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Informed Consent and Policy Regarding Prescriptions of Controlled Substances

You have agreed to a trial of opioid (narcotic) treatment for your pain. Opioids include medications such as Percocet, morphine, methadone, etc. These include any medication classified as Schedule II or III by the Drug Enforcement Administration ("DEA"). The purpose of this treatment is to reduce your pain and to improve your level of function at work, at home and/or other valued activities. Alternative therapies have been explained and offered to you. You and your doctor have elected a trial of opioid therapy as only one component of treatment. It is important that you be aware of the potential risks and side effects of these medications. You need to understand that not all pain responds to narcotic medication, and that not all people react the same way to these medications. In some situations, at the discretion of your doctor, this trial may be deemed a failure and you will be discontinued from these medications.

Additionally, there are strict laws that govern use of controlled substances for medical conditions. As a condition of treatment with these medications, the governing agreement and its provisions are attached and must be agreed to in their entirety.

Physical Side Effects

Possible side effects include mood changes, drowsiness, dizziness, constipation, nausea and/or confusion. Many of these side effects, if they occur, gradually resolve over days to weeks. Constipation often persists and may require management with medications. If other side effects persist, trials of alternative opioids may be necessary or opioids may need to be discontinued. You should not drive a car or other vehicle or operate machinery while your dose is being increased or if the medication makes you drowsy. The se dating effects of alcohol and other sedatives are additive with the side effects of opioids. It is strongly advised that you avoid alcohol while receiving opioid therapy.

Physical Dependence

Physical dependence is an expected side effect of long term use of opioids if they are prescribed on a daily basis. This means that if you take opioids continuously and stop them abruptly for any reason, you will experience a withdrawal symptom. This syndrome often includes sweating, diarrhea, irritability, sleeplessness, runny nose, tearing, muscle and bone aching, a nd dilated pupils. To prevent these symptoms, medications must be taken regularly if physical dependence is present. When opioids are discontinued, they should be tapered under the supervision of your physician. Do not abruptly stop taking your prescription without consulting your physician.

Addiction

Addiction is present when an individual experiences loss of control over the use of medications, is constantly seeking drugs, and/or experiences adverse consequences as a result of drug use, yet continues to take the medication. Most patients who use opioids are able to take medications as prescribed on a scheduled basis. They do not seek other drugs when their pain is controlled, and experience improvement in the quality of life as a result of the opioid medications; thus they are NOT addicted. Physical dependence does NOT indicate addiction. Individuals with a history of alcoholism, smoking and tobacco abuse, or drug addiction may be at increased risk for the development of addiction while using opioids.

Tolerance to Medication

Tolerance to the pain-killing effects of opioid medications is possible with continuous use. This means that although there has been no physical change in the underlying condition, an increased dose of medication is required to achieve the same level of pain control experienced when the medications were initiated. We do not fully understand why, or understand under what conditions, tolerance to the pain-killing effects of opioids occurs. When it does occur, it may require tapering and discontinuation of the medication. Sometimes tolerance can be handled by substituting a different opioid medication. Additionally, you should realize that if you have to undergo surgery for any reason, you will have a baseline opioid requirement and may experience more pain in your post operative period than someone not taking these types of medication. You will need to inform your anesthetist and surgeon that you are taking these medications so that appropriate plans can be made.

Hyperalgesia

In rare cases, the opioid medications can cause pain themselves. A sign that this may be happening if rapidly increasing doses of

medication (over a matter of weeks to months) to achieve the same relief. Unfortunately, there is no blood test or other examina tion that can reveal this. If your doctor believes this may be occurring then you will be gradually tapered of <u>ALL</u> opioids.

Risk to Unborn Children

Children born to women who are regularly taking opioids will likely be physically dependent at birth, requiring expensive long-term

hospitalization. Women of childbearing age should maintain safe and effective birth control while on opioid therapy. Should you become pregnant, immediately contact your physician. The medication may be stopped.

Patient Initials:		

- 1. By signing below, you, the patient, agree to the terms and conditions of this agreement form. This agreement is a "one strike and out" agreement. Any subsequent violation of this agreement, <u>FOR ANY REASON</u>, will result in termination of opioid therapy. If the doctor feels there have been any violations of federal, state or local laws, then these violations may be reported to law enforcement officials. You agree to hold Pain Consultants of San Diego and its employees, independent contractors, and associates harmless for any adverse outcome from this action.
- 2. You will obtain opioid pain medication prescriptions only from Pain Consultants of San Diego, and agree to fill your opioid prescriptions only at a single designated pharmacy of your choice:
- 3. Your opioid medication will be continued as long as there is demonstrated improvement in your pain level and function as determined by the prescribing physician (going to work, school, etc.)
- 4. Flare-ups or exacerbation of pain will occur from time to time and will be handled with therapies such as ice, heat, TENS, or relaxation rather than additional medications.
- 5. You must be seen at least bi-monthly by the physician or physician assistant at Pain Consultants of San Diego.
 You must make an appointment in advance. Walk-in visits for medication refills are not allowed. It is your responsibility to make an appointment in advance. Our schedule is generally open 2 weeks in advance. The pain clinic will not provide early refill, and will NEVER phone in prescriptions for controlled substances under any circumstances. You will be provided a prescription only during normal clinic hours.
- 6. You are not pregnant now, and will do your best to avoid pregnancy while on this medication, realizing that there are risks to unborn children, including, but not limited to birth defects, addiction, tolerance, and the suffering of withdrawal resulting in the need for costly and prolonged hospitalization. Women of child-bearing age will undergo pregnancy screening prior to initiation of therapy and at each regularly scheduled refill visit. Should you become pregnant, opioid medications may be tapered and stopped.
- 7. You will not receive other addictive medications such as sleeping pills (Ambien, Lunesta), tranquilizers (Valium, Xanax, etc.) or stimulants (Ritalin, etc.) from other physicians without authorization from the pain clinic.
- 8. You agree to a California Department of Justice C.U.R.E.S. report upon signing this agreement, and regular, random occasions thereafter, which will be used by Pain Consultants of San Diego to measure your compliance with this agreement. You will allow your doctor to receive information from any health care provider or pharmacist about the use of possible misuse/abuse of opioids, alcohol and other drugs. You will submit a urine or blood specimen upon initiation of this agreement, and at random, regular intervals to measure compliance with this agreement.
- 9. You will take your medication exactly as prescribed. Any changes to your prescription must be discussed with your physician *prior to changing*. You will not share or sell your prescription, and will bring unused pain medication to each subsequent visit.
- 10. If you lose or misplace your prescription, you must report this to the police department and provide us with a copy of their report before a substitute prescription will be provided. If an emergency requiring opioid treatment occurs (an Emergency Room visit, for example), you will contact this office the next working day and inform us of the circumstances.
- 11. You will agree to be seen by any specialist including a psychiatrist or addictionologist at the discretion of the prescribing doctor. You will also submit to any standardized psychological assessments required by your prescribing physician, including those administered at Pain Consultants of San Diego.
- 12. You understand that your doctor will gradually take you off of your opioid medication if you do not follow the above plan, or if your doctor believes the opioids are not helping or are harming you. You expressly agree to hold Pain Consultants of San Diego and its employees, independent contractors, and associates harmless for any real or imagined consequence from this discontinuation.
- 13. You agree to hold Pain Consultants of San Diego and your prescribing doctor totally and completely harmless for any claim arising out of use of these controlled substances, including any event attributed to overdose, side effect, development of tolerance, dependence, addiction, failure to take the medication as ordered, or dissatisfaction with the level of pain control the medications afford you.
- 14. If opioid therapy is terminated, you will be provided with a de-escalating dose plan and you will be responsible to follow it. Failure to follow the de-

escalating plan may result in experiencing intense, unpleasant physical withdrawal. Should this happen, you expressly agree to hold the prescribing physician and Pain Consultants of San Diego harmless for this experience.

15. If opioid therapy is terminated, this does not necessarily mean that you will not be able to return to Pain Consultants of San Diego for non-narcotic procedures, therapies, or medication management, it just means that your trial of opioids is considered a failure. However if further treatment is determined to be acceptable by either party, you will be provided with a list of other pain management doctors in your area, in accordance with California AB1120 (Pain Patients Bill of Rights). You will then be considered discharged from the practice and the treatment considered complete, and you expressly agree this cannot be construed as abandonment.

This agreement form has been read and understood by me, and I agree to all of the above.

Signed	Patient:	 Date:	
	Physician:	 Date:	
	Witness:	 Date:	