

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division**

JANE DOE, et al.,

Civil No. 4:23-cv-00114-RH-MAF

Plaintiffs,

v.

JOSEPH A. LADAPO, et al.,

Defendants.

_____ /

**PLAINTIFFS' REPLY TO DEFENDANTS'
RESPONSE TO PLAINTIFFS' SECOND MOTION
FOR PRELIMINARY INJUNCTION**

Plaintiffs reply to Defendants' Response in Opposition to Motion for Preliminary Injunction ("Response"), and state as follows:

A. Like the Minor Treatment Ban, SB 254 Restrictions on Adult Care Target Transgender People and thus Require Heightened Scrutiny.

Defendants offer no valid reasons for applying a different standard for assessing the constitutionality of the adult restrictions than the one already applied to the transgender adolescent ban.

SB 254 prevents "patients younger than 18 years of age" from obtaining "[s]ex-reassignment prescriptions and procedures," Fla. Stat. § 456.52(1), also known as "transition-related care" or "gender transition." In its June 6, 2023 preliminary injunction order, this Court applied heightened scrutiny to that

prohibition for at least two reasons. ECF 90 (PI Order) at 42-44. First, in order to know whether a minor may receive care, “one must know the adolescent’s sex.” *Id.* at 19. “This is a line drawn on the basis of sex, plain and simple.” *Id.* at 20. Second, “the statute and rules at issue draw lines based on transgender status.” *Id.* SB 254 prohibits the banned treatments only when needed by transgender minors, not others.

For the same reasons, the provisions of SB 254 that apply to adults also discriminate based on sex and transgender status. The same language is used to describe the treatments in the provisions of SB 254 that pertain to adults as those that pertain to minors: “sex-reassignment prescriptions or procedures.” Fla. Stat. § 456.52(2). And both provisions regulate those “prescriptions and procedures” *only* when used “to affirm a person’s perception of his or her sex if that perception is inconsistent with the person’s sex,”—in other words only when the patient is transgender. Fla. Stat. § 456.001(9)(a). So, just as with the minor treatment ban, one must know the “sex of a person to know whether or how” SB 254 and its implementing rules apply to adults. ECF 90 at 19. And, the law and rules facially target transgender adults just as SB 254 targets transgender minors.

Defendants raise no new arguments here. They argue against heightened scrutiny, as before, because both transgender men and transgender women are targeted. The only new support they offer for this argument are citations to the Sixth Circuit’s divided opinion granting an emergency stay of a district court’s order

enjoining Tennessee’s minor treatment ban. *L.W. v. Skrmetti*, 73 F.4th 408 (6th Cir. 2023). That opinion is not controlling here, and the Sixth Circuit panel itself acknowledged that “[i]t may be that the one week we have had to resolve this motion does not suffice to see our own mistakes.” *Id.* at 422. There is no reason for this Court to reverse itself based on that panel’s thin, hasty, and divided assessment.

Neither do Defendants’ efforts to cabin *Glenn* and *Bostock*’s analysis to the employment context fare any better here than they did in this Court’s consideration of SB 254’s transgender adolescent ban. *See* ECF. 90 at 19-20.

The Defendants repackage another failed argument, contending that the informed consent forms do not discriminate based on transgender status. But as this Court already held, “[a]lthough the defendants deny it, the statute and rules at issue draw lines based on transgender status.” *Id.* at 20. The mandatory consent forms, which must be executed in-person, in the presence of a physician, are requirements which apply *only* to care when provided to transgender patients and not others. This facial discrimination triggers heightened scrutiny. *Id.* at 19-25; *Glenn v. Brumby*, 663 F.3d 1312, 1315-16 (11th Cir. 2011).

Defendants also again argue that regulating medical treatments for transgender adults is not discrimination because transgender people are dissimilar to others seeking these treatments. ECF 127 at 12-13 (State’s Am. Resp. Opp. Plfs.’ PI Mot.) (“[A] person experiencing gender dysphoria is self-evidently *not* similarly

situated to any other patient.”) As this Court explained before, these differences do “not change the fact that this is differential treatment based on sex. The *reason* for sex-based differential treatment is the purported *justification* . . . the justification that must survive” heightened review. ECF 90 at 20. It is not a *reason* to avoid heightened review.

Griffin Indus. v. Irvin, 496 F.3d 1189 (11th Cir. 2007), is inapposite. Unlike here, *Griffin* was the “unusual civil rights case” alleging a class of one, *id.* at 1193, where “in the absence of class-based discrimination,” *id.* at 1202, the court was forced to independently assess whether a chicken rendering plant was similarly situated to others. *Id.* at 1200-08. Here, where SB 254 draws both a sex-based and a transgender-based classification, Defendants’ reasons for drawing this line become relevant only at stage two of this Court’s analysis *applying* heightened review, not determining whether heightened scrutiny applies.

Defendants also contend that *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022), means that heightened scrutiny does not apply because the consent forms regulate the provision of medical treatment. But *Dobbs* involved a law the Supreme Court viewed as facially neutral. *Id.* at 2246. In stark contrast, SB 254 facially classifies based on sex, and *Dobbs* does not reduce the level of scrutiny applied to sex discriminatory law or policy merely because they involve the regulation of healthcare.

B. SB 254 and the Mandatory Forms Restrict Care.

Defendants’ argument that SB 254’s adult restrictions and mandatory forms “merely provide guidelines,” rather than restrictions, is specious. ECF 127 at 15. The forms themselves identify “specific *requirements* that need to be met before and during treatment.” *Id.* at Exs. A, B, and C (emphasis added). This is apparent both in the “question and answer” portion (“What are the *requirements* to receive hormone replacement therapy (HRT)?”) and in the provisions that set forth “specific *requirements* for you to receive and continue HRT treatment[.]” 49 Fla. Admin. Reg. 2433, 2435 (July 7, 2023) (emphasis added).

Though Defendants suggest there are other supposedly “similar” forms, they cite none. Defendants cite to Florida laws that require informed consent for specific procedures – breast cancer treatments, electroconvulsive and psychosurgical treatments, and psychiatric treatments for incarcerated people. ECF 127 at 1.¹ None of these laws require or resulted in mandatory consent forms adopted by the Boards of Medicine. To the extent Plaintiffs could find any forms relating to those treatments, none state requirements for care or continuing care (Florida Breast and Cervical Cancer Detection Program applicant agreement attached as **Exhibit A**; Florida Authorization for Electroconvulsive Treatment for Resident of a State Mental Health Facility attached as **Exhibit B**). And neither of the only two consent

¹ Citations to ECF 127 correspond to page numbers in Defendants’ Memorandum, not Motion.

forms Plaintiffs could find in the Boards of Medicine rules include any requirements for care. Fla. Admin. Code R. 64B8-9.017 (providing for a mandatory informed consent form for the prescription of medical marijuana; form attached as **Exhibit C**); Fla. Admin. Code R. 64B8-9.018 (setting out a recommended consent form for cataract procedures; form attached as **Exhibit D**). In sum, unlike any other healthcare-related forms in Florida law, the challenged forms impose arbitrary and burdensome restrictions that have no medical basis and conflict with the medical standard of care. They stand in stark contrast to other examples Defendants cite and do not bear a shred of resemblance to any other Florida medical consent forms.

C. Defendants Cannot Justify an In-Person Requirement Only for Transgender Patients Initiating Care.

Contrary to Defendants' unsupported claim, there is no medical justification for SB 254's arbitrary "in-person" requirement, which applies only to transgender patients. This requirement has no medical basis and conflicts with the WPATH Standards of Care, Version 8 ("SOC 8"), which expressly authorize telehealth visits. *Dekker v. Weida*, Case No. 4:22cv325 (N.D. Fla.) ("*Dekker*"), Def's Trial Ex. 16, SOC 8, at S31 ("Assessments may be in person or through telehealth."). As the SOC 8 notes, telehealth services "reduce barriers and improve access." *Id.* at S8. This is especially critical for patients who do not live near a provider or who lack means to travel, as the United States Department of Health and Human Services has also confirmed. *See* HHS, Telehealth for LGBTQ+ Patients ("Telehealth appointments

are a safe, convenient way for LGBTQ+ patients to access healthcare” and “can also be a necessary lifeline for some patients who do not have LGBTQ+ affirming healthcare available nearby.”) (available at Telehealth.HHS.gov).

Defendants cite Dr. Stephen Levine’s testimony in an attempt to justify the in-person requirement, contending that it is necessary to provide an adequate assessment, but nothing in his testimony explains why assessments for gender dysphoria cannot be done through telehealth, which allows for more flexibility in scheduling, provider availability, and maximization of time with patients. As the WPATH SOC 8 note, what matters is not the method of care delivery, but adherence to “the principles of gender-affirming care as outlined in the SOC-8[.]” SOC 8 at S8. And if there were any doubt about the State’s inability to justify the requirement, the text of SB 254 removes it. SB 254 requires only that the mandatory *consents* be executed while the patient is “physically present in the same room” as the physician, not any *assessment*. Fla. Stat. § 456.52(2).

D. Defendants Cannot Justify Prohibiting APRN-NPs From Providing Care Only for Transgender Patients.

Defendants similarly cannot justify arbitrarily barring qualified Advanced Practice Registered Nurse – Nurse Practitioners (“APRN-NPs”) from caring for transgender patients. Defendants argue that testosterone may be abused (ECF 127 at 21-22), but SB 254 leaves non-physicians free to prescribe testosterone to non-transgender persons, a far larger group. Similarly, Defendants argue that doctors are

“better trained,” (*id.* at 25) but that explanation would apply equally to all forms of healthcare; it does not justify a restriction *solely* on transgender healthcare.

Nor does any such justification exist. As the WPATH SOC 8 explains, qualified non-physician healthcare providers are as competent as physicians to care for transgender patients. WPATH SOC, at S33 (“HCPs [healthcare providers] should have at a minimum a masters-level qualification in a clinical field related to transgender health or equivalent further clinical training and be statutorily regulated; examples include a mental health professional (MHP), general medical practitioner, nurse, or other qualified HCP.”); *see also, e.g., id.* at S34 (“The need to include an HCP with some expertise in mental health does not require the inclusion of a psychologist, psychiatrist, or social worker in each assessment. Instead, a general medical practitioner, nurse, or other qualified HCP could also fulfill this requirement[.]”); *id.* at S143 (primary care providers may include nurse practitioners and advanced practice nurses).

Defendants cite Dr. Levine’s testimony that an unnamed nurse practitioner allegedly prescribed hormone therapy without a proper assessment. ECF 127 at 25 (*citing Dekker*, Trial Tr. at 1009:19-22)). That unsupported allegation, without more, cannot justify a *sui generis* exception to Florida’s autonomous practice law, Fla. Stat. § 464.0123, only for transgender people. Dr. Levine himself acknowledged that he has no personal knowledge of how transgender healthcare is provided in Florida.

Dekker, Trial Tr. at 1011:5-8. As with the in-person requirement, the only impact of this selective restriction is to reduce care for transgender patients.

E. The Information in the Consent Forms is Misleading and, in Many Cases, Wrong.

Little else Defendants argue necessitates response, given the fulsome record before this Court. But Plaintiffs would be remiss in not flagging some of Defendants' unsupported assertions.

This Court has already found that evidence suggesting the regulated medical treatments “are ineffective is nonexistent.” ECF 90 at 28. Accordingly, Defendants cannot defend the form’s assertions that the regulated treatments are “purely speculative” or “based on very limited, poor-quality research.” ECF 127, Ex. A. This Court has dismissed those arguments. ECF 90 at 27-30. Defendants contend that the research is “low-quality,” but as the record makes clear, that is a term of art that does not mean that research showing the effectiveness of these treatments is lacking. *Dekker*, Trial Tr. 359:12-18 (Dr. Antommara). And, in any case, the forms do not speak of “low quality” evidence, they refer to “poor-quality research,” a statement with no evidentiary support. ECF 127, Ex. A.

This Court has also already rejected Defendants’ argument that off-label use means these medications do “not have U.S. Food and Drug Administration (FDA) approval.” Form DH5079-MQA at 1; Form DH5080-MQA at 1; Form DH5082-MQA at 1; Form DH5083-MQA at 1. *See also* 49 Fla. Admin. Reg. 2433, 2435 (July

7, 2023). “That the FDA approved these drugs at all confirms that, at least for one use, they are safe and effective.” ECF 90 at 38; *see also Dekker* Trial Tr. 1016:5-1018:7.

Defendants continue to rely on Drs. Hruz, Laidlaw, and Lappert to defend false statements in the forms, but this Court has already determined that their testimony is not credible. Dr. Lappert believes gender transition care is a “lie,” “a moral violation,” “a huge evil,” and “diabolical” (ECF 90, at 5); Dr. Hruz testified as a “deeply biased advocate, not as an expert” (*id.* at 5, n.8); and Dr. Laidlaw, who ended up not even testifying in the *Dekker* case at the merits phase, is a “person that’s that far off from the accepted view, even by the State[.]” *Dekker*, ECF 62 (Trial Tr. at 88:6-19).

In sum, Defendants cannot justify the many misstatements and inaccuracies in the forms. These include the forms’ statements: calling into question the efficacy of transition-related treatments; saying that there is no evidentiary support for the dosing requirements set by the Endocrine Society; and saying that psychotherapy alone is an effective treatment option – none of which are supported by any credible evidence.

F. This is Not an Informed Consent Form Like Any Other.

Defendants wrongly claim that the consent forms are like any others. For one, no other Florida mandatory consent form includes substantive requirements for

initiating care or for continued care. Second, Defendants can provide no explanation for why *only* transgender patients must be advised of side effects resulting from medications or procedures much more commonly used by non-transgender patients, and that pose the same risks to all.

Relatedly, Defendants argue that because gender dysphoria is a mental health diagnosis, ECF 127 at 24, the State can justify ongoing and recurring mental health assessments (“[b]efore beginning HRT and every two years thereafter[,]” *id.*, Ex. A) as requisites for continued care. But these ongoing mental health assessments have no medical basis and conflict with the standard of care. ECF 115-5 (Declaration of Dr. Karasic) at ¶¶ 37-38. And, despite the fact that there are myriad other mental health diagnoses, Defendants offer no explanation for why only transgender people with a mental health diagnosis must comply with these requirements.

G. The Challenged Restrictions Fail Under Any Standard of Review.

Defendants have not identified any legitimate reason to single out transgender people for these arbitrary restrictions which serve only to keep patients from getting needed care and undermine, rather than advance, patient safety and education.

Even under rational basis review, a law “must find some footing in the realities of the subject addressed by the legislation.” *Heller v. Doe*, 509 U.S. 312, 320 (1993). No such footing is evident here, much less the evidence required under heightened scrutiny.

H. Plaintiffs Are Experiencing Irreparable Harm Because of SB 254.

The adult Plaintiffs have experienced irreparable harms that will be alleviated by this Court's injunction against enforcement of SB 254 and its implementing rules.

Plaintiffs Dr. Kai Pope and Rebecca Cruz Evia had surgeries cancelled, which they were informed by their surgeons was because of SB 254. No other reasons were given for the cancellation of their surgeries and Defendants offer no evidence to suggest that if the law is enjoined their surgeries would not be rescheduled. Defendants also offer no evidence to question the urgency of Dr. Pope's or Ms. Cruz's medical needs. The fact that Dr. Pope was diagnosed "years ago[,]" ECF 127 at 26, with gender dysphoria and only scheduled his now-cancelled surgery in the last year is a reflection of what this Court has heard – a determination of medical need for treatments is individualized and based on careful assessments that take into account a patient's response to staged and ongoing care. The date of a patient's gender dysphoria diagnosis has no bearing on the time-sensitivity of their need for surgery.

Similarly, Defendants offer no evidence to rebut the harms asserted by Lucien Hamel and Olivia Noel. Mr. Hamel has been without testosterone for nearly a month and a half, missing four doses of his medication. His role as a CVS manager does not help him get medication otherwise legally barred for him. If this Court enjoins SB 254, his APRN-NP at Spektrum Health will write him a prescription. If it does

not, his provider cannot without “commit[ting] a misdemeanor of the first degree, punishable as provided” by statute. Fla Stat. §456.52(5)(c). Similarly, Defendants do not dispute that Ms. Noel cannot continue receiving treatment from the physician’s assistant (“PA”) from whom she had been receiving care. And although she has a refill, she is unable to get it filled because it was written by her PA before the effective date of SB 254.

Both Mr. Hamel and Ms. Noel will continue going without care for gender dysphoria unless and until they can establish care with a physician, obtain and attend an in-person appointment with that physician, and meet the requirements for care listed in the mandatory consent forms including getting a new “thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist,” despite no medical justification for such a requirement. Mr. Hamel and Ms. Noel have alleged, and Defendants do not dispute, that for financial and other reasons, they are unable to meet those requirements.

In the meantime, every day Mr. Lucien is without needed hormone therapy, he continues to suffer irreparable harm. And although Ms. Noel has not yet run out of the hormones she regularly takes, she will soon. Both have had ongoing care relationships disrupted and are suffering.

An injunction issued by this Court would remedy these harms.

Respectfully submitted this 11th day of August, 2023.

/s/ Jennifer Levi
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CERTIFICATE OF WORD COUNT

Pursuant to Local Rule 7.1(F), the undersigned counsel certifies that, according to Microsoft Word, the word-processing system used to prepare this Reply, there are 3,013 total words contained within the Reply.

/s/ Simone Chriss

**CERTIFICATE OF SATISFATION OF
ATTORNEY CONFERENCE REQUIREMENT**

Pursuant to Local Rule 7.1(B), counsel for the Plaintiffs conferred with counsel for the Defendants on August 9, 2023. Counsel for Defendants indicated that Defendants do not oppose the filing of this Reply.

/s/ Simone Chriss

CERTIFICATE OF SERVICE

I hereby certify that, on August 11, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system.

/s/ Simone Chriss
Counsel for Plaintiffs

EXHIBIT A



Florida Breast and Cervical Cancer Early Detection Program

Annual Applicant Agreement

The Annual Applicant Agreement (AAA) is used to obtain authorization and information from eligible women enrolled in the Florida Breast and Cervical Cancer Early Detection Program (FBCCEDP). The FBCCEDP will collect participant Protected Health Information (PHI) and Personally Identifiable Information (PII) that is required to provide patient services.

Please read each statement below and agree by signing at the bottom of the document.

As an FBCCEDP applicant, I declare that:

1. I am a Florida resident and I want to become a client of the FBCCEDP, and I may withdraw at any time.
2. My net family annual income is at or below 200% of the Federal Poverty Level (FPL) and I have no health insurance that pays for breast and cervical cancer screening exams.
3. I will no longer be eligible for FBCCEDP if my income changes to above 200% of the FPL.
4. I will call FBCCEDP Once I obtain health insurance and give them the name of the health insurance company, policy number and effective date. If my health insurance covers breast and cervical cancer screenings my screenings will no longer be paid for by FBCCEDP.
5. I will disclose any breast or cervical screening services that may impact my eligibility of enrollment in FBCCEDP.
6. I may have a share of cost for some services.
7. I will use an authorized provider for my breast and/or cervical screening examinations (breast exam, mammogram, and/or Pap test).
8. **I agree to complete any follow-up tests within 60 days. If I fail to meet these guidelines, I may be responsible for partial or full cost of all services.**
9. I will allow an exchange and release of my medical information between my health care providers, the FBCCEDP, the Florida Department of Health's Cancer Data Registry, the Centers for Disease Control and Prevention, and others related to my health care. This information could include medical history, examination and procedure results, even if they were not paid by FBCCEDP.
10. I agree to receive home phone, cellphone, email or postal mail contact from FBCCEDP and the Department of Children and Families (DCF) Medicaid Program about my health care.
11. I understand that the FBCCEDP is a breast and cervical cancer **screening** program, not a cancer treatment program.
12. If I am diagnosed with breast or cervical cancer as a result of FBCCEDP screening, I will be referred to DCF Medicaid Program which will determine if I am eligible for Medicaid benefits to cover treatment cost. I can reapply to FBCCEDP for screenings once treatment is completed.
13. This agreement is for **one** year unless my program eligibility changes. If my eligibility status changes or this agreement expires, I may be responsible for services provided during my FBCCEDP ineligible period.
14. **As authorized by federal law, Title 5 U.S. Code section 552a, collection of social security numbers by the Florida Department of Health for the FBCCEDP may be necessary in order to apply for and receive Medicaid benefits.**

If you have any questions, contact your Regional Coordinator at the local Regional FBCCEDP office:

Local Regional FBCCEDP: PASCO Phone #: (727) 619-0369

Client Signature

Date

Printed Name

Date of Birth

Client Email Address: _____



Florida Breast and Cervical Cancer Early Detection Program (FBCCEDP)

FINANCIAL ELIGIBILITY

Client Name: _____ **Date of Birth:** _____ **ID#** _____

1. Do you have Medicaid? YES NO **OR** Do you have Medicare? YES NO
2. Do you have any form of health insurance? YES NO Name of insurance _____
3. **Number of people in your Household.** _____ (include yourself, spouse or civil union partner, and dependent children)
4. **Net Household Income (After Taxes):** \$ _____ Month **OR** \$ _____ Year

Family Size	2023 DOH Scale Monthly Income	2023 DOH Scale Yearly Income
1	\$2,429.91	\$29,159.00
2	\$3,286.58	\$39,439.00
3	\$4,143.25	\$49,719.00
4	\$4,999.91	\$59,999.00
5	\$5,856.58	\$70,279.00
6	\$6,713.25	\$80,559.00
7	\$7,569.91	\$90,839.00
8	\$8,426.58	\$101,119.00
9	\$9,283.25	\$111,399.00
10	\$10,139.91	\$121,679.00

I certify that the above information is correct to the best of my knowledge and belief. I give my consent to the Department of Health to make inquiry and verify the information. I understand that I may be prosecuted under state law, if I have deliberately supplied the wrong information.

NOTE:

If I obtain health insurance coverage, while under the FBCCEDP, it is my responsibility to notify the REGIONAL FBCCEDP office as soon as possible.

Signature _____

Date _____

If you have any questions, please call the regional coordinator at _____ 727-619-0369 _____ between 8:00 a.m. and 5:00 p.m., Monday through Friday. We will make every effort to return your call in a timely manner.

I further understand that all my screening and diagnostic procedures must be completed within 60 days or payment for these services CANNOT be guaranteed.

EXHIBIT B

Electroconvulsive Therapy (ECT) Information Sheet

Electroconvulsive Therapy, more commonly known as “ECT,” is an extremely safe and effective medical treatment for certain psychiatric disorders. With this treatment, a small amount of electricity is applied to the scalp and this produces a seizure in the brain. The procedure is painless because the patient is asleep and under general anesthesia. The effectiveness of ECT in treating severe mental illnesses is recognized by the American Psychiatric Association, the American Medical Association, and the National Institute of Mental Health.

Indications for Use and Effectiveness

In the United States, about 100,000 individuals are estimated to receive ECT each year. ECT is generally used when patients have severe depressive illness, mania, some forms of schizophrenia, or a few other mental and neurological disorders. Frequently, ECT is given when patients have not responded to other treatments such as medications, when other treatments appear to be less safe or difficult for the patient to tolerate, or when patients have responded well to ECT in the past.

Not all patients improve when treated with medications or psychotherapy. For some patients, the risks of medications are greater than the risks for ECT. When patients have life-threatening psychiatric problems, such as suicidal tendencies, ECT is often recommended because it usually provides faster relief than medications. Overall, about 70 to 90 percent of depressed patients treated with ECT show substantial improvement. This makes ECT the most effective of the antidepressant treatments.

ECT is very effective in providing relief from psychiatric symptoms but permanent cures from mental illness are rare, regardless of the treatment given. To prevent relapse following ECT, most patients require further treatment with medication or with ECT. If ECT is used to protect against relapse, it is usually administered on a weekly or monthly basis.

Administration of ECT

ECT is administered by a treatment team of highly skilled health professionals including a psychiatrist, an anesthesiologist, and nurses. The physicians responsible for administering ECT are experienced specialists.

Before ECT is administered, the patient’s medical condition is carefully assessed. This included a complete medical history, a physical examination, and medical tests, as needed.

When the patient goes to the ECT treatment room, an intravenous line is started. Sensors for recording brain activity, electroencephalogram (EEG), are placed on the head. Other sensors are placed on the chest for monitoring the heart, electrocardiogram (EKG). A cuff is wrapped around the arm for monitoring the patient’s blood pressure. When everything is connected, an anesthetic medication is injected through the intravenous line that will cause the patient to sleep for 5 to 10 minutes. Once the patient falls asleep, a muscle relaxant is injected. This prevents movement so that during the seizure there are only minimal contractions of the muscles.

When the patient is completely asleep and their muscles are well relaxed, the treatment is given. A brief electrical charge is applied to the electrodes on the scalp. This stimulates the brain and produces the seizure that lasts for about a minute. Throughout the procedure, the patient receives oxygen through a mask. This continues until the patient no longer needs assistance breathing. When the treatment is completed, the patient is taken to a recovery area for monitoring by trained staff. Usually within 30 to 60 minutes, the patient can leave the recovery area. A course of treatment with ECT usually consists of six to twelve treatments. One treatment is given three times a week for a month or less.

Risks

Any medical procedure entails a certain amount of risk. However ECT is no more dangerous than minor surgery under general anesthesia, and may at times be less dangerous than treatment with antidepressant medications. This is in spite of its frequent use with the elderly and those with coexisting medical illnesses. A small number of other medical disorders increase the risk associated with ECT, and patients are carefully screened for these conditions before a psychiatrist will recommend a patient for ECT treatment.

Side Effects

After the treatment, the patient will experience some confusion on awakening. This is partly due to the anesthesia and partly due to the treatment. The confusion typically clears within the hour. Some patients have a headache which is usually relieved by Tylenol or aspirin. Other side effects like nausea, muscle ache, or soreness can last for a few hours but are relatively uncommon.

The side effect that has received the most attention is memory loss. ECT can result in two types of memory loss. The first involves rapid forgetting of new information such as conversations or things the patient has recently read. This type of memory loss is short-lived and usually does not last but a few weeks following ECT treatment. The second type of memory loss concerns events from the past. Some patients have memory gaps in the weeks or months and, less commonly, years prior to the treatment course. The amount and duration of memory problems vary among patients and more extensive memory loss is reported in a minority of patients. The extent of memory loss may vary with the type of ECT that is used and appears to be less of a concern with unilateral ECT (where one side of the head is stimulated electrically) than with bilateral ECT.

Many psychiatric illnesses result in impairments of attention and concentration. Consequently, when the psychiatric disturbance improves following ECT, there is often a improvement in these aspects of thinking. Shortly following ECT, most patients show improved scores on tests of intelligence, attention, and learning.

Myths About Brain Damage

Researchers have found no evidence that ECT damages the brain. There are medical conditions such as epilepsy that cause spontaneous seizures which, unless prolonged or otherwise complicated, do not harm the brain. ECT artificially stimulates a seizure; but ECT induced seizures occur under much more controlled conditions than those that are “naturally occurring” and are safe. A recent study by Coffey and colleagues found no changes in brain anatomy with ECT, as measured by very sensitive scans of the brain using magnetic resonance imaging (MRI) equipment. Other research has established that the amount of electricity which actually enters the brain (only a small fraction of what is applied to the scalp) is much lower in intensity and shorter in duration than that which would be necessary to damage brain tissue.

Patient Rights

Before a psychiatrist can administer ECT, he or she must first obtain written consent from the patient or, if the patient is too ill to make an informed decision for him or herself, from a court appointed representative who has been given the authority to make mental health decisions for the patient.

Under the APA’s recommended “informed consent” protocol, permission to administer ECT comes after a careful review of the treatment. The psychiatrist explains in clear language what ECT involves, what other treatments might be available, and the benefits and risks these procedures may entail. The patient or legal representative is informed of when, where, and by whom the treatment will be administered and the number of treatments expected. Questions are encouraged. The person consenting to the procedure is kept informed of progress as the treatment continues, and may withdraw consent at any time.

EXHIBIT C

Medical Marijuana Consent Form

A qualified physician may not delegate the responsibility of obtaining written informed consent to another person. The qualified patient, or the patient's parent or legal guardian if the patient is a minor, must initial each section of this consent form to indicate that the physician explained the information and, along with the qualified physician, must sign and date the informed consent form.

This consent form contains three parts. Part A must be completed by all patients. Part B is only required for patients under the age of 18 with a diagnosed terminal condition who receive a certification for medical marijuana in a smokable form. Part C is the signature block and must be completed by all patients.

Part A: Must be completed for all medical marijuana patients

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

- _____ The federal government has classified marijuana as a Schedule I controlled substance. Schedule I substances are defined, in part, as having (1) a high potential for abuse; (2) no currently accepted medical use in treatment in the United States; and (3) a lack of accepted safety for use under medical supervision. Federal law prohibits the manufacture, distribution and possession of marijuana even in states, such as Florida, which have modified their state laws to treat marijuana as a medicine.
- _____ When in the possession of medical marijuana, the patient or the patient's caregiver must have his or her medical marijuana use registry identification card in his or her possession at all times.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

- _____ Marijuana has not been approved by the Food and Drug Administration for marketing as a drug. Therefore, the "manufacture" of marijuana for medical use is not subject to any federal standards, quality control, or other federal oversight. Marijuana may contain unknown quantities of active ingredients, which may vary in potency, impurities, contaminants, and substances in addition to THC, which is the primary psychoactive chemical component of marijuana.

c. The potential for addiction.

- _____ Some studies suggest that the use of marijuana by individuals may lead to a tolerance to, dependence on, or addiction to marijuana. I understand that if I require increasingly higher doses to achieve the same benefit or if I think that I may be developing a dependency on marijuana, I should contact Dr. _____ (name of qualified physician).

d. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

- _____ The use of marijuana can affect coordination, motor skills and cognition, i.e., the ability to think, judge and reason. Driving under the influence of cannabis can double the risk of vehicular accident, which escalates if alcohol is also influencing the driver. While using medical marijuana, I should not drive, operate heavy machinery or engage in any activities that require me to be alert and/or respond quickly and I should not participate in activities that may be dangerous to myself or others. I

e. The potential side effects of medical marijuana use.

_____ Potential side effects from the use of marijuana include, but are not limited to, the following: dizziness, anxiety, confusion, sedation, low blood pressure, impairment of short term memory, euphoria, difficulty in completing complex tasks, suppression of the body's immune system, may affect the production of sex hormones that lead to adverse effects, inability to concentrate, impaired motor skills, paranoia, psychotic symptoms, general apathy, depression and/or restlessness. Marijuana may exacerbate schizophrenia in persons predisposed to that disorder. In addition, the use of medical marijuana may cause me to talk or eat in excess, alter my perception of time and space and impair my judgment. Many medical authorities claim that use of medical marijuana, especially by persons younger than 25, can result in long-term problems with attention, memory, learning, drug abuse, and schizophrenia.

There is substantial evidence of a statistical association between long-term cannabis smoking and worsening respiratory symptoms and more frequent chronic bronchitis episodes. Smoking marijuana is associated with large airway inflammation, increased airway resistance, and lung hyperinflation. Smoking cannabis, much like smoking tobacco, can introduce levels of volatile chemicals and tar in the lungs that may raise concerns about the risk of cancer and lung disease.

_____ I understand that using marijuana while consuming alcohol is not recommended. Additional side effects may become present when using both alcohol and marijuana.

_____ I agree to contact Dr. _____ if I experience any of the side effects listed above, or if I become depressed _____ or psychotic, have suicidal thoughts, or experience crying spells. I will also contact Dr. _____ if I experience respiratory problems, changes in my normal sleeping patterns, extreme fatigue, increased irritability, or begin to withdraw from my family and/or friends.

f. The risks, benefits, and drug interactions of marijuana.

_____ Signs of withdrawal can include: feelings of depression, sadness, irritability, insomnia, restlessness, agitation, loss of appetite, trouble concentrating, sleep disturbances and unusual tiredness.

_____ Symptoms of marijuana overdose include, but are not limited to, nausea, vomiting, hacking cough, disturbances in heart rhythms, numbness in the hands, feet, arms or legs, anxiety attacks and incapacitation. If I experience these symptoms, I agree to contact Dr. _____ immediately or go to the nearest emergency room.

_____ Numerous drugs are known to interact with marijuana and not all drug interactions are known. Some mixtures of medications can lead to serious and even fatal consequences.

I agree to follow the directions of Dr. _____ regarding the use of prescription and non-prescription medication. I will advise any other of my treating physician(s) of my use of medical marijuana.

_____ Marijuana may increase the risk of bleeding, low blood pressure, elevated blood sugar, liver enzymes, and other bodily systems when taken with herbs and supplements. I agree to contact Dr. _____ immediately or go to the nearest emergency room if these symptoms occur.

_____ I understand that medical marijuana may have serious risks and may cause low birthweight or other abnormalities in babies. I will advise Dr. _____ if I become pregnant, try to get pregnant, or will be breastfeeding.

g. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

Cancer

- There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancers, including glioma.

There is evidence to suggest that cannabinoids (and the endocannabinoid system more generally) may play a role in the cancer regulation processes. Due to a lack of recent, high quality reviews, a research gap exists concerning the effectiveness of cannabis or cannabinoids in treating cancer in general.

- There is conclusive evidence that oral cannabinoids are effective antiemetics in the treatment of chemotherapy-induced nausea and vomiting.

There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancer-associated anorexia-cachexia syndrome and anorexia nervosa.

Epilepsy

- There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for epilepsy.

Recent systematic reviews were unable to identify any randomized controlled trials evaluating the efficacy of cannabinoids for the treatment of epilepsy. Currently available clinical data therefore consist solely of uncontrolled case series, which do not provide high-quality evidence of efficacy. Randomized trials of the efficacy of cannabidiol for different forms of epilepsy have been completed and await publication.

Glaucoma

- There is limited evidence that cannabinoids are an ineffective treatment for improving intraocular pressure associated with glaucoma.

Lower intraocular pressure is a key target for glaucoma treatments. Nonrandomized studies in healthy volunteers and glaucoma patients have shown short-term reductions in intraocular pressure with oral, topical eye drops, and intravenous cannabinoids, suggesting the potential for therapeutic benefit. A good-quality systemic review identified a single small trial that found no effect of two cannabinoids, given as an oromucosal spray, on intraocular pressure. The quality of evidence for the finding of no effect is limited. However, to be effective, treatments targeting lower intraocular pressure must provide continual rather than transient reductions in intraocular

— Positive status for human immunodeficiency virus

- There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

— Acquired immune deficiency syndrome

- There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

— Post-traumatic stress disorder

- There is limited evidence (a single, small fair-quality trial) that nabilone is effective for improving symptoms of posttraumatic stress disorder

A single, small crossover trial suggests potential benefit from the pharmaceutical cannabinoid nabilone. This limited evidence is most applicable to male veterans and contrasts with non-randomized studies showing limited evidence of a statistical association between cannabis use (plant derived forms) and increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder. There are other trials that are in the process of being conducted and if successfully completed, they will add substantially to the knowledge base.

— Amyotrophic lateral sclerosis

- There is insufficient evidence that cannabinoids are an effective treatment for symptoms associated with amyotrophic lateral sclerosis.

Two small studies investigated the effect of dronabinol on symptoms associated with ALS. Although there were no differences from placebo in either trial, the sample sizes were small, the duration of the studies was short, and the dose of dronabinol may have been too small to ascertain any activity. The effect of cannabis was not investigated.

— Crohn's disease

- There is insufficient evidence to support or refute the conclusion that dronabinol is an effective treatment for the symptoms of irritable bowel syndrome.

Some studies suggest that marijuana in the form of cannabidiol may be beneficial in the treatment of inflammatory bowel diseases, including Crohn's disease.

Parkinson's disease

- There is insufficient evidence that cannabinoids are an effective treatment for the motor system symptoms associated with Parkinson's disease or the levodopa-induced dyskinesia.

Evidence suggests that the endocannabinoid system plays a meaningful role in certain neurodegenerative processes; thus, it may be useful to determine the efficacy of cannabinoids in treating the symptoms of neurodegenerative diseases. Small trials of oral cannabinoid preparations have demonstrated no benefit compared to a placebo in ameliorating the side effects of Parkinson's disease. A seven-patient trial of nabilone suggested that it improved the dyskinesia associated with levodopa therapy, but the sample size limits the interpretation of the data. An observational study demonstrated improved outcomes, but the lack of a control group and the small sample size are limitations.

Multiple sclerosis

- There is substantial evidence that oral cannabinoids are an effective treatment for improving patient-reported multiple sclerosis spasticity symptoms, but limited evidence for an effect on clinician-measured spasticity.

Based on evidence from randomized controlled trials included in systematic reviews, an oral cannabis extract, nabiximols, and orally administered THC are probably effective for reducing patient-reported spasticity scores in patients with MS. The effect appears to be modest. These agents have not consistently demonstrated a benefit on clinician-measured spasticity indices.

Medical conditions of same kind or class as or comparable to the above qualifying medical conditions

- The qualifying physician has provided the patient or the patient's parent or legal guardian a summary of the current research on the efficacy of marijuana to treat the patient's medical condition.
- The summary is attached to this informed consent as Addendum_____.

Terminal conditions diagnosed by a physician other than the qualified physician issuing the physician certification

- The qualifying physician has provided the patient or the patient's caregiver a summary of the current research on the efficacy of marijuana to treat the patient's terminal condition.
- The summary is attached to this informed consent as Addendum_____.

Chronic nonmalignant pain

- There is substantial evidence that cannabis is an effective treatment for chronic pain in adults.

The majority of studies on pain evaluated nabiximols outside the United States. Only a handful of studies have evaluated the use of cannabis in the United States, and all of them evaluated cannabis in flower form provided by the National Institute on Drug Abuse. In contrast, many of the cannabis products that are sold in state-regulated markets bear little resemblance to the products that are available for research at the federal level in the United States. Pain patients also use topical forms.

While the use of cannabis for the treatment of pain is supported by well controlled clinical trials, very little is known about the efficacy, dose, routes of administration, or side effects of commonly used and commercially available cannabis products in the United States.

h. That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

_____ The Department of Health submits a data set to the Consortium for Medical Marijuana Clinical Outcomes Research for each patient registered in the medical marijuana use registry that includes the patient's qualifying medical condition and the daily dose amount and forms of marijuana certified for the patient.

PART B: Certification for medical marijuana in a smokable marijuana for a patient under 18 with a diagnosed terminal condition.

_____ Initial here if you are not a patient under 18 with a diagnosed terminal condition who will be receiving medical marijuana in a smokable form. After initialing here, complete part C.

If the patient is under 18, has a diagnosed terminal condition, and will be receiving medical marijuana in a smokable form, please review and initial the remainder of Part B before completing Part C.

Respiratory Health

_____ Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also for the global burden of disease. Given the known relationships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term cannabis smoking leads to similar deleterious effects of respiratory health, and some investigators agree that cannabis smoking may be even more harmful than that of tobacco smoking. Data collected from 15 volunteers suggest that smoking one cannabis joint can lead to four times the exposure to carbon monoxide and three to five times more tar deposition than smoking a single cigarette.

Cognitive and Psychosocial Development

_____ Researchers are still studying the long-term health effects of marijuana. Most people agree that marijuana use hurts adolescents more than adults. It is during the period of adolescence and young adulthood that the neural substrates that underlie the development of cognition are most active. Adolescence marks one of the most impressive stretches of neural and behavioral change with substantial a protracted development in terms of both brain structure and function. As a result, cannabis and other substance use during this period may incur relatively greater interference in neural, social, and academic functioning compared to late developmental periods.

- There is moderate evidence of a statistical association between acute cannabis use and impairment in the cognitive domains of learning, memory, and attention.
- There is limited evidence of a statistical association between sustain abstinence form cannabis use and impairments in the cognitive domains of learning, memory, and attention.

- There is limited evidence of a statistical association between cannabis use and impaired academic achievement and education outcomes.
- There is limited evidence of a statistical association between cannabis use and increased rates of unemployment and/or low income.
- There is limited evidence of a statistical association between cannabis use and impaired social functioning or engagement in developmentally appropriate social roles.

Addiction

Marijuana, like some other brain-altering substances, can be addictive. Nearly one in 10 marijuana users will become addicted. Starting to use marijuana at a younger age can lead to a greater risk of developing a substance use disorder later in life. Adolescents who begin using marijuana before age 18 are four to seven times more likely than adults to develop a marijuana use disorder.

Part C: For certification of smoking marijuana as an appropriate route of administration for a qualified patient, other than a patient diagnosed with a terminal condition

Acknowledgement of contaminant risks.

Smokable marijuana has infectious risks that are not present in processed products. Certain molds and mildews can contaminate marijuana plants during growing, processing, storage in dispensaries and in patient homes. These contaminants can pose health risks, particularly to those who are immunosuppressed due to their disease state and treatments. While the State of Florida requires third party testing you should still inspect your product.

Respiratory Health.

Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also for the global burden of disease. Given the known relationships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term marijuana smoking leads to similar deleterious effects of respiratory health, and some investigators agree that marijuana smoking may be even more harmful than that of tobacco smoking.

Information regarding health risks of 2nd and 3rd hand smoke to other household members.

You should never smoke medical marijuana around other family members, especially children and any household guests. You should smoke outside to allow adequate ventilation and to mitigate the dangers of secondhand and thirdhand smoke to others. Marijuana should never be smoked inside vehicles or other small spaces that children will occupy even if the children are not present at the time the product is consumed.

If you use oxygen or have others in your household who use oxygen you should not smoke marijuana or any other combustible material in the vicinity of where the oxygen is in use due to the risk of fire and explosion.

Self-dosing, if permitted.

I have been given instructions or discussed guidance on self- dosing with my qualified physician if permitted to do so.

Part D: Must be completed for all medical marijuana patients

I have had the opportunity to discuss these matters with the physician and to ask questions regarding anything I may not understand or that I believe needed to be clarified. I acknowledge that Dr. _____ has informed me of the nature of a recommended treatment, including but not limited to, any recommendation regarding medical marijuana.

Dr. _____ also informed me of the risks, complications, and expected benefits of any recommended treatment, including its likelihood of success and failure. I acknowledge that Dr. _____ informed me of any alternatives to the recommended treatment, including the alternative of no treatment, and the risks and benefits. Dr. _____ has explained the information in this consent form about the medical use of marijuana.

Patient (print name) _____

Patient signature or signature of the parent or legal guardian if the patient is a minor:

_____ Date _____

I have explained the information in this consent form about the medical use of marijuana to _____ (Print patient name).

Qualified physician signature:

_____ Date _____

Witness:

_____ Date _____

EXHIBIT D

FLORIDA BOARD OF MEDICINE AND FLORIDA BOARD OF OSTEOPATHIC MEDICINE
APPROVED INFORMED CONSENT FORM FOR CATARACT OPERATION WITH OR
WITHOUT IMPLANTATION OF INTRAOCULAR LENS

DOES THE PATIENT NEED OR WANT A TRANSLATOR, INTERPRETOR OR READER?

YES _____ NO _____

TO THE PATIENT: You have the right, as a patient, to be informed about your cataract condition and the recommended surgical procedure to be used, so that you may make the decision whether or not to undergo the cataract surgery, after knowing the risks, possible complications, and alternatives involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so that you may give or withhold your consent to cataract surgery and should reflect the information provided by your eye surgeon. If you have any questions or do not understand the information, please discuss the procedure with your eye surgeon prior to signing.

WHAT IS A CATARACT, AND HOW IS IT TREATED?

The lens in the eye can become cloudy and hard, a condition known as a cataract. Cataracts can develop from normal aging, from an eye injury, various medical conditions or if you have taken certain medications such as steroids. Cataracts may cause blurred vision, dulled vision, sensitivity to light and glare, and/or ghost images. If the cataract changes vision so much that it interferes with your daily life, the cataract may need to be removed to try to improve your vision. Surgery is the only way to remove a cataract. You can decide to postpone surgery or not to have the cataract removed.

ALTERNATIVE TREATMENTS:

I understand that I may decide not to have a cataract operation, at all. However, if I do not have the cataract surgery, I understand my vision loss from the cataract usually will continue to get worse. Corrective lenses, eyeglasses, or contact lenses will not improve my vision or reverse the worsening of the cataract.

HOW WILL REMOVING THE CATARACT AFFECT MY VISION?

The goal of cataract surgery is to correct the decreased vision that was caused by the cataract. During the surgery, the ophthalmologist (eye surgeon) removes the cataract and may place in a new artificial lens called an intraocular lens or IOL. Cataract surgery will **not** correct other causes of decreased vision, such as glaucoma, optic nerve or retinal problems, diabetes, age-related macular degeneration, or dry eye. In order to obtain the best possible vision, many

Patient initials _____

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Eye Surgeon's initials _____

Date _____

people still need to wear glasses or contact lenses after cataract surgery for either near and/or distance vision, for some activities, or in low light.

WHAT ARE THE TYPES OF INTRA-OCULAR-LENSES (IOL) THAT ARE AVAILABLE FOR ME?

Your ophthalmologist will help you decide on the type of IOL that will replace your cloudy lens. There are IOLs available to treat nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. IOLs usually provide either near or distance vision-- these single focus lenses are called **monofocal IOLs**. Some more recently developed IOLs may provide for near, intermediate, and distance vision-- these multiple focus lenses are called **multifocal IOLs**. Lenses that have some focusing power are called **accommodative IOLs**. IOLs that treat astigmatism are called **toric IOLs**.

You can also have one eye corrected for near vision, and the other for distance vision, a choice called **monovision**. With monovision the implanted IOLs have two different powers, one for near vision in one eye, and one for distance vision in the other eye. Monovision allows for near and distance vision but can decrease depth perception. Although many patients adjust well to monovision, some may find it uncomfortable, which may require compensating glasses, contact lenses or another operation to change the IOL.

No IOL is perfect, and often glasses or contact lenses are needed for certain activities even if you have chosen a special IOL lens.

DO I HAVE ASTIGMATISM IN ADDITION TO MY CATARACT? ARE THERE TREATMENTS FOR IT?

Patients with nearsightedness and farsightedness may also have astigmatism. Astigmatism is caused by an irregularly shaped cornea; instead of being round like a basketball, the cornea is shaped like an American style football. This can make your vision blurry. In addition to toric IOLs, astigmatism can be reduced by glasses, contact lenses, and refractive surgery (Laser assisted in situ keratomileusis [LASIK] or Photorefractive keratectomy [PRK]).

There is also a procedure called a limbal relaxing incision (LRI), which can be done at the same time as the cataract operation, or as a separate procedure. A LRI is a small cut or incision the ophthalmologist makes into your cornea to make its shape more round. Astigmatic Keratotomy (AK) is a similar procedure that involves a smaller, more central incision in the cornea than the LRI.

Patient initials _____

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Eye Surgeon's initials _____

Date _____

Any attempt at astigmatism reduction could result in over- or under-correction, in which case glasses, contact lenses, or another procedure may be needed. None of the methods of reducing astigmatism are perfect or completely predictable, but all are designed to help reduce the amount of astigmatism present.

WHAT ARE THE RECOGNIZED RISKS OF CATARACT SURGERY?

All operations and surgical procedures have risks and can have unsuccessful results or associated complications that can injure the patient, or even cause death in some instances. The recognized, specific risks of cataract surgery include problems that can lead to loss of vision, blindness or loss of your eye. Those risks include: bleeding; infection; high eye pressure; a swollen or detached retina; a droopy eyelid; double vision; displacement of the lens or portion (fragments) of the lens; injury to the cornea, iris, sclera, conjunctivae, pupil function, or other parts of the eye and nearby structures, from the operation or the anesthesia. Sometimes pieces of the lens cannot be completely removed and the vitreous can become displaced.

The specific, recognized, risks of a Limbal Relaxing Incision (LRI) or Astigmatic Keratectomy (AK), if performed in conjunction with cataract surgery are similar to those for cataract surgery, but also include perforation to the cornea, damage to the iris, increased astigmatism, and scarring, which could cause loss of vision. Furthermore, the LRI or AK may not fully correct the astigmatism and an under- or over-correction could occur, and glasses, contacts, or another surgical procedure may be needed to correct the vision.

Depending upon your eye and the type of IOL that is used, the most serious, recognized side effects include: increased night glare or halos, double vision, ghost images, impaired depth perception, decreased contrast, blurry vision, and decreased night vision.

At the time of surgery, your ophthalmologist may decide not to implant an IOL even though you may have given prior permission to do so, or your ophthalmologist may decide to implant an IOL different from the one that you initially preferred, or agreed to on pages four and five. In addition, the IOL may later need to be repositioned, replaced, or removed by way of a subsequent surgical procedure.

No intraocular lens or power calculation is perfect and you will likely still need glasses. Calculating IOL power is difficult in patients who are highly nearsighted or farsighted, as well as in patients that have had previous eye surgeries such as cornea surgery, glaucoma surgery, refractive surgery or retina surgery. This difficulty in calculating IOL power may result in your post-operative prescription being different from what you and the doctor thought it would be. This may require you to wear glasses, contact lenses, need refractive surgery, or have an IOL exchange or piggyback lens placed. Furthermore, because only one eye is operated on at a time, you may experience a feeling of imbalance between the two eyes which may require correction.

Patient initials _____

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Eye Surgeon's initials _____

Date _____

There is no guarantee that cataract surgery or astigmatism reduction will improve your vision, even with glasses or contacts. You may need glasses or contacts for best vision. In some cases, complications may occur weeks, months or even years later.

OTHER RISKS FROM CATARACT SUGERY:

Depending upon the type of anesthesia that is used, other risks are possible. Local anesthesia may affect or damage the retina, the optic nerve and may lead to: bleeding behind the eye, double vision, and permanent vision loss, perforation of the eye, cardiopulmonary complications, and in rare cases coma or death.

If you have **OTHER KNOWN MEDICAL CONDITIONS**, such as heart disease, history of heart failure, or lung disease such as Asthma or Chronic Obstructive Pulmonary Disease, or if you are **TAKING MEDICATIONS** such as Coumadin (a blood thinner) **OR OTHER SUPPLEMENTS OR VITAMINS**, tell your ophthalmologist so that you can minimize the risk of additional complications during and after surgery.

WHAT ARE MY OUT OF POCKET COSTS?

There is usually an additional charge for multifocal, accommodating, and toric IOLs, which is not paid by insurance. Therefore you understand that you may be responsible for that additional charge.

In some cases, additional sutures to support the IOL or wound, or a vitrectomy (or other additional surgery) may be needed at the time of the procedure or at a later time. The cost for additional surgery is not included in the price paid for the cataract surgery.

I understand that I may need additional treatment with medicines or surgery after my cataract removal. One common occurrence after cataract surgery is a clouding of the capsule behind the IOL requiring a laser treatment months or years later. This additional treatment is not included in the fee for this procedure.

PATIENT’S ACCEPTANCE OF RISKS:

I have read this informed consent (or it has been read to me) and I fully understand it and the possible alternatives to cataract surgery, the risks, complications, and benefits that can result from that surgery.

By signing below, I (we) certify that this form has been fully explained to me (us) , that I (we) have filled in all the blank spaces, and that my ophthalmologist has answered all of my (our)

Patient initials _____

Eye Surgeon’s initials _____

Date _____

questions, and I (we) understand and accept the risks, benefits, and understand the alternatives of cataract surgery.

The surgery is on my _____RIGHT EYE _____LEFT EYE

_____ I am aware of the recognized specific risks related to cataract surgery that are described in this form.

_____ I am aware that no intraocular lens is perfect, and that I may still need to use glasses or contacts for at least some activities or in low light regardless of the type of lens implanted. I am aware that no intraocular lens calculation is perfect, and that it is more difficult in an eye that has had prior corneal surgery or retinal or glaucoma surgery. I am also aware that the intraocular lens may later need to be repositioned, replaced, or removed by way of a subsequent surgical procedure.

On the advice of my Ophthalmologist, he/she and I choose the following premium lenses:

_____Multifocal Intraocular Lens

_____Toric Intraocular Lens

_____Accommodative Intraocular Lens

_____Monofocal/Monovision lens (Right eye near/distance; Left eye near/distance).

_____Other_____

_____ I understand that if during surgery, my ophthalmologist is unable to use any of the premium lenses; I consent to the implantation of a Monofocal Intraocular Lens.

_____ I am aware of the recognized specific risks related to Limbal Relaxing Incision (LRI) or Astigmatic Keratectomy (AK) for Astigmatism Reduction are those that are described in this form, and I understand that any of these risks could result in loss of vision, blindness or loss of the eye, and may require me to undergo further surgery. Furthermore, the LRI or AK may not fully correct the astigmatism, and glasses, contacts, or another surgical procedure may be needed to correct the vision.

_____ On the basis of the above statements, I voluntarily consent and authorize this cataract surgery procedure.

_____ I am aware that I have the right to report adverse incidents to the Florida Board of Medicine or the Florida Board of Osteopathic Medicine.

Patient initials _____

Eye Surgeon's initials _____

Date _____

Patient Print Name: _____

Patient Signature: _____

Date: _____ **Time:** _____

(Or person authorized to sign for patient)

Witness Print Name: _____

Witness Signature: _____

Date: _____ **Time:** _____

Surgeon Print Name: _____

Surgeon Signature: _____

Date: _____ **Time:** _____

Patient initials _____

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Date _____