

 **Vanderbilt Medical Center**  
**Informed Consent for Opioid Treatment for Non-Cancer/Cancer Pain**

The purpose of this agreement is to give you information about the medications you will be taking for pain management and to assure that you and your physician/health care provider comply with all state and federal regulations concerning the prescribing of controlled substances. A trial of opioid therapy can be considered for moderate to severe pain with the intent of reducing pain and increasing function. The physician's goal is for you to have the best quality of life possible given the reality of your clinical condition. The success of treatment depends on mutual trust and honesty in the physician/patient relationship and full agreement and understanding of the risks and benefits of using opioids to treat pain.

I have agreed to use opioids (morphine-like drugs) as part of my treatment for chronic pain. I understand that these drugs can be very useful, but hide a high potential for misuse and are therefore closely controlled by the local, state, and federal government. Because my physician/health care provider is prescribing such medication to help manage my pain, I agree to the following conditions:

1. I am responsible for my pain medications. I agree to take the medication only as prescribed.
  - a. I understand that increasing my dose without the close supervision of my physician could lead to drug overdose causing severe sedation and respiratory depression and death.
  - b. I understand that decreasing or stopping my medication without the close supervision of my physician can lead to withdrawal. **Withdrawal symptoms** can include yawning, sweating, watery eyes, runny nose, anxiety, tremors, aching muscles, hot and cold flashes, "goose flesh", abdominal cramps, and diarrhea. These symptoms can occur 24-48 hours after the last dose and can last up to 3 weeks.
2. I will not request or accept controlled substance medication from any other physician or individual while I am receiving such medication from my physician/health care provider at the Pain Center.
3. There are side effects with opioid therapy, which may include, but not exclusively, skin rash, constipation, sexual dysfunction, sleeping abnormalities, sweating, edema, sedation, or the possibility of impaired cognitive (mental status) and/or motor ability. Overuse of opioids can cause decreased respiration (breathing).

It is my responsibility to notify my physician/health care provider for any side effects that continue or are severe (i.e., sedation, confusion). I am also responsible for notifying my pain physician immediately if I need to visit another physician or need to visit an emergency room due to pain, or if I become pregnant.

4. I understand that the opioid medication is strictly for my own use. The opioid should **never** be given or sold to others because it may endanger that person's health and is **against the law**.
5. I should inform my physician of all medications I am taking, including herbal remedies. Medications like Valium or Ativan; sedatives such as Soma, Xanax, Fiorinal; antihistamines like Benadryl; herbal remedies, alcohol, and cough syrup containing alcohol, codeine, or hydrocodone can interact with opioids and produce serious side effects.
6. During the time that my dose is being adjusted, I will be expected to return to the clinic as instructed by my clinic physician. After I have been placed on a stable dose, I may receive opioids from my primary care physician and will return to the pain clinic for a medical evaluation at least once every six months.
7. I understand that opioid prescriptions will **not be** mailed. If I am unable to obtain my prescriptions monthly, I will be responsible for finding a local physician who can take over the writing of my prescriptions with consultations from my pain physician.
8. Any evidence of drug hoarding, acquisition of any opioid medication or adjunctive analgesia from other physicians (which includes emergency rooms), uncontrolled dose escalation or reduction, loss of prescriptions, or failure to follow the agreement may result in termination of the doctor/patient relationship.
9. I will communicate fully with my physician to the best of my ability at the initial and all follow-up visits my pain level and functional activity along with any side effects of the medications. This information allows my physician to adjust my treatment plan accordingly.
10. You should not use any illicit substances, such as cocaine, marijuana, amphetamines, etc. while taking these medications. This may result in a change to your treatment plan, including safe discontinuation of your opioid medications when applicable or complete termination of the doctor/patient relationship.
11. The use of alcohol together with opioid medications is contraindicated.
12. I am responsible for my opioid prescriptions. I understand that:
  - a. Refill prescriptions can be written for a maximum of one month supply and will be filled at the **same pharmacy**.  
Pharmacy: \_\_\_\_\_ Phone number: \_\_\_\_\_
  - b. **It is my responsibility to schedule appointments for the next opioid refill before I leave the clinic or within 3 days of the last clinic visit.**
  - c. I am responsible for keeping my pain medications in a safe and secure place, such as a locked cabinet or safe. I am expected to protect my medications from loss or theft. I am responsible for taking the medication in the dose prescribed and for

keeping track of the amount remaining. If my medication is stolen, I will report this to my local police department and obtain a stolen item report. I will then report the stolen medication to my physician. If my medications are lost, misplaced, or stolen my physician may choose not to replace the medications or to taper and discontinue the medications.

- d. Refills will not be made as an "emergency", such as on Friday afternoon because I suddenly realize I will "run out tomorrow".
  - e. Refills can only be filled by a pharmacy in the State of Tennessee even if I am a resident of another state.
  - f. Prescriptions for pain medicine or any other prescriptions will be done only during an office visit or during regular office hours. No refills of any medications will be done during the evening or on weekends.
  - g. **You must bring back all opioid medications and adjunctive medications prescribed by your physician in the original containers/bottles at every visit.**
  - h. Prescriptions will not be written in advance due to vacations, meetings, or other commitments.
  - i. If an appointment for a prescription refill is missed, another appointment will be made as soon as possible. *Immediate* or *emergency* appointments will not be granted.
  - j. **No "walk-in" appointments for opioid refills will be granted.**
13. While physical dependence is to be expected after long-term use of opioids, **signs of addiction, abuse, or misuse shall prompt the need for substance dependence treatment as well as weaning and detoxification from the opioids.**
- a. **Physical dependence** is common to many drugs such as blood pressure medications, anti-seizure medications, and opioids. It results in biochemical changes such that abruptly stopping these drugs will cause a withdrawal response. It should be noted that physical dependence does not equal addiction. One can be dependent on insulin to treat diabetes or dependent on prednisone (steroids) to treat asthma, but one is not addicted to the insulin or prednisone.
  - b. **Addiction** is a primary, chronic neurobiologic disease with genetic, psychosocial and environmental factors influencing its development and manifestation. It is characterized by behavior that includes one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and cravings. This means the drug decreases one's quality of life. If the patient exhibits such behavior, the drug will be tapered and such a patient is not a candidate for an opioid trial. He/she will be referred to an addiction medicine specialist.
  - c. **Tolerance** means a state of adaptation in which exposure to the drug induces changes that result in a lessening of one or more of the drug's effects over time. The dose of the opioid may have to be titrated up or down to a dose that produces maximum function and a realistic decrease of the patient's pain.

14. If it appears to the physician/health care provider that there is no improvement in my daily function or quality of life from the controlled substance, my opioids may be discontinued. I will gradually taper my medication as prescribed by the physician.
15. If I have a history of alcohol or drug misuse/addiction, I must notify the physician of such history since the treatment with opioids for pain may increase the possibility of relapse. A history of addiction does not, in most instances, disqualify one for opioid treatment of pain, but starting or continuing a program for recovery **is a necessity**.
16. I will be seen on a regular basis and given prescriptions for enough medication to last from appointment to appointment, and sometimes two to three days extra **if** the prescription ends on a weekend or holiday. This extra medication is **not** to be used without the explicit permission of the prescribing physician unless an emergency requires your appointment to be deferred one or two days.
17. I agree and understand that my physician reserves the right to perform random or unannounced urine and/or blood drug testing. If requested to provide a urine or blood sample, I agree to cooperate. If I decide not to provide a urine or blood sample, I understand that my doctor may change my treatment plan, including safe discontinuation of my opioid medications when applicable or complete termination of the doctor/patient relationship. The presence of a non-prescribed drug (s) or illicit drug (s) in the urine and/or blood can be grounds for termination of the doctor/patient relationship. Urine and/or blood drug testing is not forensic testing, but is done for my benefit as a diagnostic tool and in accordance with certain legal and regulatory materials on the use of controlled substances to treat pain.
18. I agree to allow my physician/health care provider to contact any health care professional, family member, pharmacy, legal authority, or regulatory agency to obtain or provide information about my care or actions if the physician feels it is necessary.
19. I agree to a family conference or a conference with a close friend or significant other *if the physician feels it is necessary*.
20. I understand that non-compliance with the above conditions may result in a re-evaluation of my treatment plan and discontinuation of opioid therapy. I may be gradually taken off these medications, or even discharged from the clinic.

I, \_\_\_\_\_, have read the above information or it has been read to me and all my questions regarding the treatment of pain with opioids have been answered to my satisfaction. I hereby give my consent to participate in the opioid medication therapy & acknowledge receipt of this document.