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 for patients under the age of 25.

Part C is for certification of patients using smokable marijuana.

Part D 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 (I) 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 shouldcontact Dr. Nielsen.

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 understand that if I drive while under the influence of marijuana, I can be arrested for "driving under the influence."

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 youngerthan 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.

✓ 1 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. Nielsen 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. Nielsen if I experience respiratory problems, changes in my normal sleeping patterns, extreme fatigue, increasedirritability, or begin to withdraw from my family and/or friends.

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. Nielsen 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. Nielsen regarding the use of prescription andnonprescription medication.

✓ I will advise any other of my treating physician(s) of my use of medical marijuana and **will not make changes in their prescribed medications without discussing with them.**

✓ 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. Nielsen or my primary physician immediately or go to the nearest emergency room if these symptomsoccur.

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

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) mayplay 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 effectivetreatment 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 consistsolely 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 awaitpublication.

_____ **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 goodquality systemic review identified a single small trial that found no effect of two cannabinoids, given as an Oro-mucosal 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 pressure. To date, those studies showing positive effects have shown only short-term benefit on intraocular pressure (hours), suggesting a limited potential for cannabinoids in the treatment of glaucoma.

_____ **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 cannabinoidsas 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 cannabinoidsas 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 nonrandomized 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. Theeffect 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'sdisease. 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 cannabisextract, 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**

Dr. Nielsen is happy to provide 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 upon request.

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

The qualifying physician will provide 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 upon request.

✓ **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 inflower 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 andcommercially available cannabis products in the United States.

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 form for a patient under age 25 or under age 18 with a 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.

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 argue 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 (e.g.: adulthood).

• There is moderate evidence of a statistical association between acute cannabis use and impairment inthe 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 greaterrisk 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 contaminates 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 relations ships 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 ague that marijuana smoking may be even more harmful 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.

✓ **Dangers of smoking marijuana in households where oxygen is in use.**

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 by Dr. Nielsen or discussed guidance on self- dosing with my qualified physician if permitted to do so.

I understand that medical marijuana does not cure anything and is only given to relieve symptoms.

I understand that Medical Marijuana may interact negatively with other medications I'm taking and that I shouldn't become pregnant and shouldn't drive or operate machinerywhile under the influence of THC. (the psychoactive component of cannabis).

Dr. Nielsen has informed me of the risks, benefits and side effects of medical cannabis products.

I understand that Dr. Nielsen only recommends Medical Marijuana and does not act or function as my primary care physician.

I understand that it's important to tell my Physician (s) that I'm taking Medical Marijuana so he/she can monitor me and make appropriate medical decisions (for example, as Dr.Nielsen explained, the need to lower doses of meds that are psychoactive or sedating).The use of medical marijuana will most likely outweigh the potential health risks for you.This is a face to face (or video/audio chat) meeting with Dr. Richard Nielsen and my questionshave been fully explained and answered by him.

If you experience any adverse side effects including depression, anxiety attacks, psychosis, suicidal thoughts, weakness, dizziness, respiratory problems, changes in sleeping patterns, extreme fatigue, irritability, nausea, vomiting, abnormal heart rhythms,numbness in hands, feet, arms or legs, or incapacitation then stop using medical marijuana and if you feel it's necessary, go to your doctor or the emergency room for further evaluation and tell them you take medical marijuana.

 Medical Marijuana Consent Form (continued)

Part D: Must be completed for all medical marijuana patients

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

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

Dr. Nielsen can always be reached at the office 321-600-4457 or cell 570-419-4446 or through his assistant, Christine at 401-203-9560.

We recommend that you look at the FL Medical Marijuana Use Registry to stay informed of the latest FLlaw updates. Leafly.com is a good source of information also.

Patient **(print name)**_____

SIGN HERE: _____

INITIAL HERE: _____
(This is to indicate I've read all boxes above with: ___✓___

Date: _____

R C Nielsen M.D.

Richard Craig Nielsen, M.D.