INFORMED CONSENT FOR THE TREATMENT OF OPIOID ANALGESICS

The following information relates to the use of opioids (morphine-like pain killers) as part of a pain treatment plan prescribed by The Spine Specialists at Lebanon Pain Management Associates (herein named The Spine Specialists). The goal of pain treatment is to improve the ability to work and function while reducing pain. Opioids may be used to treat chronic pain when other treatment methods have failed to provide sufficient relief. Just like other therapies, opioid medication may not be effective or may cause certain side effects and toxicities. Because The Spine Specialists is responsible for making sound treatment decisions in accordance with accepted medical standards, it maintains sole discretion regarding discontinuation of opioid treatment. The following risks of treatment are presented to inform you when deciding whether to accept opioid therapy. All possible risks of therapy are not included in this informed consent document. Ask your clinician if additional risks might apply to you.

A. Opioid Definition: “A medication or illegal drug that is either derived from the opium poppy, or that mimics the effect of an opiate (a synthetic opiate). Opiate drugs are narcotic sedatives that depress activity of the central nervous system, reduce pain, and induce sleep.” Prescription opioids are pain-relieving medications used to treat moderate to severe pain. These medications can have side effects as well as serious negative physiological and psychological effects. The risks of complications and side effects increase when used with other medications. A complete review of all recent medications administered, ingested and/or prescribed will be performed at each office visit. Failure to provide all requested medication in their original prescription containers can result in discontinuance of narcotic medication.

B. Opiates can cause psychological, cognitive and physiological changes when used long term. Below is terminology that is used to describe these changes.

i. **Physical and Psychological Dependence:** The central nervous system can create physiological and psychological adaptations due to chronic exposure to a substance. If the medications are reduced or withdrawn, symptoms may be experienced such as, fear of increased pain, anxiety, increased perception of pain, abdominal pain, nausea, vomiting, headache, diarrhea, increased heart rate and/or blood pressure, insomnia, agitation, sweating, and tremors. Abrupt reduction or discontinuation of opioids requires medical supervision. Patients should notify The Spine Specialists when unable to take the prescribed opioids for more than 24 hours.

ii. **Addiction:** Addiction is the compulsive use of a drug despite physical or psychological harm caused by long-lasting chemical changes in the brain. Addiction is more likely in patients who have been addicted to other drugs, have family members with addiction, or who have certain psychological disorders. Opioid addiction is characterized by the use of opioids to satisfy a craving, or use of opioids despite potential harm. Addiction requires referral to an addiction specialist, treatment program or detoxification center. Opioids may be discontinued when addiction is identified or suspected.

iii. **Opioid Tolerance:** The need for an increased dosage of a drug over time to produce the same level of pain relief. This should not be confused with addiction.

C. Long-term opioid use can cause physiological changes that are sometimes very difficult to identify or quantify since they can occur with other medical etiologies. The following are some known reported side effects that occur without patients even being aware.

i. **Opioid Induced Immune Modulation:** Reduction in the body’s natural defenses against illness caused by chronic opioid use.

ii. **Opioid Induced Hormone Changes:** Long-term use of opioids may lower levels of hormones including estrogen, testosterone, and cortisol, which can affect the ability of your body to function normally. Sleep dysfunction, fatigue, weakness, irritability, depression, cognition, etc may be a result of these hormone changes.

iii. **Opioid Induced Abnormal Pain Sensitivity:** The use of chronic opioids paradoxically increases rather than decreases the sensation of pain.

iv. **Opioid Induced Memory Difficulties and /or Confusion:** All opioids may cause sedation, confusion, memory loss which will affect your ability to function.

v. **Other more common,** less harmful side effects of opioids include constipation, sedation, sweating, sleep disturbance, drying of saliva causing tooth and gum disease, impaired sexual performance, fatigue, nausea, memory impairment and worsening of depression

D. Many medications, especially opioids, can interfere with the ability to drive, perform intricate tasks, and make important decisions. This is especially true when starting or increasing the dose. It is essential to refrain from driving and other dangerous or important tasks while starting or adjusting opioids if the manufacturer of the opioids recommends against operating heavy machinery, The Spine Specialists will assume no liability for the decision to do so. Patients must be aware that they could be charged with “driving under the influence” (DUI) at any time for driving when using opioids.

E. Other medications such as anti-anxiety medications (i.e. Valium, Ativan, Xanax, Klonopin), sleeping aids (i.e Ambien, Restoril) and muscle relaxants (SOMA, Flexeril) to name a few can cause an increased risk of side effects including sedation, confusion, lethargy, garble speech, slow breathing, and even death. If you are every prescribed these medications by another physician, you MUST inform and discuss with us prior to taking them.

F. **Methadone,** a very potent and naturally long acting opiate, can sometimes be prescribed for pain; however, it may cause heart rhythm abnormalities in susceptible persons. Let your provider know if you have ever had an abnormal EKG or heart disease.

G. Many medications, including opioids, may harm a developing fetus. Female patients of childbearing age who are sexually active must use an effective form of birth control. If you think you may be pregnant, request a pregnancy test from your doctor before using opioids. In the event of pregnancy, The Spine Specialists should be notified immediately.

H. Controlled Substances may cause serious injury and death to children, pets and others. Opioids must be kept in a safe place, protected from theft and accidental ingestion. The Spine Specialists is not responsible for harm caused to these third parties.
AGREEMENT

Controlled substances have the potential for abuse or diversion, therefore strict accountability is necessary. For this reason, the following practices are agreed to by you, the patient, as a condition of continued prescription of controlled substances to treat your chronic pain. The Spine Specialists maintains sole discretion regarding discontinuation of controlled substance treatment. Patients must agree to abide by the following conditions in order to continue treatment at The Spine Specialists.

1. All patients receiving controlled substances are required to have a primary physician to attend to all other medical needs. The clinicians at The Spine Specialists will not assume the role of primary care provider.
2. All controlled substances must be obtained at the same pharmacy. Should the need to change pharmacies arise, our office must be informed. If a “Mail Order” Pharmacy is utilized, The Spine Specialists are not responsible for unaccounted medications due to any reason.
3. All prescribed medications by this office are to be brought to each office visit in their original bottle. This means ALL unused pills in their original pharmacy bottle.
4. No medication adjustments are permitted without prior approval from your pain clinician. Controlled substances will not be refilled early due to misuse.
5. Patients may not accept prescriptions for opioid or other controlled substance from other doctors or other without prior approval from The Spine Specialists.
6. Alcohol use is prohibited while taking controlled substances. Patient will not use any illegal drug(s) while being treated by The Spine Specialists.
7. The Spine Specialists will routinely request a urine sample to check for illegal drugs, alcohol, and other painkillers. Refusal or inability to submit a sample precludes ongoing treatment.
8. Any unused medication must be returned to The Spine Specialists. Prescriptions for different pain medications will not be issued until remaining medications are accounted for.
9. If a prescription or medication is lost or stolen, a police report will be required for replacement.
10. Therapy with controlled substances is just one part of pain treatment. Other diagnostic tests and treatments, including mental health evaluation, may be appropriate. Failure to participate in all aspects of the prescribed pain treatment plan may lead to discontinuation of other parts, including controlled substance therapy.
11. Prescriptions for controlled substances are typically issued only during appointments. They are not mailed or left for patients to pick up. Prescriptions will not be given nor refilled by the physician during weekends or evenings.
12. The following are grounds for discharge from The Spine Specialists:
   i. Altering or forging a prescription. This is a felony and will be reported to the appropriate authorities.
   ii. Dishonesty that affects the doctor-patient relationship.
   iii. Failure to appear for or to produce urine for a random drug screening on any day requested.
   iv. Use of illegal drugs or substances including but not limited to marijuana, cocaine, heroin, PCP, etc.
   v. Adulteration, dilution or substitution of a urine sample.
   vi. Argumentative, Disruptive, Threatening or violent behavior.
   vii. Noncompliance with the prescribed pain treatment plan.
13. If opioids are prescribed on a continual basis, the physicians of The Spine Specialists may perform or request any of the following: Failure to comply will result in the discontinuance of opiate treatment.
   i. **Opioid Switching**: The changing from one opioid medication to another in order to improve pain relief when tolerance occurs.
   ii. **Opioid Holiday**: A temporary discontinuance of opioid medication only to help restore the opioids ability to relieve pain.
   iii. **Opioid Decreases / Opioid Wean**: If opioid medications are not effective the dose will be gradually decreased and possibly discontinued.
   iv. **Neuropsychological Assessment**: Since chronic pain is a biopsychosocial disorder, you may be asked to be evaluated by a clinical neuropsychologist who is a psychologist with specialty training in the diagnostic assessment and treatment of patients with pain and other neuro-cognitive disorders.
   v. **Referral to a Drug Dependence Specialist**: If a physician is concerned that you are psychologically dependent or addicted on narcotics and/or illicit substances, you may be referred to a drug dependence specialist to treat this medical condition.
   vi. **Psychiatric Consultation**: If pain is affecting your mood or you have been diagnosed with a psychological disorder, you may be required to be under the care of a licensed psychiatrist for collaborative and multidisciplinary treatment.
   vii. **Cognitive-Behavioral Therapy (CBT)**: CBT is a psychotherapeutic approach that aims to treat problems concerning dysfunctional emotions, behaviors and thought process through a goal-oriented, systematic procedure.
14. Opioids are utilized in conjunction with non-opioid therapy in order to obtain the specific treatment goals. If any physician of The Spine Specialists believes the objective goals are not being achieved or the risks of opioid medications out weigh the benefits, opiate therapy will be discontinued.

15. Information concerning this agreement may be disclosed to other treating physicians, pharmacies, any relevant state and Federal law enforcement agencies including the Drug Enforcement Agency.

16. Since opiates are strong and powerful medications, we require that all providers be involved in the medical treatment process. Refusal to see any specific provider will result in discontinuing opiate medications or discharge from the practice.

I have reviewed and understand the above information. I understand and accept the above information regarding the risks of controlled substance use and agree to abide by the policies set forth in this document.

PATIENT NAME ____________________________________________ D.O.B __________________________

SIGNATURE ____________________________________________ DATE __________________________