INFORMED CONSENT AND CONDITIONS FOR TREATMENT OF CHRONIC PAIN

Basic Information

Chronic Pain - Chronic pain is a progressive disease of the nervous system, caused by failure of the body's internal pain control systems. The disease is accompanied by changes in the chemical and anatomical makeup of the spinal cord. Chronic pain is a malignancy, in the sense that when it goes untreated, it increases in intensity and spreads to areas that weren't previously affected, damaging the sufferer's health and functioning.

Goals of Treatment

1) Lowering of pain levels.
2) Reducing suffering through restoration of functioning in life activities, as close to normal as possible.
3) Arresting and reversing the damage done by chronic pain to the nervous system and overall health of the patient.

Opioids - Opioids are substances naturally produced within the body to regulate pain. They are known to the public as endorphins, which produce a state of euphoria called the runner's high. Chronic pain victims, who can't produce enough of these substances within their own bodies, often benefit from supplementation with pharmaceutical opioids.

Opioid analgesic pain medications are recognized by medical boards around the country as the cornerstone of treatment in chronic pain. Unfortunately, their use is limited by widely held, but mistaken, beliefs about their dangers, most of which are wildly overstated.

The principal opioid medications are: Morphine, Oxycodone (OxyContin), Hydrocodone (Vicodin, Lortab), Hydromorphone (Dilaudid), Methadone, Fentanyl (Duragesic, Actiq), and Codeine.

Addiction - Addiction is defined as, cravings for a substance, compulsive use, and continuing use in spite of harm. It is widely feared that exposure to opioids will lead to addiction. Research projects, such as the Boston Collaborative Study, involving over 10,000 patients treated with opioids, have revealed that this is not the case, and that addiction to opioids in pain patients is rare.

It is fairly easy to tell if a patient is addicted to opioids. If they make life better by controlling pain, he is a pain patient. If they make life worse, and use continues, addiction may be suspected. The differences are not subtle:

It is of major importance to recognize the distinction between the dysfunction that marks addiction and the improved function that marks effective pain management. Thus, **addiction and effective pain treatment have diametrically opposite endpoints and are distinguishable.**
-Dr. Scott Fishman, The Massachusetts General Hospital Handbook of Pain Management p. 499

Dependence - Dependence occurs in most patients who regularly use opioids, but is not a sign of addiction. It is a

physical reality, meaning that a patient using opioids is likely to have a flu-like withdrawal reaction if he discontinues the medication abruptly. This syndrome can be prevented, if opioids are to be discontinued, by gradually tapering the dose, rather than discontinuing the medication abruptly.

The implication of the above information is that opioids can be tried in the treatment of chronic pain, and safely withdrawn if they are not useful, or if problems arise. This is called a therapeutic trial.

Respiratory Depression/Tolerance - When an individual unaccustomed to opioids takes too large a dose it can slow or even stop breathing. But when a patient's dose of opioids is raised gradually, in a process know a titration, tolerance builds, and he can eventually take amounts that would kill a person not accustomed to these doses. Pain stimulates breathing, making respiratory depression unlikely in pain sufferers.

Tolerance also quickly develops to the "high" caused by opioids. Within as couple of days to weeks the patient returns to feeling completely normal, although he may be taking enormous doses of medication.

Getting "High" - Government sponsored research at the National Institute of Drug Abuse, has determined that the majority of people do not even enjoy opioids:

The majority of healthy non-drug-abusing volunteers **do not report euphoria** after being administered opioids in the lab either with or without pain.
Robert Mathias, NIDA NOTES Staff Writer, Research Eases Concerns About Use of Opioids To Relieve Pain, Volume 15, Number 1 (March, 2000)

Titration – This term describe the process of gradually increasing the dose of opioids until pain is controlled, and the patient reaches his best level of functioning. In patients who have been debilitated by pain for months or years, this process may go on over an extended period of time.

Many patients require a variation in their dosage from day to day, depending on their pain levels and activities. This day to day variation makes pain a moving target, which requires ongoing mini-titrations both upwards and downwards. Once a general dosage range is established, it is likely to remain stable over long periods of time.

Dosage – The range of possible doses needed to control pain varies from one patient to another, more than with any other drug in the entire field of Medicine, which means that some patients will receive dosages of a size that is staggering to the uninformed observer. Taking a higher dose has nothing to do with addiction, and does not increase danger.

The amount that allows optimal functioning is the correct dose**. There is no upper limit to the dose of opioids that can be safely used**, when the medicine is increased gradually.

Safety – Overall, opioids are the safest analgesics a doctor can prescribe. When they are used as directed, serious problems are rarely encountered.

Toxicity - Opioids are not toxic to any organ system in the body. They do no damage, even with long-term use. While an array of different side effects is possible in a patient taking any given medication, the side effect most commonly observed in opioid users, is constipation, which is easily managed. A possible exception to the statement about toxicity, is the suspicion that high dose methadone may provoke cardiac arrythmias in susceptible

individuals.

Side Effects - Opioid medications may cause a variety of side effects, including, but not limited to, nausea, vomiting, itching, dizziness, constipation, sedation dry mouth, fluid retention, weight gain, weight loss, suppression of the immune system, suppression of thyroid function, suppression of menstrual cycle, suppression of male hormone, itching, and allergic reactions.

Diversion - Opioids are dangerous when they are diverted into the hands of non-patients who intend to abuse them. These individuals are not protected against the respiratory depressant effects of opioids, by either tolerance or pain, and are likely to combine them with respiratory depressants, including alcohol and tranquilizer. The results can be tragic. The majority of deaths attributed to opioids occur in non-patients who have deliberately abused a combination of these substances.

Security - For the above reasons, the bulk of a patient's supply of opioids must be kept locked in a safe and never given, sold, or traded to anyone else.

Driving - When opioids are taken on a regular schedule, tolerance quickly develops, and the psychological "high", if there ever was one, goes away, leaving the user feeling completely normal. Long-term opioid users, as a group, have driving records for accidents and violations that are the same as everyone else's.

Pain Relief/Functioning - Opioids reliably reduce pain levels in chronic pain sufferers, however they seldom make the pain go completely away, as regularly occurs in patients with acute pain. Patients can live with this residual pain as long as their dose of opioids is titrated up to a level where they can function. This is the major benefit of opioids in chronic pain. They allow the patient to function in spite of the pain. This relieves suffering.

Death and Opioids – Deaths caused by opioids, among patients who take opioids as prescribed are virtually unheard of.

General experience suggests a death rate among chronic pain patients on opioid therapy of approximately one death per hundred patients per year from all causes. This means that patients taking opioids often die, but does not mean that opioids killed them.

Conditions of Treatment

Social, Financial, and Legal Issues

I understand that my involvement with opioid treatment will expose me to the following medical, financial, social, and legal risks, and possibly other unstated risks as well.

Patients relying on insurance reimbursement of medication expenses are subject to denial of coverage based on allegations that the treatment is not medically necessary, or that it is unconventional (not supported by the scientific medical literature) and experimental).

Chronic pain and opioid therapy may lead to family disagreement regarding the propriety or economic value of treatment, possibly resulting in divorce or estrangement from family members.

Employers or regulatory authorities may view opioid therapy as a disqualification for certain kinds of work.

Pharmacists and other health care workers may stigmatize patients on opioid therapy as addicts. Possession of opioid medications may make patients a target for robbery or police investigation.

I understand that Dr. __________ 's practice operates at the discretion of the regulatory authorities and that his licenses to practice medicine and to prescribe controlled substances may be yanked without warning. Under such circumstances, there may be no medical facility willing to continue treatment as prescribed by Dr. __________, and patients may then be subject to the risk of acute opioid withdrawal.

Addiction

I am aware that opioids have some potential to be addictive and am willing to take that risk, as long as the benefits of treatment in my situation outweigh the risks. I understand that if I do become addicted, this is a treatable condition, and I have the right to request and be referred for treatment. I am aware that addiction is defined as the continuing use of a drug or activity in spite of harm, cravings, and a decreased quality of life. I am aware that the chance of becoming addicted to my pain medicine is very low. I agree to tell my doctor my complete and honest personal drug history and that of my family to the best of my knowledge.
I agree to immediately report any psychological cravings I may experience for the substances with which I am being treated, as well as to report any adverse consequences or side effects of their use. I agree to report to Dr. ___________ any use or desire to use controlled substances for other than their intended purpose. This could include recreation, relief of stress, or getting high.

Dependence

I understand that physical dependence is an expected consequence of using opioids, and is not a sign of addiction. I understand that physical dependence on opioids means that I may have a flu-like withdrawal reaction if the medication is abruptly discontinued and that while this is seldom life threatening, it may be uncomfortable. This withdrawal reaction is preventable by tapering the dose of medication gradually, should it become necessary or desirable to discontinue treatment.

Abrupt opioid withdrawal means that I may suffer from any or all of the following: increased pain, depression, muscle cramps, irritability, nausea, vomiting, sweats, chills, 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 withdrawal is uncomfortable but not usually life threatening. In some individuals, severe withdrawal reactions may be life threatening.

I understand that these medications may be safely discontinued, when tapered slowly and that even gradual discontinuation may lead to increased sensitivity to pain. I understand that if I am pregnant or become pregnant while taking opioid medications, my child would be physically dependent on opioids at the time of birth, and withdrawal could be life threatening for the baby, if not properly managed medically.

Side Effects

I understand that opioid medications may cause a variety of side effects, including, but not limited to, nausea, vomiting, itching, dizziness, constipation, sedation, dry mouth, fluid retention, weight gain, weight loss, suppression of the immune system, suppression of thyroid function, suppression of menstrual cycle, suppression of male hormone, itching, and allergic reactions. High dose methadone is suspected of causing irregular heart beat, which can be life threatening.

Titration/Tolerance/Safety

I understand that with gradual titration and continued use I may develop a tolerance, which will allow me to take dosages of opioids that would most likely kill an opioid naïve individual, and that these large dosages are safe, as long as they are not combined with overdoses of alcohol or tranquilizers.

I understand that if I do not take opioids for a period of time, possibly as short as a few days, this tolerance can be lost, and returning directly to my previous dose can be lethal. Another gradual titration may be required.

I am aware that tolerance to analgesia means that I may require more medicine to get the same amount of pain relief. If tolerance occurs, increasing doses may or may not be effective, and may cause unacceptable side effects. On the other hand, titration is very often effective in controlling pain. The most common reason for needing a higher dose is increased physical activity. Greater pain may signal progression of an underlying disease.

Other Medical Conditions

I understand that certain chronic medical or psychiatric conditions, such as insulin-dependent diabetes, inflammatory bowel disease, sleep apnea, epilepsy, depression, and panic disorder, among others, may increase the risk of opioid therapy and complicate the process of opioid withdrawal.

Drug Interactions

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 symptoms like a bad flu, called a withdrawal syndrome. I agree not to take any of these medicines, and to tell any other doctors that I am taking an opioid as my pain medicine and can't take any of the medicines listed above.

Other Medications

I understand that opioids may be prescribed alone or in combination and that they may be supplemented with other classes of medications, such as stimulants, tranquilizers, muscle relaxants, laxatives, anti-histamines, anti-nausea medications, or anti-depressants.

I understand that the effects of sedatives, muscle relaxants, and mind-altering medications or chemicals may be dangerously increased when administered to a patient on opioid medications. I agree to inform other physicians as to which medications I am taking and to request that they consult with Dr. _____________ or his associates, regarding the co-administration of medications that may affect alertness or consciousness.

I will check with Dr. _____________ before taking any over the counter medications. Some are known to have adverse interactions with the medications I may be taking.

Unused Medication

I agree to bring any medication I will not be using, in for destruction under observation by Dr. ___________ or his staff and that this event will be noted in my chart. Medications will neveer actually be returned to the doctor.

Tylenol

I am aware that there may be a risk of liver and possibly kidney damage associated with the use of Tylenol (acetaminophen), and I understand that the risk is small except in individuals who deliberately overdose. Periodic liver function testing (GGTP) will determine if there is a potential problem, in patients using Tylenol regularly.

Alcohol/Overdose

I agree not to drink alcohol to excess, with the understanding that the majority of deaths caused by so called opioid overdoses actually occur in combination with overdoses of alcohol and other central nervous system depressants such as Valium, Xanax, and barbiturates.

Marijuana (In the states where this applies)

I agree not to use marijuana without the approval or recommendation of a licensed physician, and then only for medicinal purposes.

Pharmacy

I agree to fill all my prescriptions at only one pharmacy, whenever this is possible, because this promotes a better quality of care.

Other Providers

I agree to report any contact with other health care providers to Dr. ____________, including visits to the emergency room and encounters with mental health care providers.

Storage of Medications

I agree to keep my medication in a safe, except for what I may carry to be used throughout the day. I will provide proof of this in the form of a receipt for the purchase of a safe, or a picture of the safe itself. This provision is to keep medication from falling into the wrong hands, where it can be dangerous.

Social Responsibility

With the understanding that opioid treatment for chronic pain remains controversial, I agree to represent the issue well by being a good and productive citizen. If I remain too disabled to maintain or return to full time employment I will at least engage in some socially productive activity, such as volunteer work.

Senate Bill 402 (California Patients)

I have been informed as a patient with chronic intractable pain, in accordance with California law, that if Dr. __________ chooses not to treat me with opioid pain medication, there may be other doctors who will.

(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 term 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 a mother is on medications.

(Males only)

I am aware that chronic opioid use has been associated with low testosterone levels. This may affect 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.

Illicit Drug Use/Reporting

I agree not to participate in the use of, or any activity involving illegal drugs and to inform Dr. ____________ if I become aware that any of his other patients are involved in these activities. If I happen to use illegal drugs or abuse any substance I will inform Dr. ________________ immediately so that appropriate treatment can be arranged.

Drug Screening

I agree to random drug screening. I authorize this clinic to test my blood, urine, or hair, for the presence of illicit substances and non-prescribed medications, without prior notice, and agree to submit to psychiatric or drug abuse evaluation should the clinic staff request it.

Diversion

I agree not to sell, give, trade, or otherwise transfer any controlled substance to any other individual, as this activity constitutes a sale of drugs, and is a felony. I further understand that if someone were to die as the result of such a transaction I could be charged with manslaughter or even murder, as well as drug dealing.

Snitching

I am aware that the government routinely engages patients to testify against pain doctors and others whom they suspect of being drug "kingpins". I agree to immediately disclose any concerns to Dr. ___________, if I feel that he is simply prescribing drugs for profit, or doing anything else improper, and to leave his practice immediately if I am not satisfied that he is engaged in the good faith practice of medicine. In agreeing to this, I am making it clear that if I attempt to make such assertions at a later date, I have simply been set up to do this because of other trouble I have gotten myself into, and that whatever I say along these lines is likely to be entirely contrived and self serving.

Treatment Adherance

I agree to comply with all orders for lab testing, xrays, and treatment, and to notify Dr. __________ if there is some reason I cannot follow through with any aspect of my care in a timely fashion.

Pill Counts

I agree to unannounced counts of my medication.

Law Enforcement

I agree to report any arrests, convictions, or other contact with law enforcement to Dr. ____________.

Integrity

I agree not to lie to Dr. ____________ or to withhold any information, which might impact my treatment or his practice.

Dangers/Driving

I understand that the medications used to treat pain may impair alertness and coordination, primarily during the days following the introduction of a new medication, or when a dose has been recently increased.

I will not be involved in any activity that may be dangerous to me or someone else if I feel drowsy or am not

thinking clearly. Such activities include, but are not limited to: using heavy equipment or a motor vehicle, working at unprotected heights, or being responsible for another individual who is unable to care for himself or herself.

It is illegal to operate a motor vehicle while the ability to drive is impaired by medication, and I agree to comply with such prohibition.

Privacy
I give my consent for Dr. ____________ to discuss my care with other practitioners and pharmacists who are, or who have been involved in my treatment. This consent will be in force until revoked in writing.

With the understanding that pain and its treatment are issues that involve entire families, I give consent for Dr. ____________ to discuss my treatment with my family members. This consent will be in force until revoked in writing.

Nature of the Treatment Alliance
I understand that I am entering into a progressive doctor patient relationship, based on the concepts of teamwork and shared decision making, and that such a relationship requires my informed participation. I will do my best to remain informed, and to continue to learn about all aspects of pain management, in order to participate actively and productively in my care.

Exclusivity
I agree not to obtain pain medications from any provider other than Dr. ________ except on an emergency basis, and if this occurs, I will notify Dr. ____________ at the first opportunity.

Reciprocity
I understand that the above clause conversely entitles me to pain management sufficient to assure my optimum functioning, and that I will be expected to report accurately on the effects of my treatment,. This will include level of functioning, side effects, and whether or not I am receiving enough pain medication to reach treatment goals.

Understanding
I have read this form or have had it read to me, and I understand all of it. I have had all of my questions regarding this treatment answered to my satisfaction.

Termination
This agreement may be terminated by either party at any time and for any reason.

Informed Consent

I have suffered from chronic pain for ____ years.

The decision to attempt this form of treatment was made because my condition is serious, and other approaches have not cured my pain. These include:
Surgery __, Physical Therapy __, TENS __, Biofeedback __, Pain Clinic __, Implantable Device __, Relaxation Techniques __, Other Modalities____
____.

I understand that opioid treatment for chronic pain is the subject of social controversy. There is significant disagreement regarding the propriety and morality of this treatment, in spite of the fact that the scientific literature on this subject makes it clear that there is a subset of patients suffering from chronic pain who appear to do quite well on this treatment, but no other. I believe that I am among those who can benefit from this treatment.

I understand that the doses of medication prescribed are likely to be significantly higher than doses customarily prescribed for short-term pain management, and that other physicians, pharmacists, and medical facilities unaccustomed to this treatment may object, and refuse to continue this treatment, should I choose or need seek it elsewhere.

By signing this agreement, I voluntarily give my informed consent for the treatment of chronic pain with opioid pain medications.

Signatures:

________________________	____________________
(Patient)	(Date)
________________________	____________________
(Doctor)	(Date)

Spouses and Family Members

1. I have read and understood the above information concerning treatment of chronic pain with opioid analgesic medication.

2. I am in agreement with of the conditions of treatment listed above, and further agree to inform Dr. _____________ immediately if I become aware that any of them are being violated.

3. I specifically understand that chronic pain is a disease of the nervous system, which carries serious and progressive adverse health consequences for the victim, when allowed to progress unchecked.

4. I understand that addiction is a psycho-behavioral disorder, involving cravings for a substance or activity along with self-destructive behavioral manifestations including repeated use of the substance or activity in spite of adverse consequences. I am particularly aware of the low incidence of addiction to opioid medications in pain patients, and I understand the difference between dependence and addiction.

5. I am also aware of the low incidence of respiratory depression in pain patients who use opioids, and aware of the facts that patients are protected against this occurrence by their pain, which stimulates respiration, as well as by tolerance developed through regular use of opioids. I understand that if a patient combines their opioid medication with overdoses of alcohol or tranquilizers, there is significant risk of respiratory depression and death, and that the vast majority of opioid related deaths occur in this fashion, in non-patients.

6. I am aware that Dr. _____________ is available to answer any questions or concerns not fully explained by the above information, and I have availed myself of that opportunity to my own satisfaction prior to signing this document.

7. I agree to notify Dr. __________________ immediately if any problems occur or if I develop any reservations or questions about this treatment in the future.

8. With the above facts and conditions in mind, I comfortable with the idea of ________________________ participating in a comprehensive pain management program which may include the use of opioids, as well as a variety of other medications and treatment modalities.

9. This document is accompanied by a copy of my photo ID.

Relationship to Patient: ________________________

Printed Name: ________________________

Age: ____

DOB: ____ ____ ____

SS#: ______ ____ ________

Address: __________________________

____

____

Telephone: ______ ______ ________

Signatures: ___________________________ __________________

(Family Member) (Date)

________________________________ _____________________

(Doctor) (Date)

Next: Testimonial Letter Form

Comments/Opinions
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