

Alamance Regional Medical Center

1236 Huffman Mill Road
Burlington, NC 27215
Pain Management Centers
Opioid Informed Consent Form

Chronic Opioid/Opiate Informed Consent Form

Purpose: to legally document the process by which the healthcare provider, **NC Pain Management Services PA (NCPMS)**, has communicated to me the risks and possible complications associated with the treatment with opioids/opiates. Once completed, I will decide whether or not to authorize **NC Pain Management Services, PA (NCPMS)** and its affiliate(s) to proceed with it.

Diagnostic indications: Chronic Pain.

Purpose of Therapy: To assist in managing the patient's pain.

Benefits: Therapy should decrease the patient's pain therefore allowing him/her to be more functional and productive, while at the same time decreasing the visits to healthcare professionals and emergency departments, and decreasing the overall cost of healthcare, due to the uncontrolled pain.

Risks and benefits of not undergoing this type of therapy: Some of the possible **risks** of not undergoing this type of therapy include but are not limited to: uncontrolled chronic pain; decrease functionality and productivity due to painful restrictions; possible psychological and physical deterioration. The possible **benefits** of not undergoing this type of therapy include but are not limited to: avoiding side-effects, risks, responsibilities, and possible complications directly associated with the therapy.

Possible Alternatives to this therapy:

- Doing nothing.
- Using drugs other than opioids/opiates, such as muscle relaxants, non-steroidal anti-inflammatory medications, membrane stabilizers, etc..
- Using interventional pain management techniques.
- Using implantable devices.
- Corrective surgery.
- Physical therapy.
- Alternative medicine techniques.

Note: Some of these alternatives, although possible, are outside of the scope of this practice, or outside of recommended acceptable medical Guidelines.

Benefits of alternative therapies: Similar to those of this therapy.

Risks of alternative therapies: Each alternative has its own set of risks and possible complications. Attempting to describe each is beyond the scope of this document. Overall, they can be similar to those of this type of therapy, except for those of addiction, which tends to be more common, but not unique, to opioids/opiates.

Definitions:

- **Narcotics:** Any of a group of highly addictive analgesic drugs derived from opium or opium-like compounds. Narcotics can cause drowsiness and significant alterations of mood and behavior. The term is often used interchangeable to denote both opioids, and opiates.
- **Opioid:** Opioid is a blanket term used for any drug which binds to the opioid receptors in the central nervous system (CNS). Opioids include all of the opiates as well as any synthesized drug that attaches itself to the CNS or gastrointestinal tract opioid receptors. Synthetic Opioids include: **Methadone**, Pethidine, **Meperidine (Demerol)**, **Fentanyl**, Alfentanil, Sufentanil, Remifentanil, Carfentanil, Pentazocine, Phenazocine, **Tramadol (Ultram or Ultracet)**, and Loperamide.
- **Opiate:** Opiate is an often-misused term. Any drug which affects the opioid receptors is often incorrectly labeled an opiate, however by definition, opiates refer to alkaloids extracted from poppy pods and their semi-synthetic counterparts which bind to the opioid receptors. Basically to be called an opiate one has to either be a natural opioid receptor agonist or start the refining process with one of the natural alkaloid molecules.

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Once chemically altered, such as the process of converting Morphine into Heroin, the drug is then labeled a semi-synthetic opiate or semi-synthetic opioid - the terms can be used interchangeably. This distinction can be a little confusing since Morphine, Codeine and Thebaine are all pure alkaloids that bind to the Opioid receptors, but Papaverine, which is also a naturally occurring alkaloid inside the poppy pod is not an opiate because it does not act on the opioid receptors. Natural Opiates are: Morphine, Codeine and Thebaine. Semi-synthetic opiates (or semi-synthetic opioids) are: Heroin (diamorphine), Oxycodone, Hydrocodone, Dihydrocodeine, Hydromorphone, Oxymorphone, Buprenorphine, Etorphine, Naloxone and Naltrexone.

- **Withdrawals:** Withdrawal syndrome is most commonly used to describe the group of symptoms that occurs upon the abrupt discontinuation/separation or a decrease in dosage of the intake of medications, recreational drugs, and/or alcohol. In order to experience the symptoms of withdrawal, one must have first developed a physical dependence (often referred to as chemical dependency). This happens after consuming one or more of these substances for a certain period of time, which is both dose dependent and varies based upon the drug consumed. Contrary to withdrawals from alcohol or benzodiazepine (VALIUM, ATIVAN, XANAX, etc.), narcotic withdrawals are, for the most part, not lethal. In the case of short acting narcotics, such as morphine, withdrawals can occur 12 to 14 hours after the last dose, reaching their peak at 48 to 72 hours, and disappearing in 7 to 10 days. With longer acting narcotics, such as methadone, withdrawals can begin 24 to 48 hours after the last dose, reaching a peak at the 3rd day, and may not begin to decrease until the 3rd week. They usually consist of lacrimation, runny nose, yawning, sweating, dilated pupils, loss of appetite, goose bumps, restlessness, irritability, tremors, insomnia, sneezing, weakness, depression, nausea, vomiting, diarrhea, abdominal cramps, chills, bone and muscle pains, increased in respiratory rate, heart rate and blood pressure, muscle spasms, cold and hot flashes, increase in body temperature, anxiety, and a feeling of being ready to "climb up the walls" or "jump out of your skin". For the most part, withdrawals are more severe for the short-acting narcotics than for the long-acting.
- **Tolerance:** This is what happens when the patient's medicines are no longer as effective as they use to. Tolerance may develop to the effects of many drugs, especially the opioids, barbiturates, and other CNS (central nervous system) depressants. When this occurs, *cross-tolerance* may develop to the effects of pharmacologically related drugs. Tolerance to a pain medication will be manifested as an increase in pain after the frequent use of the analgesic (pain medication). Tolerance has been described to develop in as short as 10 days. Although this process may take as long as a year in some patients, it is safe to assume that it will occur to everybody who takes this type of medication on a regular basis. A common complaint of patients is that, "*the medications don't seem to work as well as they use to.*"
- **Physical Dependence:** (Also known as *Physiological Dependence*) Refers to a state resulting from chronic use of a drug that has produced *tolerance* and where physical symptoms of *withdrawal* result from abrupt discontinuation or dosage reduction. Physical dependence can develop from low-dose therapeutic use of certain medications as well as misuse of recreational drugs such as alcohol. The higher the dose used typically the worse the physical dependence and thus the worse the withdrawal symptoms.
- **Addiction:** The concept of drug addiction has many different definitions: According to the current Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), substance dependence is defined as: "*When an individual persists in use of alcohol or other drugs despite problems related to use of the substance, substance dependence may be diagnosed. Compulsive and repetitive use may result in tolerance to the effect of the drug and withdrawal symptoms when use is reduced or stopped. This, along with Substance Abuse are considered Substance Use Disorders...."*
The American Society of Addiction Medicine has defined addiction as a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in the individual pursuing reward and/or relief by substance use and other behaviors. The addiction is characterized by impairment in behavioral control, craving, inability to consistently abstain, and diminished recognition of significant problems with one's behaviors and interpersonal relationships. Like other chronic diseases, addiction involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.
Federal Law defines an "Addict" as "someone who has lost self-control over their own medications".

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- **Drug Holidays:** Also known as “Short-Term Detoxification”. This is the name given to the period of time during which the opioid/opiate are stopped for the purpose of treating tolerance to the medications. During the Drug Holidays, because of *cross-tolerance*, patients will not be allowed to switch to another opioid/opiate. When returning to the opioid/opiate, at the end of the Drug Holiday, the patient is likely to be started at a lower dose than the dose prior to the Drug Holiday. They should be repeated as often as necessary to allow the patient to control his/her medication tolerance, rather than allowing the medication to control the patient. Drug Holidays are done as outpatients. They can be monitored by physicians, but they are primarily managed by the patients. Because they demonstrate the patient’s ability for self-control, they serve as evidence of non-addiction. The opposite is also true. Patients that do not comply with this requirement. Federal Law defines an “Addict” as “someone who has lost self-control over their own medications”. Following this definition, it then states that “it is illegal for any physician to prescribe narcotics to an ‘addict’.” Because of this, any patients refusing to undergo a “Drug Holiday”, may be considered as having lost self-control over their medications, subsequently triggering the permanent cessation of all controlled substances by the prescribing physician. The other side of that coin is that by complying with the “Drug Holidays”, the patient demonstrates that he/she continues to have self control over their own medicines, and therefore, it makes it legal for the treating physician to continue prescribing the pain medication.

Directions: By signing my initials next to each statement, I am certifying that I have read it and that I clearly understand it. (For this following section, placing your initials next to each statement simply means that it has been read and understood.)

- _____ **Item 01:** I recognize that **NC Pain Management Services, PA (NCPMS)** does not represent my only choice of pain specialists and that there are other Pain Management Practices in close proximity and within reasonable driving distance.
- _____ **Item 02:** I am aware that as a prerequisite to entering this program, I must have an active, current Primary Care Physician (**PCP**) (Family Doctor, General Practitioner, or Internist), in charge of my general medical needs.
- _____ **Item 03:** I understand that before I can be prescribed any opioids/opiates, **NC Pain Management Services, PA (NCPMS)** and its affiliate(s), will evaluate the appropriateness of prescribing opioid/opiate medicine(s), sometimes called narcotic analgesic(s), to me for the treatment of my "Chronic Pain". This type of therapy is being considered at my request, because I believe my condition to be serious enough to warrant it, or other treatments have not helped my pain.
- _____ **Item 04:** I am aware that I am required to tell my doctor my complete and honest personal drug history and that of my family, to the best of my knowledge.
- _____ **Item 05:** I am aware that I need to **always tell my physicians the truth**, all of the truth, and nothing but the truth, and that I should **never omit** anything when it comes to my current and past medical history, including all substances, legal and illegal, that I may be using, or may have used. I have been informed and clearly understand that not **doing so may endanger my life** and/or hinder my physician’s ability to keep me away from harm.
- _____ **Item 06:** I am aware that in the event that I no longer want to continue with this type of therapy, all I have to do is to notify my physician.
- _____ **Item 07:** I am aware that there are **other types of treatments** that my doctor may want to try, in order to keep my pain and the use of these medications, to a minimum.
- _____ **Item 08:** I have been made aware of the fact that as part of the evaluation and monitoring program, **NCPMS** may conduct criminal and medication background checks, as well as psychological and functional screening tests, for the purpose of assessing my case, my particular risks and my compliance.

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- _____ **Item 09:** I understand that my physician may need to contact and communicate with any of my prior and/or current healthcare professionals, family members, pharmacies, legal authorities, or regulatory agencies, to obtain or provide information about my care or actions, *if the NCPMS' physician feels it is necessary.*
- _____ **Item 10:** I am aware that the use of opioid/opiate medications has certain **risks associated with it**, including, but not limited to, **addiction**, overdose, **death**, sleepiness or drowsiness, cognitive impairment, constipation, nausea, itching, vomiting, dizziness, allergic reaction, slowing of breathing rate, slowing of reflexes or reaction time, and possibility that the medicine will not provide complete pain relief.
- _____ **Item 11:** I am aware that some of these medications can be **harmful and even lethal**, when taken inappropriately.
- _____ **Item 12:** I am aware that these medications can be **lethal when ingested by a minor** and that I am responsible for the medication's safe keeping, storage, and handling.
- _____ **Item 13: (Males only)** I am aware that chronic opioid use has been associated with low testosterone levels in males. This may effect my mood, stamina, sexual desire and physical and sexual performance. I understand that my doctor may check my blood to see if my testosterone level is normal.
- _____ **Item 14: (Females Only)** If I plan to become pregnant or believe that I have become pregnant while taking this pain medicine, I will immediately call my obstetric doctor and this office to inform them. I am aware that, should I carry a baby to delivery while taking these medicines, the baby will be physically dependent upon opioids. I am aware that the use of opioids is not generally associated with a risk of birth defects. However, birth defects can occur whether or not the mother is on medicines and there is always the possibility that my child will have a birth defect while I am taking an opioid.
- _____ **Item 15:** I am aware that even if I do not notice it, my reflexes and reaction time might still be affected by the use of these medications.
- _____ **Item 16:** I am aware that I should never be involved in any activity that may be dangerous to me or someone else, if I feel drowsy or if I am not thinking clearly. I understand this to mean that **I should not drive, operate heavy machinery, or handle any weapons, while under the influence and effects** of these type of medications. Other activities that I should avoid may include, but are not limited to: working in a dangerous environment, or around unprotected heights, or being responsible for other individuals who are unable to care for themselves.
- _____ **Item 17:** I am aware that becoming addicted to opioid/opiate pain medications is possible. I am aware that **addiction** is defined as the use of a substance even if it causes harm, having cravings for a drug, or feeling the need to use a drug, despite the consequences. I am also aware that the development of addiction is much more common in a person who has a family or personal history of addiction.
- _____ **Item 18:** I have been informed and understand that **I will develop physical dependence** to these medications, as a result of using them. I understand that physical dependence is not the same as addiction. I am aware physical dependence means that if I markedly decrease or stop my medication, I will experience a withdrawal syndrome. This means that I may develop any or all of the following: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, irritability, aches throughout my body and a flu-like feeling. I am aware that opioid withdrawals can be very uncomfortable.
- _____ **Item 19:** I have been informed that there is a condition associated with the use of opioids/opiates, known as "**Opioid Hyperalgesia**". I understand this to be a condition where the pain medication actually makes me experience more pain by making me more susceptible to it. I am also aware that if I develop this, I will need to be taken off of these type of medications.

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- _____ **Item 20:** I have been informed and understand that **I will develop tolerance** to these medications. I understand this to mean that with time, I will get use to them and they will no longer be effective in controlling my pain. I am aware that **tolerance** means that I may require more medicine to get the same amount of pain relief. If it occurs, increasing doses may not always help and may cause unacceptable side effects. I am aware and understand that tolerance and/or failure to respond well to opioids may cause my doctor to choose another form of treatment.
- _____ **Item 21:** I understand that **NCPMS** uses “**Drug Holidays**” rather than “**Opioid Rotation**” to treat Tolerance and/or diagnose “**Opioid Hyperalgesia**”. I am aware that this is an integral part of this program’s medication management.
- _____ **Item 22:** I understand a “**Drug Holiday**” to be a period of no less than 14 consecutive days, during which I will take myself completely off of all opioid/opiate medication, with the permission and approval of my pain physician, for the purpose of counteracting the effects of tolerance. I am aware that this is usually done as an outpatient, and that during this period I will experience withdrawals.
- _____ **Item 23:** I am aware that combining these medications with certain other substances, such as **alcohol** or illegal drugs can cause undesirable effects, such as respiratory depression and death.
- _____ **Item 24:** I am also aware that combining these medications with other substances, including prescription drugs or antibiotics can result in serious complications (including death) and therefore, I am responsible for always consulting my **pharmacist** about possible **drug-to-drug interactions**, including with over-the-counter medications.
- _____ **Item 25:** I am aware that certain other medicines such as nalbuphine (Nubain™), pentazocine (Talwin™), buprenorphine (Buprenex™), and butorphanol (Stadol™), may reverse the action of the medicine I am using for pain control. Taking any of these other medicines while I am taking my pain medicines can cause bad flu-like symptoms, called “**withdrawal syndrome**” or “**abstinence syndrome**”.
- _____ **Item 26:** I am aware that I should **never take more pain medicine than prescribed**, without the express written consent of my pain management physician. In addition to the risk of being discharged from the program, I also understand that doing so can result in my **death**, due to **overdosing**.
- _____ **Item 27:** I am aware that I am responsible for **keeping these medications under lock and key**, in a safe place, away from the reach of children and everyone else but me, even if I live alone.
- _____ **Item 28:** I am aware that I will need to **tell my doctor about all other medicines** and treatments that I am receiving.
- _____ **Item 29:** I am aware that I should **never solicit or accept** any other **pain medication(s), from any other source(s)**, other than from this pain program, without the specific written consent of my pain management physician. I also understand that this means that I am responsible for notifying all other healthcare providers involved in my care that I have agreed to receive pain medications from **NCPMS only**. Furthermore, I am aware that obtaining pain medications from more than one physician constitutes “**Doctor Shopping**”, which is illegal in the state of North Carolina.
- _____ **Item 30:** I am aware and agree to follow my doctor's recommendations to go into a “**Drug Holiday**”, as described in my orientation package.
- _____ **Item 31:** I am aware that **NCPMS’** medication monitoring program requires frequent, unannounced drug screening tests.
- _____ **Item 32:** I understand that “**inconsistent**” or “**unexpected**” **drug screening tests results**, and/or tampering with the test will lead to immediate secession of therapy and dismissal from the program.

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- _____ **Item 33:** I understand that failure to comply with **NCPMS' "Medication Policy"** may result in the immediate discontinuation of the controlled substances been prescribed, as well as possible discharge from the program.
- _____ **Item 34:** I am also aware and understand that failure to follow my doctor's orders will result in my discharge from the program. I also understand that if this occurs, my doctor will not be responsible for referring me to another program or doctor.
- _____ **Item 35:** I have been made aware of the **reasons for termination of therapy**. These include, but are not limited to: unsafe use of medications and/or behavior; non-compliance due to inability to do so; development of addiction; suicidal risks; having adverse reactions, uncontrollable side-effects, or non-physiological responses to the therapy; lack of efficacy; resolution of the pain; and desire to discontinue therapy.
- _____ **Item 36:** In addition, I have also been made aware of the **reasons for termination of therapy**, and/or patient-physician relationship, with possible **discharge from the practice**. These include, but are not limited to: unsafe use of medications and/or behavior; non-compliance due to unwillingness (losing medications; not bringing medications to appointments; non-compliance with safe storage practices; non-compliance with medication policy; not following treatment Agreements; and/or not keeping scheduled appointments, tests, or consults); not following State and/or Federal statutes/Laws/regulations associated with controlled substances.
- _____ **Item 37:** I understand that signing this document does not mean that my pain physician is obligated in any way to prescribe or continue prescribing any of these medications to me.
- _____ **Item 38:** I understand that this document is self renewable, on a yearly basis.
- _____ **Item 39:** I understand that it is my responsibility to keep my family informed of the risks associated with this therapy and the fact that they will need to assist and participate in the responsibility of monitoring my use or misuse of these substances.
- _____ **Item 40:** Furthermore I understand that under the rules of this program, it is felt that for my own safety and that of others, it is strongly recommended and preferred that I share the entire content of this document with my family, as well as the responsibilities stipulated herein.
- _____ **Item 41:** I understand that once I begin to get opioid/opiate prescriptions from the **NCPMS** program, I am not to get any more narcotics from any other practices, including during emergency room visits. In addition, I understand that I should always inform my physician of all medications that I am taking, including herbal remedies, since opioid medications can interact with over-the-counter medications and other prescribed medications, especially cough syrup that contains alcohol, codeine or hydrocodone.
- _____ **Item 42:** I understand that by voluntarily signing below, I acknowledge the above information, accept the risks and responsibilities of this type of therapy, and I give **NC Pain Management Services, PA (NCPMS)** and its affiliate(s) my consent to treat me and my pain with opioids/opiates, and if necessary, to discontinue therapy.

Directions: This following section is to be signed only if you have completely read the above risks and responsibilities, understand them, and are willing to accept those and give permission for the therapy. This consent section will need to be signed before any opioid/opiate pain medications are prescribed by this program or its affiliates.

I hereby certify that I have read this form or have had it read to me, that I understand all of it, and that I have had a chance to have all of my questions answered to my satisfaction. By voluntarily signing this form, I accept the risks and responsibilities associated with this type of therapy, and I give NC Pain Management Services, PA

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(NCPMS) and its affiliate(s) my consent to treat me and my pain with opioids/opiates, and if necessary, to discontinue therapy. I agree that should I decide to terminate this agreement, I will do so in writing.

Patient's Name _____ Date of birth ____/____/____

Patient's Signature

Date

Time

Receipt of Medical Information

I acknowledge having received and being responsible for reading the content of the "**Medication Policy**" handout.

Patient's Signature

Date

Time

Family Acknowledgement

I hereby certify being the elected family representative (executor/administrator of the estate). By voluntarily signing this form, I acknowledge that the above signed patient and family member has shared the above information with the family, allowing us to be aware of the risks and responsibilities associated with this type of therapy.

Family Representative's Name _____ Relationship: _____

Signature

Date

Time