R.O.A.D. To A Better Life

Vivitrol Treatment Consent and Agreement

I. Vivitrol Medication Guide:

VIVITROL® (viv-i-trol) (naltrexone for extended-release injectable suspension)
Read this Medication Guide before you start receiving Vivitrol injections and each time you receive an injection. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.
What is the most important information I should know about Vivitrol?

Vivitrol can cause serious side effects, including:

1. Risk of opioid overdose. You can accidentally overdose in two ways.

•Vivitrol blocks the effects of opioids, such as heroin or opioid pain medicines. Do not take opioids, including opioid-containing medicines, such as heroin or prescription pain pills, to try to overcome the opioid blocking effects of Vivitrol. This can lead to serious injury, coma, or death.

•After you receive a dose of Vivitrol, its blocking effect slowly decreases and completely goes away over time. If you have used opioid street drugs or opioid-containing medicines in the past, using opioids in amounts that you used before treatment with Vivitrol can lead to overdose and death. You may also be more sensitive to the effects of lower amounts of opioids:

- ◦ after you have gone through detoxification
- ◦ when your next Vivitrol dose is due
- ◦ if you miss a dose of Vivitrol
- ◦ after you stop Vivitrol treatment

It is important that you tell your family and the people closest to you of this increased sensitivity to opioids and the risk of overdose. You or someone close to you should get emergency medical help right away if you:

•have trouble breathing •become very drowsy with slowed breathing
•have slow, shallow breathing (little chest movement with breathing)
•feel faint, very dizzy, confused, or have unusual symptoms

2. Severe reactions at the site of the injection (injection site reactions).

Some people on Vivitrol have had severe injection site reactions, including tissue death (necrosis). Some of these injection site reactions have required surgery. Call your healthcare provider right away if you notice any of the following at any of your injection sites: • intense pain • blisters • a dark scab • the area feels hard
• an open wound • lumps • large area of swelling

Tell your healthcare provider about any reaction at an injection site that concerns you, gets worse over time, or does not get better by two weeks after the injection.

3. Sudden opioid withdrawal.

Anyone who receives a Vivitrol injection must not use any type of opioid (must be opioid-free) including street drugs, prescription pain medicines, cough, cold, or diarrhea medicines that contain opioids, or opioid dependence treatments, buprenorphine or methadone, for at least 7 to 14 days before starting Vivitrol. Using opioids in the 7 to 14 days before you start receiving Vivitrol may cause you to suddenly have symptoms of opioid withdrawal when you get the Vivitrol injection.
Sudden opioid withdrawal can be severe, and you may need to go to the hospital. You must be opioid-free before receiving Vivitrol unless your healthcare provider decides that you don't need to go through detox first. Instead, your doctor may decide to give your Vivitrol injection in a medical facility that can treat you for sudden opioid withdrawal.
4. Liver damage or hepatitis. Naltrexone, the active ingredient in Vivitrol, can cause liver damage or hepatitis. Tell your healthcare provider if you have any of the following symptoms of liver problems during treatment with Vivitrol:

• yellowing of the whites of your eyes • dark urine
• stomach area pain lasting more than a few days • tiredness

Your healthcare provider may need to stop treating you with Vivitrol if you get signs or symptoms of a serious liver problem.

What is Vivitrol?

Vivitrol is a prescription injectable medicine used to:

• treat alcohol dependence. You should stop drinking before starting Vivitrol.
• prevent relapse to opioid dependence, after opioid detoxification. This means that if you take opioids or opioid-containing medicines, you must stop taking them before you start receiving Vivitrol.

To be effective, treatment with Vivitrol must be used with other alcohol or drug recovery programs such as counseling. Vivitrol may not work for everyone.

Who should <u>not</u> receive Vivitrol?

Do **not** receive Vivitrol if you:

• **are using or have a physical dependence on opioid-containing medicines or opioid street drugs**. To see whether you have a physical dependence on opioid-containing medicines or opioid street drugs, your healthcare

provider may give you a small injection of a medicine called naloxone. This is called a naloxone challenge test. If you get symptoms of opioid withdrawal after the naloxone challenge test, do not start treatment with Vivitrol at that time. Your provider may repeat the test after you have stopped using opioids to see whether it is safe to start Vivitrol.

• **are having opioid withdrawal symptoms.** Opioid withdrawal symptoms may happen when you have been taking opioid-containing medicines or opioid street drugs regularly and then stop. **Symptoms of opioid withdrawal may include:** anxiety, sleeplessness, yawning, fever, sweating, teary eyes, runny nose, goose bumps, shakiness, hot or cold flushes, muscle aches, muscle twitches, restlessness, nausea and vomiting, diarrhea, or stomach cramps. Tell your healthcare provider if you have any of these symptoms before taking Vivitrol.

• are allergic to naltrexone or any of the ingredients in Vivitrol or the liquid used to mix Vivitrol (diluent).

What should I tell my healthcare provider before receiving Vivitrol?

Before you receive Vivitrol, tell your provider if you:

• have liver problems • have kidney problems • use or abuse street (illegal) drugs
• have hemophilia or other bleeding problems • have any other medical conditions
• are pregnant or plan to become pregnant. It is not known if Vivitrol will harm your unborn baby.
• are breastfeeding. It is not known if Vivitrol passes into your milk, and if it can harm your baby. Naltrexone, the active ingredient in Vivitrol, is the same active ingredient in tablets taken by mouth that contain naltrexone. Naltrexone from tablets passes into breast milk. Talk to your doctor about whether you will breastfeed or take Vivitrol. You should not do both.

Tell your healthcare provider about all the medicines you take,

including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take any opioid-containing medicines for pain, cough or colds, or diarrhea. If you are being treated for alcohol dependence but also use or are addicted to opioid-containing medicines or opioid street drugs, it is important that you tell your healthcare provider before starting Vivitrol to avoid having sudden opioid withdrawal symptoms when you start Vivitrol treatment. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive Vivitrol?

• Vivitrol is injected by a healthcare provider, about 1 time each month.
• Vivitrol is given as an injection into a muscle in your buttocks using a special needle that comes with Vivitrol.
• After Vivitrol is injected, it lasts for a month and it cannot be removed from the body.
• If you miss your appointment for your Vivitrol injection, schedule another appointment as soon as possible.
• Whenever you need medical treatment, be sure to tell the treating healthcare provider that you are receiving Vivitrol injections and mention when you got your last dose. This is important because Vivitrol can also block the effects of opioid-containing medicines that might be prescribed for you for pain, cough or colds, or diarrhea.
• Carry written information with you at all times to alert healthcare providers that you are taking Vivitrol, so that they can treat you properly in an emergency. Ask your healthcare provider how you can get a wallet card to carry with you.

What should I avoid while receiving Vivitrol?

Do not drive a car, operate machinery, or do other dangerous activities until you know how Vivitrol affects you. Vivitrol may make you feel dizzy and sleepy.

What are the possible side effects of Vivitrol?

Vivitrol can cause serious side effects, including:

• **Depressed mood.** Sometimes this leads to suicide, or suicidal thoughts, and suicidal behavior. Tell your family members and people closest to you that you are taking Vivitrol. You, a family member, or the people closest to you should call your healthcare provider right away if you become depressed or have any of the following symptoms of depression, especially if they are new, worse, or worry you:

• You feel sad or have crying spells. • You feel hopeless or helpless.
• You have trouble paying attention • You feel tired or sleepy all the time
• You are more irritable, angry, or aggressive than usual.
• You are no longer interested in seeing your friends or doing things you used to enjoy.
• You are sleeping a lot more or a lot less than usual.
• You are more or less hungry than usual or notice a big change in your body weight.
• You have thoughts about hurting yourself or ending your life.

• **Pneumonia.** Some people receiving Vivitrol treatment have had a certain type of pneumonia that is caused by an allergic reaction. If this happens to you, you may need to be treated in the hospital. Tell your healthcare provider right away if you have any of these symptoms during treatment with Vivitrol:

• shortness of breath or wheezing • coughing that does not go away

• **Serious allergic reactions.** Serious allergic reactions can happen during or soon after an injection of Vivitrol. Tell your ROAD provider or get medical help right away if you have any of these symptoms of a serious allergic reaction.

• skin rash • chest pain • trouble breathing or wheezing
• feeling dizzy or faint • swelling of your face, eyes, mouth, or tongue

Common side effects of Vivitrol may include:

- nausea. Nausea may happen after your first Vivitrol injection and usually improves within a few days. Nausea is less likely with future injections of Vivitrol.
- sleepiness • headache • dizziness • trouble sleeping • decreased appetite
- toothache • painful joints • muscle cramps • cold symptoms • vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the side effects of Vivitrol. For more information, ask your ROAD provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **General information about Vivitrol:** For more information about Vivitrol, call 1-800-848-4876, Option #1 or go to **www.vivitrol.com.**

What are the ingredients in Vivitrol? Active ingredient: naltrexone Inactive ingredient: polylactide-co-glycolide (PLG) Diluent ingredients: carboxymethylcellulose sodium salt, polysorbate 20, sodium chloride, and water for injection.

II. Vivitrol Patient Treatment Counseling and Treatment Agreement:

Patient Initial Each Item:

_____1. I understand the frequency of **visits** will be weekly at first and then biweekly. As my recovery progresses, with the completion of group therapy/IOP and maintenance of individual psychotherapy, my visits may extend out to 4 weeks. I understand that if I relapse or miss appointments then I will return to weekly visits until assurance in my recovery is reestablished. I must call 24 hours prior to canceling an appointment. If I miss an appointment without contacting my provider (ROAD provider): I may be asked to return to more frequent visits, may not have my medication refilled until I am seen again, and I may be discharged. I understand that if I am not seen in the office as prescribed by my provider, I will be unable to obtain my prescription since the injection is coordinated with monthly visits.

_____2. I agree to have my Vivitrol Rx mailed directly to the ROAD facility or to bring it directly from the pharmacy after picking it up, in its original packaging, without signs of tampering. It will be injected or stored for my future use due to storage and refrigeration requirements.

_____3. I agree not to take any **other medications** with Vivitrol without prior permission from my ROAD provider.

_____4. I understand that **goal of treatment** for alcohol and opioid dependency is to learn to live without abusing alcohol and drugs. Vivitrol injections should continue as long as necessary to prevent relapse and then stopped

_____5. I will submit a **urine specimen** (my own urine) for drug screen (narcotic, pot, cocaine, amphetamine, PCP, alcohol, benzodiazepine, and others) upon my providers request as often as directed. My provider may ask that a clinical staff member observe me providing the appropriate specimen. If my drug screen indicates the presence of illegal/inappropriate substances, I may be discharged.

_____6. I understand that if I have previously used opioids, I may be more **sensitive to lower doses of opioids** and at risk of accidental overdose if I use opioids when my next dose is due, if I miss a dose, or after Vivitrol treatment is discontinued. It is important that I inform family members and people close to me of this increased sensitivity to opioids and the risk of overdose. I understand that because Vivitrol can block the effects of opioids, I may not perceive any effect if I self-administer heroin or any other opioid drug in small does while on Vivitrol. Further, I understand that administration of doses of heroin or any other opioid to try to bypass the blockade and get high while on Vivitrol may lead to serious injury, coma, or death. I understand that overdose deaths have occurred in the cases where opioid tolerant patients have tried to "over ride" the blocking action of Vivitrol with larger doses of opioids (even at doses previously tolerated).

_____7. I understand that I may not experience the expected effect from **opioid-containing** analgesic, antidiarrheal, or other antitussive (anti-cough) medications.

_____8. I understand that a **reaction at the site of Vivitrol injection** may occur. Reactions include pain, tenderness, induration, swelling, redness, bruising and itching. Serious injection site reactions including tissue death may occur. Some of these injection site reactions have required surgery. I should seek medical attention for worsening skin reactions.

_____9. I understand that I need to be off all opioids, including opioid-containing medicines, for at least 7-14 days before starting Vivitrol in order to avoid precipitation of **opioid withdrawal**. If I am transitioning from buprenorphine or methadone, I may be at risk for withdrawal for as long as two weeks. I understand that withdrawal caused by an opioid antagonist (Vivitrol) may be severe enough to require hospitalization if I have not been opioid-free for a sufficient number of days, and the withdrawal is different from the experience of spontaneous withdrawal that occurs with discontinuation of opioid in a dependent individual. I am not to take Vivitrol if I have any symptoms of opioid withdrawal. I understand that it is absolutely imperative that I notify my healthcare provider of any ALCOHOL dependence or of any recent use of opioids, or any history of opioid dependence before starting Vivitrol in order to avoid precipitation of opioid withdrawal.

_____10. I understand that Vivitrol may cause **liver injury** and I need to notify my healthcare provider if I develop symptoms and or signs of liver disease.

_____11. I understand that I may experience **depression** while taking Vivitrol. It is important that I inform family members and people close to me that I am taking Vivitrol and that they should call a doctor right away if I become depressed or experience symptoms of depression.

_____12. I understand that Vivitrol may cause an allergic **pneumonia**. I should immediately notify my physician if I develop signs and symptoms of pneumonia, including shortness of breath, coughing or wheezing.

_____13. I understand that I may experience **nausea/vomiting** following the initial injection of Vivitrol. These episodes of nausea tend to be mild and subside within a few days post-injection. Nausea is less likely with subsequent injections. I may also experience tiredness, headache, vomiting, decreased appetite, painful joints and muscle cramps.
_____14. I understand that **dizziness or fainting** may occur with Vivitrol treatment and I should avoid driving or operating heavy machinery until I have determined how Vivitrol affects me.
_____15. I understand **other side effects** include muscle cramps, somnolence or sedation, anorexia, decreased appetite or other appetite disorder, an elevation in eosinophils which resolves over time (and in rare instances eosinophilic pneumonia), inflammation of my nose and throat, insomnia, and toothache.
_____16. I understand that Vivitrol is **contraindicated** in individuals with acute hepatitis or liver failure, fulminent AIDS, opioid positive drug screens and any individual who have previously exhibited hypersensitivity to naltrexone, PLG (polylactide-co-glycolide), carboxymethylcellulose or any other component of the diluent.
_____17. I understand that once Vivitrol is injected, it is **not possible to remove it from my body**.
_____18. I understand that the use of Vivitrol is a form of **Medication Assisted Therapy** (MAT) helping me stay sober while I receive the appropriate psychotherapy needed for long term recovery. Vivitrol has been shown to treat alcohol and opioid dependence only when used as part of a treatment program that includes counseling and support. I will be required to attend AA meetings (with proof of attendance) and group therapy or IOP here at ROAD
_____19. I understand that I am to notify my ROAD provider if I am **breast-feeding**, if I **become pregnant**, if I think I might be pregnant, or if I am thinking about becoming pregnant.
_____20. I allow my provider to **communicate with other providers** regarding my medical care, consistent with HIPAA guidelines. Treatment disclosure may include, but is not limited to, discussing my medications with the pharmacist. I understand that records released may contain information pertaining to psychiatric treatment and/or treatment for alcohol and/or drug dependence. These records may contain confidential information about communicable diseases including Hepatitis, HIV(AIDS) or related illnesses.
_____21. I will **never alter a prescription** in ANY way. I understand this is a felony, punishable by incarceration.
_____22. I authorize ROAD and my pharmacy to cooperate fully with any city, state, or federal law enforcement agency, including New Hampshire's Board of Pharmacy and the DEA, in the investigation of any possible misuse, prescription forgery, sale or any other diversion of my medication.
_____23. I allow ROAD to receive information from any pharmacy I have used.
_____24. I understand that **rude or disrespectful treatment of staff** is not tolerated and may result in my discharge. (Ex: using profanity, raising my voice, making vulgar or inappropriate comments).
_____25. I understand that I must provide a viable **contact** number at all times (and will update the office of any changes) or my provider may not prescribe medications.
_____26. I understand the **commitment** to the program and the many appointments, therefore transportation cannot be an issue or a reason for short notice cancellations or no show appointments.
_____27. Regarding **alcohol**: I understand that I am required to not have used alcohol or alcohol containing products for the past 4 days and that I am not having any signs of Delerium Tremens (DT's). I understand that DT's may be life threatening and if any signs occur I will call 911.
_____28. Regarding **opioids**: I understand that **I must be opioid drug free (detoxed) for 7 days and for 14 days detoxed from Methadone and Buprenorphine.** If I am not detoxed than the Vivitrol injection **will** precipitate immediate and sometimes severe opioid withdrawal (to include but not limited to nausea, vomiting, muscle cramps, tremors, headache and sweating).
_____29. I understand that I need to **carry documentation** to alert medical personnel to the fact that I am taking Vivitrol (naltrexone for extended-release injectable suspension). This is important information if I need to obtain medical treatment in an emergency and am unable to tell other health care providers that I am on Vivitrol.. I agree to wear a medical alert (card, bracelet, dog tags).

I have read and understand all the information about Vivitrol treatment. I have received answers to any questions I have. I agree that I am responsible to abide by these instructions. I wish to be treated with Vivitrol.

Name _____ Date of Birth _____

Pharmacy _____ Town _____ Phone _____

Primary Care Provider _____ Town _____ Phone _____

Patient Signature _____ Patient Initials:_____ Date _____

I, the Provider, have reviewed Vivitrol risks and side effects with the patient.

Provider Signature _____ Date _____

One copy of this form is given to the patient after signing.