SAMPLE INFORMED CONSENT: Controlled Substance Agreement

Please read the information below carefully and ask your provider if you have any questions relating to the medication prescribed to you.

Using Controlled Medications to Treat Pain

a. These medications are used to treat moderate-to-severe pain of any type, and to treat anxiety and stress associated with moderate-to-severe pain.
b. These medications are best understood as potentially effective tools that can help reduce pain, improve function, and improve quality of life.
c. Using these medications requires that both the physician and patient work together in a responsible way to ensure the best outcome, lowest side effects, and least complications.

How Do Opioids work?

a. Opioid medications work at the injury site, the spinal cord, and the brain.
b. They dampen pain, but do not treat the underlying injury.
c. They may help to prevent acute pain from becoming persistent chronic pain.
d. These medications may work differently on different people because of a number of factors.
e. Side effects and complications will also individually vary.

How do Benzodiazepines work?

a. The benzodiazepines are a class of drugs with varying properties, which act by slowing down the central nervous system.
b. Benzodiazepines are useful in treating anxiety, insomnia, agitation, seizures, and muscle spasms. While Benzodiazepines do not treat acute or chronic pain, they are taken by patients with pain for other issues (such as anxiety or muscle spasms).
c. These medications may work differently on different people because of a number of factors.
d. Side effects and complications will also individually vary.

What to Expect When You Take Controlled Medications for Pain and Related Conditions

a. Pain relief.
b. Reduction of anxiety and stress caused by pain.
c. Side effects.

What Should Not Be Expected From Treatment with Controlled Medications

a. Cure of the underlying injury.
b. Total elimination of pain, anxiety, and stress.
c. Loss of ability to feel other physical pain.

Negative Effects of Controlled Medications Vary in Different People

1. Opioid Side effects
   a. Common effects include: Constipation, dry mouth, sweating, nausea, drowsiness, euphoria, forgetfulness, difficulty urinating, and itching.
b. Uncommon effects include: Confusion, hallucinations, shortness of breath, depression, lack of motivation

2. Benzodiazepines Side effects
   a. The most common side effects include: Clumsiness or unsteadiness, dizziness or lightheadedness and drowsiness; slurred speech
   b. Less common side effects include: Anxiety; confusion (may be more common in the elderly); fast, pounding, or irregular heartbeat; mental depression; abdominal or stomach cramps or pain; blurred vision or other changes in vision; changes in sexual desire or ability; constipation; diarrhea; dryness of mouth or increased thirst; false sense of well-being; headache; increased bronchial secretions or watering of mouth; muscle spasm; nausea or vomiting; problems with urination; trembling or shaking; unusual tiredness or weakness

3. Physical dependency
   a. Opioid medications will cause a physical dependency marked by abstinence syndrome when they are stopped abruptly. If these medications are stopped or rapidly decreased the patient will experience chills, goose bumps, profuse sweating, increased pain, irritability, anxiety, agitation, and diarrhea. The medicines will not cause these symptoms if taken as prescribed and any decision to stop these medications should be done under the supervision of your physician in a slow downward taper.
   b. Benzodiazepines may be habit-forming (causing mental or physical dependence), especially when taken for a long time or in high doses. Some signs of dependence on benzodiazepines are: A strong desire or need to continue taking the medicine; a need to increase the dose to receive the effects of the medicine. Withdrawal effects occurring; for example, irritability, nervousness, trouble in sleeping, abdominal or stomach cramps, trembling or shaking.

4. Misuse of medications: Addiction
   This is a psychological condition of use of a substance despite self-harm. Between six and ten percent of the population of the United States have problems with substance abuse and addiction. Controlled medications are likely to activate addictive behavior in this group of people

5. Diversion:
   It is illegal to share your controlled medications with other people. It is illegal to provide false information to a prescriber in an attempt to obtain controlled medication. It is illegal to doctor shop, or visit multiple doctors in attempt to obtain controlled medications. Federal and state laws exist to address diversion problems. It is critical that you safeguard your controlled medications and use them only as prescribed by your doctor.

6. Driving
   Studies of patients with chronic pain demonstrate improved driving skills when taking certain controlled medications, but individuals may have problems driving and need to realistically assess their own skills, as well as listen to others who drive with them to determine if they should be driving while taking these medications. You should consult the State Department of Transportation if you have questions about driving and taking controlled medications. This is especially important if your work involves driving, making
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important decisions that affect others, etc.

Common Sense Rules for Using Controlled Medications

a. Follow your doctor’s recommendations
b. Do not take more or less pills than prescribed without discussing this first with your physician and receiving permission to do so
c. Do not share medications with family or friends
d. Do not take medications from family or friends
e. Do not stop these medications abruptly. Dose reductions need to be discussed and cleared by your physician. This is important no matter which controlled medication you take.
f. Do not sell medications
g. Do not take medications in any manner other than prescribed. For example do not chew or inject your medications
h. Keep all medications out of reach of children
i. Do not leave your prescriptions or controlled medications lying around unprotected for others to steal and abuse them
j. Do not operate a motor vehicle if you feel mentally impaired using controlled medications. You are responsible for exhibiting good judgment in your daily affairs, including your use of controlled medications.
k. Alcohol use should be curtailed when using controlled medications

Continued Use of Controlled Medication is based on your physician’s judgment and a determination of whether the benefits to you of using controlled medications outweigh the risks of using them.

Your physician may discontinue treating you at his or her discretion. Your physician may require a consultation with an addiction specialist. Your physician may require more frequent visits.

We believe in treating your pain and we recognize the value of controlled medications in this process. When used properly, controlled medications can help restore comfort, function, and quality of life. However, as stated above, controlled medications may also have serious side effects and are highly controlled because of their potential for misuse and abuse. It is important to work with your physician and communicate openly and honestly with him or her about your pain control needs. By doing so, medications can be used safely and successfully.

By your signature below, you are acknowledging that you have read and reviewed these matters with your physician and that you have sufficient information to make a decision to use the controlled medications prescribed.

You should NOT sign this form if you do not believe you have enough information to make an informed decision about your use of controlled medications and how they fit in to your pain management treatment plan.

Patient Name: ________________________  Physician Signature: ________________________

Patient Signature: ________________________  Date: ________________________
SAMPLE PATIENT AGREEMENT: Controlled Substance Treatment

PATIENT NAME: ___________________________________________

PRIMARY CARE PHYSICIAN/SITE: ________________________________

I understand that this agreement between myself; _ and (insert name of medical office/group) is intended to clarify the manner in which chronic (long-term) controlled substances will be used to manage my chronic pain. Chronic controlled substance therapy for patients who do not suffer from cancer pain is a controversial issue.

I understand that there are side effects to this therapy; these include, but are not limited to, allergic reactions, depression, sedation, decreased mental ability, itching, difficulty in urinating, nausea and vomiting, loss of energy, decreased balance and falling, constipation, decreased sexual desire and function, potential for overdose and death. Care should be taken when operating machinery or driving a car while taking these medications. When controlled substances are used long-term, some particular concerns include the development of physical dependence and addiction. I understand these risks and have had my questions answered by my physician.

I understand that my (insert name of medical group) physician will prescribe controlled substances only if the following rules are adhered to:

• All controlled substance prescriptions must be obtained from your (insert name of medical group) primary care physician. If a new condition develops, such as trauma or surgery, then the physician caring for that problem may prescribe narcotics for the increase in pain that may be expected. I will notify my primary care physician within 48-hours of my receiving a narcotic or any other controlled substance from any other physician or other licensed medical provider. For females only: If I become pregnant while taking this medicine, I will immediately inform my obstetrician and obtain counseling on risks to the baby.

• I will submit urine and/or blood on request for testing at any time without prior notification to detect the use of non-prescribed drugs and medications and confirm the use of prescribed ones. I will submit to pill counts without notice as per physician’s request. I will pay any portion of the costs associated with urine and blood testing that is not covered by my insurance.

• All requests for refills must be made by contacting my (insert name of medical group) primary care physician during business hours at least 3-workdays in advance of the anticipated need for the refill. All prescriptions must be filled at the same pharmacy, which is authorized to release a record of my medications to this office upon request. A copy of this agreement will be sent to my pharmacy.
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• Pharmacy name/address/telephone:

• The daily dose may not be changed without my (insert name of medical group) primary care physician’s consent. This includes either increasing or decreasing the daily dose.

• Prescription refills will not be given prior to the planned refill date determined by the dose and quantity prescribed. I will accept generic medications.

• Accidental destruction, loss of medications or prescriptions will not be a reason to refill medications or rewrite prescriptions early. I will safeguard my controlled substance medications from use by family members, children or other unauthorized persons.

• You may be referred to an appropriate specialist to evaluate your physical condition.

• You may be asked to have an evaluation by either a psychiatrist or psychologist to help manage your medication needs.

• If your physician determines that you are not a good candidate to continue with the medication, you may be referred to a detoxification program or evaluation by a pain management center.

• These medications may be discontinued or adjusted at your physician’s discretion.

• I understand that it is my physician’s policy that all appointments must be kept or cancelled at least 2-working days in advance. I understand that the original bottle of each prescribed controlled substance medication must be brought to every visit.

I understand that I am responsible for meeting the terms of this agreement and that failure to do so will/may result in my discharge as a patient of (insert name of medical group). Grounds for dismissal from (insert name of medical group) include, but are not limited to: Evidence of recreational drug use, of drug diversion, of altering scripts (this may result in criminal prosecution), of obtaining controlled substance prescriptions from other doctors without notifying this office, abusive language toward staff, development of progressive tolerance, use of alcohol or intoxicants, engagement in criminal activities, etc.

______________________________  ________________________________
Patient’s Signature              Witness’ Signature

______________________________  ________________________________
Date                          Date