INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 05/22/2017

Completion of this form is voluntary. If not completed, the medication cannot be administered without a court order unless in an emergency. This consent is maintained in the client's record and is accessible to authorized users.

Name – Patient / Client (Last, First MI)	ID Number	Living Unit	Date of Birth

Name – Individual Preparing This Form	Name – Staff Contact	Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Anticonvulsant (Phenyltriazine)	Lamictal, Lamictal XR (lamotrigine)	Adults: immediate release 25mg—500mg ; extended release 25mg -600mg Children: The dose of this medication is age/weight determined	

The anticipated dosage range is to be individualized, may be above or below the recommended range but no medication will be administered without your informed and written consent.
Recommended daily total dosage range of manufacturer, as stated in *Physician's Desk Reference* (PDR) or another standard reference.
This medication will be administered ☐ Orally ☐ Injection ☐ Other – Specify:

1. Reason for Use of Psychotropic Medication and Benefits Expected (note if this is 'Off-Label' Use)
Include DSM-5 diagnosis or the diagnostic "working hypothesis."

2. Alternative mode(s) of treatment other than OR in addition to medications include
Note: Some of these would be applicable only in an inpatient environment.

☐ Environment and/or staff changes
☐ Positive redirection and staff interaction
☐ Individual and/or group therapy
☐ Rehabilitation treatments/therapy (OT, PT, AT)
☐ Treatment programs and approaches (habilitation)
☐ Use of behavior intervention techniques

Other Alternatives:

3. Probable consequences of NOT receiving the proposed medication are

Impairment of ☐ Work Activities ☐ Family Relationships ☐ Social Functioning

Possible increase in symptoms leading to potential

☐ Use of seclusion or restraint
☐ Limits on access to possessions
☐ Limits on personal freedoms
☐ Limit participation in treatment and activities
☐ Limits on recreation and leisure activities
☐ Intervention of law enforcement authorities
☐ Risk of harm to self or others

Other Consequences:

Note: These consequences may vary depending upon whether or not the individual is in an inpatient setting. It is also possible that in unusual situations, little or no adverse consequences may occur if the medications are not administered.

See Page 2

Client Initial _____ Date _____

4. Possible side effects, warnings, and cautions associated with this medication are listed below. This is not an all-inclusive list but is representative of items of potential clinical significance to you. For more information on this medication, you may consult further with your physician or refer to a standard text, such as the PDR. As part of monitoring some of these potential side effects, your physician may order laboratory or other tests. The treatment team will closely monitor individuals who are unable to readily communicate side effects in order to enhance care and treatment.

Continued – Possible side effects, warnings, and cautions associated with this medication.

Most Common Side Effects

The most common side effects may include: Blurred or double vision or other changes in vision; clumsiness or unsteadiness; poor coordination; dizziness; tiredness: trouble sleeping; headache; diarrhea; nausea; vomitting; indigestion.

Check with your doctor as soon as possible if skin rash occurs.

Less Common Side Effects

Less common side effects include: abdominal pain, constipation; diarrhea; dryness of mouth; indigestion; loss of strength; menstrual pain; pain; runny nose; slurred speech; trembling or shaking tiredness; vertigo; unusual weight loss.

Check with your doctor as soon as possible if you experience anxiety, confusion, depression, irritability, or other mood or mental changes; chest pain; continuous, uncontrolled back and forth and/or rolling eye movements; infection.

Rare Side Effects

Rare side effects include blistering, peeling, or loosening of skin; liver failure; dark-colored urine; fever, chills, and/or sore throat; flu-like symptoms; itching; muscle cramps, pain, or weakness; red or irritated eyes; small red or purple spots on skin; sores, ulcer, or white spots on lips or in mouth; swelling of face, mouth, hands, or feet; swollen lymph nodes; anemia; trouble in breathing; unusual bleeding or bruising; unusual tiredness or weakness; yellow eyes or skin.

Check with your doctor as soon as possible if you experience memory loss.

Caution

This medicine may increase the effects of alcohol and other central nervous system (CNS) depressants (medicines that make you drowsy or less alert). Some examples of CNS depressants are antihistamines or medicine for hay fever, other allergies, or colds; sedatives, tranquilizers, or sleeping medicine; prescription pain medicine or narcotics; barbiturates; medicine for seizures; muscle relaxants; or anesthetics, including some dental anesthetics.

Warning

BLACK BOX WARNING

Serious Dermatological Reactions

Incidence in Epilepsy Treatment: Serious rashes requiring hospitalization (including Stevens Johnson Syndrome and toxic epidermal necrolysis, or rash-related death have been caused by lamotrigine). The rate of serious rash is greater in pediatric patients than in adults. Discontinuation of treatment have occurred in approximately 0.8% of pediatric patients (2 to 16 yrs) and in 0.3% in adults who have received the drug as adjunctive therapy for epilepsy. Incidence in Bipolar/Mood Disorders Treatment: Adults In trials of bipolar and other mood disorders, the rate of serious rash was 0.08% in adult patients receiving this drug as initial monotherapy and 0.13% in adult patients receiving lamotrigine as adjunctive therapy.

Incidence in Epilepsy Treatment: Pediatric Patients In a prospectively followed cohort of 1,983 pediatric patients with epilepsy taking the adjunctive lamotrigine, there was 1 rash related death. Toxic epidermal necrolysis In worldwide post marketing experience, rare cases of TEN and/or rash related death have been reported in adult and pediatric patients, but the numbers are too few to permit a precise estimate of the rate.

Potential Risk Factors

Other than age, there are as yet no factors identified that are known to predict the risk of occurrence or the severity of rash associated with lamotrigine. Other possible risk factors (yet to be proven) include:

—concurrent use with valproate (includes valproic acid and divalproex sodium), or

—exceeding the recommended initial dose or dose escalation schedule; however, cases have been reported in the absence of these factors.

Onset, Duration, Discontinuation of Treatment

Onset: Almost all life-threatening rashes have occurred within 2 to 8 weeks of lamotrigine therapy but have also occurred after prolonged treatment (e.g., 6 months).

Duration cannot be relied upon as a means to predict the potential risk heralded by the first appearance of a rash.

Although benign rashes also occur with lamotrigine, it is not possible to predict reliably which rashes will prove to be serious of life threatening. Thus, the drug should be discontinued at the first sign of rash, unless the rash is clearly not drug related. Discontinuation of treatment may not prevent a rash from becoming life threatening or permanently disabling or disfiguring.

MONITORING RECOMMENDATIONS RELATED TO BLACK BOX DATA

—Discontinue at first sign of rash, unless the rash is not drug related.

—Discontinuation of treatment may not prevent rash from becoming life-threatening or permanently disabling.

See PDR for an all-inclusive list of side effects.

Medication: Lamictal, Lamictal XR (lamotrigine)

By my signature below, I GIVE consent for the named medication on Page 1 and anticipated dosage range. My signature also indicates that I understand the following:

1. I can refuse to give consent or can withdraw my consent at any time with written notification to the institution director or designee. This will not affect my right to change my decision at a later date. If I withdraw consent after a medication is started, I realize that the medication may not be discontinued immediately. Rather, it will be tapered as rapidly as medically safe and then discontinued so as to prevent an adverse medical consequence, such as seizures, due to rapid medication withdrawal.
2. Questions regarding this medication can be discussed with the Interdisciplinary Team, including the physician. The staff contact person can assist in making any necessary arrangements.
3. Questions regarding any behavior support plan or behavior intervention plan, which correspond with the use of the medication, can be directed to the client's social worker, case manager, or psychologist.
4. I have the right to request a review at any time of my record, pursuant to § 51.30(4)(d) or § 51.30(5)(b).
5. I have a legal right to file a complaint if I feel that client rights have been inappropriately restricted. The client's social worker, case manager, or agency/facility client rights specialist may be contacted for assistance.
6. My consent permits the dose to be changed within the **anticipated dosage range** without signing another consent.
7. I understand the reasons for the use of the medication, its potential risks and benefits, other alternative treatment(s), and the probable consequences that may occur if the proposed medication is not given. I have been given adequate time to study the information and find the information to be specific, accurate, and complete.
8. This medication consent is for a period effective immediately and not to exceed fifteen (15) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by the Interdisciplinary Team. The goal, on behalf of the client, will be to arrive at and maintain the client at the minimum effective dose.

SIGNATURES		**DATE SIGNED**
Client – If Presumed Competent to Consent/Parent of Minor/Guardian (POA-HC)	Relationship to Client ☐ Self ☐ Parent ☐ Guardian (POA-HC)	
Staff Present at Oral Discussion	Title	

Client / Parent of Minor / Guardian (POA-HC) Comments

As parent/guardian (POA-HC) was not available for signature, he/she was verbally informed of the information in this consent.

Verbal Consent

Obtained by – PRINT – Staff Name	Date Obtained	Written Consent Received ☐ Yes ☐ No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received

Client Initial _____ Date _____