CONSENT TO TREATMENT WITH BUPRENORPHINE

Buprenorphine is an FDA-approved medication for office-based treatment of opiate dependence. Qualified physicians can treat up to 275 patients at any given time for this indication. It may be used for either detoxification or maintenance therapy. It may also be used for the treatment of chronic pain. Maintenance therapy can be continued for as long as medically necessary.

Buprenorphine is classified as a partial agonist at the mu opioid receptor. As such, there is what is referred to as a "ceiling effect" with this medication. This means that above a certain dose (usually 32 mg. /day) no additional drug effect can be derived. This is one of the reasons it has such a low abuse potential. An agonist is a drug which attaches to a receptor site on a cell membrane and activates it. An antagonist is one which attaches to the receptor site but not only fails to activate it, but also blocks the site so that an agonist cannot attach. Whether buprenorphine acts as an agonist or an antagonist will depend upon the state of the patient relative to use of other opioid medications.

Acts as an agonist:
Condition #1 – The patient is opioid-neutral (has no opioid drugs in the system, and is not in opioid withdrawal) Expected result: Relief of drug craving, relief of pain.
Condition #2 - The patient is in active opioid withdrawal. Expected result: Relief of withdrawal symptoms. (Note: Because of the ceiling effect, patients withdrawing from methadone above 30 mg. /day, or extremely high dose of other opioids, may not obtain adequate relief from their withdrawal symptoms.)

Acts as an antagonist:
Condition #1 – The patient is currently dependent upon an opioid drug and takes buprenorphine. Expected result: Precipitation of immediate opioid withdrawal.
Condition #2 – The patient is currently taking buprenorphine for maintenance therapy, and takes an opioid drug. Expected result: The second drug is blocked and has no euphoric, or "high" effect. However, pain relief is not blocked.

Buprenorphine is itself an opiate drug, being derived from thebaine, a substance found in the opium poppy plant. As with any opiate, it does cause physical dependency with prolonged treatment. While withdrawal symptoms will occur with abrupt discontinuation, they will generally be less severe than with withdrawal from pure mu agonists such as oxycodone, methadone, or heroin. Typical withdrawal symptoms include muscle aches, stomach cramps, diarrhea, chills, sweats, restlessness, insomnia, muscle twitching, runny nose, nausea, and vomiting. Symptoms may last several days. To minimize such symptoms, buprenorphine should be discontinued under medical supervision.

Patients currently dependent upon opioid medications must be experiencing withdrawal symptoms before taking their first dose of buprenorphine, whether for detoxification or for maintenance. Some patients find that it can take several days of transition to get comfortable with the new medication. During that time any use of other opioid drugs may cause an increase in symptoms.

Once a patient has been stabilized on buprenorphine, the effect of other opioid drugs is blocked. An attempt to override the blockade with high doses of drugs is dangerous and may be fatal. Likewise, combination of buprenorphine with other mood-altering drugs (for example: alcohol, tranquilizers, sleeping pills, muscle relaxants) is a dangerous practice. Fatalities have occurred. Use of alcohol or any

illicit substance (for example: marijuana, cocaine, methamphetamine) is not allowed while in treatment and may be grounds for discharge from care.

Buprenorphine for use in addiction treatment is dispensed in several formulations: sublingual tablet form, sublingual film, and buccal film (the inside of the cheek). The products are designed to dissolve in the mouth and be absorbed through the lining of the mouth.. They must not be swallowed whole like most medications. If this occurs, the drug will be inactivated by the body and most of it will be lost. Place the tablet or film under the tongue (or in the case of the buccal film, against the inside of the cheek) and let it dissolve. Make sure your mouth is not dry before inserting the product. It should dissolve fairly quickly. After 3 to 5 minutes the remaining grit, if any, and saliva may be either spit out or swallowed. The film will dissolve completely. The medication is absorbed through the lining of the mouth, and from there into the bloodstream over the next 30 to 120 minutes.

Buprenorphine is dispensed together with another drug, naloxone, as products branded *Suboxone*, Bunavail, or Zubsolv. Naloxone, an opioid antagonist, is included in the formulation to prevent intravenous use of the product. By the sublingual route, naloxone is not absorbed to any appreciable extent, so when taken as directed, it has no effect. However, if the product were to be injected intravenously, it would precipitate an acute withdrawal syndrome. There is a form of buprenorphine produced without the naloxone, called *Subutex. Subutex* is available in tablet form only. This is generally only prescribed for pregnant or nursing women, and because of its increased abuse potential, we seldom prescribe it otherwise.

Buprenorphine is covered by most prescription drug plans. Some plans may require prior approval which can take 1 to 3 days. Be prepared to buy enough medication out of your own funds if necessary in order to be sure to have medication available when you need it. An average daily dose can be from $5 to $25 or more, depending on dose and whether you have coverage.

Using buprenorphine by itself is not a cure for opioid dependency. It is most useful when combined with counseling, attendance at mutual help groups such as Narcotics Anonymous, and lifestyle modifications. It also is not for everybody. Be sure to discuss all your concerns with your doctor.

The length of time a patient stays on buprenorphine maintenance depends on many factors. Because it is a proven relapse prevention tool, it stands to reason that the risk of relapse might increase at any point that the medication is discontinued. However, with participation in a comprehensive rehabilitation program, patients can learn to experience life in a new way, and develop coping and stress management skills which will comfortably sustain them in life without any further medication support. There is no research which has established exactly when the right time is to stop. This decision must be made in partnership with the prescribing physician.

Since buprenorphine may interact with, or interfere with the action of other medications, patients must make all other medical or dental providers aware that they are taking it. We will be happy, with your permission, to discuss your situation with your doctor or dentist whenever necessary. If your doctor has prescribed a new medication for you, it is always a good idea to call our office to make certain that it is safe for you to take. It is also wise to carry a card with you indicating that you are taking this medication in case you require emergency medical services.

Since buprenorphine is potentially a drug of abuse, you must be accountable to us for your medication. You must bring your medication with you to each appointment so that we can count them and be

satisfied that they are being taken as directed. Under no circumstances are you to give or sell them to others. This is a felony. We may drug test you from time to time, either at the time of a scheduled appointment, or at random times otherwise. If we call you for a random drug test, you are expected to either come to the office or go to an off-site collection facility that has the capacity for witnessed specimen collection. If we call you for a drug screen, we expect you to respond within 8 hours. Likewise, we may call you to come to the office so that we can count your pills. If we call, we expect you to come in the same day.

Medical treatment with buprenorphine is a privilege and carries with it responsibilities. Patients who violate this agreement may be referred for detoxification or to another treatment program. If you refuse such a referral, you may be discharged from our care. This would mean that we will not provide you with more medication or other treatment services. Please be reminded that sudden discontinuation of buprenorphine treatment is likely to lead to opioid withdrawal. An attempt on your own to self-medicate the withdrawal syndrome could be dangerous, and cause among other outcomes, accidental overdose and death.

It is your responsibility to keep your fees current for treatment services. We will make every reasonable effort to work with you as far as your insurance is concerned. Failure to keep your payment for services current is considered non-compliance with treatment, and may be grounds for discharge from our care.

Lost, misplaced, or stolen medications will not be replaced. You may be referred to detoxification should a shortage occur. Always keep your medication in a safe place, in the original prescription bottle, and out of reach of children, pets, or people who may not be trustworthy. We recommend keeping all medications of this type in a locked container. Medications taken with you, away from your home, must be carried in a container with the original pharmacy label, in order to be in compliance with the law.

All medications that affect the central nervous system, including buprenorphine, may cause drowsiness, and may impair a person's ability to safely operate a motor vehicle or other dangerous machinery. Always be certain that you are completely alert and have your complete faculties before driving or operating machinery.

Women who take buprenorphine should take precautions to prevent an unplanned pregnancy. If you discover that you are pregnant, inform your doctor immediately. Do not stop the medication without discussing this with your doctor.

Signature_____ Print name_____

Witnessed_____ Date_____