



INFORMED CONSENT AND CONTROLLED SUBSTANCE AGREEMENT (CDC 2022 Opioid Guideline– Aligned)

PURPOSE OF TREATMENT AND INFORMED CONSENT

I acknowledge that I have been informed of my diagnosis, the purpose of opioid and/or controlled substance therapy, reasonable alternatives to opioid therapy, and the **known risks and potential benefits** of such treatment.

I understand that, consistent with guidance from the Centers for Disease Control and Prevention (CDC), opioid therapy for chronic pain is considered **only when expected benefits for pain and function outweigh risks** to the patient.

CONSENT TO TREATMENT

I voluntarily consent to evaluation and treatment by **Dr. Bharat C. Patel** and authorized providers at **Nona Spine and Pain Institute** for the management of chronic pain.

I authorize the prescribing of **Schedule II–V controlled substances**, including opioids, when clinically indicated and when non-opioid therapies alone are insufficient.

I understand that:

- Opioids are **not first-line therapy** for chronic pain
- Opioid therapy is **not intended to cure pain**, but to improve function and quality of life
- Continued prescribing depends on the **ongoing benefit outweighing the risk**

EXPECTED BENEFITS AND LIMITATIONS (CDC-ALIGNED)

I understand and agree that:

- Complete elimination of pain is **unlikely**
- Treatment success is measured by **functional improvement**, not pain scores alone
- Opioid effectiveness may decrease over time
- Dose escalation does **not guarantee improved outcomes**

RISKS OF OPIOID AND CONTROLLED SUBSTANCE THERAPY

I understand the risks include, but are not limited to:

- Sedation, dizziness, impaired cognition or coordination
- Constipation, nausea, vomiting
- Respiratory depression and overdose
- Development of tolerance and physical dependence
- Opioid use disorder (addiction)



- Withdrawal symptoms with abrupt discontinuation
- Increased risk when combined with alcohol, benzodiazepines, or sedatives
- Death

I understand I must avoid driving or operating machinery while impaired.

FEMALE PATIENT ACKNOWLEDGMENT (IF APPLICABLE)

_____ Pregnant _____ Not Pregnant

I understand that opioid exposure during pregnancy may result in:

- Neonatal opioid withdrawal syndrome (NOWS)
- Fetal exposure with uncertain long-term effects
- Transmission through breast milk

I agree to notify my physician immediately if pregnancy occurs and acknowledge that breastfeeding while using opioids is contraindicated.

DOSING AND DURATION (CDC-ALIGNED)

I understand that:

- Opioids will be prescribed at the **lowest effective dose**
- Dosages will be **carefully individualized**
- Dose increases require documented clinical justification
- Long-term opioid therapy will be continued **only if a clinically meaningful improvement** in pain and function is demonstrated

MONITORING AND RISK MITIGATION

Consistent with CDC and Florida DOH standards, I agree to:

- **Periodic reassessment** of pain, function, and adverse effects
- **Random urine and/or blood drug testing**
- **Prescription Drug Monitoring Program (PDMP)** review
- Pill counts upon request
- Review of concurrent medications to reduce overdose risk

Failure to comply may result in tapering or discontinuation.

TAPERING AND DISCONTINUATION (CDC-ALIGNED)

I understand that opioid therapy may be **tapered or discontinued** when:



- Risks outweigh benefits
- Functional improvement is not sustained
- Side effects are significant
- I fail to comply with this agreement

I understand that tapering, when indicated, will be **individualized, gradual, and medically supervised**, unless immediate discontinuation is required for safety.

CONTROLLED SUBSTANCE AGREEMENT TERMS

I agree that:

- All opioids will be prescribed by **one provider** at Nona Spine and Pain Institute
- Medications will be filled at **one pharmacy** when possible
- Medications will be taken exactly as prescribed
- Medications will not be shared, sold, or diverted
- Lost or stolen medications are **not routinely replaced**
- Early refills will not be provided
- Refills require scheduled visits during office hours

Violation may result in discontinuation or discharge.

NON-OPIOID AND MULTIMODAL CARE

I understand that chronic pain treatment may include:

- Physical therapy
- Interventional procedures
- Behavioral or psychological therapies
- Non-opioid medications

I agree to actively participate in multimodal pain management strategies.

CERTIFICATION

I certify that:

- I have read and understand this agreement
- All questions have been answered
- No guarantees have been made
- I consent voluntarily with full understanding of risks and benefits



Patient Signature: _____ Date: _____

Patient Name (Print): _____

A handwritten signature in black ink, appearing to be "B. Patel", written over a horizontal line.

Physician:

Bharat C. Patel, MD, FIPP, DABIPP