**XXXX Pharmacy Name LOGO**

XXXX Address

Phone: XXX Fax: XXX

**INFORMED CONSENT AND WAIVER OF LIABILITY FOR**

**VIVITROL® (naltrexone for extended-release injectable suspension) INJECTIONS**

This Informed Consent and Waiver of Liability (this “**Consent and Waiver**”) has been prepared to provide you with information regarding the risks and side effects of VIVITROL® injections*.* It is important that you read this information carefully and completely. Please discuss any questions you may have with, or request any additional information you need from, the pharmacist, nurse or your physician. Once you have read and understand this information, and had any questions addressed to your satisfaction, please sign and date this Consent and Waiver. ***Do not sign this Consent and Waiver and do not receive an VIVITROL injection if you have questions about or do not understand the information you have received or are not comfortable assuming the risks that may be associated with VIVITROL.***

Patient’s Name DOB / / Street Address City State Zip Code

**PROPOSED TREATMENT**

VIVITROL (naltrexone for extended-release injectable suspension) is a prescription medicine given by injection by a pharmacist, nurse, or healthcare provider and is used for treating alcohol dependence. You should stop drinking before starting VIVITROL. It is also used to prevent relapse to opioid dependence, after opioid detoxification.

**SIDE EFFECTS AND COMPLICATIONS**

VIVITROL may cause serious side effects, including:

** Risk of opioid overdose.** You can accidentally overdose in two ways.

1. VIVITROL blocks the effects of opioids, such as heroin or opioid pain medicines. Do not try to overcome this blocking effect by taking large amounts of opioids—this can lead to serious injury, coma, or death.
2. 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

Tell your family members and people closest to you of this increased sensitivity to opioids and the risk of overdose.

** Sudden opioid withdrawal.** Sudden opioid withdrawal can be severe and may require hospitalization. To avoid this, you must stop taking any type of opioids including street drugs, prescription pain medicine, opioid containing medication, buprenorphine, and methadone for at least 7 to 14 days before starting VIVITROL. If your healthcare provider decides that a detox isn’t needed, he or she may give you VIVITROL in a medical facility that can treat sudden withdrawal.

** Injection site reactions.** Some people on VIVITROL have had severe injection site reactions, including tissue death. Call your physician right away if you notice any of the following at your injection site:

* Intense pain
* Area feels hard
* Large areas of swelling
* Lumps and/or blisters
* An open wound
* A dark scab

** Liver damage or hepatitis.** Naltrexone, the active ingredient in VIVITROL, can cause liver damage. Contact your healthcare provider if you experience any of these symptoms:

* Stomach area pain lasting more than a few days
* Dark urine
* Yellowing of the whites of your eyes
* Tiredness

** Depressed mood and/or suicidal thoughts.** Tell your family members and people close to you that you are taking VIVITROL

** Pneumonia.**  Some people who have received VIVITROL treatment have had a type of pneumonia that is caused by an allergic reaction. If this happens to you, you may need to be treated in a hospital.

** Serious allergic reactions.** Allergic reactions can happen during or soon after an injection of VIVITROL. Tell your healthcare provider or get help right away if you experience any of these symptoms:

* Skin rash - Trouble breathing or wheezing
* Swelling of face, eyes, mouth, or tongue - Chest pain
* Feeling faint or dizzy

**Common side effects of VIVITROL may include**: nausea, sleepiness, headache, dizziness, vomiting, painful joints, decreased appetite, muscle cramps, cold symptoms, trouble sleeping, toothache.

These are not all the side effects of VIVITROL. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. You are encouraged to report all side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

**PATIENTS WHO SHOULD NOT USE VIVITROL**

Do not receive VIVITROL if you:

* **Have a physical dependence on opioid containing medicines or opioid street drugs (such as heroin). Your provider may test you for dependence by giving you a small amount of naloxone. This is** called the naloxone challenge test. If you get symptoms of opioid withdrawal after the test, do not start VIVITROL treatment at that time. Symptoms include: anxiety, sleeplessness, yawning, fever, sweating, teary eyes, runny nose, shakiness, hot/cold flushes, shakiness, goosebumps, muscle aches, nausea, vomiting, diarrhea. Follow up with your healthcare provider to see when it is safe to begin treatment.
* **Are allergic to naltrexone** or any of the ingredients in VIVITROL or the liquid used to mix VIVITROL (diluent). See the medication guide for the full list of ingredients.

**THINGS TO TELL YOUR PRACTITIONER**

Before you receive VIVITROL, tell the pharmacist, nurse, and your physician if you:

* Have liver or kidney problems or any other medical conditions
* Are using street drugs
* Have hemophilia, or other bleeding problems
* Are breastfeeding or pregnant. It is not known if VIVITROL passes into milk/ will harm your unborn baby. Naltrexone from tablets pass into breast milk.
* Are being treated for alcohol dependence but also use or are addicted to opioid-containing drugs.

Tell the pharmacist, nurse and your physician about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. VIVITROL and other medicines may affect each other causing possible serious side effects. Do not start or stop any medicines while taking VIVITROL without talking to your physician first.

**THINGS TO AVOID WHILE TAKING VIVITROL**

You must stop taking opioids before receiving VIVITROL. To be effective, VIVITROL must be used with other alcohol or drug recovery programs such as counseling. VIVITROL may not work for everyone. It is not known if VIVITROL is safe and effective in children.

**PATIENT CONSENT AND WAIVER OF LIABILITY**

**I acknowledge that I have carefully and fully read this Consent and Waiver and I understand the potential risks and side effects related to the use of VIVITROL listed above and explained by my physician. I have been given the opportunity to ask questions and I have had all of my questions answered.**

**I acknowledge that PHARMACY NAME did not prescribe the medicine and is only performing the VIVITROL injections through the pharmacist and/or a nurse at my request and with my authorization, which is hereby being given.**

**In acknowledgement of the foregoing, I, for myself, my heirs, assigns, and anyone acting on my behalf, hereby waive any and all claims against PHARMACY NAME and its principals, agents, and employees, and agree to hold each them harmless from any and all liability whatsoever, arising out of, in connection with, or in any way related to the use or administration of VIVITROL.**

**I agree that this Consent and Waiver will be valid for each repeated VIVITROL injection.**

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Patient Signature Date

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Signature of Practitioner who Conducted Name

the Informed Consent Discussion