

PATIENT MEDICATION CONSENT, AGREEMENT TO REPORT ADVERSE SYMPTOMS, and ASSUMPTION OF RISK AGREEMENT

Note: No medication is absolutely positively 100% risk free. Even taking over-the-counter medicines, like Aspirin and Tylenol for example, can result in serious side effects or even death. However, all prescribed medicines are approved as safe and effective by the Food and Drug Administration (FDA), and most of the time they cause little or no harm. However, there are some specific concerns that you should be aware of with certain medicines that are commonly prescribed, and that is the purpose of this medication consent.

1. **Atypical Antipsychotics (also referred to as “Mood Stabilizers”)**: These include **ABILIFY CLOZARIL (clozapine)** [note that **CLOZARIL** has special precautions, not addressed here], **GEODON, INVEGA, RISPERIDAL, SEROQUEL, SYMBYAX, and ZYPREXA**. They may cause or result in certain adverse medical problems or conditions. The ones of most concern are the following:

- a. **Elevated blood sugar, diabetes, and weight gain**: elevated blood sugars, in some cases extreme and associated with coma or death, have been reported in patients treated with these medications. These changes may occur with or without weight gain. I agree to report any significant weight gain and/or symptoms of elevated blood sugar (including increased thirst, increased urination, increased eating, and weakness) to my doctor. Patients who develop any of these symptoms should have a test for elevated blood sugar and cholesterol.
- b. **Increased risk of stroke and a higher death rate in elderly patients with dementia**. These medications are not indicated for the treatment of agitation except in patients with schizophrenia or bipolar disorder.
- c. **Neuroleptic Malignant Syndrome (NMS)**: this is a rare but potentially life-threatening condition with symptoms of unstable blood pressure, confusion, coma, delirium, fever, and/or muscle stiffness.
- d. **Elevated prolactin levels**: this may be associated with enlarged breasts, breast discharge, sexual dysfunction, osteoporosis, and very rarely pituitary (brain) tumors.

2. **Tardive Dyskinesia (TD)**: All antipsychotic medications, including **haloperidol (HALDOL)** and **fluphenazine (PROLIXIN)**, those listed in #1 above, and others such as _____ may result in a condition called tardive dyskinesia (TD). The symptoms of TD, which are primarily abnormal movements or muscle cramps and which may be irreversible, have been explained to me and I accept the risk and agree to report any muscle cramps or abnormal movements to my doctor immediately.

3. **Benzodiazepines**: Including **lorazepam (ATIVAN), alprazolam (XANAX), clonazepam (KLONOPIN), diazepam (VALIUM)**, and others such as _____ are addicting, habit forming, and may cause dizziness, impaired memory, impaired coordination, and reaction time, and should NOT be combined with alcohol. They should be taken with caution if you have chronic obstructive pulmonary disease (COPD; emphysema) or sleep apnea. I understand that I should not stop taking these medications abruptly because of the risk of possible seizures and/or other adverse effects.

I also understand that certain sleep agents, including **AMBIEN, LUNESTA, ROZEREM, and SONATA**, and may cause similar problems. In addition, they may impair memory and rarely cause bizarre behaviors while asleep such as driving a car, eating, having sex, and other behaviors without being aware of the activity.

4. **LAMICTAL**: May cause skin reactions, including the rare Stevens-Johnson syndrome (SJS) which is a severe and life-threatening skin reaction. If you develop a skin rash, stop taking Lamictal and contact your doctor immediately. If Lamictal is stopped for any reason, such as running out of the medicine, it must be restarted gradually, just as when it was first taken.

5. **Trazodone (DESYREL)**: May cause a rare condition called “priapism,” a persistent and often painful erection of the penis that may result in impotence. This is a rare condition that must be reported to a doctor immediately. Trazodone may increase blood levels of **digoxin, phenytoin (DILANTIN)**, and decrease the level of **coumadin (WARFARIN)**. Trazodone is almost always prescribed “off label” (see # 10 below).

6. **Antidepressants**: The FDA has issued a warning that antidepressants might worsen depression and/or increase the risk of suicide. Patients and their families should be alert for the emergence of agitation, irritability, anxiety, panic attacks, insomnia, hostility, impulsivity, severe restlessness, worsening depression, suicidal thoughts, or elevated mood, especially soon after treatment has been started, the dose of the medication has been increased or decreased, or when the medication is discontinued. If any of these symptoms arise during treatment, they should be reported to the doctor immediately. The drugs that are the focus of this new warning are: **CELEXA (citalopram), CYMBALTA (duloxetine), EFFEXOR (venlafaxine), EMSAM (selegiline), LEXAPRO (escitalopram), LUVOX (fluvoxamine), PAXIL (paroxetine), PROZAC (fluoxetine), REMERON (mirtazapine), SEROQUEL (quetiapine), SERZONE (nefazodone), SYMBYAX (olanzapine/fluoxetine combination), WELLBUTRIN (bupropion), and ZOLOFT (sertraline).**

7. **Stimulants:** Including **methylphenidate and amphetamines: (ADDERALL), (CONCERTA), (DAYTRANA), (DEXEDRINE), (DESOXYN), (FOCALIN), (METADATE), (METHYL), (RITALIN), (VYVANSE)** and others; and **atomoxetine: (STRATTERA)** should not be used in children with heart conditions. The FDA has already issued such a warning for **ADDERALL**, which has been associated with rare sudden death in children and has been withdrawn from the market in Canada, and is considering issuing the warning for the other stimulants as well. These medications can worsen tics and Tourette's disorder, can cause weight loss and stunted growth, and (except for Strattera) can be habit forming.

8. **STRATTERA (atomoxetine):** Has resulted in severe liver injury. The FDA warns that the medication should be discontinued in patients who developed jaundice (yellowing of the skin or whites of the eyes) or laboratory evidence of liver injury.

9. **Pregnancy Warning:** Any medication I take may have a negative effect on an unborn child (fetus) if I am pregnant. If I am not pregnant now, I agree to discuss my medication(s) with my doctor before attempting to get pregnant. If I do become pregnant while taking medicine, I agree to immediately contact my doctor. Medications of greatest concern include **LITHIUM, BENZODIAZEPINES** (see #3 above), certain anticonvulsants like **valproic acid (DEPAKOTE)** and **carbamazepine (TEGRETOL)**, and **paroxetine (PAXIL)**.

10. **Off-label Use:** One or more of the medications I have been given is or are prescribed "off-label." This means that the medication is prescribed for a use not approved by the Food and Drug Administration (FDA), a medication that is used in doses higher than those recommended by the FDA, or for periods of treatment longer than approved by the FDA. Only atomoxetine (**STRATTERA**)—for ADHD, fluoxetine (**PROZAC**)—for depression & obsessive compulsive disorder (OCD), sertraline (**ZOLOFT**)—for OCD, fluvoxamine (**LUVOX**)—for OCD, clomipramine (**ANAFRANIL**)—for OCD, and risperidone (**RISPERDAL**)—for behavioral dyscontrol in children with autism, have FDA approval for use in children.

11. **Driving a Car or Use of Machinery:** One or more of the medications prescribed to me may adversely affect my ability to drive a motor vehicle or operate machinery. I agree not to drive or operate machinery if I feel even slightly impaired, and I take full responsibility for this liability.

12. **Combining Medications:** When taking multiple medications, there is always a chance that the side effects of any of the medications may be increased. This may be especially true when combining several medicines that can cause dizziness, drowsiness, or sedation, and this includes combining any of the medications listed in this consent form themselves, or with "pain killers" or opiates such as **DARVON, DARVOCET, DEMEROL, DILAUDID, DURAGESIC PATCHES, LORTABS, MS CONTIN, OXYCONTIN, PERCOCET, PERCODAN, VICODIN**, and others. I have informed my doctor of all the other medications I take to help insure there are no drug-drug interactions. **I also understand that I should not combine medications and alcohol.**

13. **Potential risks and benefits of taking this or these medications, as well as alternative treatments,** have been discussed with me and I accept these risks. I was given an opportunity to discuss my medications, all of my questions have been satisfactorily answered, and I was given a copy of this form to take home with me.

PATIENT SIGNATURE Date

Parent /Guardian Signature Date

Staff Signature Date