

## **Informed Consent on the Use of Pain Control with Opioid Medications**

I, \_\_\_\_\_, have been informed and clearly understand the following issues regarding the treatment of pain with opioids (i.e. Morphine or Morphine-like drugs).

1. **I understand an office visit every 4 weeks is required** for management of the medications and refills of the pain medication prescribed and will be given on a monthly basis. Failure to attend office visits will result in slow tapering and ultimate discontinuation of all opioid medications.
2. **I understand I must designate a sole pharmacy** in which to have all medications filled, and provide the doctor's office with the pharmacy phone number. Pharmacy "hopping" is not tolerated.
3. **I understand medications used will be prescribed by a single physician.** I am aware that "doctor shopping" is an unacceptable behavior. The same physician will be managing the possible side effects during use of opioids. This physician will be the only one to decide when and how opioid dosage may be increased. If the physician decides to discontinue the use of the opioids, the physician will follow me through this tapering off period and I will agree to recommendations made by the physician.
4. **I understand the use of the medication is not to completely eliminate pain.** Rather, the medication is used to significantly reduce pain so that I will be able to perform many activities of daily living as well as social activities. It is hoped that the use of these medications will improve the quality of life but it is **unexpected that pain relief will be complete.**
5. **I understand I must report significant side effects of each of the opioid medications.** For example: over-sedation, nausea, vomiting, constipation, confusion, euphoria (high feelings) and dysphoria (down feelings). Other side effects which may be related to narcotic use also include dizziness; sweating; respiratory depression (difficulty breathing); gastrointestinal upset; quick, sudden jerky movements of the arms or legs; headaches; weakness; tremor; seizure; dreams; musculature rigidity; transient hallucinations; disorientation; visual disturbances; insomnia; dry mouth; diarrhea; stomach cramps; taste alteration; flushing of the face; chills; increased or decreased heart rate; increased or decreased blood pressure; difficulty with urination; itching; skin rashes; and swelling of the skin.
6. **I understand that the use of this medication may result in physical dependence.** This condition is common to many drugs including steroids, blood pressure medications, anti-anxiety medications and anti-seizure medications, as well as opioids. Physical dependency poses no problem to me as long as I avoid abrupt discontinuation of the drug. Medication can be safely discontinued after 2 or 3 weeks of slow tapering.
7. **I understand that psychological addiction is a possible risk of the use of opioid medications.** This has been shown to be an infrequent occurrence in patients who have been diagnosed with an organic disease causing chronic pain. Psychological addiction is recognized when the individual abuses the drug to obtain mental numbness or euphoria, when the patient shows a drug craving behavior or engages in "doctor shopping," when the drug is quickly escalated without correlation with pain relief and when the patient shows a manipulative attitude toward the physician in order to obtain the drug. If I exhibit such behavior, the drug will be tapered; I will not be a candidate for continued opioid usage.
8. **I understand tolerance is also a condition which can occur with use of opioid medications.** It is defined as a need for higher opioid dose to maintain the same pain control. Usually, tolerance to sedation, euphoria, nausea and vomiting occurs more commonly than tolerance to pain relief. This condition may be controlled by switching to a different opioid medication. Tolerance can also be managed by adding a second, different drug to the opioid management. If tolerance to opioids becomes unmanageable, the opioid will be tapered and discontinued.
9. **I understand that if I develop drowsiness, sedation, or dizziness I may not drive motor vehicles or operate machinery that can jeopardize my life or other people's lives.**
10. **I understand the use of the medication is designed and prescribed only for me.** I will never distribute it to others.
11. **I understand I am responsible for contacting the physician if at any time during the use of the opioid medications drowsiness or other major side effects develop.** The phone number to contact is **970-342-2220.**
12. **I understand that I may not stop taking the opioid medications abruptly.** If this happens, withdrawal symptoms usually occur 24-48 hours after the last dose. An individual may experience yawning, sweating, watery eyes, runny nose, anxiety, tremors, aching muscles, hot or cold flashes, "goose flesh", abdominal cramps and diarrhea. The withdrawal symptoms are self-limited, but could be life-threatening. It may last a few days. In order to avoid the withdrawal symptoms, I am informed that **I must contact the physician's office 48 hours prior to needing a new prescription and that no refills will be done on Fridays, after office hours or on the weekends.**
13. **I understand that I may not take other drugs such as tranquilizers, sedatives or antihistamines without first consulting with the physician. I may not use alcohol.** The combination of the above drugs, alcohol and opioids may produce profound sedation, respiratory depression, blood pressure drop or death.

14. **I understand I must follow the physician's directions and not increase the opioid dose on my own.** Drug overdose can cause severe sedation, respiratory depression and possible death.
15. **I understand I must take the medication as prescribed by the physician.** Medications should be taken whole, and are not to be broken, chewed or crushed. Possible risk would be rapid absorption of the medication causing anxiety or death.
16. **I understand that if I am a female I should notify the physician if I am pregnant or am at possible risk of becoming pregnant.** Children born when the mother is on opioid maintenance therapy will likely be physically dependent on the opioid at birth.
17. **I understand if there is any evidence of drug hoarding, acquisition of drugs from other physicians, uncontrolled dose escalation or other aberrant behavior, this would be followed by tapering and discontinuation of opioid maintenance therapy and possible discharge from the physician's practice.**
18. **Due to increased regulatory oversight of controlled substance prescribing and associated health risks, we have instituted universal drug testing (UDT) protocol.**

#### NOTICE OF MATERIAL RISK: KNOWN SIDE EFFECTS CHRONIC OPIOID USE

The use of opioid medication may be associated with certain risks, *some of which could be fatal*

- **GI Complaints**

- Constipation - 40%-45% of patients
- Nausea -25%
- Vomiting
- Abdominal cramping and bloating
- The overall risk of gastrointestinal bleeding is similar to non-steroidal anti-inflammatory (NSAID) agents
- May need regular use of MiraLax and/or Senokot or other means to soften bowel contents and create movement of the gut such that bowel movements occur regularly

- **Urinary**

- Urinary retention (difficulty urinating)

- **Pregnancy**

- Newborn may be dependent on opioids and suffer withdrawal symptoms after birth
- May cause birth defects

- **Drug Interactions**

- Other medications may interfere with the metabolism (breakdown or elimination) of medications
- In the right setting, this could cause a potential overdose without any change to your dose of opioid medications by reducing the excretion of your medication
- In the right setting, this could cause your medications to become less effective and be used up or eliminated quicker than would be expected
- Sometimes, these effects cannot be reliably predicted

- **Tolerance**

- Increasing doses of medication may be needed over time to achieve the same (pain relieving) effect
- Tolerance is variable and may or may not occur in any one individual
- Other new, worsening, or different causes of pain may develop and need to be assessed, before any increase in medication can be provided or assigned to tolerance alone

- **Respiratory effects**

- Chronic opiate use has been shown to be associated with multiple features of sleep-disordered breathing (SDB)
- Central sleep apnea, ataxic breathing, hypoxemia, and carbon dioxide retention
- Among patients on round-the-clock opioid therapy for >6 months, SDB can be as high as 75%
- In contrast, in general population samples, sleep-disordered breathing is observed in 3-20% of persons
- Ataxic breathing has been observed in:
  - up to 92% of individuals taking a morphine-equivalent dose of 200mg
  - 61% of individuals taking under 200mg
  - just 5% of individuals not taking opioids
  - 8.9-fold increase among patients prescribed > 100mg/day relative to patients on regimens < 20mg
  - 3.7-fold increase among patients prescribed > 50mg/day.
- Among persons on higher opioid doses, the risk of opioid overdose was estimated to be 1.8% per year of opioid use
- Bronchospasm (wheezing) causing difficulty in catching your breath or shortness of breath in susceptible individuals

## NOTICE OF MATERIAL RISK: KNOWN SIDE EFFECTS CHRONIC OPIOID USE

### • **Cardiovascular System Effects**

- A large cohort study among Medicare patients with arthritis found when opioid therapy was compared with NSAIDs and Celebrex, opioid therapy was associated with a 77% increased risk of cardiovascular events (eg: myocardial infarction, heart failure).

### • **Central Nervous System Effects**

- Opioid neurotoxicity is a significant issue, especially among the elderly
- Hyperalgesia (excessive sensitivity to pain) associated with use has been reported in patients on chronic opioid therapy
- Dizziness and sedation are also central nervous system effects that can lead to unintended consequences among those receiving long-term opioid therapy such as:
  - Falls, fractures, and respiratory depression
  - Higher levels of comorbid clinical depression of up to 38%
- Use of other central nervous system depressants such as benzodiazepines, barbiturates, and alcohol can:
  - Aggravate respiratory depression
  - Progress to apnea/death
- Sleepiness
- Decreased mental abilities
- Confusion
- You must avoid alcohol while taking opioid pain medication and when driving and operating machinery

### • **Dermatological**

- Itching and/or Rash

### • **Musculoskeletal Effects**

- Relative risk of fractures of around 1.4 for elderly patients on opiate therapy
- Some estimates have placed the hazard ratio for increased fracture risk at close to 4.9 when comparing patients taking opioids to age-matched controls taking NSAIDs
- Doses of Darvon and morphine over 50mg doubled the risk of fractures in the elderly
- Annual fracture rate of 9.95%
- Simply having a hip fracture increases odds of death to almost 22% after 1 year
- Those who do survive such an event often do not regain their health-related quality of life

### • **Endocrine system effects**

- Chronic opioid therapy has been found to have a strong impact on the male and female endocrine system
- Opiates have been shown to affect the release of every hormone from the anterior pituitary: growth hormone, prolactin, thyroid-stimulating hormone, adrenocorticotropic hormone, and lutein-stimulating hormone

### • **Endocrinesystem effects - Men**

- Some of the most profound pertain to the decrease of gonadotropin-releasing hormone
- Can manifest clinically in males as hypogonadism, known as opiate-induced androgen deficiency
- Sexual dysfunction, infertility, fatigue, and decreased levels of testosterone
- Decreased testosterone is of special concern because of an increased risk of metabolic syndrome and insulin resistance

### • **Endocrine system effects – Women**

- The decreased pulsatile release of gonadotropin-releasing hormone and subsequent decrease in luteinizing and follicle-stimulating hormones may have dramatic clinical consequences in women
- Decreased circulating levels of estrogen, lower follicle-stimulating hormone, and increased prolactin can lead to osteoporosis, no menstrual cycles, and lactation

### • **Immune System Effects**

- Several types of opioids, most notably morphine and fentanyl, have intrinsic immunosuppressive effects
- They reduce glucocorticoids release and norepinephrine release
- Increase in pneumonia in elderly patients on chronic opioid therapy

### • **Physical Dependence and Withdrawal**

- Physical dependence develops within 3-4 weeks in most patients receiving daily doses of these drugs
- If your medications are abruptly stopped, symptoms of withdrawal may occur. These include: nausea, vomiting, sweating, generalized malaise (flu-like symptoms), abdominal cramps, palpitations (abnormal heartbeats)
- Withdrawal symptoms may be uncomfortable, but are rarely life threatening
- To avoid withdrawal, controlled substances (narcotics) can be slowly weaned (tapered off) under the direction of your physician

**NOTICE OF MATERIAL RISK: KNOWN SIDE EFFECTS CHRONIC OPIOID USE**

• **Certain actions on your part may cause this immediate removal of prescribing:**

- Abuse of illegal drugs
- Suspected sale or distribution of your medications
- Failure to control access to your medications and prevent others from accessing them for illegal use
- Sharing your medications with others
- Violation of any of the provisions of your medication management agreement

• **Addiction and Abuse**

- This refers to abnormal behavior directed towards acquiring or using drugs in a non-medically supervised manner
- Patients with a history of addiction issues (alcoholism, gambling, tobacco abuse, street drug abuse, or addictions to other prescribed medications i.e. benzodiazepines - Valium like medications) are at increased risk for developing addiction

• **Allergic Reactions**

- Are possible with any medication
- Usually occurs early after initiation of the medication
- Most side effects are transient and can be controlled by continued therapy or the use of other medications

• **Other effects**

- Long-term opioid treatment is associated with an 87% increase in all-cause mortality
- From a psychiatric standpoint, opioid users:
  - Exhibit a higher prevalence of depression, anxiety disorders, and bipolar disorder
  - Are more than 10 times as likely to use inpatient mental health services
- You could be a target for theft
- There are those who will watch what meds you get at the pharmacy, will dumpster dive to find potential targets, or approach you on the street to try to buy your medications or steal them from you
- A common scam is to pose as a serviceman, salesperson, or relator to get access to your home. They could hold you at gunpoint or simply ask to use your bathroom and then behind closed doors steal medications from your medicine cabinet if they are available with or without your knowledge
- Remove all labels from your prescriptions and shred them
- Recycle bottles / boxes your medications came in
- Store all medications in a lockable container to prevent loss or theft
- Do not leave medications in an unsecured area like a kitchen, hall, or medicine cabinet
- You may be approached by others to obtain a urine sample they could use to deceive a drug test

Most, but possibly not all, side effects have been listed. Each human is unique and may have unique experiences with their medications, new side effects may become known over time, or new research may find other issues/concerns with the use of chronic opioid medications.

By signing below, I hereby indicate I have been informed of the potential risks associated with chronic opioid use, and that new or developing understanding may increase or lessen this risk. I agree to take full responsibility for my actions while under the influence of prescribed medication, understand there may be unknown risks to the use of these medications, and death or the death of others could occur. I will secure my medications from the use/access of others, and I will refrain from placing myself or others at risk of harm.

**Signature of Patient** \_\_\_\_\_ **Date** \_\_\_\_\_

**Pharmacy:** \_\_\_\_\_ **Telephone #:** \_\_\_\_\_