of combat operations where I had to keep track of hundreds of sorties, or flights, and make split-second decisions based upon radar scopes, radio transmissions, and knowledge of the operation. I was at the pinnacle of my flying career.

During one intense operation, Iraq launched a rare fighter sortie, seeking to shoot down one of our reconnaissance sorties. The enemy aircraft was traveling over 1,100 knots per hour, the maximum operating speed of this fighter aircraft. In a matter of seconds, I assessed the situation and launched the F-15s, with the total engagement lasting less than ten minutes. My sensory capacity was at its optimum and helped protect our assets, including our bases, aircraft and personnel in Saudi Arabia.

Toward the end of Operation Desert Fox, I had the opportunity to do what all military pilots train to do. I flew a mission in an actual combat environment. I was doing something that all military pilots dream of — protecting U.S. citizens and allies through air power. To reach this point, a pilot has to be physically and mentally up to the challenge. I was required to have excellent eyesight for safety purposes and so that I could read the small symbols on a radar display at my duty location. My eyesight served me well, and physically, I was also in great physical shape. At age forty, my waist was nearly the same size it was in high school. In an effort to stay at the top of my profession, I worked out religiously six days a week for two to

three hours at a time. Little did I know that in three short weeks I would be sitting in a doctor's office enduring a career-threatening injury caused by my high-risk job years earlier.

1.2 An Unexpected Diagnosis

Upon arrival back in the United States, the U.S. Air Force had me readjust to non-combat operations by spending two weeks with my family. On my first duty day back at the office, I noticed my computer screen seemed to be somewhat blurry when viewed with my right eye. I immediately made an appointment with the base ophthalmologist, Colonel Vijay Hanumanthu. The next morning, I arrived at the eye clinic where a routine examination by Colonel Hanumanthu became anything but routine. The Colonel sent me downtown for an immediate evaluation with retina specialist, Dr. Massey. He had a specialized instrument that would be able to determine the cause of the blurred condition. Although Colonel Hanumanthu seemed concerned, I was not worried. I thought that at forty years old, I would simply need some bifocals.

Within an hour, I had my first evaluation. Dr. Massey used a series of instruments to look in my eye and took some pictures of them. To my dismay, after these photographs were examined, Dr. Massey told me that I had suffered a "life-altering event and had only two weeks of vision remaining." He wanted to perform emergency surgery. Dr. Massey informed me that my retinal damage was similar to age-related macular degeneration (ARMD). He further explained that I was too young for this disease, so they called it macular dystrophy, a term I had never heard. All I knew about my diagnosis was that it would blind me very quickly. I did not understand either the diagnosis or the nature of the proposed treatment. Only the next day, after gleaning information from friends who work in medicine did I begin to understand my diagnosis.

1.3 Physical Standards for Pilots

As a pilot, for whom flawless vision is a strict job requirement¹, the concept of going blind was a mind-boggling irony. Since 1982, the USAF had required me to have yearly flight physicals, checking visual acuity, hearing, weight and numerous physical attributes to ensure safe aircraft operations. Each item was compared to standards set by the FAA and the USAF.² My initial USAF flight physical noted that my vision was 20/25 uncorrected in one eye, resulting in a waiver that required me to wear glasses when in the cockpit for flight. This was the only time I wore glasses, and my yearly flight physical in August had been perfect, with my dominant right eye seeing the 20/15 line.

My transformation from combat pilot to patient disturbed me more than an aircraft emergency I had been through during a typhoon evacuation. Then I was on the point of having to tell the crew to bail out. It appeared that one of my best friends would be unable to get out of the aircraft and that he would die. As a pilot, I was able to make a decision. As a patient in this situation, I had absolutely no control.

1.4 Shock and Confusion

Like an Air Force mission director, Dr. Massey, one of the best vitreous and retina doctors in the state of Alabama, made a split-second decision. In this case, Dr. Massey had seen a blood vessel growing in my retina that was not supposed to be there. He wanted to seal this blood vessel immediately before the growth destroyed the retina or leaked blood into the eye, blocking off light to the retina. Although I understood his split-second approach, I did not fully

¹ Air Force Instruction 48-23.

² *Id.*

understand how he had come to his conclusion. Why did I require immediate surgery? I would not know the full answer until thirty hours later.

Dr. Massey presented the information as if a decision had already been made. For Dr. Massey, my problem was familiar. To me, however, it was all new and frightening. Older patients or other patients who have had previous information about macular dystrophy or degeneration might have understood the diagnosis immediately. All other patients, like me, need more information in order to comprehend the situation. The words echoed in my head: “You have two weeks of vision remaining...the surgery has to be performed now” did not foster an understanding of my medical condition.

1.5 A Priest’s Help

Seeking someone who could help me with this difficult decision, I called Father Frank Lowe at the base chapel and left him a message. Within an hour, he was standing in the examining room asking Dr. Massey the questions I should have been asking:

“He will be all right after the surgery, correct?”

“No, he will be blind within two weeks whether or not he has the surgery.”

Now I was completely confused. Why should I go through an operation now if it meant I would be losing fourteen days of vision? During the conversation between Dr. Massey and Father Lowe, I mentioned that I would be going home to see my children. Dr. Massey, agitated at this point, reiterated that the time to act was immediately.

After more questioning from Father Lowe, Dr. Massey relented and suggested a second opinion was appropriate. Dr. Kimble in Birmingham, Alabama was now my last hope. Before making the journey to Birmingham from Montgomery, I wanted at least one night with my

children. Dr. Massey warned me not to pick up my children, five through eleven-years of age; the strain could cause the rogue blood vessel to burst, destroying my retina. I was beginning to grasp the severity of my condition, but was still unsure about opting for a surgery guaranteed to blind me.

The following morning, after getting my children off to school, I was preparing to leave with Father Lowe. At that point, Colonel Hanumanthu, a very talented and professional ophthalmologist, called me with grim news: I was grounded and would never fly again. Up until that moment, I had been concerned about how an operation on my eye would affect my career as a pilot, but with this news, that hope was dashed. Colonel Hanumanthu agreed with my decision to seek a second opinion and even believed that Dr. Kimble, with his well-equipped facility and longer professional career, was a better choice of doctor. I had assurance that I was going to one of the best doctors available and had a supportive friend by my side, yet I was still anxious and unclear about the operation.

As Father Lowe and I began the two-hour journey to Birmingham, Alabama, thoughts raced through my mind. As I looked at the trees going by, I wondered if it would be the last time I would see them or, for that matter, would I be able to see anything ever again. I suddenly felt very thankful that I had taken an extra day to spend with my children—to see their faces one last time—instead of rushing to the surgery. I desperately tried to burn the images of their faces into my brain.

I reflected on the doctors' pronouncement that I was now handicapped. My image of disabled military personnel was people who had suffered injury during combat, not people with blurry eyes. My priest was driving me to a potential operation, and if I did consent to the operation, he would be driving me home.

The drive to Dr. Kimble's office in Birmingham was torturous, and my mind was in overdrive. I started to cry. Father Lowe, a literal godsend, told me he wanted to pray the rosary with me, but my eyes were too full of tears to read the rosary card in my wallet. I desperately tried to stop so that I could read it; although I did not understand why, I had been told that crying was one of the worst things for my eyes. Father Lowe helped me take my mind off of my despair through prayer. Eventually, I began reciting the rosary from memory, which brought relief to both my mind and my eyes.

1.6 A Second Opinion

Upon arriving at Dr. Kimble's office, I was scared, but had hope that Dr. Kimble knew how to cure me. My otherwise good physical health would be a benefit to my recovery process and, spiritually, I now felt at ease. I met Dr. Kimble around 10 a.m. on April 7, 1999. His approach differed greatly from Dr. Massey's.

With Father Lowe beside me, Dr. Kimble went into great detail, using terms I actually understood. He explained that the blood vessel in my eye was pushing against my retina like a tree root growing underneath a sidewalk, pushing up against the concrete and displaces the sidewalk. This errant growth would quickly distort my retina. Over the course of several weeks (the 14-day period Dr. Massey had referred to), this bad blood vessel would make a large bulge in my retina, as though someone were behind a projection screen pushing it forward, distorting the image.

Furthermore, because my errant blood vessel was not supposed to be there, it was extremely weak and susceptible to bursting. He again used the projection analogy, explaining that this blood vessel only contained a drop or two of blood; however, even such a small amount

of blood would have the same effect as putting your hand in front of a motion picture projector and blocking the light to the screen. Essentially, the blood would block out the vision reaching my retina and in turn, the blank image would proceed down the optic nerve to my brain. That eye would become blind. My brain would be receiving the distorted or blanked out images from the affected eye and would compile it with the vision from my operating eye, resulting in my brain receiving a distorted picture. Surgery was my only hope. But why should I give up my last two weeks of sight?

Dr. Kimble began to answer this question by explaining that if I did not have the surgery, nature would take its course, and the distorted vision that I would have forever in my right eye would also interfere with my left eye. If the blood vessel ruptured, the doctors would be unable to remove the blood from my eye, and the damage to the cells would last forever. Thus, my retina would never receive the light that was transformed into vision by my brain. He pointed out that my left eye was highly damaged, and total blindness was not too far off. Dr. Kimble explained that my eye and brain would work together to fill in the vision that was no longer there. Both eyes would be sending different visual images to the brain. The brain would understand that the right eye was not transmitting a complete picture and would fill in the missing vision with stars or snow, but the picture would be distorted. (In fact, this is the vision I have today). I then understood why Dr. Massey had told me I only had two weeks of vision left: the vessel would either burst or the collateral damage from the surgery would blind me.

Dr. Kimble then recommended a surgery called *photocoagulation* involving a procedure that used a laser light focused deep into the back of my eye. As the laser reached the back of my eye and centered upon the errant blood vessel, the light would heat up the blood vessel by 10° to 20° and seal it. The errant vessel not only would stop growing, but also would not contain any

blood that could be released into my eye. The surgery would involve my sitting in a normal ophthalmologist's chair while Dr. Kimble directed the light deep into my eye. A typical camera's flash lasts approximately 1/100th of a second, but the laser blast would last approximately 1/5 of a second, 20 times longer than a normal camera flash or the previous retinal photos. The only possibility of success—not becoming blind due to the surgery—was if the light remained only a couple of microns away from the fovea and those cells survived.

Dr. Kimble explained the situation in terms that I, as a pilot, could understand. He used the analogy of a bomb dropping on a building, something with which I was very familiar. The light would destroy my retinal cells, similar to how a bomb destroys its point of impact. Just as a bomb causes collateral damage with shrapnel shards, the intensity of the light from the laser also would cause damage around the point of impact. I now understood my surgery more clearly. The delicacy of the procedure meant that Dr. Kimble would be working within approximately 125 μ (microns) from my fovea—a distance considerably less than that of a fine hair. To further complicate the procedure, the expected collateral damage to my eyes was 150 μ .

After explaining the surgery in terms I understood, Dr. Kimble, in an act of extraordinary insight, professionalism and kindness, called the FAA confirmed that after receiving specialized training, I could use my airline transportation pilot license to fly with one eye. A glimmer of hope emerged, and I began to believe that this surgery was my only choice.

As the son of one of the best obstetrician/gynecologists in the city of Houston, I viewed questioning a doctor as inappropriate and unacceptable. When I was growing up, a person did not continue to discuss the diagnosis with a physician after it was given; the only option was treatment. Now I was faced with a yes-or-no decision regarding my treatment when no alternatives had been offered. This decision was completely up to me and I turned to my

spiritual beliefs — asking my father, who had passed away four months earlier, to intercede for me with God and to pray that He would give me assistance in deciding and in the long road to healing.

1.7 My First Eye Surgery

I was ready to begin the surgery when Dr. Kimble told me that a technician would give me two injections in the eye. Although I asked for general anesthesia, Dr. Kimble informed me the surgery produced better results if the patient was awake and alert. Instead of being laid out flat on a table, I would be sitting in the ophthalmologist's chair and staring at a point of light while the doctor manipulated the laser to seal the blood vessel. Like the surgeries of the eighteenth century that were performed without anesthesia, this procedure would definitely require both my consent and cooperation; when I saw the three- to four-inch needles the technician carried into the room, I wondered why this part had not been explained, and I verbally withdrew my consent for treatment. The thought of two large needles plunging into my optic nerve terrified me. Only when I learned there was no other way, did I reinstate my consent. Just as the initial consent had not initially been documented in writing, as required by law, this reinstatement was purely verbal. Dr. Kimble should have documented my consents with my signature on some paperwork.

After a first injection for pain, the technician injected the optic nerve a second time to deaden it in an attempt to keep my eye and eyelid from moving while the laser shone on it. Now it was up to Dr. Kimble and to me. The only chance of success depended on my keeping my eye extremely still. My eye could not move a single micron. At that moment, I prayed for all the saints and angels to steady Dr. Kimble's hand. I concentrated with all my might upon the steady

blinking green light until the first laser blast made everything go black. Being a true pilot and officer, I had been given my orders and took them seriously: I did not move a micron. I concentrated and stared where I hoped the light was located, and I continued to pray for the strength to keep still. After five or six bursts of light, Dr. Kimble told me we were done, and he was ecstatic. He thought he had been able to keep the light away from my fovea, since I had not moved at all. It would take several months of daily evaluations to determine if the blood vessel would continue growing; but now, I went home with hope. Everything in my right eye was black. Dr. Kimble bandaged my eye, allowing me to regain vision in my other eye.

Within two days of surgery, Colonel Hanumanthu documented my vision at 20/20. In a surprise, I would be allowed to continue flying. I received daily evaluations from Colonel Hanumanthu, along with weekly ones from Dr. Massey or Dr. Kimble. The first surgery was successful for approximately three months.

Dr Massey was frustrated with my initial refusal of the treatment and perhaps with the time it took to convince me to accept it. In addition, I now understand that despite the time spent trying to persuade me, essential information was omitted. There was an alternative surgery for my condition other than photocoagulation. If I had been aware of it, I would not have opted for photocoagulation. Since its risks (i.e., the certain destruction of cells by the laser used) are far greater than those of the alternative, subretinal membrane removal. However, if Dr. Massey had had a detailed, structured checklist, it would have greatly aided me in my decision and saved Dr. Massey time—a precious commodity to all doctors.

1.8 A Relapse

Dr. Kimble, Dr. Massey, and Colonel Hanumanthu had all told me that I had passed the danger period for a reoccurrence when tragedy struck again. Because of all the warnings, I tested my vision regularly with the Amsler grids and self-made tests. Could I read license plates, the signs on the fence at my kids' baseball games, the streamers on the bottom of the television? One fateful Saturday morning, using one of my self-created tests, I tried to read the streamer on the bottom of the television, and I became concerned again about my vision. I contacted Dr. Massey, who met me at his office on that Saturday afternoon. On Monday, Dr. Kimble was in Montgomery, and he and Dr. Massey pored over my problem. The diagnosis: the vessel had restarted growing—but now it was in the fovea. Within a two-week period of time, at the end of June, 1999, my vision went from 20/20 to 7/400 (a secondary scale used to evaluate persons with vision below 20/200). This rendered me unable to read, watch television, drive a car, or even cook. Most devastating was my inability to see my children's faces.

When the second vessel grew the clock to permanent blindness had again begun ticking on the two-week window I had been given, but now I had even less time. The doctors did not have any more options. I even asked about experimental treatments that I knew were to be conducted by Dr. Kimble. I was not a candidate because I was too young - - besides, by the time the tests started, I would be blind.

Out of this tragedy came the assistance of Colonel Hanumanthu. After this sad announcement, Colonels Hanumanthu and Dobbins (Colonel Dobbins was a physician assistant assigned to the USAF Headquarters Directorate where I was assigned) quietly sprang into action. Dr. Hanumanthu dedicated his time to researching an advanced medical procedure to restore my sight, and the two men had me call every medical center in the country that they had researched.

Dr. Hanumanthu, not only fought off two flight surgeons who both wanted to deny any further treatment, but also he did what a blind patient dreams of: He came up with a plan to ultimately restore my eyesight and found a vitreous and retina specialist who would take me.

1.9 Dr. Lambert and Subretinal Membrane Removal Surgery

Dr. Mike Lambert, a retired U.S. Air Force Colonel, who had once been the head of the U.S. Air Force's Wilford Hall Ophthalmology Department, was one of the foremost retina and vitreous specialists in the country.³ Colonel Hanumanthu, who told me that Dr. Lambert was one of the best, arranged my initial consultation with Dr. Lambert and was hopeful that Dr. Lambert could help me. I flew from Alabama to Houston, Texas, where Dr. Lambert did several tests to determine my field of vision and took photographs of my eye both before and after injecting a dye into my bloodstream.

By that time, July 1999, an ophthalmologist and flight surgeons were seeing me daily. I knew that the ophthalmologist would have me read a vision chart and follow a hand-held light. Prior to the dilation of my eyes, the doctors would measure the pressure of my eye. The ophthalmologist used a retinal prism while giving me instructions to move my eye. This movement allowed the doctors a clear view of my retina. Quite often I also was forced to endure fluorescein angiograms, photographs of the inside of my eye. This procedure of photographing my eye was ironic because I had received warnings from Drs. Hanumanthu, Jehle, Massey, and Kimble to avoid any bright lights. But the angiogram was vital to the retina specialists because it pinpointed the exact problem area. In order to get the needed photographs, an extremely bright

³ H. Michael Lambert, MD FACS, CEO, Retina and Vitreous of Texas, PLLC & Civilian Consultant in Ophthalmology to the USAF Surgeon General. Information regarding Dr. Lambert is available at <http://www.retinatexas.com/physicians.html>. (The Retina and Vitreous of Texas website states, "Our physicians are all Board Certified by the American Board of Ophthalmology and fellowship trained in diseases and surgery of the vitreous, retina and macula.").

flash was used to illuminate the back of my eye. These photographs often left me unable to see for hours after they were taken. By this time, I required a driver and someone to help me walk. I had now lost the vision in my right eye, and it did indeed affect my overall vision. When I looked at my friends, their ears were where their chins should be. I could no longer read a newspaper with my right eye, and I could not see anything in my center of vision.

At this appointment, after conducting several examinations using a prism to examine the retina, Dr. Lambert told me that he could treat me. He offered me a second procedure that had not been discussed prior to the original laser surgery. This alternative surgery involved deflating my eye, and attempting to remove the blood vessels that were destroying my eyesight. There was no further discussion of what the procedure would involve. I needed help, and I did not care what the surgery involved.

Dr. Lambert quantified the surgery for me by stating that he had operated on a law enforcement officer who went from legally blind to 20/20. This example made the surgical procedure personal and relative real to me. The law enforcement officer had the same diagnosis and was of the same age. So I saw the similarities as material for purposes of assessing the surgery. The other studies and surgeries were on people seventy to eighty years old. As far as the risks for the surgery, all I knew from Colonel Hanumanthu was that Dr. Lambert was “going to rip it out.” Dr. Lambert, who had once been a U.S. Air Force instructor pilot and had also been grounded, put me at ease. He knew exactly what I was going through.

I was dumbfounded by the fact that I was now considered legally blind. I could not read a newspaper with my bad eye, and that vision affected the good eye’s vision. My physical view of the world was now bent and distorted. In one of my self-made visual checks, I had been using a ceiling fan in the morning to see if I still had vision, but I had not realized that I was no longer

seeing inside the tips of the fan blades. My reliance on others to help restore what once seemed so natural left me exhausted and desperate.

During the four-month period from my initial diagnosis and prognosis of total blindness, I had done what many patients in such situations do: I prayed for a cure and tried to be strong for my children. When Dr. Hanumanthu found new hope with this alternative, subretinal membrane removal surgery, I stopped questioning. I did not understand the alternative procedure, nor did I care. After all, the Alabama doctors had told me at that point that there was nothing they could do for me. Therefore, once I became aware of this alternative, my next move was not to try to find out more information; instead, I immediately started praying that I would be an acceptable candidate for it. Dr. Lambert scheduled the surgery for the following week and sent me to the hospital to fill out paperwork.

1.10 Problems Encountered with Consent for Surgery

My sister, a nurse practitioner, helped me get across the street to the hospital to fill out admission paperwork for the upcoming surgery. During this visit, I had to sign certain documents that my sister, who specializes in AIDS treatment, said were improper—possibly even illegal—consents with respect to the blood transfusion. When the hospital admissions officer told me to sign this paperwork, I asked her about the possibility of receiving AIDS or HIV from a blood transfusion. She informed me that it was against the law for her to explain this to me, but my sister disagreed, explaining that the hospital was actually required by law to tell me that the transmission of HIV was a possibility, albeit a remote one. My sister added that the potential of receiving the hepatitis virus from a blood transfusion was much greater. I signed the papers but did not have the information to know what I had signed.

Only after I was being driven to the hospital a week later for the surgery and Colonel Dobbins asked how Dr. Lambert would be able to pull my eye out of my face and get the instruments into my optic nerve to operate, did I wonder about what would be done to my eye. In Dr. Lambert's office a few days before, the only discussion that Dr. Lambert and I had was about whether I would be able to see correctly again. I was never informed about the technical aspects of the procedure. Once I was at the hospital, I found out the eye removal procedure Col. Dobbins envisioned was incorrect. I asked the nurses, "How are you going to put my eye back after you pull it out?" They laughed and told me, "We only pull out eyes that have cancer and those [eyes] are not replaced."

During the hospital admissions procedure, I met with the anesthesiologist who told me I must drink absolutely no water after midnight and must stop eating food by 6 p.m. the night prior to my 6 a.m. hospital check-in. Even putting water on my toothbrush was prohibited, although it was never explained why. At no time did I receive adequate explanation about this particular protocol or any risks or alternatives. The doctors could have told me to do anything. I was completely vulnerable and desperately willing to do anything that would help me regain my sight. Still, I was glad to be receiving treatment from Dr. Lambert.

As I lay in bed in the pre-op room, I remember being excited about having the procedure and prayed about having my vision back, but the eight or ten other patients around me, all of whom were 20 or 30 years older than I, seemed very nervous. I remember being confused by this, thinking that we should all be happy that our vision would soon be restored. Looking back on their apprehension, I realize that they probably had a much better understanding of the procedure that we were about to undergo.

I underwent the procedure, but did not fully understand what had taken place until, over a year later, when my USAF physician assistant, Colonel Randy Dobbins, showed me the procedure on Dr. Lambert's webpage. Dr. Lambert, not only removed the rogue blood vessels, he also removed the scab from the initial laser surgery. Removing the scab allowed light to reach the retina cells below the scab, further helping my vision return to normal. The surgery was a great success, and I almost got to fly again. My vision returned to 20/20 from 7/400. From the literature, I have read and information I have received from doctors, my recovery is a miracle.

1.11 Post-Operative Complications

When I awoke from the sub-membrane removal operation, I was in a huge amount of pain. On wheeling me into the operating room, the nurses had stated I would have no pain after the operation. When I told the nurse who was monitoring my reawakening that my eye hurt, I was prescribed morphine and released. The morphine had no effect on decreasing the pain during the night, and the next day when the assisting physician checked my eye, I again told him about the pain. When he asked what level I considered the pain to be at using a scale of one to ten - - I responded eleven. He gasped and stated he never would have let me leave the hospital if he had realized the amount of pain I was enduring. My sister and the doctor chastised me for not making it clear to them the amount of pain, I was in. I thought my statement about pain had been clear.

The cause of my pain was a reaction of the optic nerve to steroid fluid. This steroid had been injected to re-inflate the eye and to minimize any chance of cataract development. No one detected that my eye pressure was through the roof until about three weeks post-operative when I

returned to Alabama. During my first post-surgical evaluation with Dr. Hanumanthu, he performed the first glaucoma pressure test, and the pressure was 45. (Normal is below 20.) This precipitated a new round of emergency procedures. Although I was already taking six optical drops in my eye, up to four times a day, I was prescribed a few more optical drops to combat glaucoma. Those three weeks turned out to be critical: the ophthalmologist stated that the partial vision loss, color blindness and reduction in depth perception that I subsequently experienced was due to this interaction of my optic nerve and the steroid.

One drop was a medicine developed in the 1890's, and Dr. Hanumanthu told me it would result in intense head pain. When Colonel Randy Dobbins placed the drops in my eye, the entire optic nerve immediately opened and allowed a massive exodus of the high pressure out of the eye. Even this medicine did not lower the pressure to normal, and I was now in danger of being blinded by the glaucoma. I was then placed on another old medicine, and all I was told is that the medicine was a bad pill. I did not have a clue what "bad pill" meant. Eventually, this combination of old drugs and drops did lower the internal eye pressure, and the threat of blindness from pressure subsided, but it also cost me blue and green color vision in the eye that had been operated on. Furthermore, my depth of perception was badly affected. Ultimately, this combination ended my flying career. The pill was referred to as "bad" because it tears the body up.

Colonel Hanumanthu had been forced to move to California as a direct result of helping me find a surgeon to restore my sight, since he had gone against the hospital administrator's decision not to treat me. Without him, no one was there to monitor the pill's effect on my body because the concern was the eye pressure. The lack of monitoring resulted in the valve to my stomach being damaged by this pill. This damage manifested itself only when I complained of

pain in my left arm and chest sufficient for Colonel Dobbins to have to race me to the emergency room. The valve rested near a nerve that runs across the heart and ends in the left shoulder.

These post-surgical injuries could have resulted in malpractice if the USAF doctors did not have immunity. Again, a standardized and comprehensive checklist might have alerted the USAF physicians to the standard of care with which they should have complied, or at least have alerted me to the issues of pain so that I might have aided the doctors with my recovery.

After Dr. Hanumanthu moved to California, Dr. Jehle, a civilian retina specialist hired by the Air Force, expertly took over my care. This surgeon confirmed to me that there were laser burns in my eyes. This was the third time, [approximately a year after my first surgery] that burns were diagnosed. This diagnosis confirmed what Special Forces medic, Colonel Randy Dobbins, who had experience with this problem, had actually stated initially that my retina appeared to have laser burn tracks. At that time, he told the retinal surgeon he was not qualified to make a diagnosis, but a year later, his suspicion was verified. Whether the blood vessel grew because a disease or whether, as is more probable, the burns were the result of being lased during flight operations, what mattered was the discovery of the errant blood vessel in my retina had damaged it.

An important miscommunication regarding partial loss of vision in my case can be illustrated by quoting a statement by Dr. Jehle from my medical record, in which no loss of vision is implied: “The procedure [my second surgery] was successful. His postoperative course was complicated by glaucoma. This condition was managed without difficulty with topical and systemic medications. . . . No ocular damage occurred due to this transient postoperative elevation of his IOP.”⁴

⁴ Letter from Dr. Jehle, Maxwell Air Force Base ophthalmologist, to the Department of Veterans Affairs (December 13, 2002) (on file with author).

Dr. Jehle's statement illustrates the differences understood by medical personnel and those understood by patients to the same report or opinion discussing a patient's medical condition. Dr. Jehle's letter goes on to "reveal a complete loss of color vision [in the operated eye] and [w]ith difficulty, the patient achieved a hundred seconds as compared to the normal 40 seconds."⁵ This quote means I see through a small tunnel of vision, similar to looking through a straw. As Dr. Jehle stated, no one ever expected me to get visual acuity back close to normal. As the patient I face significant vision loss. Therefore, my "partial loss of vision" is considered by ophthalmologists to be insignificant, given that I had improved from a visual acuity of 7/400 to 20/20.

To be clear, I am absolutely delighted to be able to see people's faces and read again, but my "partial loss of vision" means my right [operated eye] can no longer distinguish colors and my depth of perception is minimal. The good news is that my retina began performing again; however, I have had to adapt to my partial vision loss, which means that today, I do not see people's faces fully. Instead, I see the left side of their faces clearly, while the rest is not there. I have learned to adapt, but my story shows precisely why clear language must be used between patient and physician.

Another important miscommunication occurred in relation to my second surgery. At the end of the surgery, Dr. Lambert placed air in my eye. The purpose of the air was to press the retina back in place. For the entire time that the air bubble remained in my eye, I was to look down, preferably while laying flat on my stomach. This was a critical step in placing the retina back in its proper location. Approximately two weeks after the second surgery, while lying flat on my stomach and staring at the floor, my eyes were immediately filled with millions of stars. I had initially been given a warning that I would "have seconds of notice before blindness,

⁵ *Id.*

and...flashing and a million stars in your eyes.” I misapplied this warning to the eye bubble dissolving in my eye after the second surgery.

Prior to my first surgery, I had been told by Dr. Massey that if I saw “stars” to immediately call and get to the emergency room. In this situation, I was all alone and did not have access to a vehicle. I immediately tried to call Dr. Lambert’s office, only to find out that it was actually past 6 p.m. and the office was closed. I reached Dr. Lambert’s answering service and left a message, stating that I believed my eye was failing and I needed emergency medical attention. Dr. Lambert’s nurse called back and explained that this was normal, but the stress of thinking I was blind had already taken its toll: it had made me physically sick.

The following day the resident apologized for not having explained what I would see when the bubble was absorbed. He explained that because I had been given so much advice, he had no idea what I had been told by the other doctors. This is just one example of how, in complex eye surgeries (or surgeries in general), there are many variables to cover, and when numerous doctors are involved, it can make things very confusing for the patient.

1.12 Conclusion

It was not until well after the procedures, when the immediacy of the situation had dissipated, that I was able to reflect on the process in a more objective way. In doing so, I began to realize just how cursory my understanding of the procedures had been at the time I had had to make those grave and life-altering decisions. There were problems with the consent process with this second surgery as well. I did not ask any questions, other than whether or not Dr. Lambert could fix me, and when he said yes, that was all the reassurance I needed. As a result, I did not have a clue about how they were going to perform the surgery. The subsequent discussions

about the blood transfusion and the procedure itself were inadequate, and although I signed and completed the informed consent documents at Dr. Lambert's office and the hospital, I believe that, at this point in time, I was incompetent to make decisions because of the psychological effects of realizing I was now blind.

Numerous doctors have since remarked that my recovery of any sight is unbelievable, but that to have recovered to the extent I did — from 7/400 vision to 20/20, is virtually unheard of. The Retina and Vitreous of Texas Website boasts the result of a case in which the improvement was not as dramatic as this, one of an individual whose “[v]ision improved from 5/200 to 20/20 and has remained 20/20 for six years post-op.”⁶ Unfortunately, there are problems with my vision still, and it is closing in again in the eye on which the surgery was performed. I am barely able to see a letter on a page now. [Out of that eye.] But when I could not see at all, I prayed for God to let me see again, if only to see my children’s faces and hopefully my grandkids’ faces, too. Remembering when I could not see at all, for me to see one letter now and then is a miracle.

Although I was relieved that the results of the surgeries had been above-average successes, I wished I had had the benefit of thoroughly understanding all the aspects of informed consent in order to have the peace of mind that my decision was the right one. This paper arises from that wish. In 1999, my options were extremely limited. At that time, I was surprised at both the huge percentage of people affected by eye diseases and the dearth of procedures available to correct the resulting blindness. Although my vision is limited today, I am able to function, and as part of my rehabilitation, I am taking the step from disabled military pilot to licensed attorney in order to help people in the areas of bioethics and health law. Sharing my

⁶ Information on subretinal neovascular membranes and subretinal neovascular membrane surgery is available at http://www.retinatexas.com/neovascular_membranes.html.

experience with eye surgery, and advocating for what I believe is an appropriate informed consent procedure will allow others to make the choice that I never had.

CHAPTER 2

Background and Elements of Informed Consent

2.1 Introduction

In March 2007, Regis Philbin, the well-known co-host of an ABC morning talk show for nearly 20 years, revealed to his audience that he required heart bypass surgery.⁷ As Philbin explained his situation, he asked his audience if anyone knew what would happen to him. When no one answered, Regis turned to his co-host, Kelly Ripa, and asked her if the doctor would “crack [him] open like a lobster?”, but she did not know what heart bypass surgery entailed. He told Ripa that he had called their good friend David Letterman, a late-night television talk show host, seeking information about the surgery because Letterman had previously undergone a quadruple bypass surgery. According to Philbin, even Letterman could not explain what procedure or risks Regis was going to face less than forty-eight hours from that moment. At this point, Ripa quipped that Regis had asked two talk show hosts to explain a complicated medical procedure when the appropriate person to ask was his doctor.⁸

This dialogue reflects what patients often do: they seek information about serious medical procedures from their friends; however, as Ripa told Philbin, they need to seek it from their doctors. A patient needs to take control of his or her treatment. A clear checklist leading both the doctor and patient through the informed consent elements would help the patient to do so and would lead to truly informed consent.

⁷ *Live with Regis & Kelly*, (ABC television show broadcast February 26, 2007).

⁸ *Id.* (Mr. Philbin disclosed that he had consulted two specialists, to include the surgical team that had operated on Mr. Letterman. These surgeons were described as some of the finest heart surgeons in the nation, but neither team had explained the risk or the procedures to Mr. Philbin in a way that Mr. Philbin understood. Mr. Philbin had already consented to the surgery; however, legally he did not provide informed consent because he was not informed. He merely provided consent to treatment by the doctor. Simple consent and informed consent are two separate concepts.).

The fact that a patient such as Philbin lacks a fundamental understanding of his medical condition and treatment also reveals problems with informed consent. Heart bypass surgery, like eye surgery, is a complicated but routine operation, but Regis' reaction shows that he did not understand the surgery. Without this knowledge, how could he give informed consent? The fact is that Philbin had given consent, but without adequate information and understanding of the necessary information — it could not have been informed consent. When informed consent procedures are properly followed, patients make decisions based on understanding its elements; they make an informed choice,⁹ and although not all anxiety may be eliminated, the patient is not needlessly stressed.¹⁰

Informed consent is a relatively new legal doctrine with many twists and variables, and it is one that is frequently unknown or is misunderstood by patients.¹¹ In my case, it was years

⁹ ALBERT R. JONSEN, MARK SIEGLER & WILLIAM J. WINSLADE, *CLINICAL ETHICS*, 51-82 (McGraw-Hill 2006) (2006).

¹⁰ *Id.* at 51-82.

¹¹ Marshall B. Kapp, *Patient Autonomy in the Age of Consumer-Driven Health Care: Informed Consent and Informed Choice*, *J. LEGAL MED.*, 28: 91-117 (March, 2007), (“...interest in [informed consent] was renewed generally in 17th century political philosophy, but opposition to it by the American Medical Association led to its dormancy in the American medical context until the 20th century. (Remarking on the current practice of allowing patients to make their own medical choices, one author notes:

‘That [letting patients make their own medical choices], in itself, is a remarkable fact. Little more than a decade ago, doctors made the decisions; patients did what they were told. Doctors did not consult patients about their desires and priorities, and routinely withheld information—sometimes crucial information, such as what drugs they were on, what treatments they were being given, and what their diagnosis was. Patients were even forbidden to look at their own medical records: it wasn't their property, doctors said. They were regarded as children: too fragile and simple-minded to handle the truth, let alone make decisions. And they suffered for it.’ ATUL GAWANDE, *COMPLICATIONS: A SURGEON'S NOTES ON AN IMPERFECT SCIENCE* 210 (Metropolitan Books 2003) (2002)

“Today, there is broad consensus that, in the arena of clinical medicine, ‘[i]nformed consent is more than a legal doctrine and a trap for unwary practitioners, it is a concept central to American beliefs about individual rights and the proper relationship between patients and providers.’ (THEODORE R. LEBLANG ET AL., *INFORMED CONSENT TO MEDICAL AND SURGICAL TREATMENT*, at *LEGAL MED.* 349 (S. Sandy Sanbar ed., Murphy Publ'n 6th ed. 2004). In addition to autonomy, the informed consent doctrine also has been supported by reference to the ethical principles of authenticity, (RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 262-68 (Oxford University Press 1986), privacy, (*Id.* at 40-41) and beneficence. (President's Comm'n for the Study of Ethical Problems in Medicine & Biomedical & Behavioral Research, *In Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship* (1982) (at 42-44). ‘Since well-being can be defined only within each individual's experience, it is in most circumstances congruent to self-determination’ *Id.* at 44; accord David I. Shalowitz & Michael S. Wolf, *Shared Decision-Making and the Lower Literate Patient*, 32 *J.L. MED. & ETHICS* 759, 762 (2004) [hereinafter Shalowitz & Wolf] (‘The model of shared decision-making is intended to provide a balanced structure for clinical consultations that both promotes

after my eye surgeries, when I took my first health law class, that I learned that an informed consent doctrine existed. A clear statement of informed consent is seen in Clinical Ethics which states, “Informed consent is the usual way in which patient preferences are expressed. Informed consent is the practical application of respect for the patient's autonomy.”¹²

The present informed consent procedure for complex surgeries is inadequate, and improvements are necessary to aid both patients and physicians. The more complex and risky the surgery, the more information a patient may need; this is especially true if the doctor demands an immediate decision. In order for a patient in such a situation to give truly informed consent, a detailed and time-consuming discussion may be required. Understanding Informed Consent does not reside with the patient alone, doctors frequently contribute to the confusion by routinely misunderstanding or misapplying informed consent to their patients.¹³

2.2 Development of Informed Consent

To understand the current state of informed consent, we must first look at its historical development¹⁴ which is rooted in case law.¹⁵ Put simply, courts want to protect patients from

patient autonomy and improves health outcomes.’); Helen W. Wu Et Al., National Quality Forum, Improving Patient Safety Through Informed Consent for Patients With Limited Health Literacy (2005), available at <http://www.qualityforum.org/publications.html> (last accessed March 1, 2006); see also KARIN I. KJELGREN ET AL., *Antihypertensive Medication in Clinical Encounters*, 64 INT’L J. CARDIOLOGY 161 (1998) (linking patient participation in decision making and treatment efficacy); Erika Szabo et al., *Choice of Treatment Improves Quality of Life: A Study on Patients Undergoing Dialysis*, 157 ARCH. OF INTERN. MED. 1352 (1997) (linking patient participation in decision making and treatment efficacy); Carol Golin et al., *Impoverished Diabetic Patients Whose Doctors Facilitate Their Participation in Medical Decision Making Are More Satisfied With Their Care*, 17 J. GEN. INTERN. MED. 857 (2002) (linking patient participation in decision making and treatment efficacy.”)).

¹² JONSEN *supra* note 9, at 54-55 (2006).

¹³ *Id.*

¹⁴ *Id.* at 91-117, (“The philosophical principle of individual autonomy, or personal self-determination, lies at the heart of modern American bioethics. (See, e.g., JERRY MENIKOFF, LAW AND BIOETHICS 356 (Georgetown Univ. Press 2001) (referring to patient autonomy as ‘that leading principle in the philosopher's world of bioethics’)). This ethical precept has been transformed slowly but steadily in the United States into the enforceable legal doctrine of informed consent, reflecting the phenomenon that ‘[t]he law is society's mechanism for establishing boundaries for conduct.’ See LOIS SNYDER & CATHY LEFFLER, ETHICS MANUAL: Fifth ed., 142 ANNALS INTERN. MED. 560, 574 (2005).”).

¹⁵ JONSEN, *supra* note 9, at 51-82.

unauthorized medical treatment.¹⁶ *Slater v. Baker and Stapleton*, a 1767 case from the English courts, held a physician liable for failing to obtain consent from his patient for unauthorized contact.¹⁷ The court reasoned that the standard for physicians was to obtain the patient's consent prior to treatment. Failure to obtain such consent constituted liability on the part of "a physician who failed to meet this standard of care."¹⁸ This unauthorized contact is the intentional tort of battery.^{19,20} The consent required then was authorization by the patient to receive treatment from the doctor.²¹ This was simple consent.²²

¹⁶ Nicolas P. Terry, *Apologetic Tort Think: Autonomy and Information Torts*, 38 St. Louis L.J. 189, 191-192 (1993) ("In tort law, the symbolic appeal to self-determination has long been forgotten. In its stead, torts lawyers have developed a far less inspiring decisional tree. First, they inquire, is this a 'no-consent' case or a 'lack of informed consent' case? Second, if it is of the latter species, torts lawyers pose the jurisdiction-sensitive question of whether a patient standard or a physician standard should be applied in measuring the appropriate level of disclosure.

"The answer to the first question determines whether the case will be brought in intentional tort or negligence. If it is a 'no-consent' case, the former battery applies; if it is a 'lack of informed consent' case, negligence applies as the regulatory mechanism. But why do torts lawyers make this distinction? One thing is sure: autonomy considerations are not involved. According to a representative Wisconsin court, the reasons why battery doctrine is not applicable to 'lack of informed consent' cases include the following:

'First, the act complained of in these cases simply does not fit comfortably within the traditional concepts of battery—the intent to unlawfully touch the person of another. In cases such as the instant one, physicians are invariably acting in good faith and for the benefit of the patient . . . Second, . . . the failure to inform a patient is probably not, in the usual case, an intentional act and hence not within the traditional concept of intentional torts. Third, the act complained of in informed consent cases is not within the traditional idea of 'contact' or 'touching.' In the typical situation, as here, the physician impeccably performs the surgery or other treatment. . . . Fourth, a valid question exists with respect to whether a physician's malpractice insurance covers liability for an arguably criminal act—battery. If not, it may be asked why a physician should be required to pay out of his own pocket for what is essentially an act of negligence—failing to inform a patient of the risks indigenous to the treatment? Fifth, these essentially negligence cases do not fit the traditional mold of situations wherein punitive damages can be awarded.'")

¹⁷ JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 42 (Oxford University Press 2001).

¹⁸ *Id.* at 42.

¹⁹ *TREATISE ON HEALTH CARE LAW* 17-6 (Alexander M. Capron ed., Matthew Bender & Co., Inc. 2007) (1974)

²⁰ DAN B. DOBBS, *THE LAW OF TORTS* 52-53 (West Group 2000), (Simple battery is defined as when a defendant "intentionally causes bodily contact to the plaintiff in a way not justified by the plaintiff's apparent wishes or by a privilege, and the contact is in fact harmful or against the plaintiff's will.").

²¹ BERG, *supra* note 17, at 42.

²² *Id.* at 43, ("The courts have generally agreed that the patient has, by speaking some phrase, authorized a physician to proceed and thereby provide the physician with a defense to an action for battery.").

The application of the tort of battery persisted into the twentieth century when Judge Cardozo in 1914 made the connection between simple consent and informed consent with this now famous statement:

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages. (*Pratt v. Davis*, 224 Ill. 300 [1906]; *Mohr v. Williams*, 95 Minn. 261 [1905]). This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained.²³

This statement has served as a basis for the “patient’s right to self-determination.”²⁴ In the 1950’s, a series of cases began shaping what was to become informed consent in accordance with the patient's right to self-determination.²⁵ *Salgo v. Leland Stanford, Jr. University Board of Trustees* was where the term “informed consent” was first used.²⁶ The *Salgo* court did not define the elements required for informed consent. Instead, the court held that,

...[E]ven where consent is formally given and documented in writing, it is legally ineffective if the patient did not understand material information about the procedure that he or she was authorizing. This information includes ... not only the nature of the procedure to be performed but also its broader implications, including any risk connected with it.²⁷

Few cases deal specifically with informed consent and eye surgery; therefore, a major goal of this paper is to provide both ophthalmologists and patients a list of elements that can guide the

²³ *Schloendorff v. Soc’y of N.Y. Hosp.*, 211 N.Y. 125, 129-30 (N.Y. 1914).

²⁴ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-7, § 17.01[1][c].

²⁵ BERG, *supra* note 17, at 44, (“[T]he Supreme Court of North Carolina stated that the failure to explain the risk involved in surgery ‘may be considered a mistake on the part of the surgeon’ *Hunt v. Bradshaw*, 88 S.E.2d 762 (N.C., 1955), the element ‘that a physician had an affirmative duty of disclosure’ was added by a California court in *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170 (Cal. Ct. App. 1957).”).

²⁶ *Id.*

²⁷ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-7, § 17.02[1] (“[T]he *Salgo* court did not identify in detail what information had to be communicated to the patient to render the consent ‘informed’ or ‘educated.’ The case simply established the principle that sufficient information must be communicated to, or known by, the patient for him or her to understand the main reasons for an against undergoing the treatment.”).

dialogue for the selection of a course of treatment for eye surgeries. The elements must be intuitive and helpful in emergency eye surgery situations and must help to counter the most pervasive problem with informed consent and its elements: misapplication.²⁸

2.3 Elements of Informed Consent

My account of my experience with eight different ophthalmologists, two surgeries, and two different medical problems demonstrates that the consent I gave was neither informed nor documented and therefore not valid. I submit that the elements contained in the Treatise on Health Care Law,²⁹ complemented by those in Clinical Ethics³⁰ and enhanced with solutions to the needs I saw firsthand, would provide a framework for a much-needed comprehensive approach to complex eye surgeries. It is structured but contains room for flexibility.

True informed consent does not consist of a patient signing a form, but is a dialogue between patient and physician that enables the patient to make an educated decision about his or her body and select an appropriate course of treatment.³¹ The amount of dialogue the eye surgeon must provide will depend on the patient's knowledge of the condition. If the diagnosis is wholly unexpected, as it was to me, more information may be required. In order to be thorough, there are other forms of communication that may educate the patient further, such as pamphlets, DVDs, web-based information and patient advocates.³²

²⁸ JONSEN, *supra* note 9, at 55 (“Informed consent should not designate a mechanical recitation of facts or a pro forma signature on a piece of paper. The phrase ‘I consented the patient,’ sometimes used by young clinicians to report that the patient had signed a consent form, reveals a fundamental misunderstanding of informed consent...Despite a vast literature in law and ethics about the importance of informed consent, many studies reveal that physicians often fail to observe the practice and the spirit of informed consent.”).

²⁹ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-14 to 25, § 17.02.

³⁰ JONSEN, *supra* note 9, at 55.

³¹ *Id.*

³² KAPP, *supra* note 11, at 91-117 (March 2007). (“Furthermore, patients' medical decisions are based on the information (that is, the factual content) with which the patients are provided. Although patients' comprehension and utilization of medical information certainly is not perfect, there is confidence that the use of decision aids such as

A physician who confuses simple and informed consent does not serve his or her patients and becomes open to liability. The physician-patient dialogue will change, as a patient understands information disclosed in accordance with the informed consent elements. Time permitting, a patient with a serious or life-threatening condition can become an expert in the treatment required. A comprehensive discussion using the elements of informed consent would have greatly aided me in selecting the course of treatment most appropriate for me.

We have all seen the cowboy movies where the patient is given a stick to bite and his friends hold him down so the doctor can remove a bullet. The cowboy gives merely simple consent without information about the procedure or alternatives. In times past, consent was required for practical purposes because, without anesthesia, most patients were awake.³³ The doctor needed the patient's cooperation, if only so he or she would not fight the doctor, as he was operating.³⁴

But according to the Treatise on Health Care Law, “[t]here is also the issue of documentation [regarding informed consent] ... doing the right thing with regard to informed consent is only part of the story. It is just as important to document what was done, so that it can be proven if a legal challenge is raised.”³⁵ Doctors should understand the difference between simple consent and informed consent. Informed consent requires a dialogue that results in patients selecting their own course of treatment, referred to in *Slater* as proper documentation.^{36,37} Simple consent consisting of a mere “Okay.” is not legally permissible. This is a legal standard, and that standard is informed consent.

story boards, picture books, and interactive videos to communicate the information can improve patient decision making demonstrably.”).

³³ BERG, *supra* note 17, at 42 (Anesthesia had not yet been invented.).

³⁴ *Id.*

³⁵ MEDICAL MALPRACTICE: GUIDE TO MEDICAL ISSUES § 31.08 (LEE S. GOLDSMITH, ED.) (Matthew Bender & Co., Inc. 2007).

³⁶ 95 Eng. Rep. 860.

In order to obtain truly informed consent—a decision based on education and understanding—a checklist for the doctor and patient must address the following elements:

- (1) diagnosis; (2) nature and purpose of proposed treatment; (3) risks and consequences; (4) prognosis if proposed treatment not undertaken; (5) alternatives and their risk and consequences; and (6) other issues such as insurance coverage, medical charges, expected recovery time and the intensity and duration of any pain, plus any prohibited activities.³⁸

Other elements that might need to be disclosed are “the cost of the proposed treatment, including both the physician's fees and related expenses, and what portion of the expenses, if any, will be covered by health insurance.”³⁹ These elements are derived from my experience as a patient and from the Treatise on Health Care Law and Clinical Ethics.

2.3.1 Diagnosis

The most critical piece of information that the patient is waiting to hear from the doctor is the diagnosis.⁴⁰ The Treatise on Health Care Law affirms this in saying that it is important that the doctor have “determined, or suspects, [what] the patient's problem is” ... and when sure of the condition, “share [the information] with the patient.”⁴¹ A patient must be told truthfully, what has happened to him or her.⁴² This is the beginning of the education process. A patient uses the diagnosis to understand his or her ailments and decide on a course of treatment, as well as to evaluate the doctor, get a second opinion, and seek further information on the condition.⁴³ As defined in Clinical Ethics, informed consent is “a willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the

³⁷ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-7, §17.01[1][b].

³⁸ *Id.*, at § 17.02[2].

³⁹ *Id.*

⁴⁰ *Id.* at 17-15, § 17.02[2][a].

⁴¹ *Id.*, at 17-15.

⁴² JONSEN, *supra* note 9, at 66.

⁴³ *Id.* at 56-58.

intervention with its risks, benefits and alternatives.”⁴⁴ The diagnosis is key to an adequate disclosure by the physician.

A vital point when disclosing the diagnosis is the patient's comprehension.⁴⁵ The doctor may give an exceedingly clear and detailed explanation, but if the patient does not comprehend, the doctor cannot obtain truly informed consent.⁴⁶ One of the things that instructor pilots learn is that when a person becomes task-saturated, his or her ability to hear any more information shuts off. In the case of a patient receiving unexpected bad news, he or she may develop a barrier similar to the task-saturated pilot that cannot accept any more information, and his brain is prevented from comprehension.⁴⁷ Numerous other factors could impede comprehension such as a lack of communication skill or effort on the part of the doctor, a physician’s belief that a thorough explanation would be too time-consuming or beyond a patient’s psychological or intellectual capabilities, a physician’s failure to understand the logic of patient involvement in decisions, or a patient’s belief that decisions on medical treatment are the doctor’s to make.⁴⁸ Today, most physicians disclose the patient’s diagnosis to their patients even if it is “bad news.”⁴⁹

A Health Law hornbook states, “[A] physician must first describe the diagnosis, including the medical steps preceding diagnosis, including test and their alternatives. Since disclosure of diagnosis is so basic to the physician-patient relationship, few cases have talked about a physician’s failure to discuss it.”⁵⁰ To quote the Treatise on Health Care Law, “The

⁴⁴ *Id.* at 56.

⁴⁵ *Id.* at 58.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.* at 58-59.

⁴⁹ *Id.*

⁵⁰ BARRY R. FURROW ET. AL, HEALTH LAW 315 (West Group 2000) (1995).

issue is much less clear in cases where the physician is unsure about the diagnosis.”⁵¹ Even without the threat of litigation, physicians readily disclose the diagnosis.⁵² Very little case law exists about doctors who do not give a diagnosis, because doctors almost always disclose this information.⁵³

A rare case that went to the appellate court in Louisiana involved the patient’s claim against her doctor for failure to disclose. This claim was actually medical malpractice based on a negligence claim rather than a claim for failure to diagnose. In *Steele v. St. Paul Fire & Marine Ins. Co.*, the Louisiana appellate court found that a physician had breached his duty to disclose when he failed to inform the patient of the result of her Pap smear.⁵⁴

In my case, like almost all in the U.S., each doctor gave me his diagnosis after performing tests. The primary physicians, numerous associates and every surgeon who eventually saw me provided me a diagnosis; however, the laser burn tracks on my eyes were not discussed with me until a year after my initial surgery. I did not have more than a cursory understanding of my diagnosis at a time when I was being asked to consent to major eye surgery, maybe because I was unable to comprehend due to emotional shock or maybe due to a lack of adequate explanation.

⁵¹ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-16, § 17.02[2][a].

⁵² *Id.* at 17-15, § 17.02[2][a].

⁵³ *Id.* at 17-16.

⁵⁴ *Steele v. St. Paul Fire & Marine Ins. Co.*, 371 So. 2d 843, 849 (La. Ct. App. 1979) (“... in order for the doctor to be under a duty to disclose information to his patient, the patient must show that the information was ‘material’ to the patient’s decision in regard to undergoing the operation. In order to show that the alternative procedure in this case was ‘material’ information, the patient would have to prove that it is an accepted medical treatment. A physician, of course, would be under no duty to disclose alternative procedures which were not accepted as feasible.”).

2.3.2 Nature and Purpose of Proposed Treatment

The Health Law hornbook touches on another essential factor, stating, “[T]he nature and purpose of the proposed treatment must be discussed.”⁵⁵ The discussion of this element must be complete.⁵⁶ This discussion occurs when the physician talks to the patient about how and why the surgery will correct the problem in question.⁵⁷ It is here that the physician initiates a dialogue where the patient understands, and accepts or rejects, the proposed treatment. Often, as the physician discusses the purpose of the treatment, he or she must also explain the “probable effectiveness in accomplishing that purpose.”⁵⁸ While most physicians disclose the nature and purpose of the treatment, a physician who ignores or inadequately discusses the nature and purpose of the proposed treatment, risks not only breaching informed consent but also violating consent in general.⁵⁹ Such a physician could be charged with battery.

In his discussion of a seminal informed consent case, Arnold Rosoffs states, “*Canterbury v. Spence*, easily the most cited of informed consent cases, declares, ‘In duty-to-disclose cases, the focus of attention is more properly upon the nature and content of the physician's divulgence than the patient's understanding or consent...’”⁶⁰

The physician is not required to give a medical dissertation or teach a short course.⁶¹ The physician, however, is required to provide enough information about the nature and purpose of the treatment to enable the patient to accept or refuse the physician’s recommendation. This decision must account for the patient’s comprehension and competence.

⁵⁵ FURROW, *supra* note 50, at 315.

⁵⁶ JONSEN, *supra* note 9, at 70.

⁵⁷ *Id.* at 70.

⁵⁸ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-16, § 17.02[2][b].

⁵⁹ *Id.*

⁶⁰ Arnold J. Rosoffs, *Informed Consent in the Electronic Age*, 25 Am. J. L. and Med. 367, 374 (1999).

⁶¹ JONSEN, *supra* note 9, at 70.

The Treatise on Health Care Law states, “Failure to disclose the nature of a proposed treatment to the patient has spawned little litigation in the informed consent area.”⁶² The cases that discuss the nature and purpose of the proposed treatment list this element almost in passing. However, in *Anderson v. George H. Lanier Memorial Hosp.*, the Alabama Supreme Court held that the nature and procedure of the proposed treatment was not given.⁶³ District court erred by granting summary judgment for a doctor and hospital.⁶⁴ In this Alabama case, numerous elderly patients alleged they were incapable of giving informed consent due to lack of competence or comprehension. The appellants further alleged the doctor did not provide information on the nature and procedure of the proposed surgery, including failure to note that an experimental lens was to be implanted.⁶⁵ The doctor surgically implanted this experimental lens during cataract transplant surgery without informing the patients of the experimental basis of the lens. Only after suffering great pain and being examined by other eye doctors did the plaintiffs know the experimental basis of the lens. First, the Alabama Supreme Court noted that “claims brought under the Alabama Medical Liability Act” for failure to get informed consent prior to surgery were not barred due to the statute of limitations. Instead, it held that the hospital may have committed fraud by failing to get informed consent from the appellants.⁶⁶ This statute of limitations started only after discovery.

As *Anderson* notes, failure to get informed consent may also occasion other tort causes of action by plaintiffs.⁶⁷ Merely telling the patient, “You must undergo emergency surgery.” or “I

⁶² TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-16, § 17.02[2][b].

⁶³ *Anderson v. George H. Lanier Memorial Hosp.*, 982 F. 2d 1513, 1519 (11th Cir. 1993).

⁶⁴ *Id.* at 1520.

⁶⁵ *Id.* at 1519.

⁶⁶ *Id.* at 1519.

⁶⁷ *Id.* (“The fraud the appellants allege is that Lanier Hospital did not obtain their informed consent concerning an experimental procedure. The appellants are not arguing that their eye surgeries caused injury; instead, their claim is that they were never put on notice that they were the subjects of research. Under the ruse of removing cataracts, Dr.

will operate on you.” is not enough. The nature and purpose of the proposed treatment must include all the material facts.⁶⁸ The possible results for the surgery should be included. The doctor should also state his capability and results of previous surgeries, if he is able. These are issues that I needed answered and wanted to know about for the eye surgeries I underwent.

In my case, Dr. Massey gave me only a broad overview of the treatment plan. He essentially stated that the purpose of the proposed treatment was to seal an errant blood vessel in my eye. We did not discuss the nature of the proposed treatment, nor did Dr. Massey provide any details about the surgery. One reason for this was my lack of comprehension and my competence at that moment. I had been completely surprised by the diagnosis. In the first twenty-four hours, I truly did not understand the problem, much less the procedure to a cure. However, I was being pressured into making a life-altering decision: to be blind now or in two weeks. Those options were unsatisfactory to me. What I needed was a crash course in medicine. A systematic approach to the problem and treatment might have satisfied both my desire to know and understand my options and my doctor’s need to mitigate or prevent any further damage.

2.3.3 Risks and Consequences

This discussion of the nature and purpose of the proposed treatment leads into one of the most litigated and necessary sections of informed consent: risks and consequences. According to the Treatise on Health Care Law, this is the element that “[b]y a wide margin ... accounts for the

Torsch may have committed fraud on these appellants when he inserted experimental IOLs [experimental lens] in their eyes. Likewise, the hospital may have committed fraud if it failed to obtain their informed consent.”)

⁶⁸ *Truman v. Thomas*, 27 Cal. 3d 285, 291 (Cal. 1980) (“Material information is that which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the recommended medical procedure. (*Sard v. Hardy* (1977) 281 Md. 432, 444 [379 A.2d 1014]; *Wilkinson v. Vesey* 110 R.I. 606 ((1972), 627 [295 A.2d 676, 69 A.L.R.3d 1202])). To be material, a fact must also be one which is not commonly appreciated. (*See Canterbury v. Spence* (D.C. Cir. 1972) 464 F.2d 772, 788). If the physician knows or should know of a patient's unique concerns or lack of familiarity with medical procedures, this may expand the scope of required disclosure. (Waltz & Scheuneman, *Informed Consent to Therapy* (1970) 64 Nw. U.L. Rev. 628, 639-640.)”).

largest volume of informed consent claims. A *risk* is something that might occur in the conduct of, or as a result of, the treatment in question. A *consequence* is something that is expected to happen....”⁶⁹ This treatise goes on to say that, risks and consequences “are perhaps the most important information for a patient to consider.”⁷⁰ This element is the one with which a patient can identify and try to quantify. Patients want answers to questions such as, “Will I be okay?” or “What are my chances?” Such risk assessment by the patient is a critical step.

A Louisiana court, in *La Caze v. Collier*, stated,

Written consent to medical treatment means a consent, in writing, to any medical or surgical procedure or course of procedures which (a) sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, of disfiguring scars associated with such procedure or procedures, (b) acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner, and (c) is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent, by a person who has legal authority to consent on behalf of such patient in such circumstances. Such consent shall be presumed to be valid and effective, in the absence of proof that execution of the consent was induced by misrepresentation of material facts.⁷¹

Ophthalmologists are trained in the field of eye surgeries and vitreous and retina diseases and must provide information on the material risks⁷² to the patient.⁷³ For eye surgery, a few of

⁶⁹ TREATISE ON HEALTH CARE LAW, *supra* note 19, at § 1702[2][c].

⁷⁰ FURROW, *supra* note 50, at 315.

⁷¹ *La Caze v. Collier*, 434 So. 2d 1039, 1042 (La. 1983).

⁷² *Harbeson v. Parke Davis, Inc.*, 656 P.2d 483, 522 (Wash. 1983), (This case held the U.S. Government and three Army doctors responsible for failing to disclose the risks of a drug on children subsequently born to the parent's. Specifically the court stated, “This [Informed Consent] cause of action may arise even though the doctor's actions have not been negligent in any other way. See *Holt v. Nelson*, 11 Wash. App. 230, 523 P.2d 211, 216-17 (1974). The Washington Supreme Court expressly found this doctrine applicable to the disclosure of "material information as to the likelihood of future children being born defective. *Harbeson*, 656 P.2d at 491.”)

the risks include blindness, halo vision, loss of night vision, dry tear ducts in eyes, pain, color blindness, loss of depth perception and numerous other risks and consequences.

Another mandatory disclosure of risk and consequences involves blood transfusions and the possibility of HIV infection.⁷⁴ In my own experience with giving consent for my surgeries, I encountered misunderstanding by the hospital staff of their duties with regard to providing me with information on this subject. I considered this a material issue in my decision of whether or not to consent to the surgery. However, if I had not had a family member who is a medical professional at my side, I would have been in the position in which many people are placed of having too little or incorrect information.

Canterbury points out that the patient may have additional concerns and questions about risks and consequences that a doctor would not mention.⁷⁵ Doctors are encouraged to disclose any lengthy recuperation period, treatable infections, disclosure of any possible paralysis, death or blindness, disclosure of the skill or status of the surgeon, any impairment of the physician, and lastly, any financial gain the physician may receive from the surgery.⁷⁶ Although the courts have not uniformly adopted a standard for the disclosure of these elements, it is recommended that

(“The [informed consent] doctrine is premised on the fundamental principle that a competent individual has a right to determine what shall be done with her own body. *Smith v. Shannon*, 100 Wash. 2d 26, 666 P.2d 351, 354 (1983). To allow this determination the health care provider must provide the individual with sufficient information to make an “intelligent” decision. *Smith*, 666 P.2d at 354, (emphasis in original); *Canterbury v. Spence*, 150 U.S. App. D.C. 263, 464 F.2d 772, 786-87.”).

⁷³ FURROW, *supra* note 50, at 315.

⁷⁴ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-17, § 17.02[2][c] fn 7 (“For example, courts have recently recognized the duty to disclose the risk of HIV infection in receiving a blood transfusion, *Doe v. Johnson*, 476 N.W.2d 28 (Iowa 1991), or in being treated by an HIV-positive surgeon, *Estate of Behringer v. Medical Center at Princeton*, 249 New Jersey super 597, 592 A. 2d 1251 (Law Div. 1991).”).

⁷⁵ *Canterbury v. Spence*, 150 U.S. App. D.C. 263 (D.C. Cir. 1972) (“The context in which the duty of risk-disclosure arises is invariably the occasion for decision as to whether a particular treatment procedure is to be undertaken. To the physician, whose training enables a self-satisfying evaluation, the answer may seem clear, but it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie. To enable the patient to chart his course understandably, some familiarity with the therapeutic alternatives and their hazards becomes essential.”).

⁷⁶ FURROW, *supra* note 50, at 315-24.

they be told to the patient, as this will aid him or her in deciding whether to accept or reject the proposed course of treatment.

There are exceptions when the doctor is justified in not giving complete risks to patients.⁷⁷ These exceptions generally cover therapeutic harm, incompetence, emergency, common knowledge, and the risk being too remote to necessitate an explanation.⁷⁸ Courts have also stated that not every possible risk has to be briefed to the patient, just those that are considered material.⁷⁹ There are an infinite number of risks and consequences that depend on each individual's body. Each person's reaction to a given surgery is unique. For example, a remote risk presented itself in my case: My eye was not receiving nutrients to the RPE (retina). Colonel Hanumanthu saw in 1999 that my eyes were at risk if they did not receive normal nutrients. He did not know if a new vitamin specifically developed for the eye, OcuVite, would do any good or not, but he stated that he "did not want to find out five years from now [1999] that these vitamins [were] effective in preventing blindness."⁸⁰ Before five years had passed, his guess that they were effective was correct, and the vitamins were proven to help.⁸¹

⁷⁷ D. Scott Porch, IV, *Recent Developments in Tennessee's Doctrine of Informed Consent*, 30 U. Mem. L. Rev. 593, 596-597 ("Courts have recognized a number of situations in which disclosure of certain risks either is not required or is not possible.).

These include situations in which (1) complete and candid disclosure might adversely affect the patient's physical or psychological well-being ('therapeutic'); (2) the patient is incapable of giving consent by reason of mental disability or infancy ('incompetence'); (3) an emergency makes obtaining consent impractical ('emergency'); (4) the risk is either known to the patient or is so obvious as to justify a presumption on the physician's part that the patient knows of it ('actual knowledge' and 'common knowledge'); (5) the procedure is simple and the danger remote and commonly appreciated to be remote ('known remote risk') and (6) the physician does not know of an otherwise material risk and should not have been aware of it in the exercise of ordinary care ('physician's reasonable ignorance').

⁷⁸ *Id.*

⁷⁹ *Harbeson*, supra note 72, at 522.

⁸⁰ Nat'l Inst. of Health, *Age-Related Eye Disease Study (AREDS)*. (AREDS was a 10-year, independent study conducted by the National Eye Institute (NEI) of the National Institutes of Health that found PreservVision (once called OcuVite) "... was the one and only antioxidant vitamin and mineral supplement clinically proven effective in the AREDS study.").

⁸¹ *Id.*

After eight years, I am still learning about the risks about the surgeries I underwent. In a Tenth Circuit decision, that court stated,

It is unreasonable to require a physician under the circumstances ... to have read every single possible side effect listed in the PDR ... before obtaining [the patient's] consent to administration of the drug. At most, the treating physician under those circumstances is only required to advise the patient of the most common side effects—not those that are extremely remote and not seen by many doctors over the full span of their career. To hold otherwise is to impose an unreasonable burden on treating physicians, in effect condemning every doctor who fails to read the complete litany of warnings, precautions, and side effects listed in the PDR to every patient before using or prescribing a drug, regardless of the circumstances.⁸²

The disclosure standard the court applied was the reasonable patient standard.⁸³

Analysis of the Tennessee approach to informed consent and the disclosure of risk and consequences suggest that there are certain times that a patient should not be told the risks. The early analysis of the Tennessee informed consent discussed in 2000 in D. Scott Porch's "Recent Developments in Tennessee's Doctrine of Informed Consent" expresses the exceptions many states allow physicians, when deciding if it is appropriate to withhold certain risks from patients.⁸⁴ These Tennessee exemptions were outlined as follows:

In *Shadrick v. Coker*, (963 S.W.2d 726 (Tenn. 1998)) the Supreme Court discussed a number of situations in which a physician should not disclose the existence of certain risks. (*Id.* at 733) Health care providers are generally not required to disclose [(1)] risks that are not material, such as those that are extremely unlikely to occur or one that a reasonable patient would not care to know due to its insignificance; [(2)] risks that are obvious or already known by the patient; [(3)] risks that are unforeseeable or unknowable; or [(4)] where the patient's medical condition renders discussion of the risks and benefits of the treatment or procedure impossible or medically inadvisable, such as in an emergency where the patient

⁸² *Shinn v. St. James Mercy Hosp.*, 675 F. Supp. 94, 99 (D.N.Y. 1987).

⁸³ *Id.*

⁸⁴ *Id.* at 596-97.

is unconscious or otherwise incapable of consenting, or where full disclosure would be detrimental to the patient's total care, i.e., the patient is unduly alarmed or apprehensive to start with and additional information would overload the patient and jeopardize his or her physical or emotional well-being.⁸⁵

In the interest of leading to sound decisions on the course of treatment, these exemptions limit the level of disclosure a doctor must provide when a patient is incompetent or incapacitated.

These exceptions allow the doctor to treat a patient who cannot make an informed consent.

In *Rethinking Informed Consent*, Peter Schuck states that nationwide, courts have also recognized similar exceptions:

Courts have recognized a number of situations in which disclosure of certain risks either is not required or is not possible. These include situations in which (1) complete and candid disclosure might adversely affect the patient's physical or psychological well-being ('therapeutic'); (2) the patient is incapable of giving consent by reason of mental disability or infancy ('incompetence'); (3) an emergency makes obtaining consent impractical ('emergency'); (4) the risk is either known to the patient or is so obvious as to justify a presumption on the physician's part that the patient knows of it ('actual knowledge' and 'common knowledge'); (5) the procedure is simple and the danger remote and commonly appreciated to be remote ('known remote risk') and (6) the physician does not know of an otherwise material risk and should not have been aware of it in the exercise of ordinary care ('physician's reasonable ignorance').⁸⁶

These national exemptions limit the disclosure while allowing doctors to provide the best course of treatment. They make it practical for a doctor to actually provide informed consent without disclosures becoming overly burdensome. Besides these exemptions, states require a certain level of disclosure, which Porch also discusses, to ensure the patient is informed of the risks involved in selecting the course of treatment:

⁸⁵ Porch, *supra* note 77, at 609.

⁸⁶ Peter H. Schuck, *Rethinking Informed Consent*, 103 Yale L.J. 899, 919 (1994), (citing *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 360 (Iowa 1987)).

Courts have also varied on the issue of causation. Some have adhered to the *subjective standard*, under which the patient must prove that he or she would not have consented to the procedure if fully informed of the risks, while others have used the *objective standard*, following which the patient must prove that a reasonable person in the same situation would not have consented to the procedure had he or she been fully informed of the risks. The overwhelming majority of states employ the latter.⁸⁷

Failure to adhere to the objective standard as followed by most states must be proven according to certain criteria. The author goes on to state that:

Finally, several states have developed a requirement that the patient show by expert proof that the physician deviated from the standard of care in failing to disclose a particular risk. Some states have specific statutes that require the expert testimony.⁸⁸

The combination of disclosure standards, exemptions and the proof required for the subjective standard creates a framework for the practical application of informed consent.

Examining a specific case dealing with eye surgeries, in 1988, a Missouri court held that a doctor's failure to recommend a retinal specialist to a military veteran at a VA hospital is not an invalid informed consent when the doctor who performed the surgery was a retina specialist.⁸⁹ In fact, the veteran had been warned the retinal surgery to remove the slipped lens nucleus carried a risk of blindness. The court stated that the veteran had been properly given the risks and consequences.⁹⁰

⁸⁷ Porch, *supra* note 77, at 593 note 20.

⁸⁸ *Id.* at 596-97 note 20, ("The causation standard in Oklahoma and Oregon is whether the particular patient would have undergone the procedure had he been properly informed. *See Spencer v. Seikel*, 742 P.2d 1126 (Okla. 1987); *Arena v. Gingrich*, 748 P.2d 547 (Or. 1988).").

⁸⁹ *Zimmer v. United States*, 702 F. Supp. 757, 761 (D. Mo. 1988).

⁹⁰ *Id.* ("Plaintiff argues that Drs. Morrison and Kennealy committed medical malpractice when they failed specifically to advise him that he needed a 'retinal specialist' to perform the vitrectomy. *See* Finding of Fact No. 9. Plaintiff contends that this failure caused his loss of vision in his right eye because a 'retinal specialist' would have

Again, when looking at why disclosure is required, we must look to state court. Connecticut dismissed a case based on the patient's claim of invalid informed consent. This claim arose when numerous doctors did not disclose other tests available to find the cause of the patient's severe head pain. The patient went blind within a few months, and the suit followed. The Connecticut Supreme Court dismissed the case that was based on the claim of lack of informed consent when the doctors failing to disclose the risk of not conducting other tests. Reaffirming the precedent within the state, the court said, "Thus Connecticut cases in this area uniformly involve claims for lack of informed consent risks associated with the treatment or procedure itself, not from risks associated with failure to properly diagnose or to provide treatment or testing."⁹¹ In summation, as explained by the Appellate Court, "All the informed consent cases in Connecticut have involved the adequacy of information disclosed regarding the procedure and treatment to be performed."⁹²

successfully performed the vitrectomy without causing a retina tear; Dr. Cohen was not a 'retinal specialist;' plaintiff would have refused surgery by Dr. Cohen had he known Dr. Cohen was not a 'retinal specialist;' and Dr. Cohen caused a retina tear during the vitrectomy because he was not a 'retinal specialist.'

For several reasons, the Court rejects plaintiff's 'retinal specialist' argument. First, whatever label of expertise is placed upon a particular doctor, plaintiff needed a doctor qualified to perform a vitrectomy. Based upon his education, training and experience, and being assisted by Dr. Chan and observed by Dr. Boniuk, Dr. Cohen was qualified to perform a vitrectomy. *See* Finding of Fact No. 11. Second, plaintiff has not established that, as of July, 1985, Dr. Cohen was not a 'retinal specialist.' Third, in the circumstances presented by this case, the procedures followed by Drs. Morrison and Kennealy, and the information which they provided to plaintiff, were adequate. These circumstances were as follows: Drs. Morrison and Kennealy were residents from Barnes. During their operation on plaintiff, they were being telephonically advised by Dr. Farber, a faculty member from Barnes. On the morning after their operation on plaintiff, they surrendered responsibility for plaintiff's further treatment and care to Dr. Farber. Dr. Farber arranged for plaintiff's transfer to Barnes for vitrectomy surgery. Barnes is one of the leading institutions for eye surgery in the United States. At Barnes, vitrectomy surgery was performed by Dr. Cohen, who was qualified to perform that surgery and who may have been a 'retinal specialist.' Dr. Cohen was assisted by Dr. Chan and observed by Dr. Boniuk, both 'retinal specialists.' *See* Findings of Fact Nos. 7, 10 & 11. In these circumstances, it was not medical malpractice for Drs. Morrison and Kennealy merely to advise plaintiff that he needed to be transferred to another hospital for surgery to be performed by a doctor more experienced in the back of the eye, and for Drs. Morrison and Kennealy then to rely upon Dr. Farber arranging for appropriate further treatment and care.").

⁹¹ *Glover v. Griffin Health Servs.*, 2006 Conn. Super. LEXIS 1841, 10-11 (Conn. Super. Ct. 2006).

⁹² *Id.*

This differs from my case, in which there was a clear diagnosis. The doctors in this Connecticut case were trying to find an elusive diagnosis for the patient's severe head pains. As they searched for a diagnosis, the probable risks did not extend to the patient losing her sight. This case highlights the point that, because of each patient's unique physiology, especially in complex eye surgeries, not every risk can be covered. There are just too many variables.

2.3.4 Prognosis if the Proposed Treatment was not Undertaken

With rare exceptions, a doctor always offers the prognosis in the event that a patient refuses the proposed treatment.⁹³ If the patient refuses the proposed treatment, the doctor has a duty to warn the patient of the dangers.

The physician needs to make a determination as to whether or not the patient is competent or when he or she refuses the proposed treatment.⁹⁴ A patient may refuse a proposed treatment on several grounds. In the case of complex eye surgery, the patient may feel that the surgery involves a greater risk than the prognosis.⁹⁵ Additionally, a patient's religious or cultural beliefs may prohibit him or her from accepting the proposed treatment.⁹⁶ With a complex eye surgery, there may be the requirement for blood transfusions; a Jehovah's Witness will refuse this treatment on those grounds. The doctor should carefully explain the risks and events that will take place if the proposed treatment is not undertaken.

What happens when the physician has given a diagnosis, the patient understands the risk of the surgery, but refuses treatment? The patient's refusal is seen as a rejection to the doctor,

⁹³ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-17, § 17.02[2][e], ("In most instances, a physician proposing a certain treatment approach will readily volunteer an opinion as to what may happen if the recommendation is not adopted. Thus, litigation on this point is sparse. However, a failure to provide such information can lead to liability, as in the 1980 California ruling in *Truman v. Thomas*, 27 Cal.3rd 285 (1980)").

⁹⁴ JONSEN, *supra* note 9, at 73-83.

⁹⁵ *Id.* at 73-74.

⁹⁶ *Id.* at 75.

and the physician will readily give arguments to try to persuade the patient to follow his or her advice. Whether the doctor does so because of the Hippocratic Oath, paternalism or the belief that if the patient does not follow the recommendation, dire consequences will ensue, the doctor will normally give the patient the prognosis in the event that the proposed treatment is not undertaken.⁹⁷ The most notable case of a doctor not informing the patient is *Truman v. Thomas*,⁹⁸ in which the doctor did not inform the patient of the prognosis of cancer if the patient did not undergo a Pap smear.⁹⁹ Unfortunately, the patient did develop cancer and died at age 30.¹⁰⁰ Thus, *Truman*, as well as *Cobbs v. Grant*, “made clear that physicians’ duty of disclosure arises from their broad relationship with patients and not solely from physical touching.”^{101, 102} A doctor has a fiduciary duty, based upon accepting the patient, to provide the patient the prognosis in the event that proposed treatment is not undertaken.

The clearest disclosure I received from all of the physicians was my prognosis if I did not undergo surgery. There was absolutely no doubt that if I did not do something, I would go blind. A paper such as this can never express what it is like to face the absolute certainty that there would be no hope of ever seeing again once that first laser blast hit the back of my eye. It was only through the meticulous dialogue between the doctors, Father Lowe, other health care providers, and me that I realized that if I did not accept the treatment, there was absolutely no hope of remaining sighted. An inexplicable courage to undergo the surgery was derived from

⁹⁷ Ben Kusmin, *Swing Low, Sweet Chariot: Abandoning the Disinterested Witness Requirement for Advance Directives*, 32 Am. J. L. and Med. 93, 116, (“I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. . . . While I continue to keep this Oath unviolated, may it be granted to me to enjoy life and the practice of the art, respected by all men, in all times. But should I trespass and violate this Oath, may the reverse be my lot.”).

⁹⁸ *Truman v. Thomas*, 27 Cal.3d 285 (1980).

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 291, (“The scope of a physician's duty to disclose is set by law rather than by the custom of physicians. Citing *Cobbs v. Grant*, 8 Cal.3d 229, 242 (Cal 1972)”).

¹⁰² TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-18 to 19, § 17.02[2][e].

knowledge that I gained from the dialogue discussed above. It is my belief that vitreous and retina specialists and other ophthalmologists would be greatly served by having a checklist that would aid the discussion. I firmly believe such an approach would have eliminated some of the time it took to get me to the first surgery.

2.3.5 Requirement to Disclose Available Alternative Procedures and Their Risks

Alternate procedures give the patient options when deciding on treatment, allowing the patient to choose or reject the proposed treatment in favor of another course of treatment. I would like to have known about the subretinal membrane removal prior to undergoing laser surgery. A physician-patient dialogue progressing through diagnosis, proposed treatment and risks should lead into alternative procedures available to the patient as well as the risks associated with them.^{103, 104}

The alternative procedures presented to a patient should be “generally accepted” by the ophthalmologic profession and appropriate to the patient.¹⁰⁵ Experimental procedures do not have to be discussed if the “alternative is not considered to be within the standard of care.”¹⁰⁶ For example, in September, 1999, several experimental treatments were beginning, but Dr. Kimble was not required to inform me about these alternative experimental procedures prior to my second surgery because of their experimental nature. During my daily evaluations, I had learned about these upcoming experimental tests. That knowledge helped me to seek a surgeon who could perform the subretinal choroidal neovascular membrane (SRN) removal surgery.

¹⁰³ TREATISE ON HEALTH CARE LAW, *supra* note 19, at § 17.02[2][a-f].

¹⁰⁴ JONSEN, *supra* note 9, at 57.

¹⁰⁵ FURROW, *supra* note 50, at 324.

¹⁰⁶ *Id.*

Because the risk of any eye surgery is diminished vision or blindness, the discussion of the recommended procedure and risks, along with any alternative procedures and their risks, must be disclosed. Neither Dr. Kimble, nor Dr. Massey, ever disclosed any alternative procedures to me. In fact, if it were not for the team of other physicians supporting me, I might have never learned about the surgery that eventually restored my sight. Not only should physicians disclose available alternative procedures and their risks, but also it is their professional duty to be knowledgeable about any such mainstream procedures.

The requirement for disclosure of alternative procedures and their risks has developed through numerous cases applying the informed consent doctrine. The New Jersey Supreme Court led the way with *Teilhaver v. Greene*, setting the precedent that only alternative procedures accepted within the medical community had to be discussed.¹⁰⁷ A doctor must provide alternative(s) to the proposed procedure, but only if the alternative procedure is recognized and accepted by the medical community.¹⁰⁸ This is in agreement with the “two schools of thought doctrine,” which teaches that a quantitative versus qualitative medical procedure cannot negate the other as being unacceptable by mainstream standards.¹⁰⁹ The New Jersey Supreme Court built on the decisions from 1993 and 1974, from Connecticut and Washington courts that required doctors to disclose alternatives, even if the alternatives carried more risk¹¹⁰ or if the doctor was unable to perform the surgeries.¹¹¹

¹⁰⁷ *Teilhaver v. Greene*, 320 N.J. Super. 453, 460 (N.J. Super. 1999), (“The decision to maintain the patient in traction was a deviation from accepted medical standards and plaintiff’s poor result flowed from the fact that plaintiff had traction rather than surgery. He opined that traction was unacceptable because ‘it can’t do the job.’”).

¹⁰⁸ MARK A. HALL ET AL., *MEDICAL LIABILITY AND TREATMENT RELATIONSHIPS* 319 (Aspen Publishers 2005).

¹⁰⁹ *Id.*

¹¹⁰ *Gemme v. Goldberg*, 626 A.2d 318, 326 (Conn. App. Ct. 1993), (“...while he was aware of a viable alternative to the segmental surgery that he performed, it would have required that the plaintiff be satisfied with a less than perfect result, and he did not discuss this alternative with the patient.”).

¹¹¹ *Holt v. Nelson*, 523 P.2d 211 (Wash. App. 1974). (The Washington Court of Appeals overturned a lower court order granting summary judgment to a defendant doctor who did not give the alternative procedure of a cesarean section.).

Four cases relating to eye surgery and informed consent apply the principles of informed consent to failures of disclosure for these surgeries. In *Lambert v. Park*, a case similar to *Holt v. Nelson*, the 10th Circuit reversed a lower court ruling in which the court had not given informed consent directions to a jury.¹¹² In the Connecticut case of *Glover v. Griffin*, the element of disclosing alternative procedures and risks was an issue because it led to the dismissal of the informed consent claims. The defendants were accused of not preventing the plaintiff's blindness when the diagnosis was for head pain and migraines.¹¹³ In a Nebraska case, the informed consent doctrine was applied to a doctor who failed to obtain informed consent and operated on the wrong eye.¹¹⁴ The fourth case, in which the principles of the doctrine of informed consent were applied, reaches back to the seminal case of *Canterbury*.¹¹⁵ The New Jersey courts held that a jury is the correct body to decide factual issues in an informed consent case involving an eye surgery. The court specifically stated that the jury had to be provided with

¹¹² *Lambert v. Park*, 597 F.2d 236, 237 (10th Cir. 1979), (“The doctrine [of informed consent] stands for the proposition that before any medical procedure involving inherent risks of collateral injury is performed, the doctor has a duty to apprise the patient of both the risks of, and the alternatives to, the proposed procedure. The patient should then be allowed to weigh the risks according to his own values and choose the procedure he finds most acceptable, or to elect none at all.”).

¹¹³ *Glover v. Griffin Health Servs.*, 2006 Conn. Super. LEXIS 1841, 9-10 (Conn. Super. Ct. 2006) (“In this case, the patient sued, alleging the doctors had not prevented her blindness when they did not perform other tests in violation of the informed consent doctrine. The court stated in its opinion, ‘A surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages

“ . . . Informed consent requires a physician to provide the patient with the information which a reasonable patient would have found material for making a decision whether to embark upon a contemplated course of therapy . . . [When considering] an alleged lack of informed consent, [the court's] inquiry [is] confined to whether the physician has disclosed: (1) the nature of the procedure, (2) the risks and hazards of the procedure, (3) the alternatives to the procedure, and (4) the anticipated benefits of the procedure . . . Thus, [u]nlike the traditional action of negligence, a claim for lack of informed consent focuses not on the level of skill exercised in the performance of the procedure itself but on the adequacy of the explanation given by the physician in obtaining the patient's consent.’ (Citations omitted; internal quotation marks omitted.) *Sherwood v. Danbury Hospital*, 278 Conn. 163, 180, 896 A.2d 777 (2006).”).

¹¹⁴ *Walls v. Shreck*, 265 Neb. 683, 687 (Neb. 2003), (“A physician's duty to obtain informed consent is measured by the standard of a reasonable medical practitioner under the same or similar circumstances and must be determined by expert medical testimony establishing the prevailing standard and the defendant-practitioner's departure there from.”).

¹¹⁵ *Sgro v. Ross*, 337 N.J. Super. 220, 226 (N.J. Super. Ct. App. Div. 1998). (Applying the benchmark case of *Canterbury* to an eye surgery. “As the *Largey* Court noted, *Canterbury* drew no bright line in separating significant risks from insignificant ones, but resorted to a rule of reason ‘concluding that ‘[w]hen non-disclosure of particular risk information is open to debate by reasonable-minded-[persons], the issue is one for the finder of facts.’ *Largey*, 110 N.J. at 213, 540 A.2d 504 (quoting *Canterbury*, 464 F.2d at 788).”).

the elements of informed consent in order to decide if the doctor was liable for performing a procedure on the iris.¹¹⁶ Courts are applying informed consent to eye surgeries, and doctors need to comply with the provisions and elements in the doctrine in order to avoid liability lawsuits.

2.3.6 Other Issues

In addition to the checklists discussed thus far, consent procedures to be used in relation to eye surgeries should include a catchall for the numerous provisions that should be disclosed to the patient. Informed consent may require the discussion of insurance coverage, medical charges, expected recovery time, the intensity and duration of any pain, and any activities contraindicated for the patient (e.g., weightlifting, jogging, lifting laundry baskets or any other activity that puts strain on the eye).¹¹⁷ My experience taught me that these issues need to be discussed in terms that are precise, concrete, and explicit for the patient and include what is expected both before and after the operation. My misunderstanding and not knowing some of these issues created the most physical damage to my body and ultimately to my vision.

In “ERISA and Liability for Provision of Medical Information,” Kim Madison discusses how financing is creating two discussions for the physician.¹¹⁸ With insurance coverage often making exceptions for eye and dental coverage, and subretinal membrane removal costing over \$20,000 (even laser surgery costs in the thousands), financial issues could be a critical factor for a patient. In my situation, according to the physicians, had there been a delay due to lack of finances permanent damage may have resulted.

¹¹⁶ *Id.*

¹¹⁷ TREATISE ON HEALTH CARE LAW, *supra* note 19, at § 17.02[2][f].

¹¹⁸ Kristin Madison, *ERISA and Liability for Provision of Medical Information*, 84 N.C. L. Rev. 471 (2006), (“In *Aetna Health Inc. v. Davila*, the Supreme Court held that two individuals' suits against their respective managed care organizations (‘MCOs’) for injuries allegedly arising from coverage denials were completely preempted by the Employee Retirement Income Security Act of 1974 (‘ERISA’). This decision may encourage a structural separation between physicians and MCOs, effectively creating two independent sources of medical information about a patient's treatment - the physician's conversation with the patient and the MCO's coverage decision.”).

Another issue that must be disclosed is the financial or research gain. If this is one of the significant factors in why the doctor is recommending a certain procedure, this must be disclosed to the patient. One of the USAF vitreous and retina doctors was more interested in knowing what factor or event caused the errant blood vessel to burst in my eye than in preventing blindness in the eye. This was a significant factor for me in declining this doctor's request to operate on me. I did not believe he had my best interests at heart.

In one of the most celebrated cases about financial gain, *Moore v. Regents of University of California*,¹¹⁹ “the California Supreme Court held that to obtain a patient's informed consent, physicians must disclose any financial or other interest that they have [that] conflicts with, or even potentially conflicts with, their fiduciary duty to that patient.”¹²⁰ A doctor seeking financial gain at the expense of his patient may not provide the best care for an eye patient, and patients deserve to be equipped with the information necessary to make a determination.

¹¹⁹ *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 485 (Cal. 1990).

¹²⁰ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-19 fn 15.

CHAPTER 3

Disclosure Standards and Causes of Action

3.1 Introduction

Early in my flying career, a truly unprecedented event occurred while I was assigned to the 60th Bombardment Squadron on Andersen Air Force Base, Guam. Colonel (later Brigadier General) Bernard W. Gann announced that he was stopping all flight evaluations because he had been unable to determine what standards the flight crews were to follow and by which ones they were subsequently to be judged. There were conflicting and varying flight standards, both published and unpublished. Brigadier General Gann announced that unless the regulations were clear and understood, flight crews would not know how to employ the correct standard. He directed the Standardization and Evaluation division to clearly formulate, inform, and train the flight crews on clear standards by which the squadron flyers would be judged.

In aviation, the laws of physics and tactics determine what standard and emergency procedures allow the best possibility of mission success. This greatly contrasts with a court system that has multiple subjective standards that confuses both physicians and patients. To date, a single precise medical standard, similar to those found in aviation has not been set for eye surgeries. Utilizing Brigadier General Gann's approach, a standard for complex eye surgeries can be developed that will aid both the physician and patient in selecting the course of treatment.

Courts have developed the doctrine of informed consent as the preferred cause of action a patient may pursue against a doctor who did not fully inform a patient of the patient's options for a course of treatment. To date, the doctrine of informed consent has developed a complex and varying set of standards to evaluate the physician when the patient is harmed and brings litigation against his doctor. The dilemma I faced with my multiple surgeries illustrates the

tensions between the varying standards and their effect within the doctrine of informed consent on both the physician and patient. In order to truly understand informed consent, it is necessary to first know by what standards surgeons will be judged. Informed consent is a two-pronged doctrine. The first prong is what information must be disclosed and consists of six categories of information a doctor must convey to the patient. The second prong is the standard of disclosure, the “how” component of the information to be disclosed. The six elements of informed consent, discussed in Chapter 2, Section 2.3-2.3.6, are information that must be given to patients and that have been developed by lawyers and courts.

The concept of informed consent is relatively easy to understand; it is its application that proves difficult. Such difficulties arise due to the varying standards of disclosure to the patient of the information in each informed consent category. This second prong of the application of informed consent has four differing disclosure standards. The disclosure standards are *state-mandated*, *reasonable and prudent physician*, *reasonable patient* and a *subjective standard*.¹²¹ The standard of application of informed consent that is required is further confused by varying degrees of knowledge about the procedure, both on the part of the patient and the doctor. Even the various statutes and case laws for each jurisdiction differ.¹²²

In the previous chapter, the six elements of informed consent were discussed in detail. This chapter will walk through the disclosure standards.

¹²¹ Jonsen, *supra* note 9, at 56.

¹²² BERG ET AL., *supra* note 17, at 41.

3.2 Texas Administrative Code (TAC) § 601.2 (2006) § 601.2. Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A

In Texas there are several disclosure standards which may be applied in informed consent cases. The Texas Administrative Code requirement for disclosure is the absolute minimum for disclosing the risks associated with a complex eye surgery. At the time that Dr. Lambert performed my subretinal membrane removal surgery, Texas Revised Civil Statute Annotated Article 4590I was applicable.¹²³ However, in 2003, the Texas legislature repealed this act and replaced it with the requirements below.¹²⁴ Essentially, a Texas medical panel has developed two lists, A and B.¹²⁵ Appendix 1 of this thesis contains the Texas disclosure statute.¹²⁶ List A of the statute contains items that must be disclosed by the doctor for retinal or vitreous procedures, with the requirements codified at TAC § 601.2(f)(1) & (3) as follows:

- (f) Eye treatments and procedures.
 - (1) Eye muscle surgery.
 - (A) Additional treatment and/or surgery.
 - (B) Double vision.
 - (C) Partial or total loss of vision.
 - (3) Retinal or vitreous surgery.**
 - (A) Complications requiring additional treatment and/or surgery.
 - (B) Recurrence or spread of disease.
 - (C) Partial or total loss of vision.

Looking at the requirements under the Texas code, one realizes that the disclosures are not very demanding for the doctor.¹²⁷ This list is woefully inadequate. The legislature's desire was to protect surgeons, but it fails to protect patients because the disclosures are too minimal. One of

¹²³ TEX. REV. CIV. STAT. ANN. ART. 4590I (1998).

¹²⁴ TEX. ADMIN. CODE § 601.2 (2006).

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

the risks described to me, for example, was the loss of night vision. This loss corresponds to the Texas Medical Panel disclosure requirement of partial vision loss. I have flashing in the eyes, almost like “snow” on the television set. The problem is that, unless a person has suffered vision loss, he or she has no frame of reference for what “partial vision loss” truly means.

In 2003, Texas enacted legislation through the Texas Civil Practice and Remedies Code § 74.101 that added the reasonable patient standard for medical disclosures not covered by the Texas Medical Panel.¹²⁸ In the case of retina and vitreous surgery, the Texas Medical Disclosure panel specifically added three risk issues to be disclosed.¹²⁹ Again, the statutory requirements may leave doctors vulnerable to claims of improper disclosure for issues not covered by the Medical Disclosure Panel, but more than likely, litigation will be barred, except in the most egregious cases. The practical result will be less than complete information for a patient who is trying to make a decision about whether or not to accept or reject treatment.

3.3 The Emergence of Common Law Disclosure Standards versus a State Code

One confusing facet of informed consent is the discrepancy between the information provided and the level of detail a physician must provide when recounting it to the patient. The legal duties differ from state to state, although the surgery does not. These different disclosure standards further confuse physicians and leave open the possibility of litigation.

A disclosure standard “describes the duty of the *physician*, not the state of mind of the patient.”¹³⁰ The Texas Legislature's approach to the duty expected of physicians, a minimalist standard of disclosure, does not provide a patient the opportunity to see all the information

¹²⁸ TEX. CIV. PRAC. & REM. CODE § 74.101 (“...the only theory on which recovery may be obtained is that of negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.”) (Added by Acts 2003, 78th Leg., ch. 204, § 10.01, eff. Sept. 1, 2003).

¹²⁹ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-35, § 17.03[4][a].

¹³⁰ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-2,4 § 17.02[3][d].

needed to make an informed consent. Instead, Texas minimizes the information doctors legally are required to provide to their patients.

In Texas, the duty of disclosure an ophthalmologist or retina and vitreous specialist must fulfill consists of “complications requiring additional treatment and/or surgery, recurrence or spread of disease, and finally partial or total loss of vision.”¹³¹ This disclosure standard does not provide the patient any meaningful information because the only results required to be disclosed are little more than common sense. Ophthalmologists, and retina and vitreous specialist have a legal duty to their patients. The Texas statutory disclosure standard is a minimum; improvement to the patient is seen with the physician standard, and more so with the reasonable patient standard, as each provides increasingly more information to the patient. Applying Judge Cardozo’s proclamation that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body,” physicians owe a greater duty to their patients than the minimum.¹³² A retina and vitreous specialist has striven to be at the top of the ophthalmology field. These specialists do not accept minimal performance; thus, their duty to their patients should also be optimal. The level of disclosure these medical professionals should aim to practice is the subjective disclosure standard.¹³³

Complex eye surgeries and eye surgeries in general, carry the risk of blindness. Courts have consistently cited death, paralysis and blindness as risks that must be disclosed to patients contemplating a course of treatment with such risks. Ophthalmologists and vitreous and retina surgeons must disclose these risks to their patients. Courts have not created a separate informed consent for eye surgeries. Instead, informed consent for eye surgeries employs the elements that

¹³¹ TACP §601.2(f).

¹³² *Schloendorff*, *supra* note 23, at 129-130.

¹³³ JONSEN, *supra* note 9, at 57.

have developed through the court systems. Doctrines derived through the development of the informed consent doctrine are applicable to eye surgeries and their associated risks.¹³⁴

3.4 Physician Standard

Courts initially turned to the professional judgment of medical professionals to determine the physician's duty to the patient. The physician standard approach was first propounded when “the Kansas Supreme Court in 1960, in *Natanson v. Kline*, was the first to articulate this approach to an informed consent case...”¹³⁵ This precedent has since been frequently applied by other courts. Up to this time, there was not a standard, the courts relied on what physicians told their patients as the standard. However, after *Natanson* the courts began to apply a standard that moved away from what the particular surgeon would disclose to his patients to a standard involving what “a reasonable medical practitioner” would disclose to the patient.¹³⁶ As more cases reached the court, problems with the physician standard became evident.¹³⁷

There are three main problems with the physician standard. The first is that the differing standards of disclosure undermined “the legal right to obtain information.”¹³⁸ Next, the standard is so low that it did not provide the patient with the information required to make an informed consent decision.¹³⁹ Finally, to prove the standard of care, expert witnesses were needed;

¹³⁴ *Sgro*, *supra* note 115, at 220 (New Jersey Supreme Court applied the Informed consent doctrine and the alternative procedures disclosure requirement to a cataract surgery. See *Walls v. Shreck*, 265 Neb. 683 (NE 2003), in which court held the standard of care for a eye surgery required the doctor to get implied or expressed consent before operating. For a discussion of the disclosure of alternative risks of procedures than the surgery undertaken during eye surgery applicable with informed consent see *Glover v. Griffin Health Servs.*, 2006 Conn. Super. LEXIS 1841 (Conn. Super. Ct. 2006)).

¹³⁵ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-26, § 17.03[b].

¹³⁶ *Id.* at 17-27.

¹³⁷ BERG, *supra* note 17, at 46-47.

¹³⁸ *Id.* at 47.

¹³⁹ *Id.*

however, other physicians were rarely willing to testify against a colleague.¹⁴⁰ The courts found this conspiracy of silence to be against public policy, and in *Canterbury* the courts first articulated the reasonable patient standard of disclosure.¹⁴¹ My experiences with Dr. Massey show the problems with the physician disclosure standard. Specifically, I was not receiving the information that I needed to make a decision based upon my “right to determine what shall be done with [my] own body.”¹⁴²

The legal importance of knowing the disclosure standard applicable in a state is demonstrated in *Teilhaver v. Greene*, which states,

To establish a prima facie case of negligence in a medical malpractice action alleging deviation from the standard of care, a plaintiff must present expert testimony establishing (1) the applicable standard of care; (2) a deviation from that standard of care; and (3) that the deviation proximately caused the injury.¹⁴³

Physicians are regulated by the individual states; therefore, the disclosure standard varies from one state to another. Knowing and complying with the disclosure standard, enables the physician to meet the state’s standard of care, and protects the patient by providing information the state has determined to be the minimum required to make an informed decision on the course of treatment.

The problem with informed consent is that it is not defined and varies according to several standards, as well as by the disease or injury and the individual patient’s needs, education level and competence. We see this in *Salgo v. Leland Stanford Jr. University Board of Trustees*.¹⁴⁴

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Schloendorff*, *supra* note 23, at 129-30.

¹⁴³ *Teilhaver v. Greene*, 320 N.J. Super. 453 (N.J. Super. Ct. App. Div. 1999).

¹⁴⁴ MEDICAL MALPRACTICE: GUIDE TO MEDICAL ISSUES, *supra* note 35, at § 31.08.

“The seminal *Salgo* decision established that a patient's consent must be informed to be legally effective, without providing an operative rule on the extent and type of information that had to be disclosed.”¹⁴⁵ This conflict between what a physician is legally required to disclose and ensuring that “a patient's consent...be informed to be legally effective” is the problem with differing informed consent disclosure standards.¹⁴⁶

3.5 Reasonable Patient Standard

Courts responded in 1972 to the problems encountered with the physician standard of disclosure. In *Canterbury*, the court rejected the physician standard and instead created the reasonable patient standard.¹⁴⁷ This standard more fully allows the patient to decide what is right for his or her own body. In *Informed Consent*, Professor Berg interprets *Canterbury*, “A fair statement of the rule that emerged is the physician is required to disclose all information about a proposed treatment that a reasonable person in the patient's circumstances would find material to a decision either to undergo or forgo treatment.”¹⁴⁸ The court noted that reliance on what the physician would disclose undercut the entire purpose of informed consent.¹⁴⁹ Physicians now had a duty to inform their patients about material issues that a reasonable patient would expect to be told. The court emphasized a materiality standard that was defined as what a patient would consider material to make a decision.¹⁵⁰ A benefit of the reasonable patient disclosure standard is that physicians then began to discuss treatment with their patients.¹⁵¹

Twenty-six years later in *Sgro*, the New Jersey court stated:

¹⁴⁵ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-25, § 17.03.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 17-30-31, § 17.03[2][a-b].

¹⁴⁸ BERG, *supra* note 17, at 48.

¹⁴⁹ *Id.* at 48-49.

¹⁵⁰ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-31.

¹⁵¹ *Id.* at 49.

Largey v. Rothman, 110 N.J. 204, set a new course for the informed consent doctrine. It established that ‘the standard of informed consent related to the patient's needs, not the physician's judgment.’ *Niemiera v. Schneider*, 114 N.J. 550, 565 n.4, 555 A.2d 1112 (1989). It adopted the ‘prudent person’ or ‘materiality of risk’ standard espoused in *Canterbury v. Spence*, 150 U.S. App. D.C. 263, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064, 93 S. Ct. 560, 34 L. Ed. 2d 518 (1972). The *Canterbury* court held that the duty to disclose risks involved as part of a medical treatment, had to be measured by the needs of the patient; therefore, information that is material to and would affect the patient's decision must be disclosed. *Canterbury*, 464 F.2d at 786-87. ‘[A] risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed [medical treatment].’ *Id.* at 787 (quoting *Waltz & Scheuneman*, *Informed Consent to Therapy*, 64 N.W.U.L. Rev. 628, 640 (1970)). As the *Largey* Court noted, *Canterbury* drew no bright line in separating significant risks from insignificant ones, but resorted to a rule of reason ‘concluding that “[w]hen non-disclosure of particular risk information is open to debate by reasonable-minded-[persons], the issue is one for the finder of facts.”’ *Largey*, 110 N.J. at 213, 540 A.2d 504 (quoting *Canterbury*, 464 F.2d at 788).¹⁵²

3.6 Subjective Standard: A standard tailored to the patient

The Treatise on Health Law states, “A subjective standard (as defined in *Canterbury*) more closely reflects the underlying purpose of the doctrine of informed consent because it respects the particular patient's valuing of the pros and cons of the proposed care.”¹⁵³ A subjective standard could be problematic because the physician has to gather, interpret, and implement a great amount of detail from the patient correctly to provide the patient’s individualized information.¹⁵⁴ Therefore, the courts “adopted an objective standard for determining materiality.”¹⁵⁵ What I found extremely helpful about this standard of care is that

¹⁵² *Sgro*, 337 N.J. Super. at 226.

¹⁵³ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-31, § 17.03[2][b][i].

¹⁵⁴ *Id.* at 17-31, § 17.03[2][b][i-ii].

¹⁵⁵ *Id.* at 17-32, § 17.03[2][b][iii].

“the physician must take into account any special fears, values, sensibilities, etc., of the particular patient that are known to the physician.”¹⁵⁶ The subjective disclosure standard is employed in only two states, Oklahoma and West Virginia; however, subjective disclosure is most appropriate for complex eye surgeries.¹⁵⁷ The requirement for the subjective disclosure standard is that the physician tailor the information provided to the particular patient based upon that patient's needs.¹⁵⁸ This standard forces the physician to spend more time with his patient to understand his or her particular circumstances, vocation or profession, fears, anxieties, etc. A downside to this type of dialogue is that the time required to achieve this knowledge could severely limit the physician's ability to treat multiple patients. Additionally, if a patient later sued based on lack of informed consent, the burden of proof would rest upon the patient who is injured during the surgery because it is the injured patient's needs that set the standard for the Trier of facts.¹⁵⁹

On the other hand, it was Dr. Kimble’s knowledge of my profession as a military and civilian pilot that enabled him to convince me that surgery was my only option. When I told Dr. Kimble that my primary concern regarding my vision was the ability to see my children, he was able to make me understand that the operation would provide this chance, and I was willing to undergo this course of treatment. (I would always have memories of flying, but did not want to miss out on my children’s and grandchildren’s faces.) Upon discovering that my father had been a very successful obstetrician gynecologist, Dr. Kimble employed this knowledge to determine how much I understood medical procedures. So far, Dr. Kimble knew that my children were paramount in my life, that flying was my dream and profession, that I had some knowledge of

¹⁵⁶ *Id.*

¹⁵⁷ BERG, *supra* note 17, at 50.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

medical procedures, and that I trusted doctors. I was trying to trust Dr. Kimble, and Dr. Kimble worked with these concepts to earn my trust. He also used terminology that enabled me to understand the risks, procedures, and the purpose behind the course of treatment that he proposed. We did not cover every detail but Dr. Kimble gave me enough knowledge to understand that sealing the blood vessel immediately was essential to my chances of remaining sighted.

When my eye did fail at the end of July 1999, I had enough knowledge to ask about alternative procedures that had never been discussed. I trusted and believed Drs. Kimble and Massey when they told me that I was too young for the initial experimental tests of PhotoDynamic Therapy. I was able to converse with all three of the doctors, asking about different tests and procedures for which I might be a candidate. In fact, Colonel Hanumanthu sent Colonel Dobbins and me to find a research center or hospital that was performing operations. However, it was Colonel Hanumanthu who discovered Dr. Lambert, the doctor who would evaluate me for the subretinal membrane removal procedure. In my case, the subjective standard fit nicely. I already had enough knowledge to know that people in my condition would not be aided by a second laser surgery. Removal of the blood vessel entirely would remove the threat of a recurrence.

3.7 Legal Causes of Action against a Medical Provider

Ophthalmologists should understand the legal causes of action that can be applied against them if they fail to get proper informed consent. Generally, courts apply a negligence standard when a doctor fails to correctly obtain informed consent from the patient. In a previously

discussed case, *Teilhafer*, the New Jersey court listed three causes of action that may be applied against a doctor:

A plaintiff may bring an action against a doctor for personal injuries under at least three theories: deviation from the standard of care, *see Gardner v. Pawliw*, 150 N.J. 359, 696 A.2d 599 (1997); lack of informed consent, *see Largey v. Rothman*, 110 N.J. 204, 540 A.2d 504 (1988); and battery, *see Perna v. Pirozzi*, 92 N.J. 446, 457 A.2d 431 (1983). However, it is now clear that both deviation from the standard of care and failure to obtain informed consent are simply sub-groups of a broad claim of medical negligence.¹⁶⁰

The New Jersey decision may be used as precedent—that when a physician’s treatment is sub-standard, he or she may be subject to a cause of action of medical malpractice, which follows the negligence elements.

3.7.1 Prima Facie Case for Medical Negligence Premised on a Theory of Liability for Lack of Informed Consent

In a state cause of action against a doctor, New Jersey modified the elements of negligence and applied them to medical malpractice in *Teilhafer v.*

Greene, stating:

To establish a prima facie case for medical negligence premised on a theory of liability for lack of informed consent, a plaintiff must show (1) the physician failed to comply with the applicable standard for disclosure; (2) the undisclosed risk occurred and harmed the plaintiff; (3) a reasonable person under the circumstances would not have consented and submitted to the operation or surgical procedure had he or she been so informed; and (4) the operation or surgical procedure was a proximate cause of plaintiff’s injuries.¹⁶¹

¹⁶⁰ *Teilhafer v. Greene*, 320 N.J. Super. 453, 463 (N.J. App. Div. 1999).

¹⁶¹ *Id.*

The New Jersey decision combines duty and breach of duty for its first element.

The third and fourth elements are the causation elements, while element two is the damages element. This case was decided the same year that my surgery occurred, showing that the development of medical malpractice is still evolving.

3.7.2 Prima Facie Case for Negligence in a Medical Malpractice Action

Not only does informed consent contain elements that are required to be disclosed to the patient, but also the state standard of care must be met. The New Jersey court, in the same case, continued,

To establish a prima facie case of negligence in a medical malpractice action alleging deviation from the standard of care, a plaintiff must present expert testimony establishing (1) the applicable standard of care; (2) a deviation from that standard of care; and (3) that the deviation proximately caused the injury. *Gardner*, 150 N.J. at 375, 696 A.2d 599.¹⁶²

New Jersey adopted the objective standard of disclosure; thus, physicians know to discuss risks and the course of treatment that a reasonable patient requires to make an informed consent. This court rounded out the aspects of informed consent by defining the standard of care, in combination with defining the elements of malpractice, in order to provide the framework for informed consent in that state.

3.7.3 Medical Malpractice Claim

For a uniform cause of action for medical malpractice, the elements of negligence are appropriate in prosecuting a physician for improper treatment, or for treating a patient without

¹⁶² *Id.*

proper informed consent. Berg states the elements that must be present to form a basis for a medical malpractice case:

For a medical malpractice claim, the plaintiff must prove that (1) the doctor had a duty to the patient; (2) the doctor breached that duty to the patient; (3) the doctor's negligence was the proximate cause of the injury; (4) the doctor's negligence was the cause in fact of the injury; and (5) the patient suffered damages from this injury. All of these factors must be present to win a case of medical malpractice.¹⁶³

In both of my surgeries, for example, there were breaches of the informed consent doctrine, including failure to document consent or refusal of the procedures, failure to discuss alternative procedures, and misinformation regarding blood transfusions. Such breaches would not be actionable, however, because the causation and the damage elements fail. Specifically, the laser surgery stopped—at least temporarily—the loss of vision in my right eye that was being threatened by the rogue blood vessel. It could be argued that the subsequent blindness that occurred in June 1999 and the expenses, emotional harm and stress from the second medical procedure were damage. However, it could also be argued that the three months and two weeks of vision that I did receive from the laser surgery negated any damage. Had I not undergone the laser surgery, blindness would have occurred much sooner.

3.8 Conclusion

The discussion in this chapter demonstrates that the informed consent elements applied by courts, trying to protect patients in non-eye surgical procedures, can also be applied to complex eye surgeries. Courts throughout the nation have applied the elements of informed

¹⁶³ BERG ET AL., *supra* note 17, at 133.

consent as a means of protecting patients and, at the same time, preventing negligence by doctors.

The laws developed under the informed consent doctrine and applied by courts are just one disclosure standard. Legislatures throughout the nation have created statutes dealing with exactly what doctors must disclose to their patients. Additionally, the *physician or professional disclosure standard* is still used in numerous states throughout the nation. In this disclosure standard, the physician decides what the patient needs to know to grant informed consent. The next standard, which the courts have developed because of their disdain for the physician standard, is the *reasonable patient standard*. This standard requires a disclosure that a reasonable patient would need to make a decision for selecting or rejecting the course of treatment. The final disclosure standard is a *subjective standard*. A subjective standard “is ethically ideal.”¹⁶⁴ The subjective standard is based on what a specific patient would need to make an informed consent decision. It allows the physician to present a more focused disclosure tailored to the patient’s needs.

It is a recommendation of this paper that medical procedures to obtain informed consent be standardized by the use of a comprehensive checklist. The checklist can then be adapted to make sure that at least the reasonable patient, if not the subjective standard, is met.

¹⁶⁴ JONSEN, *supra* note 9, at 57.

CHAPTER 4

Recommendations

4.1 Introduction

Problems with informed consent arise in part because medical personnel often believe the signatures on a form constitute informed consent.¹⁶⁵ Furthermore, courts do not apply a standard disclosure for informed consent.¹⁶⁶ In addition, informed consent standard varies from state to state.¹⁶⁷ Confusion centers on what information a physician must disclose to a patient. Informed consent consists of a standard and a level of disclosure. This paper has shown the following categorical elements of informed consent utilized by the courts: diagnosis, nature and purpose of the proposed treatment, risks and consequences of the treatment, alternative treatments available, prognosis if proposed treatment is not undertaken, and other issues that constitute information material to the patient's decision regarding surgery.¹⁶⁸ Patients must understand and decide what is best for his or her body. The second element is the level of disclosure the physician must give to the patient when discussing the informed consent elements.

For standardization to be employed, the subjective disclosure standard should be employed using the checklist developed in Chapter 5. This checklist provides the level of disclosure the patient with all the information required to enable him or her to grant or withhold informed consent. The state statutes that have been enacted are the minimum and do not provide a patient enough information. Any patient who agrees to surgery using only the disclosure required in TACP §§ 601.2(f)(1), (3) must simply guess about what a correct decision is or leave all decisions up to the doctor instead of making an informed consent. TACP §§ 601.2(f)(1), (3)

¹⁶⁵ JONSEN, *supra* note 9, at 55.

¹⁶⁶ BERG, *supra* note 17, at 48.

¹⁶⁷ *Id.*

¹⁶⁸ TREATISE ON HEALTH CARE LAW, *supra* note 19, at 17-14 to 25, § 17.02 [a-f].

is the old paternalistic standard and, for public benefit, should be replaced with a checklist similar to the one described in Chapter 5.

The physician standard is an improvement over the Texas standard. With this standard, information will be provided as the doctor establishes a dialogue with the patient. A drawback to the physician disclosure is that it may not provide the patient with the information needed to make an informed consent decision if the physician specialist standard is minimal.

The subjective standard is the standard to be utilized for complex surgeries. The checklist developed in Chapter 5 provides the level of disclosure the patient needs to grant or withhold informed consent. Each of the previous standards, has weaknesses TACP §§ 601.2(f)(1), (3) is almost meaningless to the patient. The physician standard provides only the information the physician provides. And the patient standard requires the physician to give the patient to the information a reasonable patient would want. None of these three standards is efficient, in a critical time period, or sufficient and likely to aid the patient achieve the information needed to give true informed consent.

Physicians need to consider individual patients differences. In my case I was twenty to thirty years younger than a normal patient. And my occupational requirements as a pilot, needing perfect vision, were for different than the average patient. A checklist with a detailed level of disclosure would have provided a physician the procedure to discuss the level of pain I would expect. Had I known a high level of pain was abnormal I could have been precise in my post-operation recovery. Instead, this difference did result in eye damage and vision loss when my optic nerve reacted to the steroid fluid used to re-inflate my eye. The patient's need for information needs to balance with the physician's time limitations. The subjective standard of disclosure creates a standard that is flexible, allowing for patient education and needs. Using the

checklist suggested would provide an objective measurement for proof that the physician complied with informed consent requirements, providing a sound defense against potential litigation based on a lack of informed consent.

Employing these informed consent elements through the use of the checklist contained in Chapter 5 will greatly aid ophthalmologist and retina and vitreous specialists in obtaining legal informed consent from their patients. The subjective disclosure standard should be employed due to the severity and risks of eye surgeries. Physicians should strive to develop procedures enabling subjective disclosure standard, thus enabling patients to grant truly informed consent.

4.2 Recommendations when presenting the Diagnosis

Doctors and/or nurses should work with one another to determine whether the patient is competent and comprehends the diagnosis and nature and purpose of the proposed treatment. If they determine that the patient does not understand, then time permitting, the nurse, technician or doctor should use other means of explaining the diagnosis and nature and purpose of the proposed treatment. These alternative means include DVDs, the Internet, pamphlets and other instructive material.¹⁶⁹ An example of an outstanding Internet site that provides patients with a source of information for understanding eye diagnosis and the nature and purpose of the proposed treatment is found at the Retina and Vitreous of Texas website.¹⁷⁰

4.3 Recommendations when Presenting the Risks and Consequences

Looking back over all the discussions that followed my first surgery, I know that Dr. Kimble could not have discussed all the risks I was to encounter. During the four-month period

¹⁶⁹ JONSEN, *supra* note 9, at 21, 57.

¹⁷⁰ Retina and Vitreous of Texas, available at <http://www.retinatexas.com/index.html> (March 2007).

between the first and second surgery, I had become an expert on macular degeneration and dystrophy, and I knew about the disease, risks, alternative surgeries, and unfortunately, the consequences of the procedure. However, it took no less than six doctors, physician assistant Colonel Randy Dobbins, three nurses, and numerous Air Force and civilian friends, who inundated me with information daily, to get me to this point.

Complex surgeries involve many risk and consequences, as there are many variables. When numerous doctors are involved, it can be very confusing to a patient. Physicians may also miss issues or assume another physician has already covered the risks and consequences. In addition, risks and consequences are two separate issues that can be confused. In my situation, I needed to know all the options about each course of treatment—risks and consequences.

Eye doctors also need to understand how to put the risk and limitations of the respective surgeries into meaningful context for their patients. The development of a general checklist for eye surgeries, supported by supplemental materials, will aid all concerned. Dr. Lambert, who has reviewed this paper and its checklist, noted a member of his staff spends half the day going over his paperwork to ensure insurance and informed consent compliance.¹⁷¹ The checklist developed streamlines the informed consent process, complies with all legal requirements, and provides an objective means to obtain informed consent. This checklist will reduce the time for the doctor and his staff. The patient will receive all the needed information to ensure true informed consent. The doctor or nurse can refer to the checklist and supplement it when discussing the proposed eye surgery. The goal is to ensure efficient and timely informed consent in order to treat the patient correctly. Warning the patient about risks is vital. Before my surgeries, I exercised six days a week, and the doctors warned me very early on that I could no longer do any activity that would put pressure on the eye. This was a nebulous concept to me,

¹⁷¹ E-Mail from Dr. Lambert to author, (May 20, 2007) (on file with author).

but one of the doctors used the illustration of what occurred in my body with the dye injection (fluorescein angiogram) used for the photographs. The physician reminded me of how quickly the dye went from my hand to the blood vessels of my retina and explained that each time the heart beats, it puts pressure through the vessels and veins, and this pressure in turn was pushing against my retina. The eye was susceptible because of the rogue blood vessel, and this susceptibility increased after each surgery. Besides not exercising, I would not be able to lift anything heavy after the second surgery. However, this prohibition was still imprecise, so the assisting physician quantified it by saying I could not pick up anything heavier than a single tennis shoe. This put my limitation in a very exact and understandable context. When we returned to Alabama, even my eight-year-old son understood my limitation and was able to help me to ensure I did not strain my eye. Putting the limitations in specific terms helped me understand the risks I faced. Doctors must realize the importance contextualizing treatment aspects in a meaningful way.

The highly skilled physicians saw the danger in my situation and knew right away what they had to do to give me any chance of retaining my sight. What they lost sight of is how confusing and unfamiliar their procedures were to me. This is where using a checklist for complex eye surgeries would facilitate important issues by covering the basic questions, building confidence in the patient about the procedure and the physician, and enabling a patient, with no knowledge of the diagnosis or procedure, to become informed in an efficient manner.

4.4 Recommendations when Presenting the Prognosis in the Event Proposed Treatment is Not Undertaken

If faced with a patient who refuses treatment, the doctor should ideally try to figure out why the patient does not want to undergo the proposed treatment. When Dr. Kimble used

aviation terminology to explain things to me, and eliminated the fear that I would never be able to fly again, by calling the Federal Aviation Administration (FAA), I was able to listen and comprehend the proposed treatment. Before I developed this understanding, the promises I had made to my children overwhelmed me, such as the one I had made with my youngest child, Christopher, that I would take him flying one day. I thought I had failed my family, and it was Father Lowe and Dr. Kimble who assured me that the injury, I had suffered, was not my fault.

The doctor also may propose that a second opinion be sought, as Dr. Massey did with me. Including a clergy member, for a person refusing on religious grounds, may lead to a situation in which the patient is given dispensation to undergo surgery. Suggesting that I call Father Lowe was a brilliant move on Dr. Massey's part. With my priest present, he could answer the questions and fears I had about violating any church doctrine. Father Lowe became my advocate and advisor. Father Lowe's presence and ability to work with Dr. Massey, and later Dr. Kimble, was the saving grace that allowed me to gather the knowledge I needed to decide and give informed consent to undergo the first surgery.

I have sat in numerous doctors' waiting rooms and found that people from every walk of life have similar concerns when faced with these situations. Years after my second surgery, I was sitting in Dr. Lambert's office, when a gentleman probably 20 years my senior came and sat down across from me. I noticed that he was extremely worried and confused, so I asked him what was the matter. He told me that he was a truck driver, and Dr. Lambert had just told him that he had macular dystrophy. I immediately told the gentleman to trust Dr. Lambert. I explained to him what the laser surgery would do to his eye. I also explained that the goal was to seal the blood vessel from ever growing into the center of his fovea. When Dr. Lambert poked his head out of his examining room, he asked me to explain what I had been through to the truck

driver. I was later told that my discussions with the truck driver aided him, much like Father Lowe aided me.

After going through my ordeal, it is my belief that stress prevents many people from asking questions or even knowing what to ask. Patients given life-altering or life-threatening diagnoses are initially scared, while trying to understand what is happening to them and what they need to do about it. Informed consent requires scared patients to learn complicated medical procedures, adequately understand the risks and alternatives, and then grant “informed consent” quickly. Herein lies the problem with the current method of getting informed consent: a patient’s decision-making abilities are frequently impaired as he or she reels from the news of the diagnosis and shock sets in.

It would be helpful for doctors to understand the emotional impact that such diagnoses have on patients in these situations: Often they are confused, shocked and incredulous. At this point, a thorough and empathetic explanation is necessary for the patient to make a truly informed decision. It takes doctors years of medical training to understand complex procedures. So shouldn’t doctors take some time to explain them clearly to their patients? Proper informed consent is a dialogue that allows a patient to select the course of treatment that is best for him or her. People do not purchase vehicles without information on the automobile. Why should informed consent be any different?

4.5 Recommendations when presenting the Disclosure of Alternate Procedures and Risks for Eye Surgeries

Doctors must disclose alternatives to the recommended course of action and explain the risks of each alternative. If data exists to either support or refute the alternative for use with subjects of the patient's age and diagnosis, this data needs to be provided to the patient. For instance, I recently read that the laser (photocoagulation) surgery, I received, is the only surgery ever received by the majority of people afflicted with retinal diseases of subretinal membrane vessel growth. Only in rare cases is any other surgery required. According to Retina and Vitreous of Texas:

Laser treatment of these lesions will limit the size of the blind spot that the membranes can cause, and may improve reading speed somewhat, but the average visual acuity in patients that have undergone laser photocoagulation is 20/250. Laser photocoagulation, therefore, was not of much benefit in actually improving vision in patients that developed these membranes directly under the center of vision.¹⁷²

I was not advised of any alternative procedures at the time of my first surgery. For my second surgery, there were no alternatives available. Based on the fact that neither Dr. Massey nor Dr. Kimble disclosed these alternatives to me, my consent for the first surgery was invalid.

Alternatives to laser surgery include PhotoDynamic Therapy (PDT), Subretinal Neovascular Membrane removal surgery (my second operation), macular translocation and other treatments. Alternatives, if available and suitable to the patient, need to be presented in a fashion that provides the opportunity for the patient to make an informed choice. In my case, the Subretinal Neovascular Membrane removal surgery was not experimental and had already yielded successful results. Knowing what I know now, I would have opted for the Subretinal Neovascular Membrane removal surgery in the first surgery. The disclosure of alternative procedures needs to be based, not only upon the patient's suitability for procedure, but also on

¹⁷² Retina and vitreous of Texas disease page at http://www.retinatexas.com/neovascular_membranes.html

alternative procedures employed in other regions of the country. Finally, the patient has the right to know if the doctor is going to recommend a procedure that is not as effective, based on available insurance coverage, rather than the optimum surgery.

CHAPTER 5

An Informed Consent Checklist for Complex Eye Surgeries

5.1 Introduction

Recently at a new eye clinic, a nurse confided to me that she spends a tremendous amount of time trying to ensure her informed consent forms were completed in a legal manner. For this nurse, a legal informed consent meant that the form was complete, signed and filed in the patient's charts. The nurse asked me for an explanation of informed consent, and when I asked her if she explained the diagnosis, proposed treatment, risks, and alternatives, or if she just had the patient sign the form, the answer was not surprising. The nurse stated she spent a considerable amount of time to ensure that the form was properly initialed, signed, and complete; next, she made sure it was placed in the patient's medical folder and chart.

Informed consent, as it is performed in medical eye clinics, “fail[s] to observe the practice and the spirit of informed consent.”¹⁷³ As noted above, this is not to say physicians and nurses are not spending a lot of time trying to get an informed consent. This vignette has pointed out that medical professionals do spend considerable amount of time trying to make sure the paperwork is complete. Simply completing a form and checking it off your to-do list does not equate to true “informed consent.”¹⁷⁴ Without a dialogue and informed decision, there is not informed consent. Informed consent is intended to be the culmination of mutual decisions between the physician and patient on the selection for a course of treatment. It is not merely the signing of a form.

¹⁷³ JONSEN, *supra* note 9, at 55.

¹⁷⁴ *Id.*

Contributing factors to poor informed consent are misunderstandings of the purpose of informed consent, combined with the complexity of the diseases/injuries and each patient's unique differences. As previously stated, the Texas Administrative Code is a minimal approach. It would be very difficult for a patient to have a true understanding of the proposed course of treatment with this disclosure standard for an unexpected complex eye surgery, because it does not promote dialogue. The physician disclosure standard provides just enough information so that a reasonable physician would believe he had provided enough information to allow a patient to make an informed consent. In the worst scenario, the physician makes the decision for the patient. The patient then signs the forms without truly comprehending what they have signed. The reasonable patient standard provides material information based on the premise a patient needs more information to make a decision. The subjective standard should be the goal.

Since a subjective standard bases the information provided from the physician to the patient upon the individual patient's needs, this type of disclosure standard presents challenges in the form of time constraints and even litigation. A method of efficiently complying with this standard is the use of a checklist that would build on six categorical elements of informed consent, and would apply a subjective standard of disclosure.. Every medical clinic has professionals who are trained in medicine and in filling out paperwork. The checklist could replace and streamline the ad hoc methods employed by doctors and nurses yielding a more efficient and concise means to informed consent. Vitreous and retina specialists and ophthalmologists could use this checklist to allow the physician to efficiently conduct an open dialogue with the eye patient. The patient quickly gains the information needed to accept or reject the course of treatment proposed, or accept an alternative treatment, or reject all medical treatments. The patient and the physician would both benefit: The physician would save time

and have proof that all aspects of informed consent were discussed, and the patient would be capable of making a true informed consent based upon individual needs and beliefs.

The aviation industry uses checklists for normal and emergency operations. The Federal Aviation Administration and the U.S. Air Force have determined that utilizing checklists ensures all required steps in a procedure are accomplished efficiently, reduces or prevents errors, and saves lives. If a doctor omits something critical, like getting informed consent in writing, a tort lawyer has grounds to file suit against this doctor. In my case, after the doctor had spent hours trying to inform me of the procedures and risks, there was an omission of alternatives and documentation. Dr. Kimble's marathon disclosures enabled me to proceed on the one and only surgery discussed, but his omission of discussing alternative procedures could have been the linchpin in a negligence or malpractice lawsuit. Understanding, and then correctly applying, the doctrine of informed consent is important for both physicians and patients. Just as Brigadier General Gann implemented standards and checklists that established the standard for each pilot and flight crew member as clear requirements for how he or she was expected to perform, a standardized procedure for complex eye surgeries will aid the patient and the physician by giving clear instructions and expectations.

5.2 Analysis of a Physician's Informed Consent Form Currently in Use

An example of a doctor's checklist is the preoperative instruction sheet that I obtained. This sheet is primarily a checklist for the patient to take with him or her to get to the hospital safely. In terms of a true informed consent, it does not help. This checklist informs the patient of the need to abstain from food or drink after midnight, transportation to and from the hospital, and transportation to and from a visit one day postoperative. It also directs the patient to stop

blood thinners (aspirin, etc.) and includes additional directions regarding medicines to take the day of the surgery. Finally, it contains the one-sentence informed consent section, stating that the patient understands “all options, associated risks, benefits and alternatives.”

A patient, who does not understand what informed consent is, will not be aided by this sentence. This is why it is imperative for the physician to have a detailed and flexible checklist that walks the patient through the informed consent requirements and enables the patient in his or her own course of treatment and recovery.

5.3 Analysis of a Hospital Consent Form Currently in Use¹⁷⁵

In order to examine actual procedures used by a hospital that complies with the Texas code, I obtained a copy of a form entitled “Disclosure and Consent: Medical, Invasive and Surgical Procedures”,¹⁷⁶ which contains checklists in use at a Texas hospital at the time of this writing. (*See Appendices 2 and 3.*) The consideration for anyone involved with a complex eye surgery is whether or not the patient will have the ability to make an informed consent. These documents contain a number of defects with regard to informed consent which, as mentioned earlier, could expose physicians and hospitals to liability, but more likely, leave patients unprotected.

Appendix 2 is a form requesting consent to donate tissue, which contains an extensive explanation, and checklist, demonstrating that hospitals and medical personnel already use checklists daily for important issues. It is applicable to complex eye surgery, as it covers “donating tissue for medical research” if tissues or cells are removed from the patient. Appendix

¹⁷⁵ The Methodist Hospital, *Disclosure and Consent Medical, Invasive and Surgical Procedures (Form #331)*, (11/2004).

¹⁷⁶ *Id.*

3 is a three-section, fifteen-subsection checklist that attempts to walk the patient through the process of granting (or withholding) informed consent.

On the form entitled “To the Patient,” the hospital prominently states that the duty of obtaining informed consent rests with the physician, and informs patients of their specific rights to information regarding the proposed procedure. This statement is followed by “yes” and “no” check boxes where the patient is to indicate, by writing his or her initials, whether the physician has “informed [the patient] about the procedure(s) proposed for [him or her] along with the risks involved to [his or her] satisfaction.”¹⁷⁷

Next, the first seven items, the hospital checklist attempts to document informed consent has been given. The checklist provides that the patient has received the diagnosis, understands the proposed treatment, and is aware of who will perform the treatment by requiring him or her to actually write the name of the condition(s), as they “have been explained to [patient]”; the surgical, medical, and/or diagnostic procedures that are to be carried out; the name of the physician (although it is explained that additional assistants and technicians may be used, as necessary, to treat the condition); the risks associated with that treatment; risks associated with “continuing [the] present condition without treatment,…” and alternatives.¹⁷⁸ In addition, the text preceding the blank for procedures planned explicitly states, “...I voluntarily consent and authorize these procedures...”¹⁷⁹

While this method is fairly thorough in documenting exactly which doctor performing the complex eye surgery and what the patient understands regarding the diagnosis and proposed procedure, it is flawed. The form’s discussion of alternative procedures essentially states that the physician may perform other procedures, and no opportunity is given to the patient to give or

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

withhold their informed consent to additional procedures. The performance of an alternative procedure is left to the doctor's discretion. Item 3 appears to be overly broad, as it does not restrict the physician to performing the procedure covered in Item 2, which discusses the procedure(s) planned. For completeness, section 3 should also have a reference list of commonly discovered alternative or additional conditions associated with the type of complex eye surgery in question. Informed consent would require the patient to approve the alternative procedures prior to surgery (remember incapacitation is an exception). Finally, the checklist can add a yes / no block with a space for initials to allow the doctor to use "physician's judgment" for any item not listed.

Items 4 and 5 relate to the use of blood and blood products. Item 4 allows the patient to consent to the use of blood and blood products and requires the patient to circle either "do" or "do not" and initial to show his or her preference. An example of how the Methodist Hospital has adopted the precedent from *Moore*¹⁸⁰ is Item 5, which states that the retention or disposal of any tissues or parts that are surgically removed will be carried out "in accordance with [the hospital's] accustomed practice." In addition to this single checklist item, the Methodist Hospital has three entire pages dedicated to obtaining the informed consent of a tissue donor.

More defects in the form are found in the next three questions, which deal with anesthesiology and the risks of anesthesia. Item 11 requires the patient to give consent to the following phrase:

I have been given an opportunity to ask questions about my condition, alternative forms of anesthesia and treatment, risk of non-treatment, the procedures to be used, and the risks and hazards involved, and I believe that I have sufficient information to give this informed consent.

¹⁸⁰ See *supra*, note 119.

Such a statement attempts to summarize the entire informed consent agreement in one sentence. Much more dialogue must take place in order to truly obtain informed consent.

What follows in the form are the additional risk and hazards previously discussed. There are five pages of fine print with boxes containing categories and subcategories of medical procedures. Section 6(c), under the heading of “Eye Treatments and Procedures”, deals with “retinal and vitreous surgery” and eye treatments and procedures. This subsection has only three stated risks or hazards: “(1) complications requiring additional treatment and/or surgery; (2) recurrence or spread of disease; (3) partial or total loss of vision.”¹⁸¹ The Methodist Hospital checklist therefore discloses only the bare minimum required under List A of the Texas Administrative Code § 601.2. As previously stated, this minimum standard is not adequate. Furthermore, there is no discussion regarding what “partial loss of vision” means in order to help a patient to grant informed consent.

5.4 Use of Checklists to Speed the Dialogue between Physicians and Eye Patients

Physicians performing surgeries need a standardized, thorough procedural checklist to prevent errors. Keeping doctors with their patients and away from litigation is a goal. Had my doctors been in court, they could not have helped me. At first glance, it may appear that a large checklist would add to the already time-consuming duties of medical staff relating to informed consent. However, as the aviation industry has proven, large checklists are actually more efficient for completing required tasks. The checklist given in this chapter meets all the requirements of the patient while also enabling the doctor to comply with the strictest legal standards. As both a civilian and a military pilot, my training required me to learn to use

¹⁸¹ *Id.*

checklists so I would not miss anything critical or required. Doctors would benefit from similar checklists applied to complicated surgeries.

Clinics and hospitals have trained professionals that are used to completing forms. Whether it is insurance forms or informed consent documents, the medical professionals are capable and are aided by the use of checklists to complete the forms. A feasible proposal that will aid ophthalmologists and retina and vitreous physicians, as well as their staffs, in obtaining true informed consent is the following checklist for complex eye surgeries.

The following checklist should aid the doctor to efficiently obtain informed consent by offering a rational, coherent explanation of the prognosis of the eye disease or injury in the event it is left untreated. Often, time is of the essence in repairing or stopping the progression of an eye disease or injury. Thus, a checklist that facilitates a dialogue will save time and hopefully, help the patient remain sighted. The checklist has provisions for legal competence, religious, cultural, vocational, and other social factors to be used so that it will create a dialogue based on trust and understanding.

5.5 Informed Consent Checklist for Complex Eye Surgeries

Informed Consent Checklist for Complex Eye Surgeries

PURPOSE: This checklist is an aid for ophthalmologists and retina and vitreous physicians and their staffs to legally obtain informed consent from their patients for eye surgeries.

DIRECTIONS: There are six areas that the physician must discuss with the patient to obtain the patients informed consent for the course of treatment proposed. Discuss each category with the patient and ensure the patient understands each section's material. Additional information from other sources may be required due to the variation with the procedures and individual patients ability to comprehend the medical information. Informed consent is the choice that the patient deems acceptable for his or her course of treatment. Informed consent includes refusal for treatment. Document that **THE PATIENT UNDERSTANDS** each category in this checklist. Once understanding and informed consent have been given by the patient, he must sign each category **PRIOR TO SURGERY or TREATMENT**. Place a copy of this checklist in the patient's chart and medical records.

DISCLAIMER: This checklist does not cover all the possibilities that arise with each disease/injury or patient differences. Use this checklist for promoting dialogue with the patient. Modifications due to experience and variations are to be expected.

Diagnosis

Disclosure of Patient's Disease/Injury¹⁸²

1. Provide the name of the disease/injury to the patient.

Providers initials

Patients Initials

- a. _____ **Age-related Macular Degeneration (AMD) (Wet / Dry)** _____
- b. _____ **Macular dystrophy** _____
- c. _____ **Branch and Central Retinal Vein Occlusions** _____
- d. _____ **CMV Retinitis** _____
- e. _____ **Diabetic Retinopathy** _____
- f. _____ **Epiretinal Membranes (Macular Pucker)** _____
- g. _____ **Floaters, Flashes and Posterior Vitreous Detachments** _____
- h. _____ **Macular Edema (CME)** _____
- i. _____ **Macular Holes** _____
- j. _____ **Macular Translocation** _____
- k. _____ **Melanoma** _____
- l. _____ **Retinal Detachment** _____
- m. _____ **Proliferative Vitreoretinopathy (PVR)** _____
- n. _____ **PhotoDynamic Therapy (PDT)** _____
- o. _____ **Retinopathy of Prematurity** _____
- p. _____ **Subretinal Neovascular Membranes and Surgery** _____
- q. _____ **(AMD, OHS, Idiopathic, Myopia, PXE, etc.)** _____
- r. _____ **Vitrectomy** _____
- s. _____ **Injury** _____
- t. _____ **Other** _____

2. Explain the medical tests performed and the test results leading to the diagnosis.

3. Inform the patient of the certainty of the diagnosis.

¹⁸² Retina and Vitreous of Texas, discussion of eye diseases available at <http://www.retinatexas.com/diseases.html>.

4. Recommend any additional test(s) and explain the test(s) purposes. _____

a. Unsure of the disease or injury and additional tests are required to confirm.

b. Certainty of the diagnosis / Injury.

Physician

5. Provide the patient with your experience with this disease/injury.

6. Explain to the patient that they may seek a second opinion.

7. Provide the patient with a list of other qualified physicians who may provide the second opinion.

8. If a second opinion is requested; coordinate the second opinion appointment.

a. Patient has been referred to Dr. _____

b. Patient's appointment time is _____

Competence

9. Patient is legally capable of making decisions in accordance with the State laws.

a. Age _____ (legal age of majority: Alabama = 19 years old; Texas = 18 years old)

b. Legal Competence (patient has not been adjudged mentally incompetent).

Comprehension

10. Determine the patient's comprehension.

a. Education/ability to understand the information being presented.

i. Tailor the dialogue to enable the patient to understand the concepts presented.

ii. Provide the patient with pamphlets, multimedia resources (DVDs, VHS tapes discussing the disease/injury and the proposed treatment), Internet resources, and any other additional information that will be helpful in understanding the disease/injury.

b. Ask the patient to explain the diagnosis/injury (have the patient write the diagnosis/injury in the following lines):

c. Determine if the patient is able to express their concerns in a sound manner.

Religious, social or employment barriers.

11. Ascertain if the patient has a religious or social belief that prohibits or may hinder treatment.

12. Does the patient need a clergy member to help?

13. Does the patient need an interpreter?

a. Does the doctor have knowledge of such an individual who may interpret?

b. Does the physician have a staff member fluent in patient's language?

Note: It is the physician's responsibility to ensure that accurate and complete information is conveyed through a qualified, impartial interpreter, either in person or telephonically. Using a family member of the patient to fill this role runs the risk that information told to the patient may be filtered or that the patient will feel inhibited in

fully discussing his or her condition.

14. Determine if the patient has employment concerns that may prohibit or hinder the treatment plan.

- a. Does the patient's employment have physical health standards that must be met? (i.e. vision requirements, hearing acuity).
- b. If possible, contact the licensing agency to determine employability if the patient undergoes treatment and employability if treatment is refused.
- c. Is the physician required to report the patient's disease / injury to a government agency?

Voluntary Patient's Decision

15. Ensure the patient has made the decision on the course of treatment for their body without coercion from the medical staff.

16. Ensure that the patient understands that the decision is the patient's alone and the patient has not been coerced by another individual.

17. Ensure that the patient understands informed consent is required before surgery may be performed.

18. If the patient is incompetent, has the legally appointed guardian selected the course of treatment? Is the treatment medically reasonable?

19. If the patient is a minor, has the parent or legal custodian selected the course of treatment? Is the treatment medically reasonable?

Document the patient's understanding of their disease/injury and acceptance of the course of treatment.

20. Have the patient complete the following: I _____ have been advised that I have the following disease/ injury _____. I am an adult and legally capable of making medical decisions that are best for my body. By signing the following statement I, _____, attest that I am selecting the course of treatment based upon my understanding of the diagnosis of the disease / injury which is _____ and I am making this informed consent voluntarily.

Patient's signature _____ . Date _____

Nature and Purpose of the Proposed Treatment

21. The name of the surgery is _____. (patient fills in).

22. Explain to the patient the procedures that the physician will utilize in the surgery and their intended purpose.

Laser:

a. Patient will sit in ophthalmologist chair and the physician will use _____ (laser, etc) to _____ (seal the blood vessel, etc).

b. Laser-- explain to the patient that the laser light is 20 times brighter and longer in duration than any camera flash. The patient is to concentrate on the flashing light, and after the laser burst, the patient's vision will go black.

c. Explain that it is essential that the patient stay focused on the light, as this helps the

- patient not to move their eye.
- d. Explain any additional information to the patient about this form of treatment.

Subretinal membrane removal:

- a. Explain to the patient that the patient will not be awake for the surgery.
- b. **ASCERTAIN IF THE PATIENT DESIRES TO KNOW THE PROCEDURES INVOLVED before proceeding.**
 - i. Explain the procedures of the surgery (in general terms, unless the patient requests more details of the procedure).
 - ii. Explain to the patient that the surgery will attempt to cut out the blood vessel and remove any scabs caused by previous laser surgeries.
 - iii. Removal of the vessels and scabs is intended to aid the retina in functioning normally, depending on the damage already done.

Other surgeries:

- i. Explain these procedures in detail.

23. The surgery purpose is to aid me by _____

(patient's fills in the blank stating the purpose of the surgery).

24. Explain to the patient the method of anesthesia to be used: "general" (patient is unconscious) or local (patient is awake, and administered a shot).

25. Explain the anesthesia procedures if local.

26. Explain to the patient the patients duties if they are awake during the surgery.

- a. **Remain perfectly still.**

- b. Focus on the light.
- c. Re-focus on the light after each laser treatment.
- d. Keep the eye motionless.

27. The surgery is recommended for the following reason(s) _____ .

28. The patient will be informed exactly which physician will be performing the surgery.

29. The physician will be informed if a secondary physician is going to operate.

30. The patient will be given the option of allowing only the primary physician to perform the surgery:

I voluntarily request Dr. _____ as my physician, and any associates, technical assistants, or health care providers he/she deems necessary to treat my condition.¹⁸³

31. Document the patient's understanding of the surgery/treatment:

I understand that the following surgical, medical, and/or diagnostic procedures are planned for me, and I voluntarily consent and authorize these procedures¹⁸⁴:

32. Inform the patient that every surgery is unique and that no warranty or guarantee has been made as to the result or cure. _____ (patient's signature).

33. Provide the patient with a list of things the patient must do prior to surgery.

¹⁸³ Methodist Hospital, Houston Texas, form #331 (11/2004).

¹⁸⁴ *Id.*

- a. Complete this informed consent document.
- b. Complete the hospital pre-admittance paperwork.
- c. Instruct the patient of the following¹⁸⁵:
 - i. No food or drink after midnight on _____ (e.g. Candy, gum, coffee, water, etc.) — EXCEPTION: required medication may be taken the morning of surgery with a small amount of water only.
 - ii. Transportation to and from the hospital or surgery center.
 - iii. Transportation to and from one-Day postoperative visit.
 - iv. Directed to stop blood thinners (e.g. aspirin, Coumadin, Plavix, Ticlid, etc.)
 - v. Directed to take blood pressure and/or heart medication the morning of surgery.
 - vi. Directed to obtain medical clearance prior to surgery; clearance must be forwarded to surgeon.
 - vii. Received and understood directions to hospital or surgery center.
 - viii. Received and understood postoperative prescription/medications with instructions on use.
 - ix. **NOTE: DO not travel by air if you have gas injected in your eye!**
 - x. Specifically disclose any activities that may not be accomplished pre and postoperative (only picking up the weight equivalent of one tennis shoe; no physical activities such as running, jogging, weight lighting, etc).

¹⁸⁵ Retina and Vitreous of Texas Preoperative Instructions.

Risks and Consequences

34. Inform the patient of the risks, consequences and benefits for the procedure being recommended.

35. Eye surgeries have the risk of the following:

- a. **blindness**
- b. **loss of vision**
- c. **blurriness**
- d. **loss of night vision**
- e. **flashing in the eyes**
- f. **halo vision**
- g. **dry tear ducts**
- h. **pain**
- i. **other potential outcomes**

36. For retinal or vitreous surgery inform the patient of the following:

- a. **Complications requiring additional treatment and/or surgery.**
- b. **Recurrence or spread of disease.**
- c. **Partial or total loss of vision.**

Success/failure data

37. Any reliable, data on the success of the operation should be provided to the patient.

38. Any reliable data on the failure of the operation will be provided to the patient.

39. Patient has been informed that NO OUTCOME CAN BE GUARANTEED.

40. Have the patient sign the following statement:

I understand that no warranty or guarantee has been made to me as to result or cure.

_____ (Patient's signature).

41. Just as there maybe risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical, and/or diagnostic procedure planned for me. I realize that, there is a potential for infection, blood clots in veins and lungs, hemorrhage, allergic reactions, and even death in any surgical, medical, and/or diagnostic procedures. I also realize that the risks and hazards in connection with this particular procedure are (patient fills-below)¹⁸⁶:

_____.

Blood transfusions

42. Inform the patient that the risk involved with any blood transfusion could be HIV/AIDS/Hepatitis C.

Anesthesia

43. Inform the patient that anesthesia involves additional risks and hazards.

44. Inform the patient that complications that may result from the use of anesthesia, including respiratory problems, drug reaction, process, brain damage or even death. Other risks and hazards that may result from the use of general anesthetics range from minor discomfort to injury to vocal cords, teeth or eyes. Risks and hazards

¹⁸⁶ The Methodist Hospital, Houston Texas, form #331 (11/2004).

resulting from spinal or epidural anesthetics include headache and chronic pain.¹⁸⁷

Prognosis if Proposed Treatment Not Undertaken

- 45. Warn the patient of the dangers to their vision.**
- 46. Inform the patient that the surgical procedures have a limited time period to be performed. After that time the surgery may be ineffective or prohibited.**
- 47. Inform the patient of the progression of the disease or the injury if left untreated.**

Alternative Treatments

- 48. Inform the patient of alternative treatments accepted in the medical community that are available. This includes alternatives that carry more risk than other proposed treatments.**
- 49. Explain any alternative tests that are available to the patient (even if these alternatives may be performed only by another doctor).**
- 50. Explain the risks of the alternative(s) treatments.**
- 51. Some alternative treatments studies include:¹⁸⁸**
 - a. Photodynamic Therapy (PDT) Study-Approved by FDA 4/2000
 - b. Macular Translocation for CNV
 - c. Perfluoron (PFO) Phase IV Clinical Trial
 - d. Submacular Surgery Pilot Trials (SST)
 - e. Diabetic Macular Edema Studies
 - f. Perfluoron Study (PFO)

¹⁸⁷ *Id.*

¹⁸⁸ Retina and Vitreous of Texas, available at <http://www.retinatexas.com/studies.html>.

- g. Syntex Ganciclovir Implant Trials
- h. ISIS CMV Retinitis Trials
- i. RPE Transplantation Study
- j. Collaborative Ocular Melanoma

52. Inform the patient of any reliable data on the physician's evaluation and/or their success with the alternative treatments.

53. Inform the patient of any reliable data on the risks or failure of alternative treatments.

54. Any reliable data on the success of alternative treatments will be provided to the patient.

55. If the physician is unable or untrained in the alternative treatments, and the patient is a candidate for such alternative treatments, refer the patient to the physician(s) trained in the alternative procedures.

56. Inform the patient that during surgery the physician may encounter additional problems.

57. Obtain the patient's consent or denial for other eye related treatments now.

I understand that my physician may discover other or different conditions that require additional or different procedures than those planned. I authorize my physician and other health care providers to perform such other procedures as are advisable in their professional judgment.

_____ (Patient's signature).

Other Issues for Eye Surgery

58. Discuss with the patient:

- a. Insurance Coverage**
- b. Medical Charges**
- c. Expected Recover Time**
- d. The Intensity and Duration of any Pain**

59. Procedures the patient should follow if anything changes with the patient's vision prior to surgery.

60. Discuss the procedures that the patient should use to contact the physician after the surgery if pain persists or there is a change in the vision.

61. Discuss the use of the eye drops after the surgery, and explain the directions.

Completing the informed consent — documentation

62. The final step for informed consent is the documentation that the patient has been provided the information that has enabled the him/her to make an informed consent based upon knowledge and understanding of the diagnosis, nature and purpose of the proposed treatment, risks and consequences of the treatment, alternative treatments available, prognosis if proposed treatment is not undertaken, and any other issues that relate to the patient's eye surgery.

63. Have the patient sign the following statements, then place this documentation within the patient's records, medical charts and provide the patient with a copy.

64. I have been given an opportunity to ask questions about my medical condition and

understand my diagnosis, the nature and purpose of the planned surgery, including the procedures to be used, alternative treatments and forms of anesthesia available, prognosis if proposed treatment is not undertaken, and the requirements placed upon me as a patient that I must comply with (both pre and postoperative) to enhance my chances of success with this course of treatment and surgery.¹⁸⁹

65. I certify this **form** has been **fully explained to me, and I have read it or have had it read to me,** that the blank spaces had been filled in, and that I understand its contents. **I am making this informed consent voluntarily.**¹⁹⁰

Date: _____ Time: _____ A.M. P.M.

Patient/Other Legally Responsible Person Signature
Signature

Translator or Reader

Witness Signature

Witness name

Address (Street or P.O. Box)

City, State, Zip Code

¹⁸⁹ The Methodist Hospital, Houston Texas, form #331 (11/2004).

¹⁹⁰ *Id.*

CHAPTER 6

CONCLUSION

TACP §601.2(f) will not aid the patient or the physician. The physician's liability is minimal with this disclosure requirement. As indicated by the discussion of the hospital form, the hospital has provided a format that requires improvement to obtain true consent for complex eye surgeries. One improvement could be supplying hospital technicians, who spend enormous amounts of time completing the insurance and financial paperwork, with a complete informed consent checklist so that they could quickly and thoroughly provide the patient with the information necessary to facilitate the physician-patient dialogue. The main benefit to the doctor is simple: that the physician would be able to spend more time actually operating and diagnosing problems with patients, and an additional benefit is a defense to litigation. Dr. Massey and Dr. Kimble spent approximately six hours each discussing the reasons why I should agree to their proposed treatment. With a comprehensive plan, a technician might have been able to hold this discussion. For my second surgery, if equipped with a checklist, the nurses and possibly the technicians, might have understood that I was not competent to give informed consent due to my desperation to see again, could have documented this, and possibly turned consent for the treatment over to my sister, thereby eliminating a threat of litigation. Alternatively, they could have made sure that I was competent enough to understand the procedure. Again, the use of the checklist would have aided the informed consent process.

My real-life experience with two emergency surgeries, my analysis of court cases and the recommended and required elements of informed consent have been presented in this paper. The checklist developed provides a workable and efficient informed consent procedures for eye

surgeries. The checklist recommended herein incorporates the six elements of informed consent and raises the standard of disclosure to a subjective standard. Additionally, it will shield physicians from liability and provide a more efficient method for giving the patient the information required to obtain true informed consent. The checklist, presented here for eye surgeries also may be adopted for other complex medical procedures. The purpose is simple: to allow the patient autonomy over treatment for his or her body, by providing the information required to make an informed decision; and to allow the physician and his staff to understand, and correctly obtain, informed consent based upon this patient autonomy. It is my fervent hope that the suggested checklist in Chapter 5 be adopted by medical experts for utilization with eye surgeries. The goal is to provide physicians with a legally comprehensive informed consent checklist that facilitates dialogue with the patient, resulting in true informed consent BY patients.

Appendix 1¹⁹¹

Texas Medical Disclosure Panel

25 TAC § 601.2

TEXAS ADMINISTRATIVE CODE

*** THIS DOCUMENT REFLECTS ALL RULES IN EFFECT AS OF NOVEMBER 30, 2006

TITLE 25. HEALTH SERVICES
PART 7. TEXAS MEDICAL DISCLOSURE PANEL
CHAPTER 601. INFORMED CONSENT

25 TAC § 601.2 (2006)

§ 601.2. Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A

[NOTE: ONLY THE SECTION PERTAINING TO THE EYE is produced in this appendix.]

(f) Eye treatments and procedures.

(1) Eye muscle surgery.

(A) Additional treatment and/or surgery.

(B) Double vision.

(C) Partial or total loss of vision.

(2) Surgery for cataract with or without implantation of intraocular lens.

(A) Complications requiring additional treatment and/or surgery.

(B) Need for glasses or contact lenses.

(C) Complications requiring the removal of implanted lens.

(D) Partial or total loss of vision.

(3) Retinal or vitreous surgery.

(A) Complications requiring additional treatment and/or surgery.

¹⁹¹ 25 T.A.C.P. § 601.2

- (B) Recurrence or spread of disease.
- (C) Partial or total loss of vision.
- (4) Reconstructive and/or plastic surgical procedures of the eye and eye region, such as blepharoplasty, tumor, fracture, lacrimal surgery, foreign body, abscess, or trauma.
- (A) Worsening or unsatisfactory appearance.
- (B) Creation of additional problems.
- (i) Poor healing or skin loss.
- (ii) Nerve damage.
- (iii) Painful or unattractive scarring.
- (iv) Impairment of regional organs, such as eye or lip function.
- (C) Recurrence of the original condition.
- (5) Photocoagulation and/or cryotherapy.
- (A) Complications requiring additional treatment and/or surgery.
- (B) Pain.
- (C) Partial or total loss of vision.
- (6) Corneal surgery, such as corneal transplant, refractive surgery and pterygium.
- (A) Complications requiring additional treatment and/or surgery.
- (B) Possible pain.
- (C) Need for glasses or contact lenses.
- (D) Partial or total loss of vision.
- (7) Glaucoma surgery by any method.
- (A) Complications requiring additional treatment and/or surgery.
- (B) Worsening of the glaucoma.

(C) Pain.

(D) Partial or total loss of vision.

(8) Removal of the eye or its contents (enucleation or evisceration).

(A) Complications requiring additional treatment and/or surgery.

(B) Worsening or unsatisfactory appearance.

(C) Recurrence or spread of disease.

(9) Surgery for penetrating ocular injury, including intraocular foreign body.

(A) Complications requiring additional treatment and/or surgery, including removal of the eye.

(B) Chronic pain.

(C) Partial or total loss of vision.

25 TACS § 601.2

Appendix 2¹⁹²

The Methodist Hospital Form # TMH469 – Donating Tissue for Medical Research

The following pages have the Hospital Form printed as the patient and doctor receive it. Continue to the next page for the complete form.

¹⁹² The Methodist Hospital, Form TMH469 (11/2004).



TMH469

Donating Tissue for Medical Research: Any tissue removed for my care will first be examined to help diagnose my medical condition and decide how best to treat me. If any tissue remains, it may be used for medical research as explained in the information sheet given to me. My medical record may be reviewed by researchers for follow-up information. The researchers will keep the medical information they obtain about me as confidential as possible. In addition, any information that results from the research will be kept as confidential as possible; as part of that effort, any information that results from the research will not appear in my medical record. Participation in this research is voluntary. I have a right to decide about participating in research, and may change my mind up until the tissue is used in research. Once my tissue is used in research, I know I have no rights to it or to anything produced from it. The choices I make will not affect my medical care in any way.

a. I have received the information sheet explaining the use of human tissue in medical research and understand its contents.

Yes No _____ Initials

b. I agree to donate my remaining tissue to be used by The Methodist Hospital in medical research.

Yes No _____ Initials

c. I agree that someone may contact me in the future to ask questions about my health or ask me to participate in more research.

Yes No _____ Initials

Patient Signature

Date (MM/DD/YYYY)



**Donating Tissue for
Medical Research**

Form # TMH469 (11/2004)





TMH626

Donating Tissue to Self: I understand that as a result of my healthcare treatment at The Methodist Hospital (the "Hospital"), my physician may remove some of my tissue. After such removal, the tissue can either be (1) thrown away, or (2) stored at the Hospital for me in the event I need it in the future for another procedure. My tissue would only need to be stored if my physician has a reasonable belief that I might need it in the future for additional treatment, such as for an implant.

I hereby agree that, if my physician determines that I might need this tissue, my remaining tissue may be stored at the Hospital so that it can be used in my future medical care and treatment.

Yes No

I have read this consent or it has been explained to me, and I have had the opportunity to ask questions.

Signature of Patient/Representative

Date

Methodist The Methodist
Hospital
Houston, Texas

Form # TMH626 (11/2004)

**Consent to Donate
Tissue for
Non-Research Purposes**



Information For Patients Donating Tissue for Medical Research

Why should you donate tissue?

Where does tissue come from?

During your surgery, some tissue may be removed from your body. This may be the main reason for your surgery, or the tissue may be removed for diagnostic or preventative reasons. After the surgery and all the tests have been done, some of the removed tissue may be left over. This left over tissue may be a piece of skin or bone or an internal organ or a very small amount of blood. This tissue may either be discarded or destroyed because it is not needed for your care, or you may choose to donate the tissue and blood for medical research.

Your care is always our first priority. Any tissue removed from your body will always be used first and foremost to help diagnose your medical condition and decide how you can best be treated. Choosing to donate tissue will not require removal of any extra tissue or change the care you will receive in any way.

Who can donate tissue and where will the tissue be kept?

Anyone undergoing treatment at The Methodist Hospital may become a tissue donor. Your doctor may ask you to donate your tissue (blood, bodily fluids or tissue) whether or not you are in good health. If you donate your tissue, it will be transferred to one of the Tissue Banks at the hospital. If a researcher wishes to study human tissue, then he or she will ask the Tissue Bank for a tissue sample.

Why is research done with human tissue important?

Research using human tissue can help answer questions about other health problems, such as diabetes, heart disease and Alzheimer's disease. Research with tissue can help to find out more about what causes disease, how to prevent it, how to treat it, and how to cure it.

What type of research will be done with my tissue?

Many different kinds of studies may be done on human tissue. Some researchers may be able to develop new ways to treat or cure diseases. Other researchers may wish to find out if there are diseases that may be passed on in families (genetic research). Some of the researchers may help to develop new products, such as drugs and tests for diseases.

Who will do research on the donated tissue?

The tissue will be used primarily by researchers at The Methodist Hospital. However, there may also be collaborative efforts with other universities and private companies.

Will you find out the results of the research?

Neither you nor your doctor will receive the results of research done with your tissue. This is because research can take a long time and must use tissues from samples from many people before results are known. Results from research using your tissue may not be ready for many years and will not affect your care right now, but the results of the research may be helpful to people like you in the future. For these reasons, the results will not appear in your medical records. In the unlikely event that research results do become available that have significant implications for your health concerns, we will make every possible effort to contact you to discuss disclosing this information to you, provided that the results are scientifically valid and confirmed, and a course of action to ameliorate or treat these concerns is readily available.

Will anyone have access to your medical records?

In order to understand the significance of the research done on your tissue, researchers may need to know some things about you, for example, your gender, your age, your health history, and your family history. Information, pertinent to your tissues, from your medical records may be given to the researchers by the Tissue Bank records staff. However, no information that identifies you by name will be given to the researchers without your consent.

Will your privacy be protected?

Your privacy will be protected as much as possible. The people in charge of the Methodist Hospital Tissue Banks will take careful steps to prevent any private information about you, such as your name, address, or phone number, from being released to anyone. Any identifying personal information will be taken off any record associated with your tissue before it is studied and a code number will be assigned to the tissue. This would make it very difficult for any research results to be linked to you or your family. No information that identifies you by name will be given to any of the researchers.

Are there any risks to you for donating tissue?

There are no medical risks to you. However, while every effort is made to protect your confidentiality, there is a small risk of loss of privacy. Because the study results will not be entered into your medical record, there should be minimal risk to you that your insurability or employability will be affected in any way.

Are there any financial considerations?

There will be no costs to you if you agree to donate your tissue for research, nor will you receive any money or other compensation for donating your tissue. Even if the researchers are able to develop new products from the use of your tissues, you will not receive any money for your tissue donation.

Will you benefit from this research?

There will be no direct medical or personal benefit to you as a result of donating your tissue. However, the researchers hope to learn from this research and to be able to help others in the future.

What are the alternatives?

Participation in this research by donating tissue and allowing us to access your medical records is totally voluntary. The alternative is to simply not participate.

What if you have more questions?

If you have more questions about tissue donation, then please talk to your doctor or nurse or contact Dr. Alberto Ayala in The Methodist Hospital Department of Pathology at 713-441-1339 or write to the Pathology Department M.S. 205, 6565 Fannin, Houston, TX 77030. If you have any questions at any time about your rights as a research subject, you may address them to James V. Roberts, Jr., Chairman of Patient Advisory Council, Inc., Institutional Review Board, the IRB overseeing the conduct of this study at The Methodist Hospital at 251-479-5472, collect calls are accepted.

What happens next?

Once you have read this brochure, you *will have an opportunity to talk* with your doctor or nurse and make sure all your questions are answered. Then you can decide whether or not you want to donate your tissue for medical research. You are not obligated in any way to donate your tissue. The choice is up to you. Whatever you choose to do, your medical care will not be altered in any way. You do not have to explain your decision to anyone; you just have to say yes or no. You will be asked to sign a brief form to indicate whether or not you want to donate your tissue. This form will be part of your surgical consent form.

Will you be contacted in the future about this or other research involving tissue donation?

Your doctor or nurse may ask if someone can contact you in the future to request information about your health or to seek further tissue donation for later medical research. You can decide whether or not you want to be contacted in the future. You can decide now that it might be all right to contact you in the future and then change your mind later. Again, the choice is your own. You will always have the right to withdraw completely your consent for research and remove your remaining tissue from the tissue bank at any time by contacting Dr. Alberto Ayala at 713-441-1339.

Appendix 3¹⁹³

The Methodist Hospital

Disclosure and Consent; Medical, Invasive and Surgical Procedures Form

The following pages have the Hospital Form printed as the patient and doctor receive it. Continue to the next page for the complete form.

¹⁹³ The Methodist Hospital Form # 331 (11/2004)

The Methodist Hospital Disclosure and Consent; Medical, Invasive and Surgical Procedures Form

TO THE PATIENT: You have the right, as a patient, to be informed by your physician/practitioner about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you: it is simply an effort to make you better informed so you may give or withhold your consent to the procedure. **Has your physician informed you about the procedure(s) proposed for you, along with the risks involved to your satisfaction?** Y N



000331

1. I voluntarily request Dr. _____ PT. INITIALS _____ as my physician, and such associates, technical assistants and other health care providers as they may deem necessary, to treat my condition which has been explained to me as: _____
2. I understand that the following surgical, medical, and/or diagnostic procedures are planned for me, and I voluntarily consent and authorize these procedures: _____
3. I understand that my physician may discover other or different conditions that require additional or different procedures than those planned. I authorize my physician and other health care providers to perform such other procedures as are advisable in their professional judgment.
4. I (do) (do not) consent to the use of blood and blood products as deemed necessary. _____ PT. INITIALS _____
5. Any tissues or parts surgically removed may be retained or disposed of by The Methodist Hospital in accordance with its accustomed practice.
6. I understand that no warranty or guarantee has been made to me as to result or cure.
7. Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical, and/or diagnostic procedures planned for me. I realize that, common to surgical, medical, and/or diagnostic procedures is the potential for infection, blood clots in veins and lungs, hemorrhage, allergic reactions, and even death. I also realize that the risks and hazards I initial on later pages of this form, and the following risks and hazards may occur in connection with this particular procedure: _____
8. I understand that anesthesia involves additional risks and hazards, but I request the use of anesthetics for the relief and protection from pain during the planned and additional procedures. I realize the anesthesia may have to be changed, possibly without explanation to me.
9. I understand that certain complications may result from the use of any anesthetic including respiratory problems, drug reaction, paralysis, brain damage or even death. Other risks and hazards that may result from the use of general anesthetics range from minor discomfort to injury to vocal cords, teeth or eyes. I understand that other risks and hazards resulting from spinal or epidural anesthetics include headache and chronic pain.
10. I also understand that my anesthetic will be managed by one or more anesthesiology physicians (anesthesiologists). These anesthesiologists may also direct other members of my anesthesia care team including one or more Certified Registered Nurse Anesthetists (CRNAs).
11. I have been given an opportunity to ask questions about my condition, alternative forms of anesthesia and treatment, risks of nontreatment, the procedures to be used, and the risks and hazards involved, and I believe that I have sufficient information to give this informed consent.
12. I certify this form has been fully explained to me, that I have read it or have had it read to me, that the blank spaces have been filled in, and that I understand its contents.

Date: _____ Time: _____ A.M. P.M.

Patient/Other Legally Responsible Person Signature Translator or Reader Signature

Witness Name

Address (Street or P.O. Box)

City, State, Zip Code



Disclosure and Consent Medical, Invasive and Surgical Procedures

RISKS AND HAZARDS

Tissue:
I understand that my physician may use tissue other than my own, and the following are possible risks from the use of that tissue:

1. The transmission of infectious diseases, including bacterial infection.
2. Allergic reaction and other immunological responses, including rejection of the tissue.
3. Other: _____

PT INITIALS

The following are the risks and hazards associated by the Texas Medical Disclosure Panel with treatments and procedures.

The Texas Medical Disclosure Panel has not established a risk disclosure standard for the proposed procedure(s). My physician has discussed with me the risks of the procedure(s) such that I am able to give my informed consent.

PT INITIALS

Blood transfusions:

(1) fever	(4) hepatitis
(2) transfusion reaction, which may include kidney failure and or anemia	(5) AIDS
(3) heart failure	(6) other infections

PT INITIALS

Autologous Donation: I understand that in some instances, it may be possible to donate my own blood for elective medical procedures. Although this diminishes infectious disease transmission, the transfusion still carries with it the risks of adverse physiological reactions and bacterial contamination. In addition, previously donated autologous units may not always be available or adequate for transfusion needs.

I (have) (have not) made prior arrangements for autologous transfusion.

Designated Donation: I understand, that, in some cases, it is possible to arrange for designated donations (donations from friends or relatives). However, I also understand that designated donations have not been demonstrated to be safer than blood from the volunteer blood supply. In addition, designated units may not always be available or adequate for transfusion needs.

I (have) (have not) made prior arrangements for designated donations.

1. ANESTHESIA. (Risks are enumerated in the consent form).

2. DIGESTIVE SYSTEM TREATMENTS AND PROCEDURES.

(A) Cholecystectomy with or without common bile duct exploration.

- (1) Pancreatitis.
- (2) Injury to the tube between the liver and the bowel.
- (3) Retained stones in the tube between the liver and the bowel.
- (4) Narrowing or obstruction of the tube between the liver and the bowel.
- (5) Injury to the bowel and/or intestinal obstruction.

PT INITIALS

3. ENDOSCOPIC SURGERY

(A) Abdominal/Laparoscopy

- (1) Damage to intra-abdominal structures.
- (2) Intra-abdominal abscess and infectious complications.
- (3) Trocar site complications.
- (4) Conversion of the procedure to an open procedure.
- (5) Cardiac dysfunction.

PT INITIALS

(B) Thorax

- (1) Postoperative pneumothorax.
- (2) Subcutaneous emphysema.
- (3) Conversion of the procedure to an open procedure.

PT INITIALS

4. EAR TREATMENTS AND PROCEDURES.

(A) Stapedectomy.

- (1) Diminished or bad taste.
- (2) Total or partial loss of hearing in the operated ear.
- (3) Brief or long-standing dizziness.
- (4) Eardrum hole requiring more surgery.
- (5) Ringing in the ear.

PT INITIALS

(B) Reconstruction of auricle of ear for congenital deformity or trauma.

- (1) Less satisfactory appearance compared to possible alternative artificial ear.
- (2) Exposure of implanted material.

PT INITIALS

(C) Tympanoplasty with mastoidectomy.

- (1) Facial nerve paralysis.
- (2) Altered or loss of taste.
- (3) Recurrence of original disease process.
- (4) Total loss of hearing in operated ear.
- (5) Dizziness.
- (6) Ringing in the ear.

PT INITIALS

5. ENDOCRINE SYSTEM TREATMENTS AND PROCEDURES.

(A) Thyroidectomy.

- (1) Injury to nerves resulting in hoarseness or impairment of speech.
- (2) Injury to parathyroid glands resulting in low blood calcium levels that require extensive medication to avoid serious degenerative conditions, such as cataracts, brittle bones, muscle weakness and muscle irritability.
- (3) Lifelong requirement of thyroid medication.

PT INITIALS

6. EYE TREATMENTS AND PROCEDURES.

(A) Eye muscle surgery.

- (1) Additional treatment and/or surgery.
- (2) Double vision.
- (3) Partial or total loss of vision.

PT INITIALS

(B) Surgery for cataract with or without implantation of intraocular lens.

- (1) Complications requiring additional treatment and/or surgery.
- (2) Need for glasses or contact lenses.
- (3) Complications requiring the removal of implanted lens.
- (4) ~~Partial or total loss of vision.~~

PT INITIALS

(C) Retinal or vitreous surgery.

- (1) Complications requiring additional treatment and/or surgery.
- (2) Recurrence or spread of disease.
- (3) Partial or total loss of vision.

PT INITIALS

(D) ~~Reconstructive and/or plastic surgical~~ procedures of the eye and eye region, such as blepharoplasty, tumor, fracture, lacrimal surgery, foreign body, abscess, or trauma.

- (1) Worsening or unsatisfactory appearance.
- (2) Creation of additional problems such as:
 - a. Poor healing or skin loss.
 - b. Nerve damage.
 - c. Painful or unattractive scarring.
 - d. Impairment of regional organs, such as eye or lip function.
- (3) Recurrence of the original condition.

PT INITIALS

(E) **Photocoagulation and/or cryotherapy.**
 (1) Complications requiring additional treatment and/or surgery.
 (2) Pain.
 (3) Partial or total loss of vision. PT INITIALS

(F) **Corneal surgery**, such as corneal transplant, refractive surgery and pterygium.
 (1) Complications requiring additional treatment and/or surgery.
 (2) Possible pain.
 (3) Need for glasses or contact lenses.
 (4) Partial or total loss of vision. PT INITIALS

(G) **Glaucoma surgery** by any method.
 (1) Complications requiring additional treatment and/or surgery.
 (2) Worsening of the glaucoma.
 (3) Pain.
 (4) Partial or total loss of vision. PT INITIALS

(H) **Removal of the eye** or its contents (enucleation or evisceration).
 (1) Complications requiring additional treatment and/or surgery.
 (2) Worsening or unsatisfactory appearance.
 (3) Recurrence or spread of disease. PT INITIALS

(I) **Surgery for penetrating ocular injury**, including intraocular foreign body.
 (1) Complications requiring additional treatment and/or surgery, including removal of the eye.
 (2) Chronic pain.
 (3) Partial or total loss of vision. PT INITIALS

7. FEMALE GENITAL SYSTEM TREATMENTS AND PROCEDURES.

(A) **Abdominal hysterectomy (total).**
 (1) Uncontrollable leakage of urine.
 (2) Injury to bladder.
 (3) Sterility.
 (4) Injury to the tube (ureter) between the kidney and the bladder.
 (5) Injury to the bowel and/or intestinal obstruction. PT INITIALS

(B) **Vaginal hysterectomy.**
 (1) Uncontrollable leakage of urine.
 (2) Injury to bladder.
 (3) Sterility.
 (4) Injury to the tube (ureter) between the kidney and the bladder.
 (5) Injury to the bowel and/or intestinal obstruction.
 (6) Completion of operation by abdominal incision. PT INITIALS

(C) **All fallopian tube and ovarian surgery** with or without hysterectomy, including removal and lysis of adhesions.
 (1) Injury to the bowel and/or bladder.
 (2) Sterility.
 (3) Failure to obtain fertility (if applicable).
 (4) Failure to obtain sterility (if applicable).
 (5) Loss of ovarian functions or hormone production from ovary(ies). PT INITIALS

(D) **Abdominal endoscopy** (peritoneoscopy, laparoscopy).
 (1) Puncture of the bowel or blood vessel.
 (2) Abdominal infection.
 (3) Abdominal incision and operation to correct injury.
 (4) Conversion to an open procedure.
 (5) Trocar site complication. PT INITIALS

(E) **Removing fibroids** (uterine myomectomy).
 (1) Uncontrolled leakage of urine.
 (2) Injury to bladder.
 (3) Sterility.
 (4) Injury to the tube (ureter) between the kidney and the bladder.
 (5) Injury to the bowel and/or intestinal obstruction. PT INITIALS

(F) **Uterine suspension.**
 (1) Uncontrolled leakage of urine.
 (2) Injury to bladder.
 (3) Sterility.
 (4) Injury to the tube (ureter) between the kidney and the bladder.
 (5) Injury to the bowel and/or intestinal obstruction. PT INITIALS

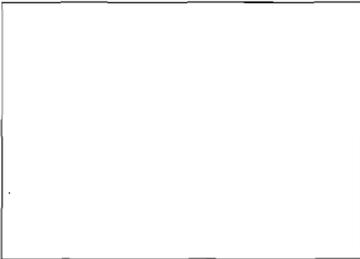
(G) **Removal of the nerves** to the uterus (presacral neurectomy).
 (1) Uncontrolled leakage of urine.
 (2) Injury to bladder.
 (3) Sterility.
 (4) Injury to the tube (ureter) between the kidney and the bladder.
 (5) Injury to the bowel and/or intestinal obstruction.
 (6) Hemorrhage, complications of hemorrhage, with additional operation. PT INITIALS

(H) **Removal of the cervix.**
 (1) Uncontrolled leakage of urine.
 (2) Injury to bladder.
 (3) Sterility.
 (4) Injury to the tube (ureter) between the kidney and the bladder.
 (5) Injury to the bowel and/or intestinal obstruction.
 (6) Completion of operation by abdominal incision. PT INITIALS

(I) **Repair of vaginal hernia** (anterior and/or posterior colporrhaphy and/or enterocele repair).
 (1) Uncontrolled leakage of urine.
 (2) Injury to bladder.
 (3) Sterility.
 (4) Injury to the tube (ureter) between the kidney and the bladder.
 (5) Injury to the bowel and/or intestinal obstruction. PT INITIALS

(J) **Abdominal suspension** of the bladder (retropubic urethropexy).
 (1) Uncontrolled leakage of urine.
 (2) Injury to bladder.
 (3) Injury to the tube (ureter) between the kidney and the bladder.
 (4) Injury to the bowel and/or intestinal obstruction. PT INITIALS

(K) **Conization of cervix.**
 (1) Hemorrhage with possible hysterectomy to control.
 (2) Sterility.
 (3) Injury to bladder.
 (4) Injury to rectum.
 (5) Failure of procedure to remove all of cervical abnormality. PT INITIALS



(L) **Dilation and curettage of uterus (diagnostic).**
 (1) Hemorrhage with possible hysterectomy.
 (2) Perforation of the uterus.
 (3) Sterility.
 (4) Injury to the bowel and/or bladder.
 (5) Abdominal incision and operation to correct injury. PT INITIALS

(M) **Dilation and curettage of uterus (obstetrical).**
 (1) Hemorrhage with possible hysterectomy to control.
 (2) Perforation of the uterus.
 (3) Sterility.
 (4) Injury to the bowel and/or bladder.
 (5) Abdominal incision and operation to correct injury.
 (6) Failure to remove all products of conception. PT INITIALS

8. INTEGUMENTARY SYSTEM TREATMENTS AND PROCEDURES.

(A) **Radical or modified radical mastectomy.**
 (Simple mastectomy excluded).
 (1) Limitation of movement of shoulder and arm.
 (2) Swelling of the arm.
 (3) Loss of the skin of the chest requiring skin graft.
 (4) Recurrence of malignancy, if present.
 (5) Decreased sensation or numbness of the inner aspect of the arm and chest wall. PT INITIALS

(B) **Reconstruction and/or plastic surgical operations of the face and neck.**
 (1) Worsening or unsatisfactory appearance.
 (2) Creation of several additional problems such as:
 a. Poor healing or skin loss.
 b. Nerve damage.
 c. Painful or unattractive scarring.
 d. Impairment of regional organs, such as eye or lip function.
 (3) Recurrence of the original condition. PT INITIALS

9. MALE GENITAL SYSTEM TREATMENTS AND PROCEDURES.

(A) **Orchidopexy** [reposition of testis(es)].
 (1) Removal of testicle.
 (2) Atrophy (shriveling) of the testicle with loss of function. PT INITIALS

(B) **Orchiectomy** [removal of the testis(es)].
 (1) Decreased sexual desire.
 (2) Difficulties with penile erection. PT INITIALS

(C) **Vasectomy.**
 (1) Loss of testicle.
 (2) Failure to produce permanent sterility. PT INITIALS

10. MATERNITY AND RELATED CASES.

(A) **Delivery (vaginal).**
 (1) Injury to bladder and/or rectum, including a hole (fistula) between bladder and vagina and/or rectum and vagina.
 (2) Hemorrhage possibly requiring blood administration and/or hysterectomy and/or artery ligation to control.
 (3) Sterility.
 (4) Brain damage, injury or even death occurring to the fetus before or during labor and/or vaginal delivery whether or not the cause is known. PT INITIALS

(B) **Delivery (cesarean section).**
 (1) Injury to bowel and/or bladder.
 (2) Sterility.
 (3) Injury to tube (ureter) between kidney and bladder.
 (4) Brain damage, injury or even death occurring to the fetus before or during labor and/or cesarean delivery whether or not the cause is known.
 (5) Uterine disease or injury requiring hysterectomy. PT INITIALS

11. MUSCULOSKELETAL SYSTEM TREATMENTS AND PROCEDURES.

(A) **Arthroplasty of all joints with mechanical device.**
 (1) Impaired function, such as shortening or deformity of an arm or leg, limp or foot drop.
 (2) Blood vessel or nerve injury.
 (3) Pain or discomfort.
 (4) Fat escaping from bone with possible damage to a vital organ.
 (5) Failure of bone to heal.
 (6) Bone infection.
 (7) Removal or replacement of any implanted device or material. PT INITIALS

(B) **Mechanical internal prosthetic device.**
 (1) Impaired function, such as shortening or deformity of an arm or leg, limp or foot drop.
 (2) Blood vessel or nerve injury.
 (3) Pain or discomfort.
 (4) Fat escaping from bone with possible damage to a vital organ.
 (5) Failure of bone to heal.
 (6) Bone infection.
 (7) Removal or replacement of any implanted device or material. PT INITIALS

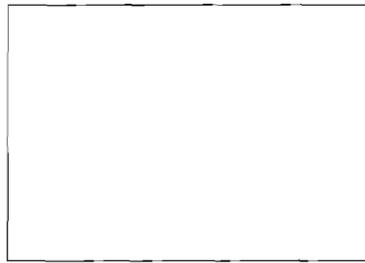
(C) **Open reduction with internal fixation.**
 (1) Impaired function, such as shortening or deformity of an arm or leg, limp or foot drop.
 (2) Blood vessel or nerve injury.
 (3) Pain or discomfort.
 (4) Fat escaping from bone with possible damage to a vital organ.
 (5) Failure of bone to heal.
 (6) Bone infection.
 (7) Removal or replacement of any implanted device or material. PT INITIALS

(D) **Osteotomy.**
 (1) Impaired function, such as shortening or deformity of an arm or leg, limp or foot drop.
 (2) Blood vessel or nerve injury.
 (3) Pain or discomfort.
 (4) Fat escaping from bone with possible damage to a vital organ.
 (5) Failure of bone to heal.
 (6) Bone infection.
 (7) Removal or replacement of any implanted device or material. PT INITIALS

(E) **Ligamentous reconstruction of joints.**
 (1) Failure of reconstruction to work.
 (2) Continued loosening of the joint.
 (3) Degenerative arthritis.
 (4) Continued pain.
 (5) Increased stiffening.
 (6) Blood vessel or nerve injury.
 (7) Cosmetic and/or functional deformity. PT INITIALS



**Disclosure and Consent
 Medical, Invasive and
 Surgical Procedures**



(F) **Children's orthopedics** (bone, joint, ligament or muscle).
 (1) Growth deformity.
 (2) Additional surgery. PT INITIALS

12. NERVOUS SYSTEM TREATMENTS AND PROCEDURES.

(A) **Craniotomy (craniectomy) for excision of brain** tissue, tumor, vascular malformation and cerebral revascularization.
 (1) Additional loss of brain function, including memory.
 (2) Recurrence or continuation of the condition that required this operation.
 (3) Stroke.
 (4) Blindness, deafness, inability to smell, double vision, coordination loss, seizures, pain, numbness and paralysis. PT INITIALS

(B) **Craniotomy (craniectomy) for cranial nerve operation** including neurectomy, avulsion, rhizotomy or neurolysis.
 (1) Numbness, impaired muscle function or paralysis.
 (2) Recurrence or continuation of the condition that required this operation.
 (3) Seizures. PT INITIALS

(C) **Spine operation.** Including: laminectomy, decompression, fusion, internal fixation or procedures for nerve root or spinal cord compression; diagnosis; pain; deformity; mechanical instability; injury; removal of tumor; abscess or hematoma. (Excluding coccygeal operations.)
 (1) Pain, numbness or clumsiness.
 (2) Impaired muscle function.
 (3) Incontinence or impotence.
 (4) Unstable spine.
 (5) Recurrence or continuation of the condition that required the operation.
 (6) Injury to major blood vessels. PT INITIALS

(D) **Peripheral nerve operation;** nerve decompression, transposition or tumor removal; neuroorrhaphy, neurectomy or neurolysis.
 (1) Numbness.
 (2) Impaired muscle function.
 (3) Recurrence or persistence of the condition that required the operation.
 (4) Continued, increased or different pain. PT INITIALS

(E) **Correction of cranial deformity.**
 (1) Loss of brain function.
 (2) Seizures.
 (3) Recurrence or continuation of the condition that required the operation. PT INITIALS

(F) **Transsphenoidal hypophysectomy** or other pituitary gland.
 (1) Spinal fluid leak.
 (2) Necessity for hormone replacement.
 (3) Recurrence or continuation of the condition that required the operation.
 (4) Nasal septal deformity or perforation. PT INITIALS

(G) **Cerebral spinal fluid** shunting procedure or revision.
 (1) Shunt obstruction or infection.
 (2) Seizure disorder.
 (3) Recurrence or continuation of brain dysfunction. PT INITIALS

13. RADIOLOGY

(A) **Angiography, aortography, arteriography** (arterial injection of contrast media-diagnostic).
 (1) Injury to artery.
 (2) Damage to parts of the body supplied by the artery with resulting loss of function or amputation.
 (3) Swelling, pain, tenderness or bleeding at the site of the blood vessel perforation.
 (4) Aggravation of the condition that necessitated the procedure.
 (5) Allergic sensitivity reaction to injected contrast media. PT INITIALS

(B) **Myelography.**
 (1) Chronic pain.
 (2) Transient headache, nausea, vomiting.
 (3) Numbness.
 (4) Impaired muscle function. PT INITIALS

(C) **Angiography with occlusion techniques-therapeutic.**
 (1) Injury to artery.
 (2) Loss or injury to body parts.
 (3) Swelling, pain tenderness or bleeding at the site of the blood vessel perforation.
 (4) Aggravation of the condition that necessitated the procedure.
 (5) Allergic sensitivity reaction to injected contrast media. PT INITIALS

(D) **Angioplasty** (intravascular dilatation technique).
 (1) Swelling, pain, tenderness or bleeding at the site of vessel puncture.
 (2) Damage to parts of the body supplied by the artery with resulting loss of function or amputation.
 (3) Injury to the vessel that may require immediate surgical intervention.
 (4) Recurrence or continuation of the original condition.
 (5) Allergic sensitivity reaction to injected contrast media. PT INITIALS

(E) **Splenoportography** (needle injection of contrast media into the spleen).
 (1) Injury to the spleen requiring blood transfusion and/or removal of the spleen. PT INITIALS

14. RESPIRATORY SYSTEM TREATMENTS AND PROCEDURES.

(A) **Excision of lesion of larynx,** vocal cords, trachea. (No risk or hazards assigned at this time.) PT INITIALS

(B) **Rhinoplasty or nasal reconstruction** with or without septoplasty.
 (1) Deformity of skin, bone or cartilage.
 (2) Creation of new problems, such as septal perforation or breathing difficulty. PT INITIALS

(C) **Submucous resection of nasal septum** or nasal septoplasty.
 (1) Persistence, recurrence or worsening of the obstruction.
 (2) Perforation of nasal septum with dryness and crusting.
 (3) External deformity of the nose. PT INITIALS



15. URINARY SYSTEM.

<input type="checkbox"/> (A) Partial nephrectomy (removal of part of the kidney). (1) Incomplete removal of stone(s) or tumor, if present. (2) Obstruction of urinary flow. (3) Leakage of urine at surgical site. (4) Injury to or loss of the kidney. (5) Damage to adjacent organs.	PT INITIALS
<input type="checkbox"/> (B) Radical nephrectomy (removal of kidney and adrenal gland for cancer). (1) Loss of the adrenal gland. (2) Incomplete removal of tumor. (3) Damage to adjacent organs.	PT INITIALS
<input type="checkbox"/> (C) Nephrectomy (removal of kidney). (1) Incomplete removal of tumor, if present. (2) Damage to adjacent organs. (3) Injury to or loss of the kidney.	PT INITIALS
<input type="checkbox"/> (D) Nephrolithotomy and pyelolithotomy (removal of kidney stone(s)). (1) Incomplete removal of stone(s). (2) Obstruction of urinary flow. (3) Leakage of urine at surgical site. (4) Injury to or loss of the kidney. (5) Damage to adjacent organs.	PT INITIALS
<input type="checkbox"/> (E) Pyeloureteroplasty (pyeloplasty or reconstruction of the kidney drainage system). (1) Obstruction of urinary flow. (2) Leakage of urine at surgical site. (3) Injury to or loss of the kidney. (4) Damage to adjacent organs.	PT INITIALS
<input type="checkbox"/> (F) Exploration of kidney or perinephric mass. (1) Incomplete removal of stone(s) or tumor, if present. (2) Leakage of urine at surgical site. (3) Injury to or loss of the kidney. (4) Damage to adjacent organs.	PT INITIALS
<input type="checkbox"/> (G) Ureteroplasty [reconstruction of ureter (tube between kidney and bladder)]. (1) Leakage of urine at surgical site. (2) Incomplete removal of the stone or tumor (when applicable). (3) Obstruction of urine flow. (4) Damage to other adjacent organs. (5) Damage to or loss of the ureter.	PT INITIALS
<input type="checkbox"/> (H) Ureterolithotomy [surgical removal of stone(s) from ureter (tube between kidney and bladder)]. (1) Leakage of urine at surgical site. (2) Incomplete removal of stones. (3) Obstruction of urine flow. (4) Damage to other adjacent organs. (5) Damage to or loss of ureter.	PT INITIALS
<input type="checkbox"/> (I) Ureterectomy [partial/complete removal of ureter (tube between kidney and bladder)]. (1) Leakage of urine at surgical site. (2) Incomplete removal of tumor (when applicable). (3) Obstruction of urine flow. (4) Damage to other adjacent organs.	PT INITIALS
<input type="checkbox"/> (J) Ureterolysis [partial/complete removal of ureter (tube between kidney and bladder from adjacent tissue)]. (1) Leakage of urine at surgical site. (2) Obstruction to urine flow. (3) Damage to other adjacent organs. (4) Damage to or loss of ureter.	PT INITIALS

<input type="checkbox"/> (K) Ureteral reimplantation [reinserting ureter (tube between kidney and bladder) into the bladder]. (1) Leakage of urine at surgical site. (2) Obstruction to urine flow. (3) Damage to or loss of ureter. (4) Backward flow of urine from bladder into ureter. (5) Damage to other adjacent organs.	PT INITIALS
<input type="checkbox"/> (L) Prostatectomy (partial or total removal of prostate). (1) Leakage of urine at surgical site. (2) Obstruction to urine flow. (3) Incontinence (difficulty with urinary control). (4) Semen passing backward into bladder. (5) Difficulty with penile erection (possible with partial and probable with total prostatectomy).	PT INITIALS
<input type="checkbox"/> (M) Total cystectomy (removal of urinary bladder). (1) Probable loss of penile erection and ejaculation in the male. (2) Damage to other adjacent organs. (3) This procedure will require an alternate method of urinary drainage.	PT INITIALS
<input type="checkbox"/> (N) Partial cystectomy (partial removal of urinary bladder). (1) Leakage of urine at surgical site. (2) Incontinence (difficulty with urinary control). (3) Backward flow of urine from bladder into ureter (tube between kidney and bladder). (4) Obstruction of urine flow. (5) Damage to other adjacent organs.	PT INITIALS
<input type="checkbox"/> (O) Urinary diversion (ileal conduit, colon conduit). (1) Blood chemistry abnormalities requiring medication. (2) Development of stones, strictures or infection. (3) Routine, lifelong medical evaluation. (4) Leakage of urine at surgical site. (5) Requires wearing a bag for urine collection.	PT INITIALS
<input type="checkbox"/> (P) Ureterosigmoidostomy (placement of kidney drainage tubes into the large bowel). (1) Blood chemistry abnormalities requiring medication. (2) Development of stones, strictures or infections. (3) Routine, lifelong medical evaluation. (4) Leakage of urine at surgical site. (5) Difficulty holding urine in the rectum.	PT INITIALS
<input type="checkbox"/> (Q) Urethroplasty (construction/reconstruction of drainage tube from bladder). (1) Leakage of urine at surgical site. (2) Stricture formation. (3) Additional operation(s).	PT INITIALS

Other: